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) **December 18, 2023**

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	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 7.01. Regulation FD Disclosure.

On December 18, 2023, Cara Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing the outcome from the dose-finding Part A of the KIND 1 study evaluating the efficacy and safety of oral difelikefalin as adjunct therapy to topical corticosteroids ("TCS") for moderate-to-severe pruritus in adult patients with atopic dermatitis ("AD"). Oral difelikefalin as adjunct to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone, resulting in the Company's decision to discontinue its clinical program in pruritus associated with AD. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 7.01.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company's filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing.

Item 8.01. Other Information.

On December 18, 2023, the Company issued the Press Release announcing the outcome from the dose-finding Part A of the KIND 1 study evaluating the efficacy and safety of oral difelikefalin as adjunct therapy to TCS for moderate-to-severe pruritus in adult patients with AD. Oral difelikefalin as adjunct to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone, resulting in the Company's decision to discontinue its clinical program in pruritus associated with AD.

The Phase 3, two-part, multicenter, randomized, double-blind, placebo-controlled, 12-week study was designed to investigate the use of oral difelikefalin as adjunctive treatment to topical corticosteroids in approximately 287 patients with AD. Patients were randomized to receive oral difelikefalin 0.25 mg tablets twice a day ("BID") plus TCS, difelikefalin 0.5 mg tablets BID plus TCS, placebo tablets BID plus TCS or placebo tablets BID plus vehicle.

Primary Endpoint

The primary efficacy endpoint was the proportion of patients with a ≥4-point improvement at Week 12 from baseline in the worst itch numerical rating scale.

Oral difelikefalin as adjunct therapy to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone. Oral difelikefalin was generally well tolerated with a safety profile similar to prior trials.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated December 18, 2023
104	Cover page interactive data file (formatted as Inline XBRL)

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/ RYAN MAYNARD
Ryan Maynard
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: December 18, 2023

Exhibit 99.1

Cara Therapeutics Announces Outcome from Dose-Finding Part A of KIND 1 Study Evaluating Oral Difelikefalin for Moderate-to-Severe Pruritus in Patients with Atopic Dermatitis

– Oral difelikefalin as adjunct to topical corticosteroids (TCS) did not demonstrate meaningful clinical benefit compared to TCS alone; As a result, Cara will discontinue its clinical program in pruritus associated with atopic dermatitis –

– Late-stage oral difelikefalin clinical programs for pruritus associated with notalgia paresthetica and advanced chronic kidney disease continue to enroll on track with key data readouts expected in 2H24 –

– Cara expects to end 2023 with approximately $100 million in cash –

STAMFORD, Conn., December 18, 2023 – Cara Therapeutics, Inc. (Nasdaq: CARA), a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus, today announced the outcome from the dose-finding Part A of the KIND 1 study evaluating the efficacy and safety of oral difelikefalin as adjunct therapy to topical corticosteroids (TCS) for moderate-to-severe pruritus in adult patients with atopic dermatitis (AD). Oral difelikefalin as adjunct to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone, resulting in the Company's decision to discontinue its clinical program in pruritus associated with atopic dermatitis.

"We are disappointed with the outcome of this study recognizing that comparing the adjunctive use of oral difelikefalin with TCS to TCS alone represented a high clinical bar based on anticipated real-world commercial use. Importantly, we believe that there is no readthrough to our other late-stage clinical programs for oral difelikefalin as monotherapy without TCS in different indications and patient populations, namely notalgia paresthetica (NP) and advanced chronic kidney disease (CKD)," said Joana Goncalves, MD, Chief Medical Officer of Cara Therapeutics. "On behalf of the Cara team, I would like to thank the patients and investigators who participated in this trial and our team for their unwavering commitment to its execution."

KIND 1 was a Phase 3, two-part, multicenter, randomized, double-blind, controlled study to evaluate the efficacy and safety of oral difelikefalin as adjunct therapy to TCS for moderate-to-severe pruritus in adults with AD. In Part A, patients (n=287) were randomized to receive oral difelikefalin 0.25 mg tablets twice a day (BID) plus TCS, difelikefalin 0.5 mg tablets BID plus TCS, placebo tablets BID plus TCS or placebo tablets BID plus vehicle. The primary endpoint was the proportion of patients with a ≥4-point improvement at Week 12 from baseline in the worst itch NRS.

Oral difelikefalin as adjunct therapy to TCS did not demonstrate a meaningful clinical benefit compared to TCS alone. Oral difelikefalin was generally well tolerated with a safety profile similar to prior trials.

Cara expects to end 2023 with approximately $100 million in cash. This amount includes the $17.5 million already received from HealthCare Royalty, less certain expenses, and the first milestone payment of $20 million, which was triggered by the achievement of the milestone this month and is expected to be received by year-end 2023.

About Cara Therapeutics

Cara Therapeutics is a commercial-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company's KORSUVA® (difelikefalin) injection is the first and only FDA-approved treatment for moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. The Company is developing an oral formulation of difelikefalin and has a Phase 3 program ongoing for the treatment of moderate-to-severe pruritus in patients with advanced chronic kidney disease and a Phase 2/3 program for moderate-to-severe pruritus in patients with notalgia paresthetica. For more information, visit www.CaraTherapeutics.com and follow the company on X (Twitter), LinkedIn and Instagram.

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 Company's plans to discontinue its clinical program in pruritus associated with atopic dermatitis, timing of enrollment and data readouts from the Company's planned and ongoing clinical trials, and the Company's cash balance at year end. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include the risks inherent in the launch of new products, including that our commercial partners may not perform as expected, risks inherent in the clinical and regulatory development of pharmaceutical products, and the risks 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 ending December 31, 2022 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2023. 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, except as required by law.

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