

Dicerna Pharmaceuticals Inc
Form 8-K
April 23, 2018

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): April 18, 2018

DICERNA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36281
(Commission

File Number)
87 Cambridgepark Drive

20-5993609
(I.R.S. Employer

Identification Number)

Edgar Filing: Dicerna Pharmaceuticals Inc - Form 8-K

Cambridge, MA 02140

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (617) 621-8097

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 (See General Instruction A.2 below):

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-4c)
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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) of the Exchange Act.

Item 1.01. Entry into a Material Definitive Agreement.

Settlement Agreement

On April 18, 2018, Dicerna Pharmaceuticals, Inc. (the Company) and Alnylam Pharmaceuticals, Inc. (Alnylam) entered into a Confidential Settlement Agreement and General Release (the Settlement Agreement) resolving all ongoing litigation between the Company and Alnylam.

The terms of the Settlement Agreement include mutual releases and dismissals with prejudice of all claims and counterclaims in the following litigation between the parties: (i) *Alnylam Pharmaceuticals, Inc. v. Dicerna Pharmaceuticals, Inc.*, No. 15-4126 pending in the Massachusetts Superior Court for Middlesex County and (ii) *Dicerna Pharmaceuticals, Inc., v. Alnylam Pharmaceuticals, Inc.* No.1:17-cv-11466 pending in the United States District Court for the District of Massachusetts.

Pursuant to the terms of the Settlement Agreement, the Company will make the following payments to Alnylam:

- (a) a \$2 million up-front payment in cash,
- (b) an additional \$13 million in cash, to be paid as 10% of any up front or first year cash consideration that the Company receives pursuant to future partnerships and collaborations related to GalNAc-conjugated RNAi research and development (excluding any amounts received or to be received by the Company from its existing collaboration with Boehringer Ingelheim International GmbH), provided that the \$13 million must be paid by no later than April 28, 2022, and
- (c) issuance of shares of the Company's common stock (the Shares) pursuant to a share issuance agreement between the parties (the Share Issuance Agreement).

Under the Settlement Agreement, the Company will be restricted in its development and other activities relating to oligonucleotide-based therapeutics directed toward a defined set of Alnylam targets, for periods ranging from 18 months up to four years (the Oligo Restrictions). The Oligo Restrictions pertain to targets where Dicerna does not have, or does not currently intend to have, a therapeutic program, or are expected to be consistent with Dicerna's execution on programs in the normal course of business.

The Settlement Agreement does not include (i) any admission of liability or wrongdoing by either party or (ii) any licenses to any other intellectual property from either party.

Share Issuance Agreement

The Company and Alnylam entered into the Share Issuance Agreement on April 20, 2018. Pursuant to the Share Issuance Agreement, the Company agreed to issue to Alnylam 983,208 Shares not for cash, but in satisfaction of the Company's obligation under the Settlement Agreement to deliver Shares to Alnylam. The Share Issuance Agreement contains customary representations and warranties of each party.

Pursuant to the terms of the Share Issuance Agreement, Alnylam may not, without the prior approval of the Company, dispose of any of the Shares for a six-month period of time commencing on the closing date of the Share issuance (the Lock-Up Period). Thereafter, through the fifth anniversary of the closing date of the Share issuance, Alnylam will only dispose of the maximum number of Shares that it would be permitted to dispose if the Shares were subject to the volume restrictions set forth in Rule 144(e) of the Securities Act of 1933, as amended (the Securities Act).

Subject to any applicable confidential treatment, the Settlement Agreement and Share Issuance Agreement will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ending June 30, 2018.

Item 3.02. Unregistered Sale of Equity Securities.

As described in the section titled *Share Issuance Agreement* in Item 1.01 of this Current Report on Form 8-K, which is incorporated in this Item 3.02 by reference, the Company agreed to sell 983,208 Shares to Alnylam on April 20, 2018 pursuant to the Share Issuance Agreement. The Shares were offered and will be issued in a private placement exempt from registration pursuant to Section 4(a)(2) of the Securities Act, or Regulation D promulgated thereunder, as transactions by an issuer not involving a public offering. The purchaser of the Shares has represented it will acquire the Shares for investment only and not with a view to or for sale in connection with any distribution thereof, and an appropriate legend will be applied to the Shares. Based on the shares of Common Stock outstanding as of March 31, 2018, the Shares will represent approximately 1.9% of the outstanding shares of the Company's Common Stock.

Item 7.01 Regulation FD Disclosure.

The Company believes that the Oligo Restrictions will not have any material impact on either the GalXC RNAi technology platform or the Company's plans for clinical development:

DCR-PHXC, an investigational treatment for all forms of primary hyperoxaluria, is currently in Phase 1 clinical trials with proof-of-concept data expected in the second half of 2018.

DCR-HBVS, an investigational treatment for chronic hepatitis B virus, is in pre-clinical development and the Company anticipates filing an investigational new drug (IND) application or clinical trial application (CTA) during the fourth quarter of 2018.

An undisclosed rare disease program, which the Company intends to advance into clinical trials in conjunction with a collaborator, with an anticipated IND or CTA filing in the second half of 2018. As of March 31, 2018, the Company had cash, cash equivalents and held-to-maturity investments of \$97.8 million.

The information in this Item 7.01 is intended to be furnished and shall not be deemed filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information contained herein shall not be incorporated by reference into any filing with the United States Securities and Exchange Commission (SEC) made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Cautionary Note on Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Examples of forward-looking statements include, among others, statements we make regarding: the impact of the Oligo Restrictions on the GalXC platform and the Company's development plans, the timing of data and IND or CTA filings, and the timing of the \$13 million payment to Alynham. Applicable risks and uncertainties include those relating to our research and development, such as that our discovery-stage and preclinical programs do not advance into the clinic or result in approved products on a timely or cost effective basis or at all, and other risks identified under the heading Risk Factors included in our most recent Form 10-K filing and in other future filings with the SEC. The forward-looking statements contained in this Current Report on Form 8-K reflect the Company's current views with respect to future events, and the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

SIGNATURES

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.

Date: April 23, 2018

DICERNA PHARMACEUTICALS, INC.

By: /s/ Douglas M. Fambrough, III.
Douglas M. Fambrough, III., Ph.D.
Chief Executive Officer