
UNITED STATES
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

July 9, 2015

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))
-
-
-

Item 1.01. Entry into a Material Definitive Agreement

On July 9, 2015, Discovery Laboratories, Inc., a Delaware corporation (the “Company”) and certain affiliates of Deerfield Management Company, L.P. (“Deerfield”) entered into an amendment (the “Amendment”) to that certain Facility Agreement dated as of February 13, 2013 (the “Facility Agreement”) by and between the Company and Deerfield in order to better align the Company’s obligations thereunder with anticipated milestones under its clinical development program for AEROSURF®.

AEROSURF is the Company’s lead development program for its combination drug/device product that combines its proprietary lyophilized KL₄ surfactant with its capillary aerosol generator (“CAG”) technology and is being developed potentially to deliver aerosolized KL₄ surfactant to premature infants with respiratory distress syndrome (“RDS”) without having to use invasive endotracheal intubation and mechanical ventilation. The Company recently completed and released the results of its initial AEROSURF phase 2a clinical trial. The key objectives of that trial were achieved, including (1) the primary objective of demonstrating safety and tolerability of a single exposure of aerosolized KL₄ surfactant administered in three escalating inhaled doses to premature infants 29 to 34 week gestational age and receiving nasal continuous positive airway pressure (nCPAP) for RDS, compared to infants receiving nCPAP; (2) establishing proof of concept for the Company’s proprietary technology platform based on physiological data suggesting that aerosolized KL₄ surfactant is being delivered into the lung of premature infants; and (3) acceptable performance of the novel capillary aerosol generator (CAG) technology in the neonatal intensive care unit (NICU).

In addition, the Company is planning to complete the following phase 2 clinical trials going forward: (1) a phase 2a study designed to evaluate the safety and tolerability of aerosolized KL₄ surfactant administered in higher and repeat doses in premature infants 29 to 34 weeks gestational age who are receiving nCPAP for RDS, compared to infants receiving nCPAP alone; (2) a phase 2a clinical study that is designed to assess the safety and tolerability of aerosolized KL₄ surfactant administered in escalating doses to premature infants 26 to 28 weeks gestational age, with an ability to administer repeat doses; and (3) a phase 2b clinical trial that will be designed to determine the optimal dose and define the expected efficacy margin of AEROSURF treatment. The Company expects to complete the phase 2a clinical studies, which should provide further insight and data to support the design of the planned AEROSURF phase 2b clinical program, in the fourth quarter of 2015. The Company expects to complete the AEROSURF phase 2b clinical trial in mid-2016.

Under the Facility Agreement, Deerfield agreed to provide financing to the Company and thereafter advanced \$30 million on a secured basis, subject to the terms and conditions set forth in the Facility Agreement. The principal amounts outstanding under the Facility Agreement are payable in three equal installments of \$10 million in February 2017, 2018, and 2019; provided that the amounts payable on each of February 2017 and 2018 may be deferred for one year if on such anniversary date the Company has achieved market capitalization levels in each year pursuant to the definition of “Equity Value” in the Facility Agreement.

Under the terms of the Amendment, upon execution, the Company agreed to prepay in cash \$2.5 million of the principal amounts outstanding under the Facility Agreement, to be applied to the principal installments due under the Facility Agreement in the order of their maturity, subject to reallocation of the prepayment to the principal installments due under the Facility Agreement in the inverse order of their maturity if a Strategic Transaction (as defined below) is not completed on or before December 31, 2015. If the Company completes a Strategic Transaction on or before December 31, 2015 and, within five business days, prepays an additional \$2.5 million of the principal amounts then outstanding under the Facility Agreement, then upon such prepayment, the payment dates for the remaining principal installments due under the Facility Agreement shall be amended to eliminate the installment due in February 2017 and to adjust the amounts due in each of February 2018 and 2019 to \$12.5 million and \$12.5 million, respectively.

For the purposes of the Amendment, the term “Strategic Transaction” shall mean a transaction or series of transactions, each of which may take the form of a strategic partnership, collaboration arrangement or other similar transaction or a public offering or other equity financing, that results in the infusion to the Company of sufficient additional capital such that the Company reasonably believes that it will have available sufficient cash to support the AEROSURF clinical program, pay its debt service obligations and fund its operations through at least the third quarter of 2016.

In addition, the Company has agreed to pay Deerfield's expenses (including reasonable counsel fees and expenses of up to \$15,000) incurred in connection with the Amendment. All other provisions of the Facility Agreement shall remain in full force and effect.

