**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**

**March 6, 2012**

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 8.01. Other Events.**

On March 6, 2012, Discovery Laboratories, Inc. (the "Company"), issued a press release announcing that on March 6, 2012 the U.S. Food and Drug Administration (FDA) granted marketing approval for the Company's lead $KL_4$ surfactant drug product, SURFAXIN® (lucinactant) for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine and provides healthcare practitioners with an alternative to the animal-derived surfactants that today are the standard of care to manage RDS in premature infants. A copy of the press release is attached hereto as Exhibit 99.1 and the text of such release is incorporated by reference herein.

In connection with the above announcement, the Company also is disclosing that it is planning to implement an operating plan intended to result in the commercial introduction of SURFAXIN in the U.S. in late 2012. In that regard, it expects to develop its own focused, specialty respiratory critical care commercial and medical affairs organization specializing in neonatal indications, beginning with SURFAXIN and, if approved, its other $KL_4$ surfactant products for RDS: SURFAXIN LS™ and AEROSURF®. The Company's strategy will focus primarily on hospitals with Neonatal Intensive Care Units (NICUs) believed to represent a significant portion of the current surfactant market in the U.S. To execute this strategy, the Company expects to incur annual expenses of approximately $12 - $13 million for commercial and medical affairs capabilities. The Company believes that this strategy will provide it direct control over its U.S. sales and marketing activities and permit it to establish a strong medical affairs presence in NICUs nationwide. The Company expects to be able to leverage this presence and the experience it will gain from introducing SURFAXIN nationwide to provide for an effective and efficient introduction of SURFAXIN LS and AEROSURF, if approved.

The Company expects that its commercial and medical affairs organization will also support the planned commercial introduction of AFECTAIR® in the U.S. and other major markets throughout the world. AFECTAIR devices are a series of novel ventilator circuit / patient interface connectors that simplify the delivery of inhaled therapies (potentially including the Company's aerosolized $KL_4$ surfactant) to critical-care patients requiring ventilatory support by introducing the inhaled therapy directly at the patient interface and minimizing the number of connections in the ventilator circuit. It is believed that AFECTAIR will be of interest to a number of hospitals that, in addition to those with NICUs, have adult intensive care units (ICUs), pediatric intensive care units (PICUs) and critical care centers where AFECTAIR could be used to benefit critical care patients. Accordingly, the Company plans to further support the launch of AFECTAIR in the U.S. and the European Union through arrangements with third-party distributors experienced in introducing respiratory medical devices into hospitals. The Company expects that its commercial and medical affairs organizations will work in a coordinated manner with third-party distributors to assure that all hospitals with critical care facilities are aware of, and have access to, the AFECTAIR devices.

The Company has recently registered its initial AFECTAIR device, which has been designed for use with jet nebulizers and other aerosol generators, in the U.S. as a Class I, exempt medical device. The Company is planning to implement a regulatory and manufacturing plan that, if successful, could position it to initiate the commercial introduction of the initial AFECTAIR device in the U.S. and the European Union in the fourth quarter of 2012, and a second AFECTAIR device, AFECTAIR® DUO, which is being designed for use with vibrating mesh nebulizers (VMN), metered dose inhalers (MDI) and other aerosol generators, in 2013.

*Financial Update*

With the regulatory approval for SURFAXIN and initiation of activities with respect to the commercial introduction of SURFAXIN in U.S., as well as the registration and potential commercial introduction of AFECTAIR in the U.S. and the European Union, the Company believes it is better positioned to raise the capital required to execute the commercial introduction of SURFAXIN and AFECTAIR and to support its operations. It also believes that it is better positioned to potentially identify and enter into strategic alliances and other similar transactions that could provide development and international commercial expertise, as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support development and introduction of its pipeline products, beginning with SURFAXIN LS and AEROSURF, in various markets around the world. Although the Company is actively engaged in discussions with potential strategic and/or financial partners, there can be no assurance that any financing transaction or strategic alliance will be successfully concluded or available on terms favorable or acceptable to the Company.

The Company's business strategy and key planning goals for the remainder of 2012 include, among other things: (i) the commercial introduction of SURFAXIN in the U.S., and of AFECTAIR in the U.S. and the European Union, (ii) securing a strategic alliance to support the development and, if approved, eventual commercial introduction of SURFAXIN LS and AEROSURF in the European Union and markets outside the U.S., (iii) advancement of the SURFAXIN LS and AEROSURF development programs to be in a position to initiate planned Phase 3 and Phase 2 clinical trials, respectively, after securing a potential strategic partner, and (iv) procuring the capital believed to be necessary and desirable to support the Company's activities until such time as the net revenues from its approved products, from potential strategic alliance and other collaboration arrangements, and from other future sources, such as warrant exercises, are sufficient to offset cash flow requirements.

