

ADEONA PHARMACEUTICALS, INC.
Form 8-K
November 21, 2011

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

Date of Report (date of earliest event reported): November 18, 2011

Adeona Pharmaceuticals, Inc.
(Exact name of registrant as specified in charter)

Nevada
(State or other jurisdiction of incorporation)

01-12584
(Commission File Number)

13-3808303
(IRS Employer Identification No.)

3985 Research Park Drive, Suite 200
Ann Arbor, MI 48108

(Address of principal executive offices and zip code)

(734) 332-7800

(Registrant's telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of 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(b) 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.

Exclusive Channel Partner Agreement

On November 18, 2011, Adeona Pharmaceuticals, Inc. (the “Company”) entered into an Exclusive Channel Collaboration Agreement (the “Channel Agreement”) with Intrexon Corporation (“Intrexon”) that governs a “channel collaboration” arrangement in which the Company will use Intrexon’s technology directed towards the production of prostaglandin synthase, through the use of in vivo conditionally regulated embedded controllable bioreactors for the treatment of pulmonary arterial hypertension (“PAH”) (collectively, the “PAH Program”). The Channel Agreement establishes committees comprised of Company and Intrexon representatives that will govern activities related to the PAH Program in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts and intellectual property.

The Channel Agreement grants the Company a worldwide license to use specified patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of products involving the production of prostaglandin synthase (PGIS) through the use of an in vivo conditionally regulated embedded controllable bioreactor for the treatment of PAH in humans (“Adeona Products”). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Adeona Products, and otherwise is non-exclusive. The Company may not sublicense the rights described without Intrexon’s written consent.

Under the Channel Agreement, and subject to certain exceptions, the Company is responsible for, among other things, the performance of the PAH Program including the development, commercialization and certain aspects of manufacturing of Adeona Products. Among other things, Intrexon is responsible for the costs of establishing manufacturing capabilities and facilities for the bulk manufacture of products developed under the PAH Program, certain other aspects of manufacturing, costs of discovery-stage research with respect to platform improvements and costs of filing, prosecution and maintenance of Intrexon’s patents.

Subject to certain expense allocations and other offsets provided in the Channel Agreement, the Company will pay Intrexon 50% of the cumulative net quarterly profits derived from the sale of Adeona Products, calculated on an Adeona Product-by-Adeona Product basis. The Company has likewise agreed to pay Intrexon 50% of quarterly revenue obtained from a sublicensor in the event of a sublicensing arrangement. In addition, in partial consideration for each party’s execution and delivery of the Channel Agreement, the Company entered into the Stock Purchase Agreement (as defined below) and the Registration Rights Agreement (as defined below). The Channel Agreement, Stock Purchase Agreement and Registration Rights Agreements shall collectively be referred as the “Agreements”.

If NYSE Amex approval of the issuance of the securities under the Stock Purchase Agreement is not received by January 17, 2012 (60 days from the date of the execution of the Channel Agreement), Intrexon has the right to terminate the Agreements. During the first 18 months, neither the Company nor Intrexon may terminate the Channel Agreement, except under limited circumstances. Following the first 18 months, the Company may voluntarily terminate the Channel Agreement upon 90 days written notice to Intrexon. Following the first 18 months, Intrexon may also terminate the Channel Agreement if the Company elects not to pursue the development of a PAH Program identified by Intrexon that is a “Superior Therapy” as defined in the Channel Agreement.

Upon termination of the Channel Agreement, the Company may continue to develop and commercialize any Adeona Product that, at the time of termination:

- is being commercialized by the Company,
- has received regulatory approval,

- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority,
-

is the subject of at least an ongoing Phase 2 clinical trial (in the case of a termination by Intrexon due to a Company uncured breach or a voluntary termination by the Company), or an ongoing Phase 1 clinical trial in the Field (as defined in the Channel Agreement) (in the case of a termination by the Company due to an Intrexon uncured breach or a termination by Intrexon following an unconsented assignment by the Company or the Company's election not to pursue development of a Superior Therapy), or

- the Company has spent at least \$4,500,000 developing.

The Company's obligation to pay 50% of net profits or revenue described above with respect to these "retained" products will survive termination of the Channel Agreement.

Stock Purchase Agreement and Registration Rights Agreement

On November 18, 2011, the Company entered into a Stock Purchase Agreement with Intrexon pursuant to which the Company has agreed to issue to Intrexon a number of shares of Company common stock equal to 9.995% of the number of shares of Company common stock issued and outstanding following and giving effect to such issuance (the "First Tranche Shares") at a purchase price equal to the \$0.001 par value of such shares, which issuance will be deemed paid in partial consideration for the execution and delivery of the Channel Agreement.

