



1) What happened in the past EXACTLY, why denied by FDA, what had to change

1- Received FDA Approvable letter April 2006 – DSCO answered November 1, 2007.

Warrington, PA — November 1, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO) announced that it has submitted its formal response to the U.S. Food and Drug Administration's (FDA) April 2006 Approvable Letter for Surfaxin® for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA's guidelines provide that within 14 days of receipt of the formal submission, if the FDA has accepted the submission as a complete response, it should provide a review classification that determines the targeted review timeframe. Discovery Labs anticipates that the FDA will designate the formal response as a Class 2 submission, thereby allowing for a six-month review period with a target PDUFA date in the second quarter of 2008. The April 2006 Approvable Letter for Surfaxin primarily focused on the chemistry, manufacturing and controls (CMC) section of the Surfaxin New Drug Application (NDA). The Approvable Letter did not require any additional clinical trials, but did request additional information predominantly 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 obtained guidance from the FDA on the appropriate path to potentially gain approval of Surfaxin. Based on the guidance obtained, Discovery Labs completed a number of projects to generate additional data that it believes addresses the outstanding CMC issues identified in the Approvable Letter. These additional data are included in the formal response. The formal response also includes six-month stability data on the new Surfaxin process validation batches that were manufactured after the December 2006 meeting with the FDA. At that meeting, Discovery Labs presented information regarding its comprehensive investigation and remediation of the April 2006 process validation stability failure. The meeting also established that Discovery Labs' new Surfaxin process validation batches must demonstrate acceptable stability through six-months prior to the filing of the formal response to the Approvable Letter. Since their manufacture, these new process validation batches have been monitored in accordance with a

comprehensive stability testing protocol that complies with International Conference on Harmonization (ICH) guidelines, and will continue to be monitored at least through the Surfaxin proposed shelf-life.

2- FDA Accepted complete respond from DSCO November 16, 2007. Set PDUFA date for May 1, 2008.

Warrington, PA, November 16, 2007 — 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® (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).

3- Received second FDA Approvable letter May 2008 –

Discovery Labs Receives an Approvable Letter from FDA for Surfaxin® for RDS

Warrington, PA — May 2, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) today announced that it has received an Approvable Letter from the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. This official notification sets forth the remaining conditions that must be satisfied to gain U.S. marketing approval for Surfaxin.

The Approvable Letter was received in the evening of May 1, 2008, the PDUFA date that had been established for Surfaxin. Prior to receiving this Approvable Letter, Discovery Labs had finalized Surfaxin labeling discussions with the FDA. In addition, the FDA had completed its pre-approval inspection of Discovery Labs' manufacturing facility in Totowa, NJ and recently issued an Establishment Inspection Report (EIR) reflecting a successful inspection. Discovery Labs is assessing the Approvable Letter and will contact the FDA within the next few days to discuss required actions and timing to gain Surfaxin approval. Discovery Labs expects to be in a position early next week to provide guidance regarding its plans and timeline considerations to address the Approvable Letter.

4- DSCO meets with FDA to clarify, June 2008 –

Discovery Labs and FDA Meet to Clarify Limited Items in SURFAXIN Approvable Letter

Warrington, PA – June 19, 2008, -- Discovery Laboratories, Inc. (Nasdaq:DSCO) held a teleconference on June 18, 2008 with the U.S. Food and Drug Administration (FDA) to discuss Discovery Labs' approach to addressing key remaining items identified in the May 1, 2008 Approvable Letter to potentially gain U.S. marketing approval of SURFAXIN® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Discovery Labs received clarification on its proposals and, although timeline assessment is continuing, believes that it could submit its formal response to the Approvable Letter in September 2008. Discovery Labs also believes that this response may be designated by the FDA as a Class 1 resubmission with a target review period of 60 days.

