SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

October 17, 2013

Date of Report (Date of earliest event reported)

Discovery Laboratories, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-26422**	**94-3171943**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

2600 Kelly Road, Suite 100
Warrington, Pennsylvania 18976
(Address of principal executive offices)

(215) 488-9300
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD Disclosure.

On October 17, 2013, Discovery Laboratories, Inc. (the “Company” or "Discovery Labs"), a specialty biotechnology company focused on advancing a new standard of care for critical care patients with respiratory disease, will hold a conference call and webcast to discuss its AEROSURF® program at 10:00 AM ET on October 17, 2013. A copy of the presentation materials is attached as Exhibit 99.1 hereto.

Pursuant to General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 hereto are being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise be subject to the liabilities of that section, nor is it incorporated by reference into any filing of Discovery Laboratories, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On October 17, 2013, the Company issued a press release announcing that it has submitted an Investigational New Drug (IND) Application to the U.S. Food and Drug Administration (FDA) for its initial AEROSURF phase 2 clinical trial. The FDA has confirmed receipt of the IND and has indicated that, unless otherwise notified during its review, the Company may initiate its phase 2 clinical program after a 30-day period. Discovery Labs anticipates patient enrollment could begin in the fourth quarter of 2013. The Company’s press release is attached as Exhibit 99.2 hereto.

AEROSURF is a novel investigational drug-device combination product being developed to deliver Discovery Labs’ KL_4 surfactant in aerosolized form to premature infants with respiratory distress syndrome (RDS). AEROSURF combines the Company’s proprietary KL_4 surfactant drug technologies with its proprietary drug delivery technologies to potentially allow for the administration of aerosolized KL_4 surfactant to premature infants without the need for invasive endotracheal intubation and mechanical intubation, and may enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated.

In 2012, the FDA approved the Company’s first drug product, SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants who are at high risk for RDS. SURFAXIN is based on the Company’s KL_4 surfactant technology and is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal-derived surfactants. Using the foundation of the SURFAXIN KL_4 surfactant drug technology, the Company is developing a lyophilized (freeze-dried) dosage form of KL_4 surfactant that can be stored as a powder and resuspended to liquid form prior to use, with the objective of improving ease of use for healthcare practitioners, as well as potentially prolonging shelf life and eliminating the need for cold-chain storage. The Company has completed a technology transfer of the lyophilized surfactant manufacturing process and is developing this dosage form with DSM Pharmaceuticals, Inc. (DSM), its contract manufacturer with expertise in lyophilized products. DSM has manufactured an initial supply of clinical drug product and will manufacture the clinical drug supply needed to complete the Company's phase 2 clinical program. The Company is planning with DSM for the further development of this lyophilized KL_4 surfactant, potentially for its AEROSURF phase 3 program and commercial supply.

The Company has also made progress with its proprietary capillary aerosol generator (CAG) and, with the assistance of Battelle Memorial Institute (Battelle), has completed development of a clinic-ready CAG device, which has been subjected to a rigorous design verification program and is being manufactured for use in the phase 2 clinical program. The CAG has been designed to produce aerosolized KL_4 surfactant in volumes up to ten times the output produced by currently available aerosol devices.

About RDS

RDS is a condition in which premature infants are born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen. Premature infants born prior to 37 weeks gestation have not fully developed their own natural lung surfactant and therefore need treatment to sustain life. RDS is experienced in approximately half of the babies born between 26 and 32 weeks gestational age. The incidence of RDS approaches 100% in babies born less than 26 weeks gestational age. RDS can result in long-term respiratory problems and death.

Neonatologists' Dilemma

Premature infants with RDS often require endotracheal intubation and mechanical ventilation to provide respiratory support and to administer surfactant (usually within the first hours of birth). Unfortunately, many infants relapse following initial surfactant therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, increasing their risk of developing further serious respiratory complications. Neonatologists generally try to avoid mechanically ventilating infants due to the perceived risks associated with intubation, such as the risk of trauma and the need for paralytic agents and sedation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits of invasive surfactant administration clearly outweigh the associated risks.

For all but the very low birth weight infants with severe RDS, a common ventilatory support treatment alternative to intubation and mechanical ventilation is nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and require subsequent surfactant administration via intubation and mechanical ventilation.

As it is not possible to ascertain in advance which patients will experience nCPAP failure, neonatologists are faced with a dilemma, because the outcome for those infants who experience nCPAP failure and receive delayed surfactant therapy may not be as favorable as the outcome for those infants who receive surfactant therapy in the first hours of life.

In the United States, approximately 360,000 premature births occur each year, of which approximately 45,000 premature infants receive surfactants administered via endotracheal intubation and mechanical ventilation as the first line of therapy. Of the infants that are treated initially with nCPAP alone, approximately 45,000 will experience nCPAP failure and require subsequent endotracheal intubation and surfactant therapy.