As of December 31, 2011, the Company had cash and cash equivalents of $10.2 million. At the present time, the Company believes that it has sufficient capital to fund its operations into the second quarter of 2012. To execute its business strategy, the Company will need to secure infusions of capital and believes that such capital may be obtained from a combination of some or all of the following sources:

- Exercise of outstanding warrants:

    - In February 2011, the Company issued 15-month warrants to purchase five million shares of its common stock at an exercise price of $2.94 per share (15-month warrants) that expire on May 22, 2012. Through, March 5, 2012, holders of the 15-month warrants have exercised warrants to purchase 275,000 shares of common stock, resulting in gross proceeds to the Company of $809,970. If the market price of the common stock should be greater than $2.94 per share in the period prior to the May 2012 expiration date, and if holders of the 15-month warrants decide in their discretion to exercise additional warrants, the Company potentially could raise up to an additional $13.9 million in proceeds from the exercise of the 15-month warrants.

    - Also in February 2011, the Company issued five-year warrants to purchase five million shares of its common stock at an exercise price of $3.20 per share (2011 five-year warrants). These warrants expire in February 2016. As of March 5, 2012, the exercise price of the 2011 five-year warrants was $3.20 per share. If the market price of the common stock were to exceed $3.20 at any time prior to the expiration of the five-year warrants in February 2016, and if the holders of the five-year warrants were to exercise the warrants in their discretion, the Company could realize up to $16.0 million in additional proceeds from the exercise of the five-year warrants. (The 2011 five-year warrants contain anti-dilutive provisions that adjust the exercise price if the Company issues any common stock, securities convertible into common stock, or other securities (subject to certain exceptions) at a value below the then-existing exercise price of the 2011 five-year warrants. If the Company should complete a financing or other similar transaction involving the issuance of securities at values less than the then-existing exercise price of the 2011 five-year warrants, the exercise price of the 2011 five-year warrants may be adjusted downward).

    - There can be no assurance that the market price of the common stock will remain at levels that make exercise of outstanding warrants likely, that holders of outstanding warrants will choose to exercise any or all of their warrants prior to the warrant expiration date. If the holders of outstanding warrants do exercise their warrants, because the exercise price will most likely be below the then-current market value of the common stock, any such exercises will have a dilutive effect on stockholders' interests.

- Equity financings in the public capital markets, including but not limited to potential additional financings under our CEFF and ATM Programs:

    - The Company has a Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. (Kingsbridge) that could allow it, at its discretion, to raise capital (subject to certain conditions, including volume limitations) at a time and in amounts deemed suitable to support its business plans. Based on the closing market price of the common stock on March 5, 2012 ($3.58) and assuming that all shares available under the CEFF are issued, the potential availability under the CEFF is approximately $3.6 million.

- In December 2011, the Company entered into a Sales Agency Agreement with Lazard Capital Markets LLC (Lazard), pursuant to which Lazard, as exclusive agent, may, at the Company's sole discretion and at such times that the Company may choose, sell up to a maximum of $15 million of shares of common stock through an "at-the-market" program (ATM Program). The ATM Program has a term of two years, subject to earlier termination. The Company is not required to sell any shares under the ATM Program and may adjust or cancel any order to sell at any time, although it will continue to be responsible for all trade executions that may have occurred prior to the time of adjustment or cancellation. Based on the closing market price of the common stock on March 5, 2012 ($3.58), and assuming that the full amount available under the ATM Program ($15 million) is sold, the Company may issue up to approximately 4.2 million additional shares under the ATM Program.

- In addition to these programs, the Company plans from time to time to consider equity public offerings to secure additional capital and strengthen the Company's financial condition.

- There can be no assurance, however, that the CEFF will be available at any time, or, even if available, that the Company will utilize the CEFF prior to its expiration in June 2013; that the Company will issue any shares pursuant to the ATM Program, or that the entire amount provided under the ATM Program will be realized prior the expiration or earlier termination of the ATM Program; or that the Company will undertake any financings or similar transactions, on favorable terms or otherwise. Even if the Company is able to raise additional capital through additional financings, such financings may only be available on unattractive terms, or, if consummated at prices below then-current market value, which could result in dilution of stockholders' interests.

- Upfront and milestone payments and co-funding of development activities associated with potential strategic alliances or other similar transactions:

  - The Company is engaged in discussions with potential strategic partners who could provide development and commercial expertise as well as financial resources (potentially in the form of upfront payments, milestone payments, commercialization royalties and a sharing of research and development expenses) to support the development of SURFAXIN LS and AEROSURF and, if approved, the introduction of these products in Europe and various markets outside the U.S.. There can be no assurance, however, that the Company will be successful in concluding any strategic alliance, collaboration or other financing transaction.