On May 1, 2008, Discovery Labs received an Approvable Letter from the FDA for SURFAXIN. Prior to receiving the Approvable Letter, Discovery Labs had made notable progress towards gaining FDA approval of SURFAXIN, including agreeing with the FDA on the form of the SURFAXIN package insert and successfully concluding a pre-approval inspection of Discovery Labs' manufacturing operations. The Approvable Letter did not require any additional clinical trials to gain SURFAXIN approval.

On May 14, Discovery Labs submitted a pre-meeting information package to the FDA that outlined Discovery Labs' proposals for responding to select items identified in the Approvable Letter. The purpose of the meeting was to clarify and reach agreement with the FDA on the remaining steps necessary to achieve SURFAXIN approval, prior to filing a formal response to the Approvable Letter. Importantly, the meeting confirmed Discovery Labs' approach to finalizing SURFAXIN drug product specifications. With the exception of two items, Discovery Labs can prepare its responses using readily available data. The FDA has requested that Discovery Labs provide additional preclinical data and related information for two items.

One of the two items requires additional SURFAXIN biological activity test data.

These additional data will be correlated with results of previously conducted preclinical studies and also will be used to justify the acceptance criteria for this biological activity test. The other item involves justifying the proposed specifications for certain lipid-related impurities in the individual active pharmaceutical ingredients (APIs) that comprise SURFAXIN. Discovery Labs' approach to justifying the levels of these lipid-related API impurities was based, in part, on their being present in the human lung at levels equal to or greater than that in SURFAXIN. The FDA has requested additional information about the levels of these lipid-related API impurities in the neonatal lung. Discovery Labs believes that it will be able to develop this information based on existing scientific literature. Discovery Labs presently anticipates completing the activities related to finalizing these two items in order to submit its formal response to the Approvable Letter in September 2008.

[5- DSCO submits FDA complete response to second Approvable letter, October 2008 –](#)

Discovery Labs Submits Complete Response to May 2008 FDA Approvable Letter for Surfaxin® for RDS

Warrington, PA — October 17, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO)

today submitted its Complete Response to the May 2008 Approvable Letter issued by the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA's guidelines provide that by October 31, the FDA will determine the classification of the submission and notify Discovery Labs of its target date for potential approval of Surfaxin. Discovery Labs believes that the FDA may designate the Complete Response as a Class 1 resubmission, which would result in a target review period of sixty-days and potential approval of Surfaxin in 2008. The May 2008 Approvable Letter contains requirements that must be addressed to gain U.S. marketing approval for Surfaxin. All of these requirements have been addressed in the Complete Response. Discovery Labs met with the FDA on June 18, 2008 to clarify and reach agreement on addressing certain key requirements in the Approvable Letter, including the following:

- Discovery Labs must satisfy International Conference of Harmonization (ICH) guidelines for the proposed specifications for certain lipid-related impurities in two phospholipid drug substances that are contained in the Surfaxin drug product. The Complete Response includes data and other information to demonstrate that the lipid-related impurities in the two phospholipids can be produced at levels that satisfy ICH guidelines.
- Discovery Labs agreed to conduct additional Surfaxin preclinical studies, at a dose level requested by the FDA, using a Surfaxin biological activity test (a quality control and stability release test) and a well-characterized RDS animal model. The Complete Response includes data from these successfully concluded studies. Discovery Labs believes that the data obtained further confirms the comparability of Surfaxin drug product used in Discovery Labs' Phase 3 clinical trials to the commercial manufacturing process for Surfaxin and supports the determination of final acceptance criteria for the Surfaxin biological activity test. The May 2008 Approvable Letter did not require any additional clinical trials. Prior to receiving the Approvable Letter, Discovery Labs had made notable progress towards gaining FDA approval of Surfaxin, including agreeing with the FDA on the content of the Surfaxin package insert and successfully concluding a pre-approval inspection of Discovery Labs' manufacturing operations. Discovery Labs believes, based on its understanding of the FDA guidelines, that the FDA may designate this Complete Response as a Class 1 resubmission, which would result in a target review period of 60 days and potential approval of Surfaxin in 2008. However, the FDA has the discretion to designate any resubmission as Class 2, which would result in a 6-month target review period.

