
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 10, 2014

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))
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Item 1.01. Entry into a Material Definitive Agreement

On October 10, 2014, Discovery Laboratories, Inc., a Delaware corporation (the "Company"), entered into a Collaboration Agreement (the "Collaboration Agreement") with Battelle Memorial Institute ("Battelle") providing for the further development of the Company's capillary aerosol generator ("CAG") for potential use in the Company's planned phase 3 clinical program for AEROSURF® for the treatment of respiratory distress syndrome ("RDS") in premature infants and, if AEROSURF is approved for commercial sale by the U.S. Food and Drug Administration (the "FDA"), the European Commission or other applicable regulatory authority, initial commercial supply.

Pursuant to the Collaboration Agreement, the Company and Battelle will work together to (i) define the requirements of the phase 3 CAG and disposable dose packs (together, the "AEROSURF System") as well as a detailed project plan for the remaining stages of the project ("Stage 1"), (ii) develop the AEROSURF System in accordance with the project plan ("Stage 2"), and (iii) complete all required testing, verification and documentation to be in a position to manufacture AEROSURF Systems for the Company's AEROSURF phase 3 clinical program ("Stage 3"). Upon completion of the three-stage project plan under the Collaboration Agreement, the Company and Battelle intend to negotiate in good faith to enter into an agreement for the manufacture of AEROSURF Systems for the AEROSURF phase 3 clinical program, and, if AEROSURF is approved, to negotiate in good faith to enter into a supply agreement providing for an initial commercial supply of AEROSURF Systems.

Each of the Company and Battelle will designate a project manager, who will manage the project plan on a daily basis. A Steering Committee, comprised equally of members appointed by the Company and by Battelle, will oversee the work performed by the project managers and work to reach consensus on the handling of all matters referred to it with respect to the collaboration and the project plan. The foregoing notwithstanding, the Company will retain final decision-making authority on all matters relating to the design, registration, manufacture, packaging, marketing, distribution and sale of the AEROSURF System. The Company and Battelle will share equally in the costs of Stage 1 activities. Following completion of Stage 1, the Company and Battelle will agree on the details and projected costs of the project plan for Stages 2 and 3. The parties will share equally in the costs of the project plan for Stages 2 and 3 as set forth in the project plan. Battelle will bear the entire cost of any cost overruns associated with execution of the project plan and the Company will bear the entire cost of any increase in the agreed upon project plan costs resulting from changes in the scope of the product requirements as agreed in Stage 1 and set forth in the project plan.

In connection with the Collaboration Agreement, the Company issued to Battelle two warrants to purchase shares of the Company's common stock, par value \$.001 per share ("Common Stock"), each having a term of 10 years, subject to earlier termination under certain circumstances set forth therein, and an exercise price of \$5.00 per share, including (i) a warrant to purchase up to 1,000,000 shares of the Company's common stock, exercisable upon successful completion by Battelle of the Stage 3 activities (the "Initial Warrant"), and (ii) a warrant to purchase 500,000 shares of the Company's common stock (the "Additional Warrant;" together with the "Initial Warrant," the "Warrants"), provided that the Additional Warrant is exercisable if and only if the Stage 3 activities are successfully completed by Battelle no later than May 31, 2016, which date may be adjusted as provided in the Collaboration Agreement. The Company and Battelle have agreed to execute a registration rights agreement relating to the resale of the Common Stock underlying the Warrants (the "Warrant Shares"). The Warrants may be exercised for cash only, except that, in the event a registration statement is not effective at the time of exercise and if an exemption from registration is otherwise available at that time, the Warrants may be exercised on a cashless basis. The Company relied on the exemption from registration contained in Regulation D, Rule 506 thereunder, for the issuance of the Warrants and the Warrant Shares.

In addition to the Warrants, if Battelle successfully completes the Stage 3 activities, the Company has agreed to pay royalties to Battelle equal to a low single-digit percentage of the worldwide net sales and license royalties on sales of AEROSURF for the treatment of RDS in premature infants, up to an aggregate limit of \$25 million.

The Collaboration Agreement provides that, unless sooner terminated by a party as therein provided, its term shall continue until the Company fulfills its payment obligations to Battelle. The Collaboration Agreement may be terminated by a party under certain circumstances, including (i) a declaration of bankruptcy by either party, (ii) a "failure of purpose" as that term is defined in the Collaboration Agreement, including without limitation, a good faith determination by the parties that the objectives of the AEROSURF clinical program, the FDA registration of AEROSURF, or the expected outcomes of the project plan cannot be achieved, or (iii) a material breach by either party.

AEROSURF is a novel investigational combination product that combines the Company's KL4 surfactant with its CAG. The Company is developing AEROSURF for premature infants with or at risk for developing RDS. The administration of surfactants currently can only be administered by endotracheal intubation supported with mechanical ventilation, both invasive procedures that may result in serious respiratory conditions and complications. Consequently, neonatologists often will not treat infants who could benefit from surfactant therapy unless the potential benefits of surfactant therapy outweigh the risks associated with such invasive administration procedures. AEROSURF potentially will provide practitioners with the ability to deliver surfactant therapy using a less-invasive method of administration and thereby may enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated.

The foregoing summary is qualified in its entirety by reference to the text of the Collaboration Agreement and related documents, to be included as Exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.

