

---

**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 24, 2012**

Date of Report (Date of earliest event reported)

**Discovery Laboratories, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**000-26422**  
(Commission File Number)

**94-3171943**  
(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:

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

On October 24, 2012, Discovery Laboratories, Inc. (the "Company") issued a press release providing a commercial update of the activities related to the commercial introduction of SURFAXIN® and AFECTAIR®. SURFAXIN is the first and only peptide-containing, surfactant approved by the U.S. Food and Drug Administration (FDA) and the only alternative to animal-derived surfactants that today are the standard of care to manage RDS in premature infants. AFECTAIR was developed initially as part of the Company's AEROSURF® development program and is being developed as a series of proprietary disposable ventilator circuit/patient interface connectors that simplify the delivery of aerosolized medications to critical-care patients requiring ventilatory support. The initial AFECTAIR device has been developed for use with infants receiving ventilatory support in the Neonatal Intensive Care Unit (NICU) and Pediatric Intensive Care Unit (PICU). The Company has registered its AFECTAIR devices in the U.S. as a Class I, exempt medical device. A copy of the release ("Press Release") is attached hereto as Exhibit 99.1 and the text of such release is incorporated by reference herein.

The Company announced that it continues to make progress in its efforts to prepare for launch. Among other things, to assure product continuity, the Company has enhanced its quality control and assurance infrastructure with additional hiring of highly-qualified scientific, technical and analytical personnel and systems implementation. During a recent review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, the Company determined that one of its analytical chemistry methods used to assess its drug product's conformance to specifications requires improvement and that an update to product specifications will be necessary. The Company has proactively communicated its findings regarding this analytical method to the FDA, has initiated a plan to improve and validate its analytical method, and plans to submit updated product specifications to the FDA. Based on the anticipated time required to improve the method, submit updated specifications, and await confirmation from the FDA, the Company anticipates that, if its plan is successful, the availability of SURFAXIN drug product will be delayed until early in the second quarter of 2013. This is not expected to have a material adverse effect on the Company's business or financial position, in part, because the Company's commercial launch plans for SURFAXIN during this period has always been to focus initially on formulary acceptance.

The Company anticipates that the initial AFECTAIR device will be commercially available in December 2012. This initial device is intended for use in infants receiving ventilatory support in the neonatal and pediatric intensive care units (NICU, PICU). Because the Company expects that the same hospitals that purchase SURFAXIN are likely to purchase AFECTAIR, the Company's commercial and medical affairs organizations will be responsible for the commercial introduction of this product.

*Conference Call*

The Company will hold a conference call and webcast on October 24, 2012 at 10:00 AM EDT to discuss its commercialization plans for SURFAXIN and AFECTAIR. Information relating to a live webcast of the conference call, including a slide presentation, is set forth in the press release. A copy of the slide presentation accompanying the conference call and webcast ("Slide Presentation") attached hereto as Exhibit 99.2 and the text thereof is incorporated by reference herein. The Slide Presentation is qualified in its entirety by the Company's periodic filings with the Securities and Exchange Commission (SEC), including this Form 8-K and the Company's most recent reports on Form 10-K, 8-K and 10-Q, and any amendments thereto.

*Projections and Assumptions*

The Company's estimates of market size, business opportunities and analyses and assumptions included in the Press Release, Slide Presentation and conference call are based in part on its analysis of data derived from the following sources, among others: with respect to SURFAXIN, account estimated patient populations, expected adoption rates of SURFAXIN drug product, current pricing, and economics and anticipated potential pharmaco-economic benefits are based, in part, on the following sources: Annual Summary of Vital Statistics: 2006, *Pediatrics*, Martin et. al.; CDC National Vital Statistics, 2005; IMS Midas Data MAT, December 2010; HCUP Hospital Discharge data, 2008; Hospital Insurance Claim Database, 2009; Management and Outcomes of Very Low Birth Weight, *New England Journal of Medicine* (NEJM), 2008, Eichenwald, Stark; Market Intelligence Report on Number of ICU Beds in EU5 Countries; Vermont Oxford Network Data, 2006; and the Company's Primary Market Research, December 2010, May 2011 and June 2012; as well as the Company's analysis of the Phase 3 SELECT and STAR trials of SURFAXIN.