6- FDA Accepted SECOND complete respond from DSCO November 7, 2008. Set PDUFA date for April 17, 2009.

FDA Establishes Target Action Date of April 17, 2009 for Potential Approval of Discovery Labs' Surfaxin®
Warrington, PA, November 7, 2008 — Discovery Laboratories, Inc.
(Nasdaq: DSCO), today announced that the U.S. Food and Drug Administration (FDA) has accepted for review Discovery Labs' Complete Response for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The FDA has designated the Complete Response as a Class 2 resubmission and has established April 17, 2009 as its target action date under the Prescription Drug User Fee Act (PDUFA) to complete its review and potentially grant marketing approval for Surfaxin.

7- Received THIRD FDA Approvable letter April 2009 –

Discovery Labs Receives Complete Response from FDA for Surfaxin for Prevention of RDS

Conference Call Today at 9:00 AM

Warrington, PA — April 20, 2009 — Discovery Laboratories, Inc.
(Nasdaq: DSCO) today announced that, on April 17, 2009, it received a Complete Response letter from the U.S. Food and Drug Administration (FDA) for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. In its letter, the FDA focuses primarily on certain aspects of a Surfaxin biological activity test (BAT, a quality control stability and release test) that must be addressed before the Surfaxin application can be approved. Discovery Labs will host a conference call today at 9:00 AM. The call-in number for the conference call is 866-332-5218. Discovery Labs believes that it has already submitted data necessary to respond to the questions raised by the FDA in the Complete Response letter and that its New Drug Application (NDA) is sufficient to gain marketing approval of Surfaxin. At this time, there are no questions regarding Discovery Labs' Phase 3 clinical trials, no comments regarding drug substance impurities, and no issues related to the manufacturing process for Surfaxin. Discovery Labs plans to seek an end of review meeting with the FDA to be scheduled as soon as possible. If the meeting is successful, Discovery Labs anticipates that Surfaxin may be approved in 2009. In its Complete Response letter, the FDA focused on whether the BAT can adequately distinguish change in Surfaxin drug product over time and whether Discovery Labs has adequately validated the BAT and determined its final acceptance criteria. Validation of the BAT would confirm the comparability of Surfaxin drug product used in the clinical trials to the commercial Surfaxin drug product. Discovery Labs believes that data already submitted to the FDA support the comparability of Surfaxin clinical drug product to commercial Surfaxin drug product and demonstrate

that the BAT can adequately distinguish change in Surfaxin over time and is an appropriate test for monitoring Surfaxin biological activity throughout its shelf-life. The BAT is only one of numerous methods that Discovery Labs employs in an extensive quality surveillance program to assess product quality and stability of Surfaxin. These highly sophisticated tests monitor the quality of Surfaxin at release and through its shelf-life and represent very sensitive methods for detecting changes in product quality and identifying defective product. In the Complete Response letter, the FDA also indicated that Discovery Labs needs to tighten one drug product specification, which can be readily implemented. The Complete Response letter also contained routine requests to update safety and other information in the NDA as well as information requests about certain regulatory matters. In addition, the FDA has approved the trade name Surfaxin. Discovery Labs is analyzing all aspects of its business with an immediate intention to conserve cash. Although there can be no assurances, Discovery Labs is also exploring strategic alternatives, including, but not limited to, potential additional financings, as well as potential business alliances, commercial and development partnerships and other similar opportunities.

8- DSCO and FDA establish Path for potential SURFAXIN approval September 2009 –

Discovery Labs and FDA Establish Path for Potential SURFAXIN Approval

FDA Supports Proposed BAT Optimization and Approach for Limited Clinical Trial

Warrington, PA – September 30, 2009 -- Discovery Laboratories, Inc. (Nasdaq:DSCO) held a teleconference on September 29, 2009 with the U.S. Food and Drug Administration (FDA). The meeting established an approach to potentially resolve the remaining primary issue that Discovery Labs must address to gain U.S. marketing approval of Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. The meeting focused on Discovery Labs' plans regarding optimization and final method validation of its fetal rabbit Biological Activity Test (BAT, a quality control and stability release test) and a proposed limited Surfaxin clinical trial design, which would simultaneously employ the newly-optimized BAT.