Discovery Labs estimates that approximately 160,000 premature infants in the U.S. could potentially benefit from early surfactant therapy to address surfactant deficiency or insufficiency. More than 70% of surfactant deficient infants (approximately 115,000) do not receive first-line surfactant therapy and instead receive nCPAP alone.

The estimates and data included in this discussion have been derived from the following sources, among others: IMS MIDAS data (MAT Sept 2008); CDC National Vital Statistics, 2005, Births by birth weight (CDC Website); “Annual Summary of Vital Statistics: 2006”, Pediatrics, Martin et al.; Vermont Oxford Network (VON) data, 2006; UNICEF data, 2005 (website); Discovery Labs’ primary market research (2010).

Proposed Clinical Program

The primary goal of the initial phase of the proposed AEROSURF phase 2 program, phase 2A, is to assess the safety and tolerability of the AEROSURF drug product. This phase is an escalating dose study evaluating three dose levels of aerosolized KL_4 surfactant. The comparator is nCPAP alone. The study will be conducted in three centers in the U.S. and is expected to be completed by mid-2014. The design of the second phase of the study, phase 2B, will be informed by the results of phase 2A. The primary objective will be to determine the optimal dose and expected efficacy margin. This phase is expected to be conducted in multiple centers and completed by mid-2015. The Company plans to invest approximately $8-10 million to cover direct costs of the proposed phase 2 clinical program for the period including the fourth quarter 2013 through mid-2015, having invested approximately $7 million for the period from the beginning of 2012 through September 30, 2013 for (i) development of the clinic-ready CAG, (ii) manufacture of clinical supply of lyophilized KL_4 surfactant, and (iii) preparation activities for the phase 2 clinical program.

AEROSURF Revenue Expectations and Exclusivities

Based on the expected number of infants that do not receive first-line surfactant therapy and the perceived potential pharmacoeconomic benefits that might be derived from delivering surfactants without endotracheal intubation and mechanical ventilation, the Company anticipates that the market potential for AEROSURF in the U.S. is in the range of $600 million to over $1 billion. The Company believes that the opportunity in markets outside the U.S. is potentially comparable to the U.S. However, there can be no assurance that the Company will succeed in gaining approval to market AEROSURF in the U.S. market or in markets outside the U.S., nor can there be assurance that the Company’s revenues estimates will be achieved.

The Company continues to invest in patent and other exclusivities to protect the AEROSURF brand. The United States Patent and Trade Office (USPTO) recently issued a Notice of Allowance for a patent entitled “Capillary System With Fluidic Element,” which will provide additional exclusivity regarding certain proprietary and technical aspects of its capillary aerosol generator (CAG) technology. The Company is also pursuing various other potential exclusivities, including protection of trade secrets, applications to secure potential orphan drug designation, and various other drug product patent initiatives.

Financial Update

As of September 30, 2013, the Company had cash and cash equivalents of $21.2 million. Net cash outflows for the quarter ended September 30, 2013 were approximately $10.1 million.

ATM Program Transaction

Beginning on October 4, 2013, the Company initiated an offering under its At-the-Market Equity Offering Sales Agreement (ATM Program) with Stifel, Nicolaus & Company, Incorporated (Stifel) dated February 11, 2013. The Company issued 713,920 shares of its common stock at various prices, resulting in net proceeds to the Company of approximately $1.9 million, after deducting commissions due to Stifel, as the sales agent.

Deerfield Facility

Pursuant to the terms of a Facility Agreement dated February 13, 2013 (Deerfield Facility) with affiliates of Deerfield Management Company, L.P. (Deerfield), Deerfield agreed to loan the Company up to $30 million on a secured basis on the terms outlined in the Deerfield Facility. Deerfield advanced $10 million upon execution of the Deerfield Facility and agreed to advance an additional $20 million, subject to certain conditions, following the first commercial sale of SURFAXIN, provided that the first sale occurs not later than December 31, 2013. With the recent FDA approval of updated product specifications for SURFAXIN, the Company has manufactured commercial product and, upon completion of final release testing, expects to initiate the commercial launch of SURFAXIN in the fourth quarter of 2013. The Company anticipates that it will meet the requirements and become eligible to receive the $20 million advance from Deerfield, although there can be no assurance that it will be successful.

For a further discussion of the Deerfield Facility, including the terms of such facility, and the fees and common stock warrants issuable in connection therewith, see the Company’s Annual Report on Form 10-K for the year ended December 31, 2012, “Item 7 – Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources.”