The Company's estimates of market size, business opportunities and analyses and assumptions with respect to AFECTAIR are based in part on its analysis of data derived from the following sources, among others: with respect to AFECTAIR, NICU patient population based on CDC, March of Dimes (2010); PICU and ICU patient populations estimated based on number of beds in the US relative to the number of NICU beds; IMS Hospital Demographic Database (2011); Primary market research, Oct 2012; patient populations in the EU5 based on TforG market data for EU5 (2010) - ~50% ICU beds per capita in Europe vs US; patient populations in rest of world, the Company's estimate; Unit Price and Units per Patient, the Company's primary market research (May 2011 and Oct 2012); percent of patients on respiratory support, the Company's primary market research, Oct 2012.

The Company provides estimates and projections to give the reader an understanding of its strategic priorities, but the reader is cautioned not to rely on the Company's estimates and projections. To the extent that statements in this Current Report on Form 8-K are not strictly historical, including such estimates and projections as well as any 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 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.

#### *Financial Update*

As of September 30, 2012, the Company had cash and cash equivalents of \$36.1 million. Net cash outflows before financing activities for the quarter ended September 30, 2012 were approximately \$9.9 million. For the fourth quarter 2012, the Company anticipates net operating cash outflows of approximately \$9.5 million, before taking into account financing activities.

#### *Other Information*

With respect to the Company's SURFAXIN manufacturing strategy, because of the limited size of the market, the number of vials produced per lot of SURFAXIN, and the limited volume of drug product stocked by hospitals generally, the Company does not plan to build a significant inventory of SURFAXIN drug product. For this reason, the need to modify and validate a SURFAXIN analytical chemistry method will not result in a loss of inventory. At the same time, the anticipated time line for availability of SURFAXIN drug product early in the second quarter 2012 includes time to manufacture, release, package and deliver newly-manufactured SURFAXIN drug product to the Company's warehouse services provider.

The Company plans to attend several neonatal medical conferences in the fourth quarter of 2012, where the commercial and medical affairs teams will be available to discuss SURFAXIN and/or AFECTAIR. In addition, at certain of these conferences, the results of new studies and new analyses providing expanded information to neonatal healthcare professionals regarding SURFAXIN and AFECTAIR will be presented.

#### **Disclosure Notice**

The information in the Press Release, Slide Presentation, conference call and this 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, including plans to execute a program to improve and validate one of the SURFAXIN analytical chemistry methods used to assess its drug product's conformance to specifications, and prepare and submit to the FDA information supporting a request to update certain SURFAXIN product specifications. 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 improve and validate the analytical method, which can be time-consuming and unpredictable; the risk that the Company will be unable to successfully complete the work necessary to support its submission to the FDA within the timeline outlined above, if at all; risks that the FDA will not accept the Company's submission, or may require additional information that would require additional time, or may not respond within the time outlined in the guidelines set forth in the Prescription Drug User Fee Act (PDUFA) (which suggest four months for submissions of the type planned by the Company), or may deny the Company's request to update the product specifications; and the risk that the Company may identify unforeseen problems that have not yet been discovered that could adversely affect the Company's plans. In addition, the FDA may determine to initiate a facility inspection to review the Company's approach and response to dealing with the issues identified in its review of the analytical method. Any failure to satisfy any issues raised by the FDA could significantly delay, or preclude outright, gaining approval of updated product specifications, or could result in an action by the FDA to restrict the Company's ability to commercialize some or all of the Company's products, which could potentially delay or prevent the commercial availability of SURFAXIN drug product.

