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 23, 2015

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.)**

1 Parrott Drive **Shelton, Connecticut**	**06484**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (203) 567-1500

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 July 23, 2015, Cara Therapeutics, Inc. issued a press release announcing results from the Phase 2 clinical trial of its product candidate I.V. CR845 for the treatment of moderate to severe uremic pruritus. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 23, 2015

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: July 23, 2015

Cara Therapeutics Announces Positive Results From Phase 2 Trial in Uremic Pruritus

Novel peripheral kappa opioid I.V. CR845 achieved statistically-significant results on primary endpoint of reducing worst itch intensity

Trial demonstrated statistically significant results on secondary endpoint of quality of life improvements with additional positive trend on itch-related sleep disturbances

I.V. CR845 found to be safe and well-tolerated in dialysis patients

Conference call today at 8:30 a.m. ET to discuss results and next steps

SHELTON, CONN., July 23, 2015— Cara Therapeutics, Inc. (NASDAQ: CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to selectively target peripheral kappa opioid receptors, today announced statistically significant topline results from its Phase 2 trial of its lead kappa opioid agonist, CR845, for the treatment of moderate to severe uremic pruritus (UP). Uremic pruritus is a chronic systemic itch condition in patients with renal failure, often receiving hemodialysis. There are currently no approved products in the United States for the condition.

“These results demonstrate the potential of our lead candidate CR845 to address an additional indication of significant unmet need beyond our lead I.V. CR845 program in acute pain,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “With this encouraging data, we plan to engage the FDA in a formal meeting to guide the structure of a potential Phase 3 pivotal trial, which we would expect to begin in 2016.”

The Phase 2 trial was a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy of I.V. CR845 compared to placebo in reducing the intensity of itch in dialysis patients over a two-week dosing period. The trial enrolled 65 dialysis patients at multiple sites in the United States.

The primary endpoint of the Phase 2 trial was the change from baseline of the average worst itching during the second week of treatment, as recorded on a visual analog scale (VAS). Patients receiving I.V. CR845 experienced a 54 percent greater reduction in worst itch scores than those receiving placebo (p-value = 0.016), with an average reduction of -48 percent from baseline as measured by the VAS. I.V. CR845-treated patients exhibited statistically significant reductions in both daytime (-51 percent, p=0.03) and nighttime (-75 percent, p=0.007) worst itch scores compared to placebo treatment.

Secondary endpoints focused on quality of life measures associated with pruritus using a series of previously validated self-assessment scales, including the Skindex 10 score. Patients receiving I.V. CR845 experienced a 71 percent greater reduction in the average total Skindex 10 score at the end the two-week treatment period than those receiving placebo (p-value=0.031). The total score average included positive trends in patients receiving I.V. CR845 for each of the three Skindex 10 domains: disease, mood/emotional distress (statistically significant reduction, p-value = 0.046) and social functioning. Another secondary measure, itch-related sleep disturbances based on the Itch MOS Sleep Problems Index II, showed a positive trend in patients receiving I.V. CR845, with a 62 percent improvement compared to placebo, although this trend was not observed to be statistically significant.

I.V. CR845 was shown to be safe and well tolerated during the study with no CR845-related serious adverse events (AEs) reported. The most common AEs were transient numbness and dizziness, with no episodes of the CNS side effects (e.g., dysphoria and hallucinations) that have impeded the development of centrally-acting kappa opioids.

“The results of the CR845 Phase 2 study are very encouraging. The data demonstrate a robust effect of reducing both daytime and nocturnal itching by an objective scoring system as well as anecdotal quality of life histories,” said Dr. James Tumlin, Professor, Department of Medicine, University of Tennessee and a Principal Investigator on the trial. “With no approved therapy and the limited efficacy of current options, CR845 provides an opportunity to alleviate the pain and discomfort of this persistent clinical problem among ESRD patients.”

There are more than 400,000 patients in the United States and 2.2 million globally undergoing hemodialysis and it is estimated that as many as 50 percent of these patients suffer from renal or uremic pruritus. Currently, there are no approved products in the United States for the condition, which can often be severe and resistant to treatment with traditional itch treatments, such as corticosteroids and antihistamines.

“We are excited by these topline results in uremic pruritus, which show that I.V. CR845 holds significant clinical potential in this indication of significant unmet need for dialysis patients,” said Joseph Stauffer, D.O., M.B.A., Chief Medical Officer of Cara Therapeutics. “I.V. CR845 demonstrated a statistically significant effect, not only on our primary endpoint of reducing the itch intensity for dialysis patients, but also in important quality of life measurements, along with a favorable safety and tolerability profile.”

Conference Call

Cara management will host a conference call today at 8:30 a.m. ET to discuss the UP 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 93878802. 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 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 440 subjects dosed to date, I.V. CR845 was found to be safe and well tolerated, without incurring the dysphoric and psychotomimetic side effects that have been reported with centrally acting (CNS-active) kappa opioid receptor agonists. Cara expects to initiate its Phase 3 Program of I.V. CR845 for acute pain with a first adaptive pivotal trial in laparoscopic abdominal surgery in 3Q'15. In addition, a Phase 2 trial of CR845 in osteoarthritis patients using an oral tablet formulation is planned for 3Q'15.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates that target the body's peripheral nervous system and have demonstrated 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 for meeting with the FDA regarding the results of the Company's Phase 2 trial of I.V. CR845 in in dialysis patients experiencing uremic pruritus, the potential for the advancement of I.V. CR845 to advance into a pivotal trial program, the potential future successful clinical and regulatory development of I.V. CR845 for uremic pruritus, and the expected timing of planned clinical trials for the Company's other development programs. 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 Therapeutics' filings with the Securities and Exchange Commission, including the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2014 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. Cara Therapeutics 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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