

DICERNA PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 11/02/17 for the Period Ending 10/27/17

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**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): October 27, 2017

DICERNA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36281
(Commission
File Number)

20-5993609
(I.R.S. Employer
Identification Number)

87 Cambridgepark Drive
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 October 27, 2017, Dicerna Pharmaceuticals, Inc., a Delaware Corporation (“Dicerna”), entered into a Collaborative Research and License Agreement (the “Agreement”) with Boehringer Ingelheim International GmbH, a wholly-owned subsidiary of C.H. Boehringer Sohn AG & Co. KG (“Boehringer”). Under the terms of the Agreement, Dicerna and Boehringer will jointly research and develop product candidates that target a specific disease-linked gene in the hepatocytes for the treatment of chronic liver disease using the GalXC platform, Dicerna’s proprietary RNAi-based technology. The Agreement is for the development of product candidates against one target gene with an option for Boehringer to add the development of product candidates that target a second gene.

Dicerna will work exclusively with Boehringer to develop the product candidates against the undisclosed target gene. Dicerna will be responsible for the discovery and initial profiling of the product candidates, including primary pre-clinical studies, synthesis, and delivery. Boehringer will be responsible for evaluating and selecting the product candidates for further development. If Boehringer selects one or more product candidates, it will be responsible for further pre-clinical development, clinical development, manufacturing and commercialization of those products.

Pursuant to the Agreement, Dicerna granted Boehringer a worldwide license in connection with the research and development of the product candidates and will transfer to Boehringer intellectual property rights of the product candidates selected by Boehringer for clinical development and commercialization. Dicerna also may provide assistance to Boehringer in order to help Boehringer further develop selected product candidates.

Under the terms of the Agreement, Boehringer agreed to pay Dicerna a non-refundable upfront payment of \$10 million. During the term of the research program, Boehringer will reimburse Dicerna cost of materials and third party expenses that have been included in the preclinical studies up to an agreed-upon limit. Dicerna is eligible to receive up to \$191 million in potential development and commercial milestones. Dicerna is also eligible to receive royalty payments on potential global net sales, subject to certain adjustments, tiered from high single digits up to low double-digits. Boehringer’s option to add a second target would provide for an option fee payment and success-based development and commercialization milestones and royalty payments to Dicerna.

The Agreement includes various representations, warranties, covenants, indemnities and other provisions customary for transactions of this nature. Boehringer may terminate the Agreement at any time without cause following a specified notice period. Either party may terminate the Agreement in the event of an uncured material breach.

The foregoing summary is qualified in its entirety by reference to the Agreement. Dicerna will seek from the Securities and Exchange Commission confidential treatment for portions of the Agreement, which Agreement, subject to such confidential treatment, will be filed as an exhibit to Dicerna’s Annual Report on Form 10-K for the period ended December 31, 2017.

FORWARD LOOKING STATEMENTS

In this Form 8-K, Dicerna makes certain forward-looking statements regarding the collaboration with Boehringer. These forward-looking statements involve highly significant risks and uncertainties, including but not limited to: (i) laboratory research and clinical trials are long, expensive and uncertain processes and the successful completion of future development and regulatory milestones will be required in order for Dicerna to realize future milestone payments under the Agreement, (ii) the risk of failure of any product candidate prior to regulatory approval is high and can occur at any stage due to efficacy, safety or other factors but is particularly high for pre-clinical product candidates and the Boehringer collaboration is at the pre-clinical stage, (iii) any significant failure would likely result in reduced or no further payments to Dicerna from Boehringer, (iv) competing alternative therapies that are under development could reduce the commercial potential of the products which could materially reduce Dicerna's royalty revenue and sales milestones under the Agreement, (v) the Agreement could be terminated by Boehringer at any time without cause, (vi) Boehringer and Dicerna may be unsuccessful in obtaining regulatory approval of the products, (vii) the products may fail to achieve a minimally acceptable commercial profile based on results of clinical trials or competing therapies that target one or more of the same indications, (viii) Dicerna's patent applications for the products which have not already issued may not issue, or even if such patents issue, the claims contained in such pending patents and patents that have already been issued to Dicerna may not provide sufficient market exclusivity, (ix) current patents and future patents that may issue may be invalid or unenforceable and (x) potential future third-party intellectual property disputes. Other important risks and uncertainties are detailed in Dicerna's reports and other filings with the SEC including its most recent Quarterly Report on Form 10-Q. Actual results could differ materially from the forward-looking statements. Dicerna undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.

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: November 2, 2017

DICERNA PHARMACEUTICALS, INC.

By: /s/ John B. Green
John B. Green
Chief Financial Officer