

Cara Therapeutics, Inc.
Form 8-K
May 23, 2018

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): May 17, 2018

CARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36279
(Commission

File Number)

75-3175693
(IRS Employer

Identification No.)

4 Stamford Plaza

107 Elm Street, 9th Floor

Stamford, Connecticut
(Address of principal executive offices)

06902
(Zip Code)

Registrant's telephone number, including area code: (203) 406-3700

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.):

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 May 17, 2018, Cara Therapeutics, Inc. (Cara or the Company) entered into a license agreement (the Vifor Agreement) with Vifor Fresenius Medical Care Renal Pharma Ltd (Vifor Fresenius), a joint venture between Vifor Pharma Group and Fresenius Medical Care, under which Cara granted Vifor Fresenius a license to seek regulatory approval to commercialize, import, export, use, distribute, offer for sale, promote, sell and otherwise commercialize Cara s product candidate CR845/ difelikefalin Injection for all therapeutic uses to prevent, inhibit or treat itch associated with pruritus in hemodialysis and peritoneal-dialysis patients worldwide (excluding the United States, Japan and South Korea). The Vifor Agreement also provides that Cara and Vifor Fresenius will promote CR845/difelikefalin Injection together under a profit sharing arrangement based on net sales to the dialysis clinics of Fresenius Medical Care North America.

Cara is responsible, at its own cost, to undertake clinical and non-clinical development to gain approval in the United States, and to provide all content and subject matter expertise required for registration with the European Medicines Agency (the EMA) in the European Union that will be needed by Vifor Fresenius for such registration, including participation in regulatory meetings, as needed. If third-party costs incurred by Cara with respect to its clinical development for the EMA registration exceed \$20.0 million, such excess costs will be shared equally by the Company and Vifor Fresenius. Vifor Fresenius will contribute, at its own cost, its clinical development expertise.

Within 120 days of execution of the Vifor Agreement, Cara and Vifor Fresenius will make efforts to agree on terms of a supply agreement, which will be entered no later than 120 days before the filing of a marketing authorization for CR845/difelikefalin Injection in a licensed country. The supply agreement will co-terminate with the Vifor Agreement.

Upon entry into the Vifor Agreement, Vifor Fresenius initiated a non-refundable, non-creditable \$50 million upfront payment to Cara and purchased 1,174,827 shares of Cara s common stock for \$20 million, at a price of \$17.024 per share. In addition, Cara is eligible to receive from Vifor Fresenius regulatory and commercial milestone payments in the aggregate of up to \$470 million, consisting of up to \$30 million in regulatory milestones and up to \$440 million in tiered commercial milestones, all of which are sales-related. Cara is also eligible to receive tiered double-digit royalty payments based on annual net sales, as defined, of CR845/difelikefalin Injection in the licensed territories. Under the terms of the co-promotion arrangement, subject to the terms and conditions of the Vifor Agreement, Cara and Vifor Fresenius are generally entitled to an equal share of profits from net sales of CR845/difelikefalin Injection to the dialysis clinics of Fresenius Medical Care North America.

The Vifor Agreement terminates, on a product-by-product and country-by-country basis, at the latest of (a) the expiration of all patent rights licensed to Vifor Fresenius covering CR845/difelikefalin Injection; (b) the expiration of all regulatory and data exclusivity applicable to CR845/difelikefalin Injection in such country and (c) the tenth anniversary of the first commercial sale of CR845/difelikefalin Injection in such country.

In addition, upon the earlier of (1) the acceptance for filing of an NDA covering CR845/difelikefalin Injection submitted to the FDA (after completion of the Phase 3 program) or (2) May 17, 2021, the Vifor Agreement may be terminated by Vifor Fresenius, either in its entirety or with respect to any licensed countries, with such termination effective upon 12 months notice.

The description of the Vifor Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the complete text of the Vifor Agreement which will be filed as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ending June 30, 2018.

Item 3.02 Unregistered Sale of Equity Securities.

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The information in Item 1.01 above relating to issuance of shares of Cara's common stock to Vifor Fresenius is incorporated by reference into this Item 3.02.

Neither Cara nor Vifor Fresenius engaged any investment advisors with respect to the issuance of such shares and no finders' fees were paid to any party in connection therewith. The issuance of such shares was made in reliance on the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506(b) of Regulation D thereunder.

Neither this Current Report on Form 8-K nor any exhibit attached hereto is an offer to sell or the solicitation of an offer to buy shares of common stock or other securities of Cara.

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.

CARA THERAPEUTICS, INC.

By: /s/ Mani Mohindru
Mani Mohindru, Ph.D.
Chief Financial Officer and Chief Strategy Officer
(Principal Financial and Accounting Officer)

Date: May 23, 2018