

Dicerna Pharmaceuticals Inc
Form 8-K
January 04, 2019

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): December 31, 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)

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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-4(c))
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.

On December 31, 2018, Dicerna Pharmaceuticals, Inc. (the Company) and Boehringer Ingelheim International GmbH, a wholly-owned subsidiary of C.H. Boehringer Sohn AG & Co. KG (BI) entered into an Additional Target Agreement (the ATA). In October 2018, BI exercised its option under a Collaborative Research and License Agreement between the Company and BI, dated October 27, 2017 (the Original Agreement) to add the development of product candidates targeting an additional gene (the Additional Target) to the development activities governed by the Original Agreement.

The ATA provides a research work plan for the Additional Target. The ATA also amends the Original Agreement to provide BI with the option to add the development of product candidates targeting a further additional gene to the Original Agreement (the Second Option) for a three-year period, and to provide for the delivery of a replacement product candidate by the Company to BI in the event that a product candidate under the Original Agreement or the ATA fails at certain stages of pre-clinical or clinical development.

Under the terms of the ATA, in accordance with the terms of the Original Agreement, BI will pay the Company a non-refundable upfront payment (the Option Payment) of \$5.0 million to exercise its initial option for development related to the Additional Target. Under the terms of the ATA, during the term of the research program, BI will reimburse the Company for certain expenses. The Company is eligible to receive up to \$170.0 million in potential development and commercial milestones related to the Additional Target. The Company is also eligible to receive tiered royalty payments on potential global net sales, subject to certain adjustments, in the mid-single digits. Other than as set forth in the ATA, development of the Additional Target will be subject to the terms of the Original Agreement.

Under the ATA, if BI elects, in its sole discretion, to exercise the Second Option, the parties would agree to a research work plan and budget for the additional gene and negotiate development and commercialization milestones and royalty payments to the Company. BI would make another option fee payment to the Company of \$5.0 million.

The foregoing summary of the material terms of the ATA is qualified in its entirety by reference to the ATA and the Original Agreement. The Company will seek confidential treatment from the Securities and Exchange Commission for portions of the ATA, and, subject to such confidential treatment, the ATA will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

Item 2.02 Results of Operations and Financial Condition.

The Company had cash, cash equivalents, and held-to-maturity investments of approximately \$302.6 million as of December 31, 2018. This does not include \$94.5 million of expected near-term net receipts from: (i) the Company's expected receipt of the Option Payment, in the amount of \$5.0 million; (ii) the Company's expected receipt of an upfront payment in the amount of \$100.0 million from the Company's recent collaboration with Eli Lilly and Company (Lilly), as disclosed in the Company's Current Report on Form 8-K filed on October 29, 2018; and (iii) the Company's expected final payment to Alnylam Pharmaceuticals, Inc. (Alnylam) in the amount of \$10.5 million pursuant to a Confidential Settlement Agreement and General Release attached as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018, filed on August 8, 2018. The Company believes that its current cash, cash-equivalents and held-to-maturity investments, in addition to the Option Payment and the expected upfront payment from Lilly, and reduced by the cash payment to Alnylam, will be sufficient to fund the execution of its current clinical and operating plan beyond 2020. This estimate assumes no new funding from additional collaboration agreements or from external financing events and no significant unanticipated changes in costs and expenses.

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The information in this Item 2.02 is intended to be furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 or 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein shall not be incorporated by reference into any of the Company's filings with the United States Securities and Exchange Commission, 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: (i) the Option Payment, (ii) the expected upfront Lilly payment, (iii) the cash payment to Alnylam, (iv) development or sales milestone payments, or royalty payments, (v) therapeutic and commercial potential of GalXC inferred from the statements regarding such payments, (vi) the Second Option, and (vii) guidance related to the anticipated duration and usage of current cash and cash equivalents. The process by which an early stage platform such as GalXC could potentially lead to an approved product is long and subject to highly significant risks, particularly with respect to a pre-clinical research collaboration. Applicable risks and uncertainties include those relating to our pre-clinical research and other risks identified under the heading **Risk Factors** included in the Company's most recent Form 10-Q 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: January 4, 2019

DICERNA PHARMACEUTICALS, INC.

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