

Dicerna Pharmaceuticals Inc
Form 8-K
October 13, 2016

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 13, 2016

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)

Item 8.01 Other Events.

This Current Report on Form 8-K (this Current Report) updates the Annual Report on Form 10-K of Dicerna Pharmaceuticals, Inc. (the Company or Dicerna) for the year ended December 31, 2015 (the 2015 Annual Report) and Dicerna s most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 (the 2016¹ Quarter Report) to reflect, among other things, the following:

Effective in the third quarter of 2016, Dicerna will focus its resources on its GalXCTM RNAi platform, for the treatment of rare diseases involving the liver and for other therapeutic areas involving the liver, such as chronic liver diseases, cardiovascular diseases and viral infectious diseases.

Under this plan, Dicerna will transition its primary hyperoxaluria (PH) development program to focus on DCR-PHXC, a subcutaneously delivered GalXC clinical candidate, which was announced earlier this year. The Company will discontinue its development program for DCR-PH1, an investigational therapy formulated in an EnCoreTM lipid nanoparticle (LNP) delivery system obtained through a licensing agreement with Arbutus Biopharma Corporation (formerly known as Tekmira Pharmaceuticals Corporation). Based on the DCR-PH1 proof-of-concept data in humans, the utility of the GalXC platform, and the DCR-PHXC preclinical data, the Company believes DCR-PHXC has the potential to be a better therapeutic candidate for patients with PH.

The Company will also discontinue clinical development of DCR-MYC, a DsiRNA-based therapeutic formulated as an LNP for delivery to solid tumors, because preliminary results do not meet the Company s expectations for further development. In addition to DCR-MYC, Dicerna has a second oncology program, DCR-BCAT, which targets the WNT-beta-catenin pathway. Given the Company s focus on advancing its GalXC-based programs, Dicerna will seek strategic alternatives to further develop DCR-BCAT, which employs an improved and enhanced EnCore LNP delivery capability, compared to earlier versions of the technology.

The preceding and certain other information is filed hereunder as Exhibit 99.1 and Exhibit 99.2 which are incorporated herein by reference. Item 9.01 of this Current Report updates the information contained in Part I, Item 1, Business in the 2015 Annual Report and in Part II, Item 1A, Risk Factors in the 2016¹ Quarter Report.

By virtue of this Current Report, the Company will be able to incorporate the updated information by reference into future registration statements or post-effective amendments to existing registration statements. This Current Report does not update for any other changes since the filing of the 2015 Annual Report and the 2016² Quarter Report.

Cautionary Note on Forward-Looking Statements

This Current Report (including the exhibits) includes forward-looking statements, including, for example, potential therapeutic and drug discovery capabilities, the Company s expected timeline of development and licensing plans. 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. Applicable risks and uncertainties include those relating to the Company s clinical and preclinical research and other risks identified under the heading Risk Factors included in Exhibit 99.2 to this Current Report and in other future filings with the SEC. The forward-looking statements contained in this Current Report reflect Dicerna s current views with respect to future events, and Dicerna does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

Description

**Exhibit
No.**

- 99.1 Updates to Part I, Item 1, Business in Dicerna s 2015 Annual Report on Form 10-K
- 99.2 Updates to Part II, Item 1A, Risk Factors in Dicerna s 2016 ^{2nd} Quarter Report on Form 10-Q

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: October 13, 2016

DICERNA PHARMACEUTICALS, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Updates to Part I, Item 1, Business in Dicerna s 2015 Annual Report on Form 10-K
99.2	Updates to Part II, Item 1A, Risk Factors in Dicerna s 2016 ¹ Quarter Report on Form 10-Q