The foregoing summary is qualified in its entirety by reference to the text of the Amendment, which is attached hereto as Exhibit 10.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[10.1](#) Amendment dated July 9, 2015 to Facility Agreement dated February 13, 2013 by and between the Company and Deerfield

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.

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: July 9, 2015

FIRST AMENDMENT TO FACILITY AGREEMENT

FIRST AMENDMENT TO FACILITY AGREEMENT (this "Amendment"), dated as of July 9, 2015, by and among DISCOVERY LABORATORIES, INC., a Delaware corporation ("Borrower"), DEERFIELD PRIVATE DESIGN FUND II, L.P., DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P. and DEERFIELD SPECIAL SITUATIONS FUND, L.P. (collectively referred to as the "Lenders" and together with the Borrower, the "Parties").

RECITALS:

A. Borrower and Lenders have entered into that certain Facility Agreement dated as of February 13, 2013 (as the same may be amended, modified, restated or otherwise supplemented from time to time, the "Facility Agreement").

B. Borrower has requested Lenders amend the Facility Agreement to, among other things, provide for extension of the dates for required repayment of the Loan and Lenders are willing to amend the Facility Agreement on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements contained herein, the Parties agree as follows:

1. Defined Terms. Capitalized terms used herein which are defined in the Facility Agreement or other Transaction Documents, unless otherwise defined herein, shall have the meanings ascribed to them in the Facility Agreement and the other Transaction Documents. The Recitals to this Amendment are incorporated herein in their entirety by this reference thereto.

2. Amendments to Facility Agreement. Upon the satisfaction of the conditions set forth in Section 3 of this Amendment, the Facility Agreement is hereby amended as follows:

a. Section 1.1 of the Facility Agreement is hereby amended to add the following additional defined terms:

"Stock" means all shares of capital stock (whether denominated as Common Stock or preferred stock), or other equity interest (regardless of how designated) of or in a Person (other than an individual), whether voting or non-voting.

"Stock Equivalents" means all securities, including debt securities, convertible into or exchangeable for Stock or any other Stock Equivalent and all warrants, options or other rights to purchase, subscribe for or otherwise acquire any Stock or any other Stock Equivalent, whether or not presently convertible, exchangeable or exercisable.

"Strategic Transaction" shall mean a transaction or series of transactions, each of which may take the form of a strategic partnership, collaboration arrangement or similar transaction or a public offering of Stock or Stock Equivalents or other equity financing, that results in the infusion to Borrower of sufficient capital such that Borrower reasonably believes that it will have available sufficient cash to support the AEROSURF® clinical program, satisfy Borrower's debt service obligations and fund Borrower's business operations through at least the third fiscal quarter of 2016.

b. Borrower shall on the date of this Amendment, prepay the outstanding principal amount of the Notes in the amount of \$2,500,000, which shall be applied pro rata to the principal installments due under the Notes in the order of their maturity, subject to reapplication by the Lenders to the principal installments due under the Notes in the inverse order of their maturity if notice of a Strategic Transaction occurring on or before December 31, 2015 is not received by Lenders as provided below.

c. Borrower shall provide Lenders with written notice of the occurrence of any Strategic Transaction occurring on or prior to December 31, 2015 within one Business Day of the occurrence thereof. Borrower may, within five Business Days of a Strategic Transaction occurring on or prior to December 31, 2015, prepay the outstanding principal amount of the Notes, in an amount of \$2,500,000, which payment shall be applied pro rata to the principal installments due under the Notes in the order of their maturity. Upon such prepayment, subject to the provisions of Section 2.3(a) of the Facility Agreement with respect to the deferral of the principal amount of the Notes due on the Fifth Anniversary if the Fifth Anniversary Deferral Criteria is satisfied, the then outstanding principal amount of the Notes shall be repayable as follows:

(i) On February 13, 2018 the Borrower shall repay \$12,500,000 of the outstanding principal amount of the Notes; and

(ii) On the earliest of (1) February 13, 2019, (2) such earlier date the principal amount of the Notes is declared to be or automatically becomes due and payable following an Event of Default or (3) as provided in Section 5.3 of the Facility Agreement, the Borrower shall repay the remaining outstanding principal amount of the Notes.

3. Conditions Precedent. The effectiveness of this Amendment is subject to the following conditions precedent:

a. Amendment. The Borrower and the Lenders shall have each executed this Amendment and Lenders shall have received the prepayment referred to in Section 2(b) of this Amendment.

b. Performance; No Default. The Borrower shall have performed and complied with all agreements and conditions contained in the Facility Agreement and the other Transaction Documents to be performed by or complied with by the Borrower prior to the date hereof.

c. Reimbursement of Expenses. The Borrower shall have reimbursed Lenders for all out-of-pocket fees and expenses, including reasonable legal fees and expenses not to exceed \$15,000, incurred by Lenders in connection with the negotiation, documentation and closing of this Amendment.