Disclosure Notice

The information in the Press Release, Slide Presentation, conference call and this Current Report on Form 8-K includes or is expected to include certain "forward-looking" statements relating, among other things, to the Company's plans to manufacture and release SURFAXIN drug product for commercial sale and to conduct its initial AEROSURF phase 2 clinical trial. As noted above, these and other similar statements are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. While the Company currently believes that it will succeed in meeting the timelines outlined in the Press Release, Slide Presentation, conference call and this Form 8-K, such forward-looking statements are subject to a variety of risks and uncertainties that could cause actual results to be materially different. These risks and uncertainties include, but are not limited to, risks related to activities to the Company's research and development activities, including, among other things, (i) time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or failure, and (ii) regulatory requirements relating to development and manufacture of the drug and aerosol delivery components of the Company's combination drug/device products, as well as those risks and uncertainties 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. Any forward-looking statement in this Current Report on Form 8-K and related exhibits speaks only as of the date on which it is made. The Company assumes no obligation to update or revise any forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Presentation Materials dated October 17, 2013
99.2	Press release dated October 17, 2013

Cautionary Note Regarding Forward-looking Statements:

To the extent that statements in this Current Report on Form 8-K 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, cash outflows, future revenues, the timing of planned clinical trials 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 Current Report are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. Such 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. Any forward-looking statement made by the Company in this Current Report on Form 8-K is based only on information currently available to the Company and speaks only as of the date on which it is made. The Company undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Discovery Laboratories, Inc.

By /s/ John G. Cooper
Name: John G. Cooper
Title: President and Chief Executive Officer

Date: October 17, 2013

Exhibit 99.1

DiscoveryLabs
Inspired Innovation

October 17, 2013

Investor Conference Call

Discovery Laboratories, Inc.

NASDAQ: DSCO

Forward Looking Statement

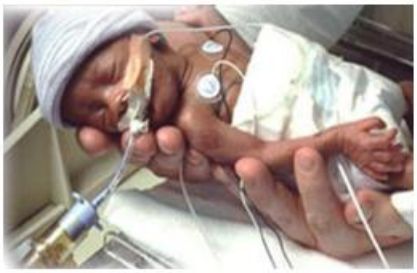
To the extent that statements in this presentation are not strictly historical, including statements about the Company's business strategy, outlook, objectives, plans, intentions, goals, future financial conditions, future collaboration agreements, the success of the Company's product development, or 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 presentation are subject to certain risks and uncertainties that could cause actual results to differ materially from the statements made. These risks are further described in the Company's periodic filings with the Securities and Exchange Commission (SEC), including the most recent reports on Form 10-K, 8-K and 10-Q, and any amendments thereto ("Company Filings").

This presentation under no circumstances shall be construed as an offer to sell or as a solicitation of an offer to buy any of the Company's securities. In addition, the information presented in this deck is qualified in its entirety by the Company Filings. The reader is encouraged to refer to the Company Filings for a fuller discussion of the matters presented here.

DiscoveryLabs. Inspired Innovation

Discovery Labs (DSCO)

A specialty biotechnology company focused on advancing a new standard of care for critical care patients with respiratory disease



Initial focus - Neonatology: Transform the treatment of respiratory distress syndrome (RDS)

DSCO Technology: Potential to improve the treatment of RDS and expand, over time, the estimated annual world-wide RDS market to $1+ billion

Estimates based on data derived from the following sources, among others: IMS MIDAS data (MAT Sept 2008); CDC National Vital Statistics, 2005, Births by birth weight (CDC Website); "Annual Summary of Vital Statistics: 2006", Pediatrics/Martin et al.; Vermont Oxford Network (VON) data, 2006; UNICEF data, 2005 (website); DiscoveryLabs' primary market research (2010).

DiscoveryLabs. Inspired Innovation

Transformation begins with SURFAXIN®

Surfaxin (lucinactant) Intratracheal Suspension

The first FDA-approved synthetic, peptide-containing (KL_4) surfactant for use in RDS

- Only alternative to animal-derived surfactants available in the U.S.
- First approved therapy in over 10 years for the prevention of RDS
- Direct clinical outcome comparisons to the current standard of care, animal-derived surfactants, Survanta® and Curosurf®

Commercial launch Q4 2013

- Established U.S. specialty commercial and medical affairs team
- Focused on neonatal critical care centers
- Clinical and pharmacoeconomic data expected to redefine the value of surfactant therapy

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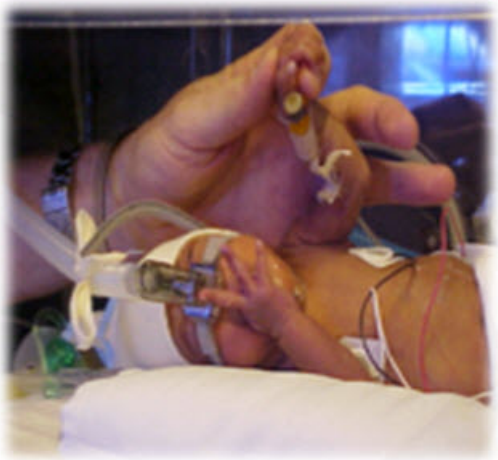
AEROSURF®

AEROSURF®: Drug-device product designed to deliver aerosolized KL_4 surfactant directly into the lungs via nCPAP



Being developed with the potential to:

- Reduce the need for intubation or mechanical ventilation for pulmonary surfactant delivery
- Enable treatment of a significantly greater number of premature infants at risk for RDS who could benefit from surfactant therapy but are currently not treated