In addition, although the Company currently believes that it will be successful in meeting its strategic planning goals within the time frames outlined in the Press Release, Slide Presentation, conference call and this Form 8-K, there can be no assurance that the Company will successfully raise the funds required to meet its near-term capital requirements, through financing or similar transactions, or otherwise; that the Company will successfully complete the commercial introduction of SURFAXIN and AFECTAIR; that the revenues the Company may realize from the sale of SURFAXIN and AFECTAIR will be in line with current expectations; that the Company will successfully identify one or more strategic partners or collaboration arrangements to support development and, if approved, commercial introduction of the SURFAXIN LS and AEROSURF product candidates; that the Company will successfully initiate the planned clinical programs for SURFAXIN LS and AEROSURF as planned, if at all, or that the Company will successfully develop and gain approval, in the United States and elsewhere, to market SURFAXIN LS and AEROSURF; or that the revenues, if any, that the Company generates in the future will be sufficient at any time to fund the further development of its research and development programs and support our operations. If the Company is unable to identify appropriate sources of capital to support the development of its commercial and medical affairs organization, it may be unable to launch its products and therefore, would be unable to generate revenues from our approved products to support its business. If the Company is unable to identify and enter into strategic alliances for the development of SURFAXIN LS and AEROSURE, and if approved, commercialization of SURFAXIN LS and AEROSURF in the European Union and other markets outside the U.S., the Company may be unable to fund planned clinical trials, which would have a material adverse effect on its research and development programs.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

[99.1](#) Press release dated October 24, 2012

[99.2](#) Slide Presentation dated October 24, 2012

## 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/ W. Thomas Amick          

Name: W. Thomas Amick

Title: Chairman of the Board and Chief Executive Officer

Date: October 24, 2012



**Discovery Labs Provides Commercial Update for SURFAXIN® and AFECTAIR®**

*Conference Call Today at 10:00 am EDT – Details Below*

**Warrington, PA – October 24, 2012** – Discovery Laboratories, Inc. (Nasdaq: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today reports a commercial update for SURFAXIN® and AFECTAIR®. The Company has initiated commercial launch activities for both products by training and deploying its newly-formed commercial and medical affairs organizations with the goal of securing hospital formulary acceptance for SURFAXIN, expected to be commercially available in the second quarter of 2013, and adoption of AFECTAIR with an anticipated product availability in December 2012.

As the Company continues to make progress in its launch readiness efforts, Discovery Labs has:

- Held its first national meeting to welcome and complete the training of its newly-hired field sales force, national accounts team and medical science liaison team,
- Deployed its field force with the primary objective of gaining hospital formulary acceptance for SURFAXIN and adoption of AFECTAIR,
- Executed or is finalizing group purchasing organization and national account contracts,
- Continues to manufacture SURFAXIN at a commercial scale as it has for several years,
- Established supply chain distribution and warehouse arrangements,
- Enhanced its quality control and assurance infrastructure with additional hiring of highly-qualified scientific, technical and analytical personnel and systems implementation.

During a recent review of the results and processes related to the analytical testing and quality control of SURFAXIN drug product, Discovery Labs determined that one of its analytical chemistry methods used to assess its drug product's conformance to specifications requires improvement and that an update to product specifications will be necessary.

Discovery Labs has proactively communicated its findings regarding this analytical method to the U.S. Food and Drug Administration (FDA), has initiated a plan to improve and validate its analytical method, and plans to submit updated product specifications to the FDA. Based on the anticipated time required to improve the method, submit updated specifications, and await confirmation from the FDA, Discovery Labs anticipates that, if its plan is successful, the availability of SURFAXIN drug product will be delayed until early in the second quarter of 2013. This is not expected to have a material adverse effect on the Company's business or financial position, in part, because the Company's commercial launch plan for SURFAXIN during this period has always been to focus initially on formulary acceptance.

Discovery Labs anticipates commercial availability of its initial AFECTAIR device in December 2012. This initial device is intended for use in infants receiving ventilatory support in the neonatal and pediatric intensive care units (NICU, PICU). Because Discovery Labs expects that the same hospitals that purchase SURFAXIN are likely to purchase AFECTAIR, the Company's commercial and medical affairs organizations will be responsible for the commercial introduction of this product.

