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) **June 12, 2024**

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.)
400 Atlantic Street **Suite 500** **Stamford, Connecticut** (Address of principal executive offices)		**06901** (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 June 12, 2024, Cara Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing the outcome from the dose-finding Part A of the KOURAGE-1 study evaluating the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in adult patients with notalgia paresthetica ("NP"). Oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo, resulting in the Company's decision to discontinue the clinical program in NP. 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 June 12, 2024, the Company issued the Press Release announcing the outcome from the dose-finding Part A of the KOURAGE-1 study evaluating the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in adult patients with NP. Oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo, resulting in the Company's decision to discontinue the clinical program in NP.

The Phase 2/3, two-part, multicenter, randomized, double-blind, placebo-controlled, 8-week study was designed to investigate the use of oral difelikefalin for moderate-to-severe pruritus in adult patients with NP. In Part A, patients were randomized to one of four arms: oral difelikefalin 2 mg twice a day ("BID"), 1 mg BID, 0.25 mg BID or placebo BID for 8 weeks.

Primary Endpoint

The primary endpoint was the proportion of patients achieving a ≥4-point improvement from baseline in the weekly mean of the daily 24-hour Itch-Numeric Rating Scale (I-NRS) score at Week 8.

Oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo. The drug 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 June 12, 2024
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: June 12, 2024

Exhibit 99.1

Cara Therapeutics Announces Outcome of Part A of KOURAGE-1 Study Evaluating Oral Difelikefalin in Notalgia Paresthetica

– Oral difelikefalin did not demonstrate meaningful clinical benefit compared to placebo –

– Company will discontinue clinical program in NP and explore strategic alternatives –

STAMFORD, Conn., June 12, 2024 – Cara Therapeutics, Inc. (Nasdaq: CARA), a development-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 KOURAGE-1 study evaluating the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in adult patients with notalgia paresthetica (NP). Oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo, resulting in the Company's decision to discontinue the clinical program in NP.

"Given our strong proof-of-concept results in NP and the significant unmet need in this sensory neuropathy, we are disappointed that oral difelikefalin did not demonstrate a meaningful improvement in pruritus compared to placebo in the KOURAGE-1 Part A study," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "We are grateful for the patients and investigators who participated in this study. We will be winding down the Phase 2/3 clinical program in NP and exploring strategic alternatives focused on maximizing shareholder value."

KOURAGE-1 Part A was a multicenter, randomized, double-blind, placebo-controlled study designed to inform the dose and sample size for the pivotal portions of the Phase 2/3 clinical program. In Part A, 214 patients were randomized to one of four arms: oral difelikefalin 2 mg twice a day (BID), 1 mg BID, 0.25 mg BID or placebo BID for 8 weeks. The primary endpoint was the proportion of patients achieving a ≥4-point improvement from baseline in the weekly mean of the daily 24-hour Itch-Numeric Rating Scale (I-NRS) score at Week 8.

Oral difelikefalin did not demonstrate a meaningful clinical benefit at any dose compared to placebo. The drug was generally well tolerated with a safety profile similar to prior trials.

As of March 31, 2024, the Company had approximately $70 million in cash, cash equivalents, and marketable securities.

About Cara Therapeutics

Cara Therapeutics is a development-stage biopharmaceutical company leading a new treatment paradigm to improve the lives of patients suffering from pruritus. The Company developed an IV formulation of difelikefalin, which is approved in the United States, EU, and multiple other countries for the treatment of moderate-to-severe pruritus associated with advanced chronic kidney disease in adults undergoing hemodialysis. The IV formulation is out-licensed worldwide. 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 winding down of the Company's Phase 2/3 clinical program in NP, the exploration of strategic alternatives and other statements that are not historical facts. 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 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 ending December 31, 2023 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended March 31, 2024. 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.

MEDIA CONTACT:
Annie Spinetta
6 Degrees
973-768-2170
aspinetta@6degreespr.com

INVESTOR CONTACT:
Iris Francesconi, Ph.D.
Cara Therapeutics
203-406-3700
investor@caratherapeutics.com