4. Representations and Warranties. The Borrower hereby represents and warrants to Lenders as follows:

a. As of the date hereof, except as expressly modified by the amendments in Section 2 above, the representations and warranties of Borrower contained in the Transaction Documents are (i) in the case of representations and warranties qualified by “materiality,” “Material Adverse Effect” or similar language, true and correct in all respects and (ii) in the case of all other representations and warranties, true and correct in all material respects, in each case on and as of the date hereof as if made as of the date of this Amendment, except to the extent that any such representation or warranty relates to a specific date, in which case such representation and warranty shall be true and correct in all respects or all material respects, as applicable, as of such earlier date;

b. No Event of Default exists; and

c. The Borrower has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Amendment and each of the other Transaction Documents to which it is a party and otherwise to carry out its obligations hereunder and thereunder. The Borrower’s execution and delivery of each of this Amendment and the other Transaction Documents to which it is a party and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action on the part of the Borrower, and no further corporate action is required by the Borrower, its Board of Directors or its stockholders in connection therewith other than in connection with the Required Approvals (as defined below). Each of the Amendment and the other Transaction Documents to which it is a party has been (or upon delivery will have been) duly executed by the Borrower and is, or when delivered in accordance with the terms hereof, will constitute the legal, valid and binding obligation of the Borrower enforceable against the Borrower in accordance with their terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally the enforcement of, creditors’ rights and remedies or by other equitable principles of general application. The execution, delivery and performance of this Amendment by the Borrower and the consummation of the transactions therein contemplated will not (A) conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any Lien (other than Permitted Liens) upon any assets of the Borrower pursuant to, any agreement to which the Borrower is a party or by which the Borrower is bound or to which any of the assets of the Borrower is subject, (B) result in any violation of or conflict with the provisions of the Organizational Documents, (C) result in the violation of any Applicable Law or (D) result in the violation of any judgment, order, rule, regulation or decree of any Governmental Authority. No consent, approval, authorization or order of, or registration or filing with any Governmental Authority is required for the execution, delivery and performance of any of the Amendment and the other Transaction Documents or for the consummation by the Borrower of the transactions contemplated thereby except for those that have been made or obtained prior to the date of this Agreement (the “Required Approvals”).

5. No Further Amendments; Ratification of Liability. Except as amended hereby, the Facility Agreement and each of the other Transaction Documents shall remain unchanged and in full force and effect in accordance with their respective terms. Borrower as a debtor, grantor, pledgor, guarantor or assignor, or in any similar capacity in which it has granted Liens or acted as an accommodation party or guarantor, as the case may be, hereby ratifies, confirms and reaffirms its liabilities, its payment and performance obligations (contingent or otherwise) and its agreements under the Facility Agreement and the other Transaction Documents, all as amended by this Amendment and the liens and security interests granted, created and perfected thereby. The Lenders' agreement to the terms of this Amendment or any other amendment of the Facility Agreement or any other Transaction Document shall not be deemed to establish or create a custom or course of dealing among Borrower and Lenders. This Amendment, together with the other Transaction Documents, contains the entire agreement among Borrower and Lenders contemplated by this Amendment.

6. Incorporation by Reference. The provisions of Article 6 of the Facility Agreement are incorporated herein by reference *mutatis mutandis*.

[Remainder of Page Intentionally Left Blank, signature page follows]

BORROWER:

DISCOVERY LABORATORIES, INC.

By: /s/ John Tattory
Name: John Tattory
Title: Senior Vice President and
Chief Financial Officer

LENDERS:

DEERFIELD PRIVATE DESIGN FUND II, L.P.

By: Deerfield Mgmt., L.P., its General Partner
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark
Name: David J. Clark
Title: Authorized Signatory

DEERFIELD PRIVATE DESIGN INTERNATIONAL II, L.P.

By: Deerfield Mgmt., L.P., its General Partner
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark
Name: David J. Clark
Title: Authorized Signatory

DEERFIELD SPECIAL SITUATIONS FUND, L.P.

By: Deerfield Mgmt., L.P., its General Partner
By: J.E. Flynn Capital, LLC, its General Partner

By: /s/ David J. Clark
Name: David J. Clark
Title: Authorized Signatory