Phase 2 clinical program – October 2013, filed IND with FDA

Anticipate first patient enrollment in Q4'2013

First ever clinical trial with an aerosolized surfactant intended to support product registration in the U.S. and international markets

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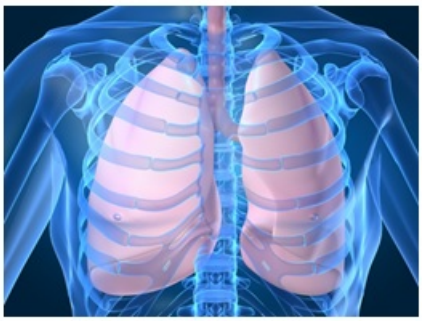
Technology: The Catalyst for Transformation

Unmet Medical Need

Pulmonary surfactant is essential for normal breathing



Surfactant deficiency and dysfunction is associated with many respiratory disorders

Historically, therapeutic surfactant products sourced from animal lungs – use and innovation limited

DSCO Technology Platform

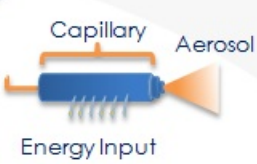
KL4 Surfactant

Proprietary synthetic, peptide-containing surfactant that is structurally similar to human pulmonary surfactant

Initial KL4 surfactant-based product: SURFAXIN®- FDA approved

Q3'13 - Established lyophilized KL4 surfactant manufacturing capability

Aerosol Drug Delivery



Proprietary high output aerosol generator - up to 10 times higher than current generators

KL4 surfactant aerosolized via CAG retains properties of a fully functioning surfactant

Q3'13 - Device successfully passed rigorous verification testing – ready for clinical programs

Cochrane & Revak, *Science*. 1991
Manalo et al. *Pediatr Res*. 1996;39:947-52.
Manalo et al. *Lung*. 1997;45:97-104.
Numata et al, *Proc Nat Acad of Sci*, Dec 09

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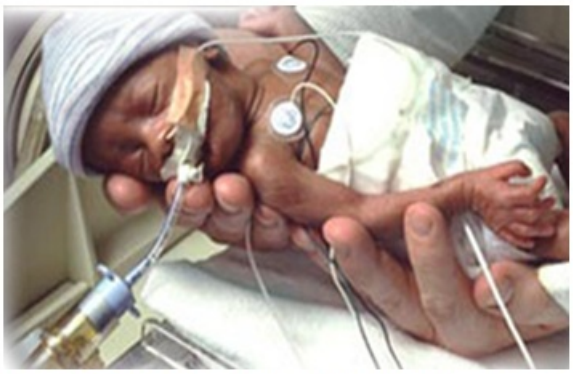
RDS: The Neonatologist's Dilemma – Intubate or not?

Option A:

Surfactant replacement therapy

Intubation and invasive mechanical ventilation (MV) required



Neonatologists will only intubate in cases of severe RDS where the benefits of invasive surfactant administration clearly outweigh the associated risk

Option B:

Nasal continuous positive airway pressure (nCPAP)

Does not address the fundamental problem of surfactant deficiency

The dilemma…not possible to ascertain in advance which infants will succeed or fail on nCPAP

Approx. 30% to 50% of infants do not respond ("nCPAP failure") and require subsequent surfactant administration via intubation / MV

Estimates based on data derived from the following sources, among others: IMS MIDAS data (MAT Sept 2008); CDC National Vital Statistics, 2005, Births by birth weight (CDC Website); "Annual Summary of Vital Statistics: 2006", Pediatrics, Martin et al.; Vermont Oxford Network (VON) data, 2006; UNICEF data, 2005 (website); Discovery Labs' primary market research (2010).

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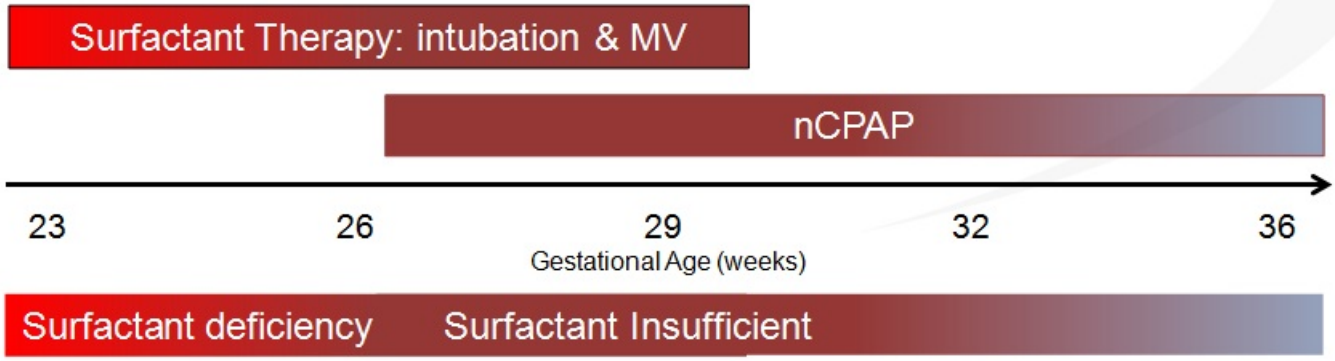
RDS in the U.S. - Unmet medical need