At the meeting, the FDA indicated that Discovery Labs' proposed program to optimize and validate the BAT is reasonable. The program is intended, among other things, to confirm that the BAT can adequately distinguish change in Surfaxin biological activity over time. As a result of the meeting, Discovery Labs believes that it has reached an understanding with the FDA and is confident that it will be able to optimize the BAT to the satisfaction of the FDA. Discovery Labs intends to employ the optimized BAT in conjunction with all of Discovery Labs' KL₄ surfactant pipeline programs, including the potential limited Surfaxin clinical trial.

In addition, Discovery Labs received guidance from the FDA on its proposed limited clinical trial design. The trial design is intended to primarily assess a pharmacodynamic (PD) response following Surfaxin administration in preterm

infants with RDS. This design was selected to address FDA requirements for Surfaxin approval while limiting trial expense and duration. The FDA indicated that a PD-based approach is consistent with their expectation for a limited clinical trial and also provided direction regarding trial design specifics. The final clinical trial design will be subject to FDA review following submission of a formal protocol. Discovery Labs expects to finalize a protocol and anticipates submitting it to the FDA in mid-fourth quarter of 2009.

W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs, commented, “We are pleased with the guidance received and outcomes obtained from our interaction with the FDA. This guidance provides a viable option for Surfaxin and meaningfully supports advancing our pipeline initiatives to potentially address a broad range of respiratory diseases such as RDS, Acute Respiratory Failure, Acute Lung Injury and Cystic Fibrosis. We look forward to continued productive dialogue with the FDA.

Our most advanced programs from our KL₄ surfactant pipeline, Surfaxin, Surfaxin LS™ and

Aerosurf®, have the potential to greatly improve the management of RDS and to redefine the RDS market. Our top priority is to secure strategic alliance partners and access capital to advance our pipeline and build shareholder value. As we move forward, we will take into account further interaction with the FDA and make strategic assessment, together with existing and potential new partners to determine the appropriate level and timing of Surfaxin investment and to maximize the value of our KL₄ pipeline for RDS.”

Background

On April 17, 2009, Discovery Labs received a Complete Response letter from the FDA for Surfaxin for RDS and on June 2, 2009, conducted a related meeting focusing primarily on certain aspects of the BAT, specifically whether preclinical data generated using both the BAT and a well-established preterm lamb model of RDS adequately supports the comparability of Surfaxin clinical drug product to the to-be-manufactured Surfaxin, and whether the BAT can adequately distinguish change in Surfaxin biological activity over time.

During the conduct of Phase 3 clinical trials for Surfaxin, Discovery Labs employed an array of quality control tests, but did not employ the BAT to evaluate biological activity of the Surfaxin clinical drug product. After completing the Phase 3 clinical trials, in accordance with discussions with the FDA, Discovery Labs validated and implemented the BAT as a recurring quality control test to confirm biological activity for Surfaxin release and stability testing. Based on guidance received from the FDA in meetings with the FDA in 2006 and 2008, Discovery Labs conducted a series of preclinical experiments to establish comparability between Surfaxin drug product used in Phase 3 clinical trials and the Surfaxin drug product intended to be manufactured for commercial use. Accordingly, Discovery Labs initiated a series of side-by-side studies employing both the preterm lamb model of RDS and the BAT and believes that the correlated results demonstrate comparability and support approval of Surfaxin.

At the June 2 meeting with the FDA, Discovery Labs presented data from the preterm lamb model and BAT studies, together with a comprehensive statistical evaluation of such data, intended to establish the comparability of clinical drug product to Surfaxin drug product to be manufactured for commercial use. The comprehensive statistical evaluation was a comparative regression analysis using an accepted FDA statistical method. Discovery Labs believes that the data and related statistical evaluation are highly supportive of the comparability of clinical drug product to commercial Surfaxin.