---

## 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 [https://us.reg.meeting-stream.com/discoverylaboratories\\_102412](https://us.reg.meeting-stream.com/discoverylaboratories_102412) and [www.discoverylabs.com](http://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 (866) 332-5218 (U.S.) or (706) 679-3237 (international). The passcode for the call is 55058190. A replay of the conference call will be available through October 31, 2012. 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](http://www.discoverylabs.com).

## About SURFAXIN

SURFAXIN (lucinactant) intratracheal suspension is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first and only peptide-containing, surfactant approved by the FDA and the only alternative to animal-derived surfactants.

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 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](http://www.surfaxin.com). Information contained in, or accessible through, this website does not constitute a part of, and is not incorporated into, this press release.

## About AFECTAIR

AFECTAIR was developed initially as part of the AEROSURF® development program and is being developed as a series of proprietary disposable ventilator circuit/patient interface connectors that simplify the delivery of aerosolized medications to critical-care patients requiring ventilatory support. According to national health statistics and market assessment data, it is estimated that each year more than 1.3 million patients in the United States and European Union receive aerosolized medications while requiring ventilator support. Discovery Labs is implementing a business plan that potentially will allow for the commercial introduction of the initial AFECTAIR device in the United States in late 2012.

## DISCLOSURE NOTICE

Readers are referred to, and encouraged to read in their entirety, the Form 8-K that Discovery Labs filed with the Securities and Exchange Commission (SEC) concurrently with the issuance of this press release, and Discovery Labs' Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 to be filed with the SEC, which includes further detail on the Company's business plans and operations, financial condition and results of operations.

## Forward-Looking Statements

*The information in this press release includes certain "forward-looking" statements relating, among other things, to Discovery Labs' plans to manufacture and release SURFAXIN drug product for commercial sale, including plans to execute a program to improve and validate a particular analytical chemistry method, and prepare and submit to the FDA information supporting a request to update SURFAXIN product specifications.*

---

*These and other similar statements included herein are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. While Discovery Labs currently believes that it will succeed in meeting the timelines outlined above, such forward-looking statements are subject to a variety of risks and uncertainties that could cause actual results to be materially different. Examples of such risks and uncertainties, including those related to the Company's research and development programs, are described in Discovery Labs' filings with the SEC, 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.*

**Contact Information:**

Media Relations:

Michael Parks, Pitch360 - 484.356.7105 or Michael@pitch360inc.com

Investor Relations:

Michael Rice, LifeSci Advisors - 917.282.3242

John G. Cooper, President and Chief Financial Officer - 215.488.9490

---





October 2012

SURFAXIN® & AFECTAIR® US Commercialization  
Update

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, including the Form 8-K that includes this presentation deck (referred to herein as "Related Form 8-K"), for a fuller discussion of the matters presented here.

# Teleconference Overview

---

- Introduction – Significant opportunity in Neonatal Critical Care
- US Neonatology Market Preparation
- **SURFAXIN**<sup>®</sup> US Product Launch
- **AFFECTAIR**<sup>®</sup> US Product Launch
- **AEROSURF**<sup>®</sup> Update
- Financial / Strategic Considerations
- Q&A

# DSCO: Improving The Standard of Respiratory Critical Care

---

A specialty biotechnology company focused on creating life-saving solutions for critical care patients with respiratory disease and improving the standard of care for pulmonary medicine.

- KL<sub>4</sub> surfactant technology – a synthetic, peptide-containing surfactant that is structurally similar to human pulmonary surfactant



- Aerosolized drug delivery technologies to improve delivery of therapies to critical care patients

# Initial Focus: Respiratory Distress Syndrome (RDS) in Premature Infants

---

*KL<sub>4</sub> surfactant portfolio has the potential to greatly improve the management of RDS and, over time, expand the current RDS estimated worldwide annual market of \$200 million to a \$1 billion market opportunity*

Significant unmet need – affects one out of four premature babies, RDS is the most prevalent respiratory problem in the NICU

Leading cause of death among preterm infants; may result in long-term complications

RDS mortality and morbidity rates have not meaningfully improved in the last decade



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).