360,000 premature infants each year are at risk for RDS; 160,000 would likely benefit from early surfactant therapy to address surfactant deficiency or insufficiency

- Option A: 45,000 with severe RDS receive 1st line surfactant via intubation / MV
- Option B: More than 70% of surfactant deficient infants (115,000) do not receive 1st line surfactant therapy and instead receive nCPAP alone
  - Approximately 45,000 infants experience nCPAP failure and require subsequent surfactant therapy via intubation / MV



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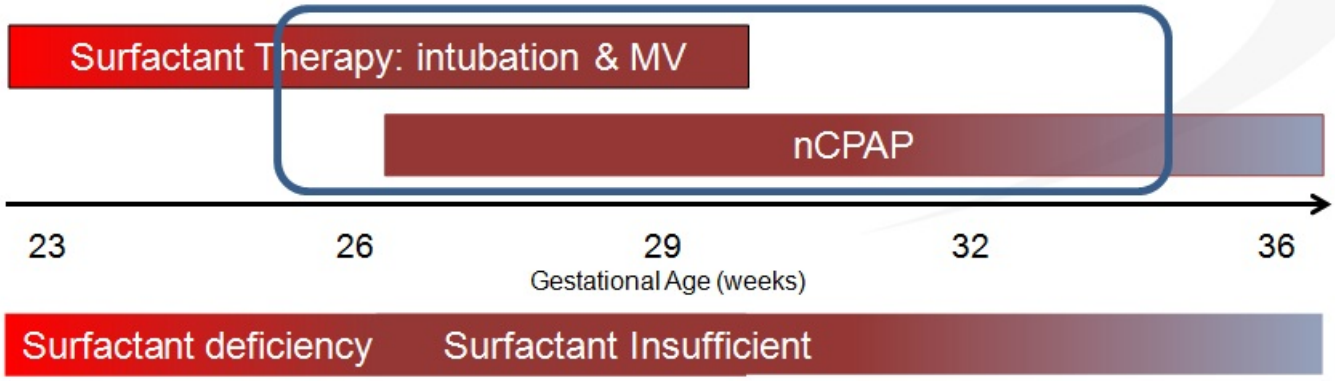
AEROSURF®: Potential to Resolve Neonatologist's Dilemma

160,000 premature infants in the U.S. would likely benefit from early surfactant therapy to address surfactant deficiency or insufficiency

- Option A: 45,000 with severe RDS receive 1st line surfactant via intubation / MV
- Option B: More than 70% of surfactant-deficient infants (115,000) do not receive 1st line surfactant therapy and instead receive nCPAP alone

AEROSURF®

A potential new 1st line therapeutic option in conjunction with nCPAP



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AEROSURF® proposed development program

Primary goal – Address an unmet medical need – deliver aerosolized surfactant to preterm infants receiving nCPAP

- Clinical Target – Treatment of RDS in preterm infants receiving nCPAP
- Primary Comparator – nCPAP alone
- Key secondary program objectives:
  - Reduce nCPAP failure rate vs. nCPAP alone (currently at 30-50% in US)
  - Reduce key complications of prematurity – focus on reducing rate of BPD
  - Establish pharmacoeconomic benefit – avoidance of need for MV – primary cost driver in NICU
- Initiating phase 2 clinical program :
  - Phase 2a – Safety and tolerability
  - Phase 2b – Determination of dose and efficacy margin

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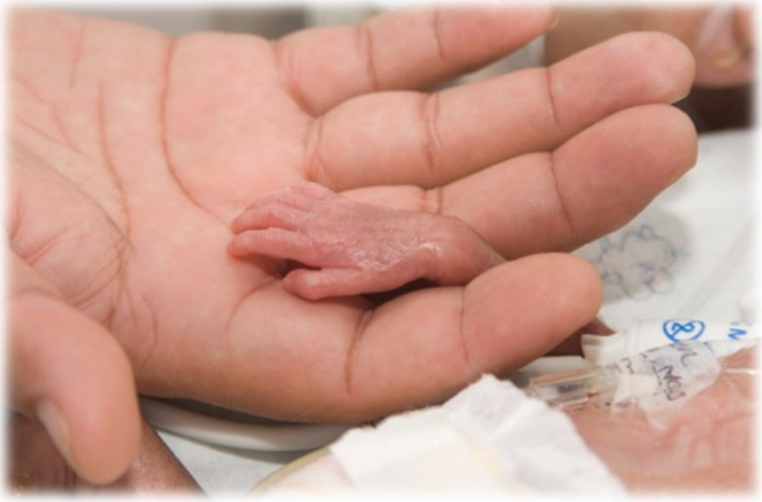
AEROSURF® - Phase 2 Program