The Company has also agreed to issue additional shares of Company common stock to Intrexon upon dosing of the first patient in a Company-sponsored Phase II clinical trial in the United States, or similar study as the parties may agree in a country other than the United States, of an Adeona Product under the Exclusive Collaboration Agreement. Upon satisfaction of such contingency, the Company has agreed to issue to Intrexon an additional number of shares equal to the number of the First Tranche Shares, subject to certain adjustments (the "Second Tranche Shares"), for a purchase price equal to the \$0.001 par value of such shares, which issuance will be deemed paid in partial consideration for the execution and delivery of the Channel Agreement.

Also based on the Company's currently issued and outstanding shares of common stock, the First Tranche Shares and, if issued upon satisfaction of the condition described above, the Second Tranche Shares, will each be comprised of 3,123,558 shares. Such share amounts will be adjusted based on changes, if any, in the number of shares of the Company's common stock issued and outstanding between the date of this report and the date of the First Tranche closing.

Under the Stock Purchase Agreement, Intrexon is entitled, at its election, to:

(i) participate in future securities offerings of the Company that constitute "Qualified Financings" and purchase securities equal to 19.99% of the number of shares of common stock or other securities sold in such offering. For this purpose, a "Qualified Financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least \$5,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended (the "Securities Act"), at the time of issuance or the Company agrees to register the resale of such shares, and

(ii) without restriction, purchase an additional number of shares of Common Stock in the open market, or otherwise, that do not exceed an additional 10% of the number of shares of Common Stock then issued and outstanding;

The Stock Purchase Agreement contains a standstill provision pursuant to which, among other things, Intrexon has agreed that, for a period of three years, subject to certain exceptions and unless invited in writing by the Company to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the Company; any tender or exchange offer, merger, consolidation or other business combination involving the Company; any recapitalization, restructuring, liquidation,

dissolution or other extraordinary transaction with respect to the Company; or any “solicitation” of “proxies” or consents to vote any voting securities of the Company, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a “group” with respect to any securities of the Company; (iii) otherwise act to seek to control or influence the management, Board of Directors or policies of the Company; (iv) take any action reasonably expected to force the Company to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing. .

In connection with the transactions contemplated by the Stock Purchase Agreement, and pursuant to a Registration Rights Agreement to be executed and delivered by the parties at the First Tranche closing, the Company will agree to file a “resale” registration statement (the “Registration Statement”) registering the resale of the First Tranche Shares within 120 days of the First Tranche Closing. Under that agreement, the Company will be obligated to use its reasonable best efforts to cause the “resale” registration statement to be declared effective as promptly as practicable after filing and to maintain the effectiveness of the registration statement until all securities therein are sold or are otherwise can be sold pursuant to Rule 144, without any restrictions.

The foregoing description of each of the Channel Agreement, the Stock Purchase Agreement and the form of Registration Rights Agreement is qualified in its entirety by reference to such agreements, which are filed as Exhibits 10.1, 10.2 and 10.3 to this Current Report, respectively, and are incorporated herein by reference. The benefits of the representations and warranties set forth in the Channel Agreement, the Stock Purchase Agreement and the form of Registration Rights Agreement are intended to be relied upon by the parties to such agreements only and, except as otherwise expressly provided therein, do not constitute continuing representations and warranties to any other party or for any other purpose. The press release dated November 21, 2011 announcing the transactions described above is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure in Item 1.01 is incorporated herein by reference thereto. The offer and issuance of the First Tranche Shares and the Second Tranche Shares will not be registered under the Securities Act at the time of issuance, and therefore may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. For these issuances, the Company is relying on the exemption from federal registration under Section 4(2) of the Securities Act, based on the Company’s belief that the offer and sale of the First Tranche Shares and the Second Tranche Shares has not and will not involve a public offering as Intrexon is an “accredited investor” as defined under Section 501 promulgated under the Securities Act and no general solicitation has been involved in the offering.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|-------------|--|
| 10.1 | Exclusive Channel Collaboration Agreement by and between Adeona Pharmaceuticals, Inc. and Intrexon Corporation dated as of November 18, 2011 ** |
| 10.2 | Stock Purchase Agreement by and between Adeona Pharmaceuticals, Inc. and Intrexon Corporation dated as of November 18, 2011 |
| 10.3 | Form of Registration Rights Agreement by and between Adeona Pharmaceuticals, Inc. and Intrexon Corporation (incorporated by reference to Exhibit A to the Stock Purchase Agreement filed as Exhibit 10.1 to this report) |
| 99.1 | Press Release dated November 21, 2011 |

**Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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.

Dated: November 21, 2011

ADEONA PHARMACEUTICALS, INC.
(Registrant)

By: /s/ James S. Kuo
Name: James S. Kuo
Title: President and Chief Executive Officer

INDEX OF EXHIBITS

| Exhibit No. | Description |
|-------------|---|
| 10.1 | Exclusive Channel Collaboration Agreement by and between Adeona Pharmaceuticals, Inc. and Intrexon Corporation dated as of November 18, 2011 ** |
| 10.2 | Stock Purchase Agreement by and between Adeona Pharmaceuticals, Inc. and Intrexon Corporation dated as of November 18, 2011 |
| 99.1 | Press Release dated November 21, 2011 |

**Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
