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 28, 2017

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))

Item 8.01. Other Events.

On March 28, 2017, Cara Therapeutics, Inc. issued a press release announcing results from Part A of its two-part Phase 2/3 adaptive design trial of its product candidate, I.V. CR845, in dialysis patients suffering from moderate-to-severe uremic pruritus. A copy of this press release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 28, 2017.

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/ Josef Schoell
Josef Schoell
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 28, 2017

Cara Therapeutics Announces Positive Top-Line Data From Part A of Phase 2/3 Trial of I.V. CR845 in Chronic Kidney Disease-Associated Pruritus

– *Met primary endpoint with 68% reduction in worst itching scores versus placebo after eight-week treatment period (p<0.0019)* –

– *Met secondary endpoint in quality of life domains versus placebo after eight-week treatment period (p<0.0007)* –

– *I.V. CR845 well tolerated after eight weeks of treatment* –

– *Conference call today at 8:30 a.m. EDT to review results and next steps* –

STAMFORD, Conn., March 28, 2017 – Cara Therapeutics, Inc. (Nasdaq:CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors, today announced positive top-line results from Part A of its Phase 2/3 trial showing that I.V. CR845 met both primary and secondary endpoints for efficacy (reduced itching and improved quality of life, respectively) in patients with uremic pruritus (UP) with statistical significance. UP is an intractable and debilitating systemic itch condition with a high prevalence in patients with chronic kidney disease (CKD), for which there are no approved therapies in the United States.

“We are extremely pleased with these results, where I.V. CR845 demonstrated sustained clinical and quality of life benefits in dialysis patients suffering from UP and supports the viability of this therapeutic approach for the long-term treatment of this unmet medical need,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “As a next step, we plan to meet with the FDA to finalize the trial design of Part B of this Phase 2/3 study and to initiate patient recruitment later this year.”

“These exciting results underscore I.V. CR845’s potential, if successfully developed, to become an approved therapy in the U.S. for CKD patients suffering from UP,” said Gil Yosipovitch, M.D., Professor of Dermatology, Miller School of Medicine, and Director of the Miami Itch Center at the University of Miami. “There is an unmet medical need for an effective long-term therapy for treating this intractable pruritus and providing meaningful improvement in the quality of life of these patients under dialysis treatment.”

“This study demonstrated encouraging, statistically significant improvements across quality of life measures for hemodialysis patients with this condition,” said Mark Unruh, M.D., Chair of the Department of Internal Medicine at the University of New Mexico School of Medicine. “Importantly, these improvements persisted for the entire eight-week treatment period, with the anti-itch effect apparently sustained over time, suggesting that CR845 has the potential to be an effective treatment for this difficult condition, if successfully developed and approved.”

I.V. CR845 Phase 2/3 UP Trial Design and Top-line Results

Part A of the Phase 2/3 UP trial was a randomized, double-blind, placebo-controlled trial of three doses of I.V. CR845 (0.5 ug/kg, 1.0 ug/kg, and 1.5 ug/kg) administered three times per week after dialysis over an eight-week treatment period in 174 patients with moderate-to-severe UP.

The primary endpoint was the change from baseline of the mean worst itching score for week eight (days 51-57) based on a validated 0-10 Numeric Rating Scale (NRS). Patients receiving I.V. CR845 experienced a 68 percent greater reduction from baseline in worst itch scores than those receiving placebo (p-value<0.0019).

The secondary endpoint focused on quality of life measures associated with pruritus using the Skindex-10 score, a validated self-assessment scale with higher scores indicating worse quality of life. Patients receiving I.V. CR845 experienced a 100 percent greater reduction from baseline in the average total Skindex-10 score at week eight than those receiving placebo (p-value<0.0007). The total average Skindex-10 score reflected statistically significant reductions in each of the three Skindex-10 domains; disease (p-value=0.0001), mood/emotional distress (p-value=0.01), and social functioning (p-value=0.009).

Overall, I.V. CR845 was well tolerated over the eight-week treatment period and the unblinded Drug Safety Monitoring Board did not report any significant drug-related events during the course of the trial. The most common adverse events were transient paresthesia (primarily mid-facial tingling or numbness) and dizziness, as reported in previous clinical studies of I.V. CR845.

Cara plans to meet with the U.S. Food and Drug Administration (FDA) for an end-of-Phase 2 meeting to review the results to determine an optimal dose to take into Part B of this Phase 2/3 study, and define the broader path towards approval. Pending discussions with the FDA, Part B of the study is intended to be a randomized, double-blind, placebo-controlled trial of I.V. CR845 administered three times per week after dialysis over a 12-week treatment period in up to 240 patients with moderate-to-severe UP.

Conference Call

Cara management will host a conference call today at 8:30 a.m. ET to discuss the trial results and next steps for the program.

To participate in the conference call, please dial 855-445-2816 (domestic) or 484-756-4300 (international) and refer to conference ID 97080265. A live webcast of the call can be accessed under “Events and Presentations” in the News & Investors section of the Company’s website at www.caratherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

About Uremic Pruritus

Uremic pruritus (UP) is an intractable systemic itch condition that occurs with the greatest frequency and intensity in chronic kidney disease (CKD) patients under hemodialysis (HD) and peritoneal dialysis; however, pruritus has also been reported in CKD patients who are not yet on dialysis. Aggregate, longitudinal, multi-country studies estimate the weighted prevalence of UP to be approximately 40 percent of patients with end-stage renal disease (ESRD), with approximately 24 percent of patients reporting severe pruritus. Similarly, the majority of dialysis patients (approximately 60-70 percent) report pruritus, with 30 to 40 percent reporting moderate or severe pruritus. Recent data from the ITCH National Registry Study showed that among those with pruritus, 59 percent had experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years with currently employed anti-pruritic treatments, such as anti-histamines and corticosteroids, which are unable to provide consistent adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms that impair quality of life (such as poor sleep quality), and is associated with depression. UP is also an independent predictor of mortality among HD patients, mainly related to increased risk of inflammation and infections.

About CR845

CR845 is a peripherally-acting kappa opioid receptor agonist currently in development for the treatment of acute and chronic pain and pruritus. In multiple randomized, double-blind, placebo-controlled Phase 2 trials in patients undergoing laparoscopic hysterectomy or bunionectomy procedures, I.V. CR845 treatment resulted in statistically significant reductions in pain intensity and opioid-related side effects. In more than 600 subjects dosed to date, I.V. CR845 was found to be well-tolerated, without incurring the dysphoric and psychotomimetic side effects that have been reported with centrally-acting (CNS-active) kappa opioid receptor agonists, and lacking the respiratory depression and abuse liability of mu opioid receptor agonists. Top-line data from a Phase 2b trial of CR845 in chronic pain associated with osteoarthritis and a conditional power analysis from an adaptive Phase 3 trial in postoperative pain are expected in the second quarter of 2017.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates, led by CR845, that target the body’s peripheral nervous system and have demonstrated initial efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available pain therapeutics.

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 expected timing of the initiation of Part B of the trial for I.V. CR845 for UP, timing of a meeting with the FDA and any initiation of enrollment of a Phase 3 trial for I.V.CR845 for UP, the ability of these trials to demonstrate an extended patient benefit, the potential for I.V. CR845 to be a therapeutic option for UP and the expected timing for announcement of the results of other ongoing clinical trials. 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, 2016 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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