Phase 2a

Primary objective: To evaluate the safety and tolerability of a single exposure to aerosolized KL_4 surfactant

- Escalating dose study evaluating three doses of increasing amounts of aerosolized KL_4 surfactant
- Comparator: nCPAP alone
- Patient population: preterm infants 26 to 32 weeks GA receiving nCPAP (n ~ 60 patients)
- Three US Centers w/established track record of successful participation in multicenter clinical trials in preterm infants
- The study is expected to complete by mid-2014



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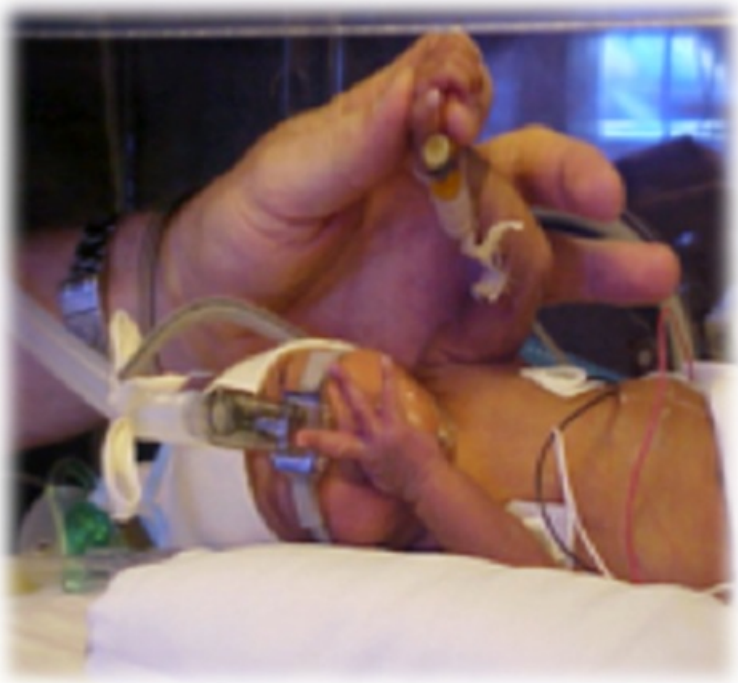
AEROSURF® - Phase 2 Program



Phase 2b

Primary objective: Determination of dose and efficacy margin

- Determination of optimal dose for phase 3 study.
- Define expected efficacy margin
- Patient population: preterm infants 26 to 32 weeks GA on nCPAP
  (n ~ 150 patients TBD post-Ph2a)
- Multicenter clinical trial
- The study is expected to complete by mid-2015

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AEROSURF® - Business Considerations

Comparatively modest incremental investment to achieve important phase 2 milestones

2012 – Q3'2013: Approx. $7M invested to develop capillary aerosol generator (CAG) for clinical program, cGMP lyophilized KL_4-surfactant dosage form, and preparation for phase 2 clinical trial

Q4'2013 – mid-2015: Approx. $8 -10M in direct cost for Phase 2a/2b trial

Continuing to expand AEROSURF exclusivities

Recent announcement of CAG-related US Notice of Allowance; multiple new Rx and device initiatives underway; orphan-eligible US/EU

Established U.S. specialty commercial and medical affairs team – AEROSURF illustrates long-term commitment to innovation in neonatology

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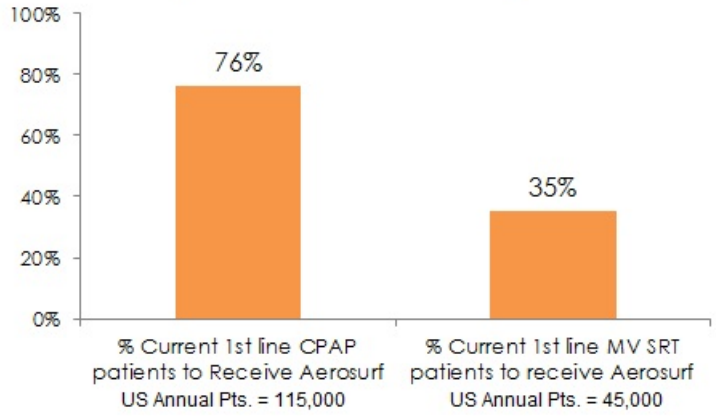
AEROSURF® - Market Considerations

Unmet medical need: Approx.160,000 infants would likely benefit from early surfactant therapy of which 115,000 infants receive only nCPAP as first line therapy

A mechanically ventilated patient is much more costly to treat vs. a non-ventilated patient in the NICU (>$55,000 vs. <$8,000 respectively)[1];

Cost of hospitalization for patient with chronic lung disease (BPD) is over $100,000[1]

Expected AEROSURF Usage[2]



U.S. market potential for AEROSURF – $600M to $1.0B+ [3]

International market is comparable[4]

1 Cost of hospitalization for preterm and low birth weight infants in the United States. Russell RB. Pediatrics 2007; 120(1): e1-9
2 Discovery Labs Market Research April 2010 (n=30)
3 Discovery Labs estimate based on available data
4 Estimates based on data derived from the following sources, among others: IMS MIDAS data (MAT Sept 2008); Vermont Oxford Network (VON) data, 2006; UNICEF data, 2005 (website);.

