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): August 20, 2019

CARA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36279**	**75-3175693**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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.

License Agreement with Enteris Biopharma, Inc.

On August 20, 2019, Cara Therapeutics, Inc. (the "Company") entered into a Non-Exclusive License Agreement (the "License Agreement") with Enteris Biopharma, Inc. ("Enteris"). Pursuant to the License Agreement, Enteris granted to the Company a non-exclusive, royalty-bearing license, including the right to grant sublicenses, under certain proprietary technology and patent rights related to or covering formulations for oral delivery of peptide active pharmaceutical ingredients with functional excipients to enhance permeability and/or solubility, known as Enteris's Peptelligence® technology, to develop, manufacture and commercialize products using such technology worldwide, excluding Japan and South Korea.

As consideration for the licensed rights under the License Agreement, the Company agreed to pay an upfront fee equal to $8,000,000, consisting of $4,000,000 payable in cash and $4,000,000 payable in shares of the Company's common stock pursuant to the Purchase Agreement (as defined below). The Company is also obligated, pursuant to the License Agreement, to pay Enteris (1) milestone payments upon the achievement of certain development, regulatory and commercial milestones and (2) low-single digit royalty percentages on net sales of licensed products, subject to reductions in specified circumstances. Until the second anniversary of the entry into the License Agreement, the Company has the right, but not the obligation, to terminate its obligation to pay any royalties under the License Agreement in exchange for a lump sum payment in cash (the "Royalty Buyout"). Subject to certain conditions, the Company may elect to pay 50% of the lump sum due under the Royalty Buyout in shares of the Company's common stock pursuant to the Purchase Agreement.

The License Agreement will expire on a country-by-country, licensed product-by-licensed product basis upon the later of (1) the expiration (or invalidation) of all valid claims in licensed patent rights that cover such product in such country, (2) the end of the calendar quarter in which generic competition (as defined in the License Agreement" occurs for such product in such country and (3) ten years from the first commercial sale of such product.

Either party may terminate the License Agreement upon written notice if the other party has failed to remedy a material breach within 60 days (or 30 days in the case of a material breach of a payment obligation). Enteris my terminate the License Agreement upon 30 days' written notice to the Company if the Company or any of its affiliates formally challenge the validity of any licensed patent rights or assists a third party in doing so. The Company may terminate the License Agreement for any reason or no reason (a) prior to receipt of first regulatory approval for a licensed product in the United States for any indication upon 30 days' prior written notice to Enteris or (b) on or after receipt of first regulatory approval for a licensed product in the United States for any indication upon 60 days' prior written notice to Enteris.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the text of such agreement. The Company plans to file the License Agreement with its Quarterly Report on Form 10-Q for the period ending September 30, 2019.

Stock Purchase Agreement with Enteris Biopharma, Inc.

In connection with the License Agreement, on August 20, 2019, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with Enteris and its affiliate, EBP Holdco LLC (together with Enteris, "Purchaser"), pursuant to which the Company issued and sold to Purchaser 170,793 shares of its common stock in a private placement (the "Private Placement"). Such shares were issued in satisfaction of the $4,000,000 portion of the upfront fee payable in shares of the Company's common stock pursuant to the License Agreement and for no additional consideration, based on a purchase price of $23.42 per share, which was equal to the 30-day volume weighted average price of the Company's common stock on August 20, 2019. In addition, if the Company exercises its the Royalty Buyout option, it may elect to make 50% of the payment in stock by issuing additional shares of the Company's common stock valued at the 30-day volume weighted average price of the Company's common stock as of such exercise. Pursuant to the Purchase Agreement, the Company must use commercially reasonable efforts to effect the registration and sale of any shares issued and sold to Purchaser thereunder in accordance with the applicable requirements of the Securities Act of 1933, as amended (the "Securities Act"), including the filing of registration statement with the SEC promptly and, in any event within 30 days of the entry into the License Agreement. In addition, the Purchase Agreement includes customary representations, warranties and covenants by the Company.

The foregoing description of the Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to the text of such agreement. The Company plans to file the Purchase Agreement with its Quarterly Report on Form 10-Q for the period ending September 30, 2019.

