# SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

### FORM 8-K/A

## **CURRENT REPORT**

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

### March 28, 2008

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:

- 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))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

# Item 1.01. Amendment of a Material Agreement.

On April 3, 2008, Discovery Laboratories, Inc. (the "Company") filed a current report on Form 8-K (the "Initial Report") regarding the entry into an Amended and Restated License Agreement with Philip Morris USA Inc., d/b/a Chrysalis Technologies. The Company is filing this amendment solely to attach the April 2, 2008 Press Release referenced as Exhibit 99.1 to the Initial Report. The Press Release is filed as Exhibit 99.1 to this report and incorporated herein by reference.

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 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.

# Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits:
  - 99.1 Press Release of Discovery Laboratories, Inc., dated April 2, 2008.

#### **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/ Robert J. Capetola

Robert J. Capetola, Ph.D. President and Chief Executive Officer

Date: April 11, 2008



# Discovery Labs and Chrysalis Technologies Modify Collaboration for Future Development of Aerosolized Drug Device Products

Warrington, PA — April 2, 2008 — Discovery Laboratories, Inc. (Nasdaq: DSCO) and Chrysalis Technologies (a division of Philip Morris USA, Inc.) have been collaborating to develop combination drug device products that unite Discovery Labs' precision-engineered synthetic surfactant with Chrysalis' novel capillary aerosolization technology to address respiratory diseases. To date, the collaboration has focused on developing a prototype device for use in Discovery Labs' upcoming Phase 2 clinical trials for Aerosurf™, aerosolized Surfactant Replacement Therapy (SRT) for premature infants. Under the modified collaboration, Discovery Labs will assume full responsibility, effective July 1, 2008, to further develop the capillary aerosolization technology into devices for potential clinical and commercial application.

Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery Labs, commented, "Our aerosolized SRT combined with this robust capillary aerosolization technology has the potential to transform respiratory medicine. We believe in the potential of this technology and now have full development control. Combining our surfactant expertise with Chrysalis' unique technology knowhow has been appropriate for the development of the initial prototype device system. In anticipation of developing the next generation device for late stage clinical and commercial applications, we have been building our own internal medical device engineering expertise. We have also begun working with a leading engineering and design firm that has a successful track record of developing innovative devices for major companies in the medical and pharmaceutical industries."

The modification provides for Chrysalis' continued development support through June 30, 2008, after which Chrysalis will cease operations for reasons unrelated to this collaboration and the Chrysalis technology. Additionally, the modification provides for transfer to Discovery Labs of the aerosol technology know-how, engineering design work, and related materials. Chrysalis' continued support and the technology transfer are in line with the current development plans to optimize the initial prototype device, which upon success, will be used in Discovery Labs' anticipated Aerosurf Phase 2 clinical trials.

Discovery Labs retains its exclusive worldwide rights to the capillary aerosolization technology for use with pulmonary surfactants for all respiratory diseases and now has also received expanded rights in the United States to the capillary aerosolization technology for use with other drugs for respiratory diseases in the hospital setting.

Keeping with the original intent of the collaboration, under which Chrysalis was primarily responsible for device development, Chrysalis has also agreed to provide \$4.5 million to Discovery Labs to support further development. The modification also significantly reduces the original royalties due Chrysalis from a multi-tiered royalty structure (that escalated upon attaining collaboration product revenues greater than \$500 million and \$1 billion) to a low single-digit base royalty that now applies to all product revenues. Discovery Labs believes this reduction in royalties may facilitate future potential collaborative arrangements to co-develop and/or commercialize aerosolized SRT.

### Discovery Labs' Proprietary Aerosolized KL-4 Surfactant Technology - Aerosurf™ and Future Applications

Aerosolized KL-4 surfactant technology has the therapeutic potential to reestablish airway patency, improve pulmonary mechanics and act as an antiinflammatory in a host of respiratory diseases that are associated with surfactant dysfunction and a loss of patency. Serious respiratory problems are some of the
most prevalent medical issues facing premature infants in the Neonatal Intensive Care Unit (NICU). There are more than 1 million premature infants born
annually worldwide at risk for respiratory problems associated with surfactant dysfunction. Neonatologists generally try to avoid mechanically ventilating these
patients because doing so requires intubation (the invasive insertion of a breathing tube down the trachea). The potential utility of a non-invasive method of
delivering SRT to treat premature infants suffering from an array of respiratory disorders has been recognized by the neonatal medical community. Aerosurf is a
precision-engineered aerosolized SRT administered via nasal continuous positive airway pressure (nCPAP) which is being developed to potentially treat
premature infants with respiratory conditions in the NICU. Discovery Labs plans to apply the experience obtained in the development of Aerosurf to potentially
develop aerosolized SRT to treat several pediatric and adult respiratory disorders, including Cystic Fibrosis, ALI, COPD, and asthma.