However, the FDA stated at the June 2 meeting that data generated from the preterm lamb model and BAT studies must demonstrate, in a point-to-point analysis, the same relative changes in respiratory compliance between both models over time. Based on this standard, Discovery Labs believes that establishment of comparability in this manner would be an extremely high hurdle and that, from the FDA's perspective, the data analysis provided by Discovery Labs did not meet that standard.

In addition, the FDA suggested that the comparability studies in the preterm lamb model and the BAT would not be necessary if the BAT had been implemented to assess Surfaxin drug product used in the Phase 3 clinical trials. The FDA also suggested that, to increase the likelihood of gaining Surfaxin approval and as an alternative to demonstrating comparability using the preterm lamb model and BAT, Discovery Labs could consider conducting a limited clinical trial, while simultaneously employing the BAT, as a path forward to Surfaxin approval.

9- DSCO submits Trial Protocol to FDA for potential SURFAXIN approval - November 2009 –

Discovery Labs Submits SURFAXIN Pharmacodynamic Trial Protocol to FDA

Potential Resolution of Key Remaining Issue for Approval

Warrington, PA – November 17, 2009 -- Discovery Laboratories, Inc. (Nasdaq:DSCO) announced today that it has submitted to the U.S. Food and Drug Administration (FDA) its proposed protocol for a Surfaxin® (lucinactant) limited clinical trial. The protocol incorporates a clinical trial design that is primarily intended to assess a pharmacodynamic (PD) response following Surfaxin administration in preterm infants with Respiratory Distress Syndrome (RDS). Discovery Labs proposed this trial design in response to a comment by the FDA that a limited clinical trial could potentially resolve the key remaining issue for approval of Surfaxin for the prevention of RDS in premature infants.

Discovery Labs received a Complete Response Letter for Surfaxin in April 2009. At an end-of-review meeting with the FDA on June 2, 2009, the FDA suggested that, to increase the likelihood of gaining Surfaxin approval, Discovery Labs could consider conducting a limited clinical trial. On September 29, 2009, Discovery Labs held a teleconference with the FDA to discuss, among other things, whether a PD approach

would satisfy the FDA's requirement for a limited clinical trial. Typically, PD-based clinical trials primarily assess short-term, physiologic responses to therapy and, therefore, are generally less expensive and of shorter duration than trials that have clinical outcomes as a primary endpoint. The FDA indicated that Discovery Labs' proposed concept of a PD trial design is acceptable and also provided direction regarding certain trial design specifics.

Employing the FDA's guidance, Discovery Labs worked closely with leading academic neonatologists to design the PD protocol. The final protocol and clinical trial design is subject to FDA review and comment. In accordance with the FDA's guidance, Discovery Labs expects to receive the FDA comments early in the first quarter 2010. At that time, Discovery Labs will be in a position to estimate the expected costs and duration of the trial and make a strategic assessment, with existing and potential new partners, regarding any investment in a potential limited clinical trial for Surfaxin for RDS.

[10- DSCO receives FDA guidance for potential SURFAXIN approval - February 2010 –](#)

Discovery Labs Receives FDA Guidance Regarding Pathway to Potential

SURFAXIN® Approval

Warrington, PA – February 16, 2010 -- Discovery Laboratories, Inc. (Nasdaq:DSCO)

announced today that, in response to written guidance recently received from the U.S. Food and Drug Administration (FDA), it will now focus on a pathway that would entail solely performing additional preclinical work, instead of conducting a limited clinical trial, to potentially gain FDA marketing approval for Surfaxin® (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. Based on prior guidance received from the FDA,