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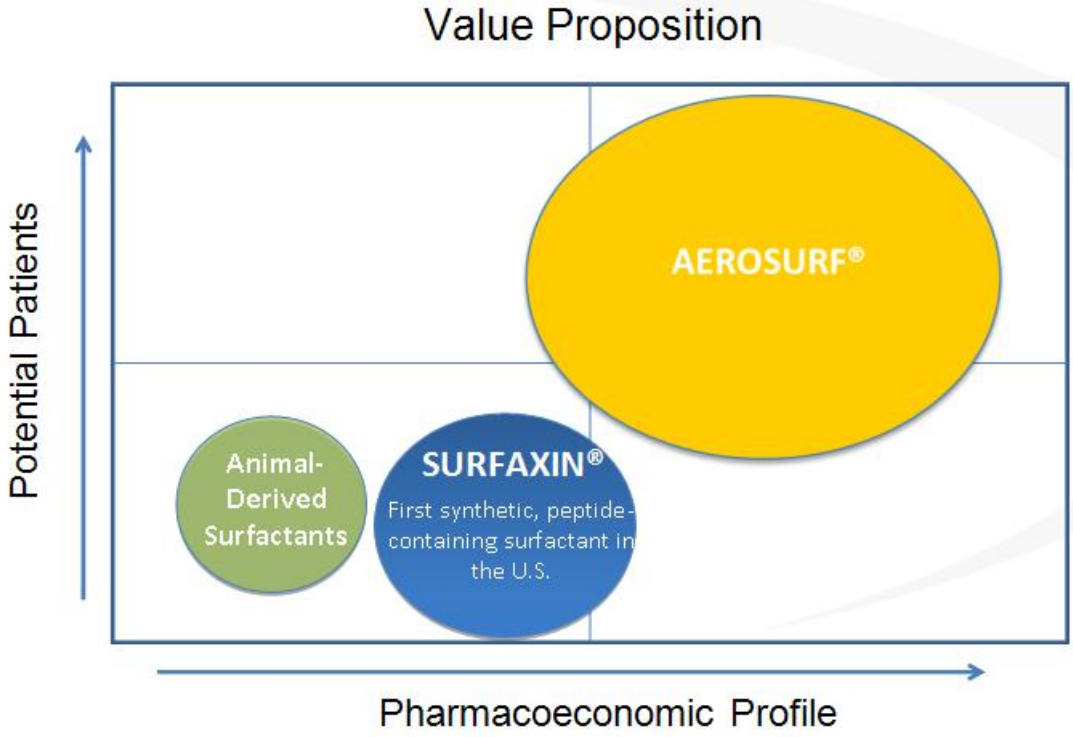
DSCO: Transforming the treatment of RDS in neonatology



DiscoveryLabs
Inspired Innovation

Q&A

Exhibit 99.2

Discovery Labs Announces IND Submission for AEROSURF®

Important Neonatal Clinical Development Program Expected to Begin 4Q'13

Conference Call Today at 10:00 a.m. EDT

Warrington, PA — October 17, 2013 — Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard of respiratory critical care, today announced that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) to initiate its AEROSURF® phase 2 clinical program. The FDA has confirmed receipt of the IND and has indicated that, unless otherwise notified during its review, the Company may initiate the phase 2 clinical program after a 30-day period. Discovery Labs anticipates patient enrollment could begin in the fourth quarter of 2013. The Company will host a conference call this morning at 10:00 AM ET to discuss the AEROSURF program. Conference call details are below.

"The filing of our AEROSURF IND with the FDA represents an important milestone for our Company and a first step towards a potentially transformational medical advancement for the neonatology community and the infants they care for," said John G. Cooper, Chief Executive Officer at Discovery Labs.

AEROSURF is a novel investigational drug-device combination product being developed to deliver Discovery Labs' KL_4 surfactant in aerosolized form to premature infants with respiratory distress syndrome (RDS). AEROSURF could potentially allow for the administration of KL_4 surfactant to premature infants without invasive endotracheal intubation, and may enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated.

"The AEROSURF program is leveraging important advancements in our novel technology platform," said Russell Clayton, DO, Senior Vice President, Research and Development, at Discovery Labs. "Our synthetic KL_4 surfactant technology was recently validated with the FDA approval of SURFAXIN® for the prevention of RDS in infants at high risk for RDS. We are now combining our KL_4 surfactant with our proprietary drug delivery technologies to potentially deliver aerosolized KL_4 surfactant to patients with respiratory disease, with an initial focus on the unmet medical needs in premature infants with RDS."

