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): **March 25, 2020**

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**	**06902**
(Address of principal executive offices)	(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 8.01 Other Events.

On March, 25, 2020, Cara Therapeutics, Inc. issued a press release reporting clinical updates. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	
99.1	Press release dated March 25, 2020.

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/ Derek Chalmers
Derek Chalmers
Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2020

Exhibit 99.1

Cara Therapeutics Reports Clinical Updates

- On track to report topline data for KALM-2 Phase 3 global trial of KORSUVA™ Injection in second quarter –

- On track to complete interim statistical analysis for ongoing Phase 2 trial of Oral KORSUVA in atopic dermatitis in second quarter -

- Timeline to submit KORSUVA Injection New Drug Application to FDA in second half of 2020 remains unchanged -

STAMFORD, Conn., March 25, 2020 – Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs, today announced that it is on track to report topline data in the second quarter of 2020 from its ongoing pivotal KALM-2 Phase 3 global trial of KORSUVA™ Injection in hemodialysis patients with moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP). The Company also plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for KORSUVA Injection in the second half of 2020.

“Despite the ongoing situation with COVID-19, and in accordance with the FDA’s updated guidance for conducting clinical trials, we are pleased that we remain in-line with our timetable to report topline data from KALM-2 in the second quarter,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “We continue to make significant progress across our entire Phase 3 program for KORSUVA Injection, including supportive safety studies, and still expect to submit our NDA in the second half of this year.”

Cara is also currently evaluating Oral KORSUVA in two ongoing Phase 2 trials for atopic dermatitis (AD) patients with moderate-to-severe pruritus and patients with pruritus and hepatic impairment due to primary biliary cholangitis (PBC), respectively. As previously announced, the Company expects to complete an interim statistical analysis for the ongoing Phase 2 trial in AD patients in the second quarter of this year. In addition, data from the previously reported positive Phase 2 dose-ranging trial of Oral KORSUVA for the treatment of pruritus in patients with moderate-to-severe CKD will be presented as a late-breaker oral virtual presentation at the National Kidney Foundation Spring Clinical Meeting on March 26, 2020.

About the KALM-2 Phase 3 Trial

KALM-2 is a Phase 3, global, multicenter, randomized, double-blind, placebo-controlled, 12-week trial (with a 52-week open label extension phase) designed to evaluate the safety and efficacy of 0.5 mcg/kg KORSUVA (CR845/difelikefalin) Injection in 430 hemodialysis patients with moderate-to-severe pruritus.

The primary efficacy endpoint is the proportion of patients achieving at least a 3-point improvement from baseline in the weekly mean of the daily 24-hour Worst Itching Intensity Numeric Rating Scale (WI-NRS) score at week 12. Secondary endpoints include assessment of the proportion of patients achieving >4-point improvement from baseline in weekly mean of the daily 24-hour WI-NRS score at week 12 as well as itch-related quality of life changes measured using the validated self-assessment 5-D itch and Skindex-10 scales.

The pivotal KALM-1 Phase 3 US trial is complete and topline data were reported in May 2019. The trial met the primary endpoint, with a statistically significant improvement in the proportion of patients on KORSUVA Injection achieving a 3-point or greater improvement in the mean WI-NRS score versus placebo (p=0.000019). The trial also met all secondary endpoints and KORSUVA Injection was generally well-tolerated through 12 weeks of treatment with a safety profile consistent with prior clinical trials.

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 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 the Company's KALM-1 Phase 3 trial 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 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 CKD, AD and PBC.

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 ongoing trials and future development of the Company’s product candidates, including the timing for completion and reporting of topline results of Cara’s KALM-2 Phase 3 clinical trial and the timing of the interim statistical analysis for its Phase 2 clinical trial for atopic dermatitis, the timing for submission of an NDA for KORSUVA Injection, the impacts on these clinical and regulatory timelines of the COVID-19 pandemic, and the potential for KORSUVA to be a therapeutic option for pruritus or atopic dermatitis. 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, 2019 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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