## DSCO Near-term Priorities

---

**SURFAXIN**<sup>®</sup> is the first FDA approved (March 2012) synthetic, peptide-containing surfactant for use in RDS and the only alternative to animal-derived surfactants in the U.S.

**AFECTAIR**<sup>®</sup> was cleared for marketing in the U.S. by the FDA in Feb. 2012

1. Launch **SURFAXIN** and **AFECTAIR** neonatal device in the U.S. through our commercial and medical affairs organizations specializing in neonatal respiratory critical care – beginning in Q4 2012
2. **AEROSURF**<sup>®</sup> is being developed to deliver aerosolized KL<sub>4</sub> surfactant without the need for intubation – phase 2 clinical trials are anticipated to begin in 2H 2013
3. Establish strategic alliance to develop and commercialize our RDS portfolio for markets outside the U.S. (target Q1 2013)

## Priority 1 – Preparing the Market for **SURFAXIN**<sup>®</sup> and **AFFECTAIR**<sup>®</sup>

---

- Commercial and medical affairs field teams in place
  - Extensive experience in respiratory critical care / hospital setting, including pharmaceuticals and medical devices
  - First National Meeting Held in October
- Short term goals:
  - National account agreements in place
  - SURFAXIN formulary meetings in ~200 out of 300 target accounts
  - Commitment for **SURFAXIN**<sup>®</sup> purchase in 100 target accounts
  - Commitment for **AFFECTAIR**<sup>®</sup> user experience program in at least 200 target accounts
- Adjusting timeline for **SURFAXIN** product availability to early Q2 2013
- On track for **AFFECTAIR** product availability in 4Q12 – anticipate stocking in December

## Priority 1 – Cont' d SURFAXIN® Product Availability

---

Technical team leadership has been focused on business supply continuity

- **Manufacturing:** Discovery Labs has been manufacturing at a commercial scale for several years.
- **Supply Chain:** Warehouse & specialty distributor agreements are in place
- **Quality control:** Infrastructure has been enhanced with the hiring of highly-qualified scientific, technical and analytic personnel and systems implementation
- **Recent Developments:**
  - An analytical chemistry methods requires improvement and an update to product specifications will be necessary
  - Discovery Labs has proactively communicated its findings to the FDA
  - Initiated plan to improve and validate the analytical method
  - Plans to submit updated product specifications to FDA
  - SURFAXIN drug product is expected to be available early in the second quarter of 2013.

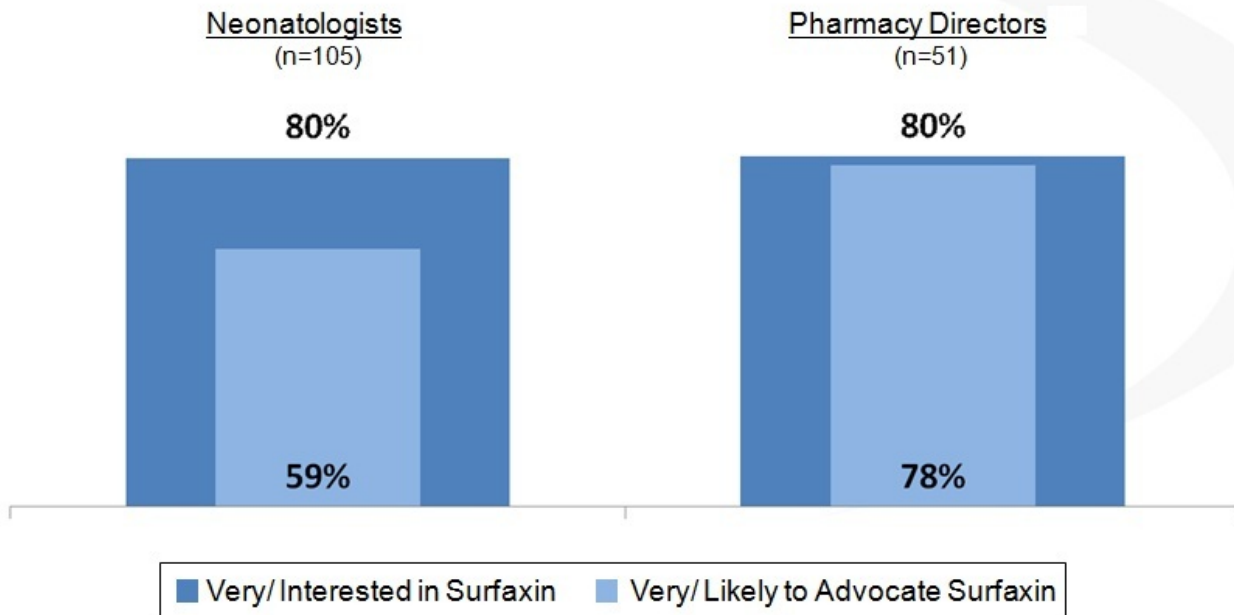
Refer to Related Form 8-K for a discussion of the risks and uncertainties related to the matters on this slide