Conference Call and Webcast Details
Discovery Labs will hold a conference call and webcast today at 10:00 AM EDT to discuss the foregoing. A live webcast of the conference call, including a slide presentation, is available at http://bit.ly/17KTf5r and www.discoverylabs.com. An archive of the webcast will be available on Discovery Labs' Investor Relations web site.

For “listen-only” participants and those who wish to take part in the question and answer portion of the call, the dial-in numbers are (877) 215-0093 (U.S.) or (706) 679-3237 (international). The passcode for the call is 86481667. The replay number is (855) 859-2056 or (404) 537-3406 using the same conference call passcode listed above. A replay will also be available at www.discoverylabs.com.

About RDS and the Neonatologist’s Dilemma

RDS is a condition in which premature infants are born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen. Premature infants born prior to 37 weeks gestation have not fully developed their own natural lung surfactant and therefore need treatment to sustain life. RDS is experienced in approximately half of the babies born between 26 and 32 weeks gestational age. The incidence of RDS approaches 100 percent in babies born less than 26 weeks gestational age. RDS can result in long-term respiratory problems and death.

Premature infants with RDS often require endotracheal intubation and mechanical ventilation to provide respiratory support and to administer surfactant (usually within the first hours of birth). Unfortunately, many infants relapse following initial surfactant therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, increasing their risk of developing further serious respiratory complications. Neonatologists generally try to avoid intubation. As a result, many neonatologists will only intubate in cases of severe respiratory disease, where the benefits of invasive surfactant administration clearly outweigh the associated risks.

For all but the very low birth weight infants with severe RDS, a common ventilatory support treatment alternative to intubation and mechanical ventilation is nasal continuous positive airway pressure (nCPAP). Unfortunately, a significant number of infants do not respond adequately to nCPAP, an outcome referred to as nCPAP failure, and require subsequent surfactant administration via intubation and mechanical ventilation.

As it is not possible to ascertain in advance which patients will experience nCPAP failure, neonatologists are faced with a dilemma, because the outcome for those infants who experience nCPAP failure and receive delayed surfactant therapy may not be as favorable as the outcome for those infants who receive surfactant therapy in the first hours of life.

Discovery Labs estimates that, on an annual basis, approximately 160,000 premature infants in the U.S. could potentially benefit from early surfactant therapy to address surfactant deficiency or insufficiency. More than 70 percent of surfactant deficient infants (approximately 115,000) do not receive first-line surfactant therapy and instead receive nCPAP alone.

Discovery Labs believes that the neonatal medical community increasingly recognizes the potential of a synthetic, peptide-containing surfactant, such as SURFAXIN and, importantly, a less-invasive method of delivering surfactant, such as AEROSURF, to treat premature infants at risk of suffering from respiratory disorders.

About Discovery Labs
Discovery Laboratories, Inc. is a specialty biotechnology company focused on advancing a new standard in respiratory critical care. Discovery Labs' technology platforms include a novel proprietary KL_4 surfactant, a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant, and proprietary drug delivery technologies being developed to enable efficient delivery of aerosolized KL_4 surfactant and other inhaled therapies. Discovery Labs' strategy is initially focused on neonatology and improving the management of respiratory distress syndrome (RDS) in premature infants. Discovery Labs believes that its RDS product portfolio has the potential to become the new standard of care for RDS and, over time, enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated.

ABOUT SURFAXIN®
The U.S. Food and Drug Administration (FDA) approved SURFAXIN® (lucinactant) Intratracheal Suspension for the prevention of RDS in premature infants who are at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved by the FDA and the only alternative to animal derived surfactants.

IMPORTANT SAFETY INFORMATION
SURFAXIN is intended for intratracheal use only. The administration of exogenous surfactants, including SURFAXIN, can rapidly affect oxygenation and lung compliance. SURFAXIN should be administered only by clinicians trained and experienced with intubation, ventilator management, and general care of premature infants in a highly supervised clinical setting. Infants receiving SURFAXIN should receive frequent clinical assessments so that oxygen and ventilatory support can be modified to respond to changes in respiratory status.

Most common adverse reactions associated with the use of SURFAXIN are endotracheal tube reflux, pallor, endotracheal tube obstruction, and need for dose interruption. During SURFAXIN administration, if bradycardia, oxygen desaturation, endotracheal tube reflux, or airway obstruction occurs, administration should be interrupted and the infant's clinical condition assessed and stabilized.

SURFAXIN is not indicated for use in acute respiratory distress syndrome (ARDS).

For more information about SURFAXIN, please visit www.surfaxin.com.

Forward-Looking Statements
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. Examples of such risks and uncertainties include those related to Discovery Labs' research and development activities, including, among other things, (i) time-consuming and expensive pre-clinical studies, clinical trials and other efforts, which may be subject to potentially significant delays or regulatory holds, or failure, and (ii) regulatory requirements relating to development and manufacture of the drug and aerosol delivery components of Discovery Labs' combination drug/device products, as well as those risks and uncertainties 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. Any forward-looking statement in this release speaks only as of the date on which it is made. Discovery Labs assumes no obligation to update or revise any forward-looking statements.

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