Discovery Labs expected that a limited, pharmacodynamic-based (PD) clinical trial in preterm infants would be required to address the sole remaining Chemistry, Manufacturing & Control (CMC) issue regarding the final validation of a fetal rabbit Biological Activity Test (BAT, an important quality control release and stability test) necessary for Surfaxin approval. The recently-received guidance from the FDA advises that since an acceptable and well-established animal model (preterm lamb) of RDS already exists and this model could be used as an acceptable alternative to a clinical trial in human preterm infants, that a PD clinical trial approach is not appropriate. Compared to the conduct of a PD clinical trial, a comprehensive preclinical program, if successful, presents an opportunity to significantly reduce the time and expense required to gain potential Surfaxin approval and Discovery Labs believes a Complete Response could be submitted to the FDA in the first quarter of 2011. The safety and efficacy of Surfaxin for RDS has previously been demonstrated in a comprehensive Phase 3 clinical

program. Consistent with previous communications from the FDA, there continues to be no questions regarding clinical trial data and no indication that the FDA has any concerns related to other quality assurance tests or the manufacturing process for Surfaxin. The FDA has also acknowledged that Discovery Labs had successfully demonstrated in the preterm lamb model the comparability of Surfaxin clinical drug product to the to-be-marketed Surfaxin drug product.

Comprehensive Preclinical Program to Resolve Remaining CMC Issue

In September 2009, Discovery Labs discussed in detail with the FDA a proposed process to optimize the precision of the BAT method and its subsequent validation. Following the FDA's supportive assessment of the proposed optimization process, Discovery Labs initiated BAT optimization activities and a related revalidation program which is well underway and presently meeting all pre-specified acceptance criteria. Upon successful conclusion of BAT optimization and revalidation, Discovery Labs plans to conduct a series of prospectively-designed, side-by-side preclinical studies employing the optimized BAT and the well-established preterm lamb model of RDS. The results from these studies are intended to satisfy the FDA as to the BAT's ability to adequately discriminate biologically active from inactive Surfaxin drug product and establish the Surfaxin drug product's final acceptance criteria (with respect to biological activity as assessed by the BAT) for release and ongoing stability. Discovery Labs believes that implementing these method improvements to optimize the BAT make it more likely that the results of the planned preclinical program will demonstrate the level of comparability between data generated using the BAT and the preterm lamb model that the FDA requires.

The comprehensive preclinical program will employ several different Surfaxin batches to assess the short-term physiologic responses to Surfaxin (via measurement of respiratory compliance) after administration in both the preterm lamb model and the optimized BAT at various time points. The resulting data will be examined to evaluate the relative changes, over time, in biological activity upon Surfaxin administration to determine the degree of comparability between the optimized BAT and the preterm lamb model. The FDA has previously invited Discovery Labs to seek FDA advice with respect to the ongoing BAT optimization and revalidation process. Discovery Labs also plans to seek FDA advice regarding important aspects of the preclinical program, including study design and appropriate success criteria. Discovery Labs believes that continued interactions with the FDA are an important element in assuring the adequacy of the preclinical program. The comprehensive preclinical program will utilize Discovery Labs' extensive experience with both the BAT and the well-established preterm lamb model and take into account (i) the FDA's recent supportive assessment of Discovery Labs' proposed BAT optimization and revalidation, (ii) the encouraging progress of the ongoing BAT optimization and revalidation, (iii) the FDA's recognition of the utility of the well-established preterm lamb RDS model as an acceptable animal model for human preterm RDS, and (iv) Discovery Labs' comprehensive experience and existing relationships with well-recognized academic centers of excellence who routinely employ the preterm lamb model and have demonstrated expertise in measuring respiratory compliance in this model.

W. Thomas Amick, Chairman and interim Chief Executive Officer of Discovery Labs, commented, "The comprehensive preclinical program as a path to resolve our remaining CMC issue represents a potentially streamlined approach to gaining potential Surfaxin

approval, as compared to conducting a PD clinical trial. Discovery Labs believes that it is in an advantaged position to prospectively design the preclinical program to satisfy the FDA's requirements. We have worked productively with the FDA to advance the BAT optimization program and intend to avail ourselves of the FDA's willingness to provide continued guidance as we work through final steps for potential Surfaxin approval." Discovery Labs has a number of significant development milestones through the next year. With respect to Surfaxin, Discovery Labs anticipates completing the BAT optimization program in the second quarter of 2010 which could position it to conduct the remainder of the preclinical program with a goal of filing a Complete Response for Surfaxin in the first quarter of 2011.

