

Edgar Filing: Edge Therapeutics, Inc. - Form 8-K

Edge Therapeutics, Inc.
Form 8-K
July 06, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): June 30, 2017

Edge Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

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|---|--|---|
| Delaware (State or Other Jurisdiction of Incorporation or Organization) | 001-37568 (Commission File Number) | 26-4231384 (I.R.S. Employer Identification No.) |
|---|--|---|

300 Connell Drive, Suite 4000
Berkeley Heights, NJ 07922
(800) 208-3343

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Not Applicable
(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 (17CFR 240.14a-12)

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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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 under the Securities Act (17 CFR 230.405) or Rule 12b-2 under the Exchange Act (17 CFR 240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) under the Exchange Act.

Item 1.01 – Entry into a Material Definitive Agreement

Amended and Restated Master Formulation Restated Development Agreement with Oakwood

On June 30, 2017, Edge Therapeutics, Inc. (“Edge”) entered into an Amended and Restated Master Formulation Development Agreement (the “Restated Development Agreement”) with Oakwood Laboratories, L.L.C. (“Oakwood”), pursuant to which Oakwood will continue to provide Edge with certain drug formulation development and non-commercial manufacturing services for EG-1962, Edge’s lead product candidate, in accordance with project plans to be entered into from time to time. Oakwood is currently performing process engineering, optimization and other scale up activities for Edge and is currently the sole manufacturer of EG-1962 used in Edge’s ongoing NEWTON 2 Phase 3 pivotal trial for EG-1962.

Under the Restated Development Agreement, Edge agreed to pay Oakwood to perform services under agreed upon project plans and to pay Oakwood up to an aggregate of \$4.50 million upon the achievement of various regulatory milestones, but no later than April 1, 2019. Certain of these payments are subject to acceleration in the event that Edge closes an equity or similar financing in excess of a predetermined amount.

As additional consideration for performance under the Restated Development Agreement and the Supply Agreement (as defined below), Edge agreed to pay Oakwood a royalty, during the Royalty Term, in an amount equal to a low single digit percentage of net sales of EG-1962, regardless of the manufacturer or supplier thereof. The “Royalty Term” is the period commencing upon the commercial launch of EG-1962 by Edge and continuing until twelve (12) years following such launch.

The term of the Restated Development Agreement continues until the expiration or termination of the Supply Agreement (the “Term”). Edge has the right to terminate project plans upon the occurrence of various circumstances described in the Restated Development Agreement. In the event Edge terminates the most recent project plan attached to the Restated Development Agreement prior to completion (including due to Edge’s decision to discontinue the development or commercialization of EG-1962), Edge must pay to Oakwood a termination fee. Either party has the right to terminate the Restated Development Agreement upon sixty (60) days written notice for failure to cure a material breach during the applicable cure period. Edge can terminate the Restated Development Agreement immediately upon notice to Oakwood if Oakwood’s annual financial audit report required to be provided to Edge contains any going concern or similar qualification or if Oakwood fails to maintain a pre-determined working capital ratio. Either party may also terminate the Restated Development Agreement immediately in the event of certain failures with regard to validation of the manufacturing process and other specified regulatory failures.

The foregoing description of the Restated Development Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Restated Development Agreement, which Edge expects to file as an exhibit to Edge’s Quarterly Report on Form 10-Q for the period ending June 30, 2017.

Commercial Supply Agreement with Oakwood

Concurrent with its entry into the Restated Development Agreement, on June 30, 2017, Edge entered into a Manufacturing and Supply Agreement with Oakwood (the “Supply Agreement”), pursuant to which Oakwood will manufacture and supply, and Edge will purchase from Oakwood, EG-1962 in commercial quantities following the commercial launch of the product.

Pursuant to the Supply Agreement, the price per unit of EG-1962 to be purchased by Edge is based on the expected commercially usable units per batch. In addition, Edge has agreed to pay Oakwood milestone payments that could total up to an aggregate of \$2.25 million upon the achievement of certain development and regulatory milestones.

Edge shall have no minimum order requirement under the Supply Agreement until the third (3rd) year following commercial launch of EG-1962. Beginning in the third year following commercial launch and continuing until the fifth year following commercial launch, Edge shall be required to (x) order, at a minimum, the greater of (a) five (5) batches and (b) fifty percent (50%) of the aggregate vials of EG-1962 purchased by Edge from all sources in such year (such greater amount being the “Minimum Order Commitment”) or (y) pay a catch-up price to Oakwood, as described below. In the event that Edge fails to order the Minimum Order Commitment, Edge shall be required to pay to Oakwood a catch-up price calculated based on the amount of EG-1962 actually ordered by Edge during the applicable time period.

The term of the Supply Agreement shall continue (unless earlier terminated) until three (3) years following commercial launch of EG-1962. Thereafter, the Supply Agreement shall automatically renew for additional two (2)-year periods unless Edge provides notice of non-renewal at least twelve (12) months prior to the end of the then-current term. The Supply Agreement shall also terminate automatically upon the termination of the Restated Development Agreement for any reason. Following the first anniversary of the commercial launch of EG-1962, either party may terminate upon two (2) years written notice. Further, either party may terminate the Supply Agreement upon a material breach by the other party that fails to be cured in the applicable cure period.

Edge may terminate the Supply Agreement immediately upon notice to Oakwood in the event that (a) any regulatory authority requires or causes the withdrawal of EG-1962 from the market or (b) Edge ceases to develop or commercialize EG-1962; provided, that in the latter case of termination prior to completion of the most recent project plan attached to the Restated Development Agreement, Edge must pay to Oakwood a termination fee.

The foregoing description of the Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Supply Agreement, which Edge expects to file as an exhibit to Edge’s Quarterly Report on Form 10-Q for the period ending June 30, 2017.

Item 8.01 – Other Events

On July 6, 2017, Edge issued a press release announcing the entry into the Restated Development Agreement and Supply Agreement with Oakwood. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 – Financial Statements and Exhibits

(d) Exhibits

| Exhibit No. | Description |
|-------------|-------------|
|-------------|-------------|

| | |
|------|-----------------------------------|
| 99.1 | Press Release, dated July 6, 2017 |
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 6, 2017 Edge Therapeutics, Inc.

By: /s/ Albert Marchio

Name: Albert Marchio

Title: Chief Accounting and Administrative Officer, Interim Chief Financial Officer

Index to Exhibits

Exhibit Description

99.1 Press release dated July 6, 2017