- Secured debt arrangements to fund working capital and/or investment in capital assets:

  - In the future, the Company believes that debt could potentially be a component of its capital structure and financing plans. Future debt arrangements could take the form of capital equipment financing facilities, revolving working capital lines of credit, term loans and other similar transactions to satisfy the Company's working capital requirements.

The Company believes, if it is successful in implementing its strategic business plan, the anticipated net revenues from the sale of SURFAXIN and AFECTAIR, when combined with the other sources of anticipated revenue, including from potential strategic alliances and collaboration arrangements to support the SURFAXIN LS and AEROSURF development programs, potentially could be sufficient to support future operations without having to undertake further dilutive financings. In that event, the Company would nevertheless continue to consider financings and similar transactions that would strengthen its financial condition and potentially build stockholder value.

Although the Company currently believes that it will be successful in meeting its strategic planning goals within the time frame set forth above, 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 fund and build its own commercial organization to support the commercial introduction of SURFAXIN and AFECTAIR; that the Company will successfully execute the launch of SURFAXIN and AFECTAIR within the anticipated time frame; 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; 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 its 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 its 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 AEROSURF, 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 March 6, 2012

**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 our product development, our plans regarding the anticipated commercial introduction of SURFAXIN and AFECTAIR, the anticipated strategic alliance for the development and commercialization of SURFAXIN LS and AFECTAIR 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.

**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: March 6, 2012

**Exhibit 99.1**

**Discovery Labs Announces FDA Approval of SURFAXIN® (lucinactant) for Prevention of Respiratory Distress Syndrome**

*SURFAXIN is the First FDA-Approved Synthetic, Peptide-Containing Surfactant*

*Conference Call Tomorrow at 10 a.m. EST*

**Warrington, PA — March 06, 2012**— Discovery Laboratories, Inc. (NASDAQ: DSCO), a specialty biotechnology company dedicated to advancing a new standard in respiratory critical care, today announced that the United States Food and Drug Administration (FDA) has approved SURFAXIN (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants at high risk for RDS. SURFAXIN is the first synthetic, peptide-containing surfactant approved for use in neonatal medicine. Discovery Labs anticipates that SURFAXIN will be commercially available in the United States in late 2012.

"The approval of SURFAXIN is an important medical advancement for the neonatology community and parents of preterm infants who will soon have an effective alternative to animal-derived surfactants to prevent the development of RDS," said W. Thomas Amick, Chairman of the Board and Chief Executive Officer of Discovery Labs. "This is a significant milestone in our continuing efforts to develop a pipeline of products to further advance the standard of respiratory critical care."

RDS is a condition in which premature infants are born with an insufficient amount of pulmonary surfactant, a substance produced naturally in the lungs and essential for breathing. Today, infants with RDS often require animal-derived surfactant replacement therapy along with mechanical ventilation to survive. Approximately 90,000 premature infants in the United States are treated annually with currently available animal-derived surfactants.

Discovery Labs will hold a conference call tomorrow, March 7th, 2012 at 10:00 a.m. EST to further discuss the foregoing. The call in number is (877) 215-0093. The international call in number is (706) 679-3237. The passcode is 58400332. This audio webcast will be available through a live broadcast on the Internet at http://us.meeting-stream.com/discoverylaboratories_030212 and www.discoverylabs.com. The replay number to hear the conference call is (855) 859-2056 or (404) 537-3406 using the same conference call password listed above.

**ABOUT SURFAXIN**
SURFAXIN (lucinactant intratracheal suspension) is a synthetic, peptide-containing surfactant. SURFAXIN is indicated for the prevention of respiratory distress syndrome (RDS) in premature infants at high risk for RDS. The safety and efficacy of SURFAXIN for the prevention of RDS in premature infants was demonstrated in a large, multinational phase 3 clinical program that included 1294 patients. Discovery Labs anticipates that SURFAXIN will be commercially available in late 2012.

**IMPORTANT SAFETY INFORMATION**
SURFAXIN (lucinactant intratracheal suspension) 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.

**ABOUT DISCOVERY LABS**
Discovery Laboratories, Inc. is a specialty biotechnology company with one focus – to advance a new standard in respiratory critical care. Discovery Labs' novel proprietary $KL_4$ surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, lyophilized, and aerosolized dosage forms. Discovery Labs is also developing its proprietary drug delivery technologies to enable efficient delivery of aerosolized $KL_4$ surfactant and other inhaled therapies. Discovery Labs believes that its proprietary technologies make it possible, for the first time, to develop a significant pipeline of products to address a variety of respiratory diseases for which there frequently are few or no approved therapies. For more information, please visit our website at www.Discoverylabs.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, including those related to the timing of a commercial launch of SURFAXIN and market acceptance of SURFAXIN, are 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. The Company assumes no obligation to update or revise any forward-looking statements.*

**Contact Information:**

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