The novel, proprietary capillary aerosolization technology is designed to produce high-volume aerosols and has the potential to enable targeted upper respiratory or deep lung delivery of therapies. Aerosols are created by pumping the drug formulation through a small, heated capillary. Upon exiting the capillary, the vapor stream quickly cools and slows in velocity, yielding a dense aerosol. The particle size can be readily controlled and adjusted through device modifications and drug formulation changes.

In May 2007, Discovery Labs presented to the medical community data from pre-clinical studies using aerosolized KL-4 surfactant. In these studies, KL-4 surfactant was aerosolized to compare its capillary aerosolization technology to commercially available aerosol generator devices. The studies demonstrated that KL-4 surfactant maintains its chemical structure and essential functional activity post-aerosolization. In addition, the capillary aerosolization technology generated a nearly 10-fold higher aerosol output rate than the other study devices.

Discovery Labs' design engineers, together with Chrysalis and contract manufacturers, continue to optimize the initial prototype device incorporating the capillary aerosolization technology. Discovery Labs' contract manufacturer is preparing to manufacture prototype devices and once development milestones have been achieved, the devices will be used in planned Phase 2 clinical trials. Additionally, Discovery Labs has met with and received guidance from the U.S. Food and Drug Administration (FDA) with respect to the design of a proposed Phase 2 clinical program. Discovery Labs is also engaged in further development of the capillary aerosolization technology, including conceptualization and development of the next-generation device, which it plans to use in potential Phase 2 and Phase 3 clinical trials and, if approved, in future commercial activities.

### **About Discovery Labs**

Discovery Laboratories, Inc. is a biotechnology company developing Surfactant Replacement Therapies (SRT) for respiratory diseases. Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' technology produces a precision-engineered surfactant that is designed to closely mimic the essential properties of natural human lung surfactant.

Discovery Labs' lead product candidate, Surfaxin<sup>®</sup>, is the subject of an Approvable Letter from the FDA for the prevention of Respiratory Distress Syndrome in premature infants and has a targeted approval PDFUA date of May 1, 2008. Surfaxin is also being developed for other neonatal and pediatric indications. Aerosurf<sup>TM</sup>, Discovery Labs' aerosolized SRT, is being developed to potentially obviate the need for intubation and conventional mechanical ventilation and holds the promise to significantly expand the use of surfactants in respiratory medicine. For more information, please visit our website at <a href="https://www.Discoverylabs.com">www.Discoverylabs.com</a>.

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, including, without limitation, the risks that: Discovery Labs may be unable to profitably develop and market its products; Discovery Labs may not be able to raise additional capital or enter into additional collaboration agreements (including strategic alliances for development or commercialization of SRT); changes in the national or international political and regulatory environment may make it more difficult to gain FDA or other regulatory approval of drug products; Discovery Labs' significant, time-consuming and costly research and development activities, including pre-clinical studies, clinical trials and other efforts to gain regulatory approval for any products may not progress or may be subject to potentially significant delays or regulatory holds, or fail; Discovery Labs may not succeed in the FDA or other regulatory agency review process, including that such regulatory authority may not approve the marketing and sale of a drug product or may withhold, delay and/or limit marketing of a drug product by indication or impose other label limitations; Discovery Labs' recently-submitted Complete Response to the Approvable Letter may not satisfy the FDA; Discovery Labs may be unable to successfully transfer its manufacturing technology to third-party contract manufacturers or its contract manufacturers or any of its materials suppliers may encounter problems manufacturing drug products or drug substances on a timely basis or manufacture in amounts sufficient to meet demand; Discovery Labs and its collaborators may be unable to develop, manufacture and successfully commercialize products that combine Discovery Labs' drug products with innovative aerosolization technologies; Discovery Labs may be unable to develop a successful sales and marketing organization in a timely manner and its marketing and advertising consultants may not succeed in developing market awareness of its products; upon approval of a product candidate, Discovery Labs may not adequately forecast customer demand; Discovery Labs or its development partners, collaborators or marketing partners may not be able to attract or maintain qualified personnel; Discovery Labs may be unable to maintain and protect the patents and licenses related to its SRT; other companies may develop competing therapies and/or technologies or health care reform may adversely affect Discovery Labs; and Discovery Labs may become involved in securities, product liability and other litigation. The foregoing risks and others are further 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.

### **Company Contact:**

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