Furthermore, Discovery Labs anticipates advancing its clinical programs for its RDS pipeline candidates, Surfaxin LS™ and Aerosurf® in 2010. Additionally, in the first half of 2010, Discovery Labs' KL4 pipeline programs are expected to yield important Phase 2 clinical milestones, including results from an ongoing clinical trial in children up to two years of age with Acute Respiratory Failure and an investigator-initiated clinical trial for patients with Cystic Fibrosis. An important financial objective for Discovery Labs is to secure the necessary capital, preferably through strategic alliances, to advance these clinical-stage initiatives.

2) Market potential with sources, competitors, etc., other uses for device or what it is

Surfaxin®(Lucinactant) Long-Term Survival Advantage vs. Comparators Published in *Pediatrics*

*Surfaxin demonstrates statistically significant 1-year survival advantage vs. animal-derived surfactants **Survanta® and Curosurf®***

Warrington, PA — May 31, 2007 — Discovery Laboratories, Inc. (Nasdaq: DSCO), announces publication of the one-year follow-up results from its SELECT and STAR Phase 3 clinical trials for Surfaxin®, in *Pediatrics*, the premier medical journal for pediatric healthcare practitioners. The longterm data from the SELECT and STAR trials concluded that Surfaxin demonstrated a statistically significant survival advantage relative to existing animal-derived surfactants, **Survanta®** and **Curosurf®**.

Surfaxin is pending approval and has received an Approvable Letter from the United States Food and Drug Administration (FDA) for the prevention of RDS in premature infants. The article published in *Pediatrics* is entitled: One-Year Follow-up of Very Preterm Infants Who Received Lucinactant for Prevention of

Respiratory Distress Syndrome: Results from 2 Multicenter Randomized, Controlled Trials (*Moya et al.*) *Pediatrics* Vol. 119 No. 6 June 2007.

Fernando Moya, M.D., Chair of the SELECT study Steering Committee and Director of Neonatology at the Coastal Area Health Education Center, North Carolina, commented, “The long-term outcomes from the pooled analysis are particularly important because they suggest that a next-generation surfactant therapy, such as Surfaxin, may save more babies’ lives while improving their chances for a healthy future. The prospective assessment of long-term outcomes from the SELECT and STAR trials is unique given direct comparisons between surfactant products. The data set from this recently published analysis sets a new bar for this category.”

Key Data Highlights:

- Treatment with Surfaxin significantly improved survival ($p=0.05$) through one-year of life compared with animal-derived surfactants, Survanta and Curosurf.
- Surfaxin significantly improved survival ($p=0.04$) through one-year of life when directly compared with Curosurf, the current market leader in Europe and current market growth driver in United States.
- Although treatment with Surfaxin improved survival in preterm children, no differences in neurologic outcomes through one-year of life were observed between treatment groups, however, Surfaxin demonstrated a statistically significant ($p\leq 0.05$) reduction in two important assessments of neurologic outcomes (reflex abnormality and gross tone) versus Survanta.

Robert J. Capetola, President and CEO of Discovery Labs, commented, “Publication of these data in *Pediatrics* represents an important validation of Surfaxin, the cornerstone of Discovery’s broad SRT pipeline. The neonatal medical community has repeatedly indicated a strong interest in long-term outcomes assessment. No such assessment from the registration trials supporting use of currently prescribed animal-derived products has, to our knowledge, ever been conducted. Discovery is committed to provide this critically important information to the neonatal community. The article by Dr. Moya *et al.* supports a defined survival advantage for Surfaxin compared with current standard of care. We believe these long-term data will support significant differentiation for Surfaxin.”

About Surfaxin

Surfaxin is a precision-engineered version of natural human lung surfactant and contains Discovery Labs’ 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 the 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.

