

**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): July 26, 2021

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	CARA	The Nasdaq Stock Market LLC

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 July 26, 2021, Cara Therapeutics, Inc. (“Cara”) entered into an API Commercial Supply Agreement (the “Agreement”) with Polypeptide Laboratories S.A. (“PPL”) that defines each party’s responsibilities with respect to PPL’s manufacture and supply of the active pharmaceutical agreement CR845/difelikefalin (“API”) for the Company’s KORSUVA I.V. product candidate (the “Product Candidate”). Cara has submitted a new drug application to the U.S. Food and Drug Administration (the “FDA”) with respect to the Product Candidate for the treatment of moderate-to-severe pruritus in hemodialysis patients.

Under the Agreement, PPL shall manufacture API at its facility for sale and supply to Cara, in the amounts as set forth in purchase orders to be provided by Cara. Cara will be required to purchase its requirements of API for each year of the term of the agreement, based on internal forecasts.

The Agreement will continue until the fifth anniversary of the approval by the FDA of the new drug application for KORSUVA I.V, unless the Agreement is earlier terminated, and will automatically be extended for successive five year periods unless either party gives notice to the other party of its intention to terminate.

The FDA has conditionally accepted KORSUVA as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

The foregoing description of the terms of the Agreement is only a summary, does not purport to be complete and is qualified in its entirety by reference to the Agreement, which the Company intends to file as an exhibit to the Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2021. Unless otherwise defined herein, the capitalized terms used above shall have the same meaning ascribed to them in the Agreement.

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/ THOMAS REILLY
Thomas Reilly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 3, 2021