# Preparing the Market for SURFAXIN®

Recent Market Survey: High Interest in SURFAXIN®

Favorable Baseline Assessment of Interest and Likelihood to Advocate for SURFAXIN on NICU Formulary\*



Data on file, Discovery Laboratories, Inc. 2012  
\* Baseline assessment prior to customer interaction with DSCO field team

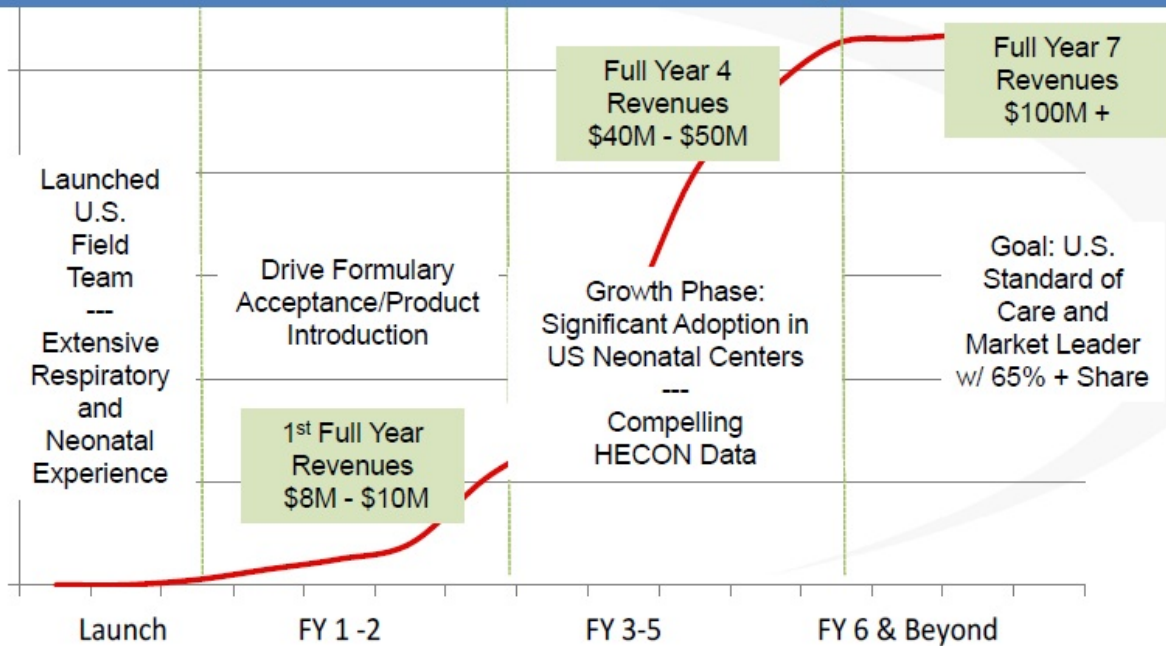
## **SURFAXIN<sup>®</sup> NICU Market Economics & Pricing**

