Dicerna Pharmaceuticals Inc
Form 8-K
April 23, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 23, 2015

DICERNA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36281**	**20-5993609**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

87 Cambridgepark Drive

Cambridge, Massachusetts 02140

(Address of principal executive offices, including zip code)

(617) 621-8097

(Registrant s telephone number, including area code)

N/A

(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 (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))

Item 8.01 Other Events

On April 23, 2015 Dicerna Pharmaceuticals, Inc. (NASDAQ: DRNA), a leading developer of RNA interference (RNAi) therapeutics, announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to DCR-PH1, the company s therapeutic candidate for the treatment of primary hyperoxaluria type 1 (PH1). PH1 is a severe, rare, inherited disorder of the liver that often results in kidney failure, and for which there are no approved therapies.

The Orphan Drug Designation program, administered by the FDA s Office of Orphan Products Development (OOPD), provides orphan status to drugs which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a therapeutic drug. DCR-PH1 is Dicerna s proprietary DsiRNA-EX-based therapeutic candidate being developed for the treatment of PH1. In a genetic mouse model of PH1, Dicerna has shown that DCR-PH1 knocks down the gene transcript that encodes for the enzyme glycolate oxidase (GO) and reduces the excretion of oxalate in the urine.

Cautionary Note on Forward-Looking Statements

This 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. DCR-PH1 is in preclinical development, and the process by which a preclinical therapeutic candidate could potentially lead to an approved drug is long and subject to significant risks and uncertainties. Orphan Drug Designation does not assure a faster or more probable regulatory path. Applicable risks and uncertainties include those relating to our preclinical and clinical research 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 Form 8-K 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.

SIGNATURES

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

DICERNA PHARMACEUTICALS, INC.

Date: April 23, 2015

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

President & Chief Executive Officer