Item 3.02. Unregistered Sales of Equity Securities

The information contained in Item 1.01 relating to the Warrants and the Warrant Shares is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1](#) Press release dated October 15, 2014, announcing execution of the Collaboration Agreement.

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 15, 2014



DISCOVERY LABS ANNOUNCES STRATEGIC COLLABORATION WITH BATTELLE FOR AEROSURF® PROGRAM

- Companies will Co-Invest to Advance Aerosolization Technology to a Phase 3 / Commercial-Ready Device -

Warrington, PA, October 15, 2014 — **Discovery Laboratories, Inc. (Nasdaq: DSCO)** today announced that it has entered into a strategic collaboration with Battelle, the world's largest independent research and development organization with 35 years of specific expertise in aerosol science. The parties intend to further develop Discovery Labs' proprietary capillary aerosol generator (CAG) for use in the planned AEROSURF® phase 3 clinical program and, if approved, initial commercialization. The arrangement also reflects the plan to negotiate agreements to provide for the manufacture of phase 3 clinical devices and, if AEROSURF is approved, initial commercial supply. The CAG is currently being used in neonatal intensive care units for the company's AEROSURF phase 2 clinical program for the treatment of respiratory distress syndrome (RDS) in premature infants. Battelle and Discovery Labs generally will share equally in the agreed costs of the device development for the AEROSURF RDS program. In consideration for its investment and expertise, Battelle will receive warrants and future royalties on AEROSURF sales and license sales revenues.

"This collaboration brings us a partner with world class capabilities in aerosol device design and manufacture, in addition to the clear financial benefits," commented John G. Cooper, Discovery Labs' President and Chief Executive Officer. "Battelle has a successful track record of working with companies developing medical devices from development stage through ultimate FDA approval. They also have extensive experience with our aerosolization technology, and played a key role in preparing the CAG for use in our current AEROSURF phase 2 program. Now we are going to leverage those experiences and their development, quality and regulatory expertise to further support the AEROSURF opportunity. We look forward to our continued and expanded relationship."

"One of our missions is to support what we believe to be transformational medical advances," commented Bob Wilkins, MBChB, FRCA, a Battelle Vice President of Strategic Development. "Based on our work to date and our assessment of the opportunity, we believe that AEROSURF addresses a significant unmet medical need, and represents a potential revolution in the management of infants with respiratory distress syndrome. We are excited to combine our expertise in aerosol drug delivery device development with Discovery Labs' expertise in synthetic surfactant technology and neonatal RDS."

Under the terms of the agreement, Battelle and Discovery Labs will co-invest in the development of an AEROSURF phase 3 clinic-ready aerosol device. Upon execution of the agreement, Battelle received two warrants to purchase a total of 1.5 million shares of Discovery Labs' common stock at an exercise price of \$5.00 per share, each warrant with a 10-year term. The first warrant to purchase 1 million shares is exercisable only upon successful development of an aerosol device that is ready for a potential AEROSURF phase 3 clinical program. The second warrant to purchase 0.5 million shares will become exercisable only upon meeting the aforementioned milestone by a certain date. In addition, if AEROSURF receives regulatory approval for the treatment of RDS, Battelle will receive a low single-digit royalty on Discovery Labs' AEROSURF commercial revenues, subject to an aggregate cap of \$25 million.

AEROSURF is a novel investigational combination drug-device product being developed to deliver the company's synthetic KL4 surfactant in aerosolized form via nasal continuous positive airway pressure (nCPAP) to premature infants with RDS. AEROSURF could potentially allow for the administration of KL4 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. Discovery Labs is developing its proprietary aerosolization drug delivery technologies, including the CAG, to enable efficient delivery of aerosolized KL4 surfactant. The company is currently conducting a phase 2 clinical program for AEROSURF employing the current version of the CAG.

The information included in this press release about Discovery Labs' collaboration with Battelle is subject in its entirety to the definitive terms of the collaboration agreement, the warrants and other related documents. Additional information, including a description of the collaboration documents, is provided in a Current Report on Form 8-K that is expected to be filed today with the Securities and Exchange Commission ("SEC"). A redacted version of the agreement, together with other collaboration documents, is expected to be filed with Discovery Labs' Quarterly Report on Form 10-Q for the period ending September 30, 2014, which is expected to be filed with the SEC on or before November 10, 2014.

This press release is neither an offer to sell nor a solicitation of an offer to buy the securities discussed herein, nor shall there be any sale of securities in any state or other jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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 KL4 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 KL4 surfactant. 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, to enable the treatment of a significantly greater number of premature infants who could benefit from surfactant therapy but are currently not treated. SURFAXIN® (lucinactant) Intratracheal Suspension, Discovery Labs' first KL4 surfactant-based product, is the only available synthetic alternative to animal derived surfactants approved by the U.S. Food and Drug Administration (FDA). Full prescribing information can be found at <http://www.surfaxin.com>.

For more information, please visit the company's website at www.Discoverylabs.com.

About Battelle

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit www.battelle.org.

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. Forward-looking statements often include words such as "will," "intends," "plans," "believes" and words and terms of similar substance. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from the statements made. Examples of such risks and uncertainties, including those affecting Discovery Labs' ability successfully to complete its development programs and realize the potential benefits of its RDS product portfolio (including AEROSURF), 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. Discovery Labs assumes no obligation to update or revise any forward-looking statements.

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