---

- Uncomplicated U.S. reimbursement under DRG
- Federal Supply Schedule (FSS) agreement submitted – limited impact on business
- Use of pharmacoeconomic data is expected to redefine the value proposition for surfactant replacement therapy
  - **SURFAXIN<sup>®</sup>** reintubation data analysis is a potential key driver for formulary
- **SURFAXIN** Pricing
  - Wholesale Acquisition Cost (WAC) = \$860.00 for 8.5 ml vial
  - GPO contract price will be set at modest premium to Curosurf<sup>®</sup> 3ml vial

# SURFAXIN® Commercial Strategy & Revenue Potential

Use clinical and pharmacoeconomic data to redefine the value of surfactant therapy



Refer to Related Form 8-K for a discussion of the assumptions and related risks related to the projections reflected on this slide

## AFECTAIR® US Commercial Launch on Track

---

- **AFECTAIR®** strategy: create a new market based on unmet need associated with challenges of aerosol delivery today
- Launching initial device for use in infants requiring ventilatory support in the NICU/PICU
- Approximately 355K NICU/PICU eligible patients in US each year
- Due to inefficiency of current technologies, less than 25% of eligible NICU patients receive aerosolized Rx today – potential growth opportunity
- Aerosolized medications are routinely administered to PICU patients – potential opportunity to improve standard of care

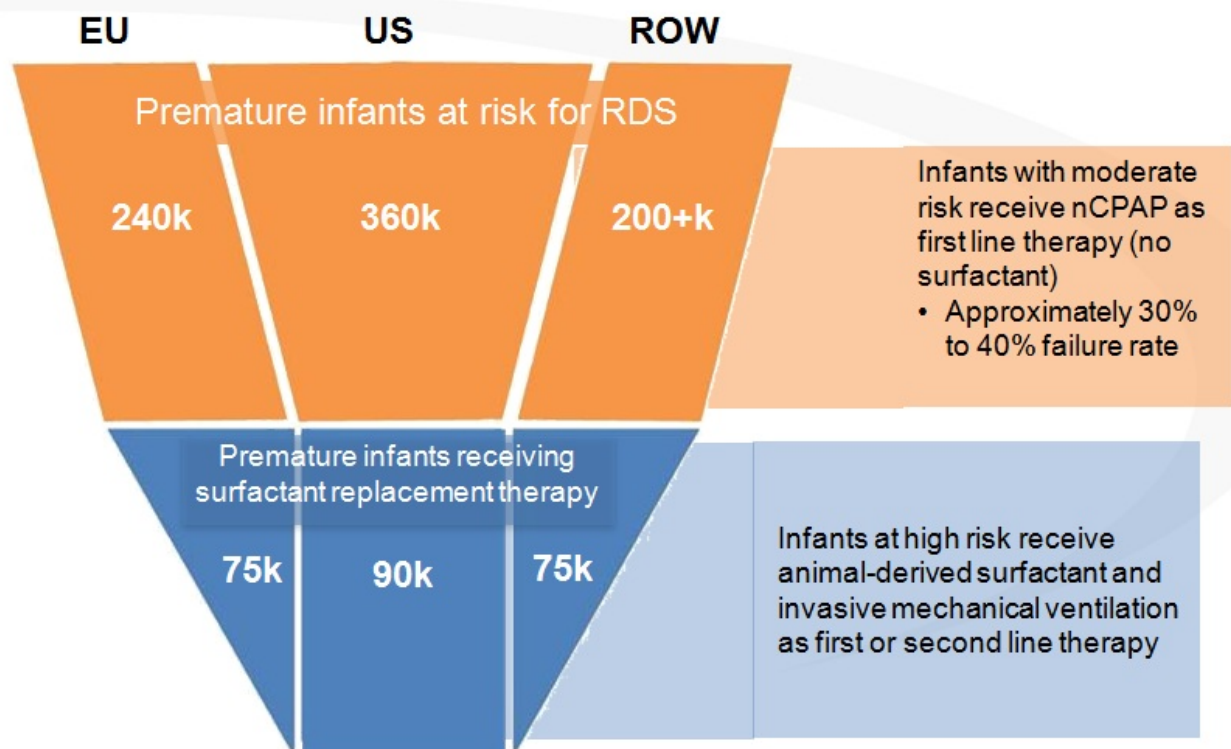
## **AFECTAIR<sup>®</sup>** US Commercial Launch on Track