Item 3.02 Unregistered Sales of Equity Securities.

The information in Item 1.01 above under the caption "Stock Purchase Agreement with Enteris Biopharma, Inc." is incorporated by reference into this Item 3.02.

The Private Placement is exempt from the registration requirements of the Securities Act pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and in reliance on similar exemptions under applicable state laws. Purchaser has represented that it is an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act, and is acquiring the Company's common stock for investment only and not with a view towards the resale or distribution of such shares. The Company's common stock has been offered without any general solicitation by the Company or its representatives.

Neither the Company nor Purchaser has engaged any investment advisors with respect to the issuance by the Company of its common stock to Purchaser in the Private Placement, and no finders' fees were paid to any party in connection therewith.

The shares of the Company's common stock issued and sold in the Private Placement may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to such shares under the Securities Act or an applicable exemption from the registration requirements. This Current Report on Form 8-K does not constitute an offer to sell, or a solicitation of an offer to buy, any security and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offering would be unlawful.

Item 8.01 Other Events.

On August 21, 2019, the Company issued a press release announcing the entry into the License Agreement and Purchase Agreement with Purchaser. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Cautionary Statement Regarding Forward-Looking Statements

This report includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Current Report on Form 8-K, including statements concerning anticipated payments under the License Agreement, the Company's future issuance of shares of common stock pursuant to the Purchase Agreement, and the registration of shares of the Company's common stock under the Securities Act. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "plans," or the negative thereof or other comparable terminology. Although the Company believes that the expectations reflected in the forward-looking statements contained herein are reasonable, such expectations or any of the forward-looking statements may prove to be incorrect and actual results could differ materially from those projected or assumed in the forward-looking statements. Any forward-looking statements are subject to inherent risks and uncertainties, including, but not limited to, the risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof and the Company does not intend to update any forward-looking statements except as required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 21, 2019.

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
(Principal Financial and Accounting Officer)

Date: August 21, 2019

Cara Therapeutics Enters into Commercial License Agreement with Enteris BioPharma, Inc. for Peptelligence® Oral Formulation Technology

- Peptelligence® technology currently used in Oral KORSUVA™ formulation –

STAMFORD, Conn., August 21, 2019 – Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities with a primary focus on the treatment of pruritus by selectively targeting peripheral kappa opioid receptors, today announced that it has entered into a non-exclusive commercial license agreement with Enteris BioPharma, Inc. for oral formulation rights to Enteris' Peptelligence® Technology.

"We are pleased to take another important step in advancing Oral KORSUVA™ as a potential novel treatment for chronic pruritus by entering into this commercial formulation license," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "With three ongoing Phase 2 trials across a range of patient populations for whom pruritus remains a significant unmet need, we are now well positioned to continue Oral KORSUVA's development and potential future commercialization."

Summary of the License Agreement

Under the terms of the License Agreement, Enteris granted Cara a non-exclusive license to its Peptelligence Technology to develop and commercialize Oral KORSUVA in any indication worldwide, excluding South Korea and Japan. Enteris will receive an upfront payment of $8 million, including $4 million in cash and $4 million in Cara common stock. Enteris is also eligible to receive development, regulatory and tiered commercial milestone payments, as well as low, single-digit royalties based on net sales in the licensed territory. Cara retains the right to buy out the royalty obligation for a period of two years under prespecified conditions.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA (CR845/difelikefalin), a first-in-class KOR agonist that targets KORs located in the peripheral nervous system, and on immune cells. In a Phase 3 and two Phase 2 trials,

KORSUVA (CR845/difelikefalin) Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in pruritus-related quality of life measures in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP), and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Oral KORSUVA is in Phase 2 trials for the treatment of pruritus in patients with chronic kidney disease, atopic dermatitis, and primary biliary cholangitis.

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.

Forward-looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of these forward-looking statements include statements concerning the potential for Oral KORSUVA to be a therapeutic option for pruritus and the advantages of entering into the license agreement with Enteris. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in Cara’s filings with the Securities and Exchange Commission, including the “Risk Factors” section of Cara’s Annual Report on Form 10-K for the year ended December 31, 2018 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, Cara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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