Dicerna Pharmaceuticals Inc
Form 8-K
November 18, 2014

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): November 16, 2014

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.)**

480 Arsenal Street

Building 1, Suite 120

Watertown, Massachusetts 02472

(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 1.01 Entry into a Material Definitive Agreement

On November 16, 2014 (the Effective Date), Dicerna Pharmaceuticals, Inc., a Delaware corporation (Dicarna), entered into a License Agreement (the License Agreement) and a Development and Supply Agreement (the Development and Supply Agreement) with Protiva Biotherapeutics Inc. (Protiva) and Tekmira Pharmaceuticals Corporation (Tekmira).

Under the terms of the License Agreement, Protiva and Tekmira grant Dicerna an exclusive (except with respect to previously granted license rights), worldwide license to use Protiva and Tekmira s proprietary lipid nanoparticle (LNP) technology for delivery of certain therapeutics to treat primary hyperoxaluria type 1 (PH1). During the term of the License Agreement, Dicerna will not in-license from a third party for use with a licensed product a drug delivery system competitive with Protiva s LNP technology, provided, however, that if Dicerna in-licenses such a delivery system from a third party after the first commercial sale of a licensed product, the license grant of the LNP technology to Dicerna will thereafter be on a non-exclusive basis.

Dicerna made an upfront payment of $2,500,000 in connection with the signing of the License Agreement. Dicerna will make potential total development and approval milestone payments of $22,000,000. Dicerna is also required to pay a mid-single digit percentage royalty on all net sales of licensed products during the royalty period. The royalty period in a country is the longer of the expiration of the data exclusivity granted by the country s regulatory authority, the last to expire of certain patent claims applicable to products sold in such country, and the 10 year anniversary of the commencement of commercial sales in such country. The License Agreement may be terminated if: (i) either party commits a material, uncured breach, (ii) Dicerna does not use commercially reasonable efforts to develop or commercialize the licensed product, (iii) Dicerna commences an action challenging the validity of the licensed patents; or (iv) if either party initiates bankruptcy, liquidation or similar proceedings.

Contemporaneously with the execution of the License Agreement, Dicerna, Protiva and Tekmira entered into the Development and Supply Agreement. Under the terms of the Development and Supply Agreement, Protiva will perform certain development and other services for Dicerna and manufacture and test licensed products for Dicerna, including: (i) the manufacture of all licensed products for pre-clinical testing and development, (ii) design of the final licensed product formulation to be used as the clinical development candidate, (iii) manufacture of the final formulated licensed product for clinical trials, (iv) assistance in the preparation of regulatory submissions and interactions with the FDA and its foreign equivalents, and (v) performing technical transfer to Dicerna s selected contract manufacturer for the licensed product. Dicerna will pay Protiva on a time and materials basis at an agreed upon FTE rate and with an administrative mark-up on the acquisition of materials.

The Development and Supply Agreement provides that intellectual property developed by a single party pursuant to activities contemplated by the agreement and not based on the practice of certain confidential information or intellectual property of the other party or directed solely to the other party s materials provided pursuant to the agreement shall be owned by such party. The agreement provides for joint ownership of certain jointly developed intellectual property as well as joint or collaborative prosecution, maintenance, and defense of such intellectual property.

The term of the Development and Supply Agreement is the last to occur of: (i) five years after the Effective Date, (ii) the last date of expiry of any GMP batch manufactured by Protiva under the Development and Supply Agreement, or (iii) the completion of certain technical transfer activities by Protiva. The Development and Supply Agreement may be terminated if: (i) either party commits a material, uncured breach, (ii) either party initiates bankruptcy, liquidation or similar proceedings, or (iii) the License Agreement is terminated.

Both agreements contain customary mutual indemnification, arbitration, and insurance maintenance provisions. The Development and Supply Agreement contains customary, mutual provisions regarding non-solicitation of employees.

The foregoing summary is qualified in its entirety by reference to the License Agreement and the Development and Supply Agreement, which will each be filed as an exhibit to the Company s Annual Report on Form 10-K for the year ended December 31, 2014.

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: November 18, 2014

By: */s/* James E. Dentzer
James E. Dentzer
Chief Financial Officer