---

- Key launch tactic: user experience program
- Final pricing to be determined through feedback from user experience program
- Expect to stock warehouse with **AFECTAIR<sup>®</sup>** commercial product in December 2012
- Management believes revenue potential for the initial device is approximately \$10M in U.S. with comparably-sized revenue potential in international markets; 2013 guidance approximately \$500k - \$1M

Refer to Related Form 8-K for a discussion of the assumptions and related risks related to the projections reflected on this slide; Discovery Labs primary market research; data on file 2012

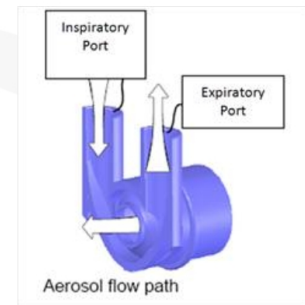
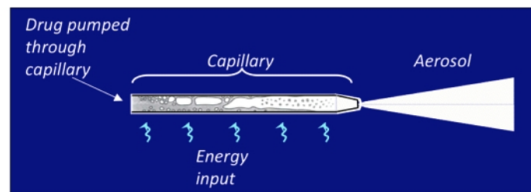
## RDS: Significant patient population underserved by undifferentiated animal-derived surfactants



RDS population estimates based on data derived from the following sources: 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.

## Priority 2: Initiate **AEROSURF**<sup>®</sup> P2 Clinical Program

- **AEROSURF**<sup>®</sup> Architecture & Key initiatives:



- Lyophilized KL<sub>4</sub> Surfactant: process tech transfer to CMO underway; Target to complete commercial scale process validation by mid-2013
- Capillary Aerosol Generator: Contracted with 3<sup>rd</sup> party expert team; targeting delivery of 'clinic-ready' devices mid-2013
- KOL /Scientific Advisory Board
- Initiation of **AEROSURF** P2 clinical trial on track for 2H13

## Priority 3: International Strategic Partnership for RDS

---

- Desirable Partner Characteristics:
  - Invests in innovative, specialty opportunities, i.e. – pediatric respiratory critical care
  - Has strong hospital commercial presence – focus on EU and potentially other major markets
  - Financial strength
  - Views our product(s) as important part of its portfolio – **AEROSURF®** is deal anchor
- Alliance – development / commercial
  - Exclusive license / fees & milestones/ R&D collaboration/ commercial share via royalties and milestones
  - Potential to expand alliance with future innovation
- In active discussion with multiple parties
  - Company believes it remains on track to potentially complete a transaction in 1Q13, although there can be no assurances



# KL4 Surfactant Portfolio: Potential to Transform RDS

## Synthetic KL4 Surfactant

**Surfaxin<sup>®</sup>**  
(lucinactant)

First synthetic peptide-containing surfactant and alternative to animal-derived surfactants

FDA Approved for Respiratory Distress Syndrome (RDS)

Goal: US Standard of Care  
Potential Revenues: \$75M+

## Aerosolized KL4 Surfactant

**AEROSURF<sup>™</sup>**

Potential to avoid invasive intubation and expand eligible patient population that could benefit from surfactant therapy

Preparing for phase 2 Program

Goal: Redefine RDS treatment paradigm  
Potential Revenues: \$1B

## Lyophilized KL4 Surfactant

**Surfaxin<sup>™</sup> LS**  
lucinactant intratracheal suspension

Potential to improve safety, simplify drug administration, optimize handling & shelf-life

Preparing for phase 3 program

Goal: Global line extension of SURFAXIN  
Potential Revenues: \$250M

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).

**DiscoveryLabs<sup>™</sup>**  
Inspired Innovation

---



# Q&A