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) **January 17, 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.)

4 Stamford Plaza **107 Elm Street, 9th Floor** **Stamford, Connecticut** (Address of principal executive offices)	**06902** (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 2.05. Costs Associated with Exit or Disposal Activities.

On January 17, 2024, in connection with a review of the company's strategic priorities, the Board of Directors of Cara Therapeutics, Inc. (the "Company") approved a strategic reprioritization to focus the Company's resources on the Company's late stage clinical program evaluating oral difelikefalin in pruritus associated with notalgia paresthetica, and approved the termination of the Company's Phase 3 clinical program evaluating oral difelikefalin in pruritus associated with advanced chronic kidney disease, including the termination of the ongoing KICK 1 and KICK 2 clinical trials. In connection with the termination of the oral chronic kidney disease program, the Board of Directors also approved a reduction in the Company's workforce, which the Company expects to substantially complete by January 31, 2024. The Company anticipates recognizing between $2.5 million and $3 million in total charges in the first quarter of 2024 in connection with the reduction in force. These charges will consist primarily of one-time cash charges for termination benefits.

Item 7.01. Regulation FD Disclosure.

On January 22, 2024, the Company issued a press release (the "Press Release") announcing its strategic reprioritization plan and the reduction in force. 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.

After giving effect to the strategic reprioritization and reduction in force described herein, the Company now expects that its capital resources will be sufficient to fund its currently anticipated operating plan into 2026.

On January 22, 2024, the Company also announced that Frédérique Menzaghi, Ph.D., Chief Scientific Officer and SVP of Research & Development, will depart the Company, effective February 2, 2024.

Forward-Looking Statements

Statements contained in this report 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 strategic plans to focus its resources on the development of oral difelikefalin for the treatment of pruritus associated with notalgia paresthetica and to discontinue the development of oral difelikefalin in advanced chronic kidney disease, the expected costs of the reduction in force and the timing of recognition of such charges, and the Company's cash runway. 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 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 report 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated January 22, 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: January 22, 2024

Exhibit 99.1

Cara Therapeutics Prioritizes Late-Stage Notalgia Paresthetica Program and Extends Cash Runway into 2026

– Focus on Phase 2/3 program in notalgia paresthetica (NP), a neuropathic disorder with significant unmet need –

– Phase 3 program in advanced chronic kidney disease (CKD) to be discontinued –

– Planned workforce reduction of up to 50% –

– Cara ended 2023 with approximately $101 million in cash; runway extended into 2026 –

– Company to host conference call and webcast today at 8:30 a.m. EST –

STAMFORD, Conn., January 22, 2024 – Cara Therapeutics, Inc. (Nasdaq: CARA) today announced it will focus its resources on the oral difelikefalin Phase 2/3 clinical program in notalgia paresthetica (NP) and significantly reduce its operating expenses. These measures will extend the Company's cash runway into 2026, enabling the expected completion of the NP clinical program.

"We are sharpening our clinical focus on the rapidly progressing Phase 2/3 study in NP, which we believe is the therapeutic indication with the greatest commercial potential for oral difelikefalin," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "Following careful consideration, we have decided to discontinue our work in advanced chronic kidney disease (CKD). I would like to thank the patients and investigators who have participated in our advanced CKD clinical program, as well as our employees for their commitment to transforming the lives of CKD patients suffering from pruritus."

Mr. Posner continued, "Unfortunately, as a result of the difficult decision to restructure the Company, many of our talented team members will depart the organization. I am deeply grateful for their dedicated service and support of our mission. We expect the changes we are making to extend our cash runway into 2026, allowing us to reach all expected key value-inflection milestones in the NP clinical program."

Focus on Late-Stage Notalgia Paresthetica Clinical Program

Enrollment in the Phase 2/3 clinical program evaluating oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with NP, known as KOURAGE, is progressing ahead of the Company's projections. A data readout from the dose-finding portion of the program is expected in the third quarter of 2024. Final topline results from the first pivotal study are expected by the end of 2025 with the second pivotal study results in early 2026.

NP is a common but under-recognized neuropathic disorder characterized by chronic pruritus affecting the upper back. NP is challenging to manage, as there are currently no FDA-approved therapies to treat the disorder. Oral difelikefalin is the only therapy in development for NP. NP represents a sizable, underserved patient population with an estimated addressable market of 650,000 patients in the U.S. who are under the care of a healthcare provider, not accounting for those who are undiagnosed.

Leadership Update

Frédérique Menzaghi, Ph.D., Chief Scientific Officer and SVP of Research & Development, will depart the Company, effective February 2, 2024.

“On behalf of the entire Cara team, I would like to express our sincere gratitude to Fred for all her contributions and dedication to the organization over the past 20 years. As one of Cara’s founders, her scientific leadership helped shape the trajectory of the company from start-up to a publicly traded company,” said Mr. Posner.

Conference Call & Webcast

Cara will host a conference call and webcast today at 8:30 a.m. EST to discuss the corporate update.

To participate in the conference call, please register here. Registrants will receive the dial-in numbers and a unique PIN.

A live audio webcast and archived replay of the call will be available under “Events & Presentations” in the Investors section of the Company’s website at www.CaraTherapeutics.com.

About the KOURAGE Phase 2/3 Clinical Program in Notalgia Paresthetica

KOURAGE is a Phase 2/3 clinical program evaluating oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica (NP). The program is comprised of two studies – KOURAGE 1 and KOURAGE 2 – which are double-blind, placebo-controlled, 8-week studies with patients allowed to roll-over into open-label 52-week extensions.

KOURAGE 1 is composed of two parts. The dose-finding portion of KOURAGE 1 (Part A) is expected to include 200 patients who will be randomized equally to four arms (0.25 mg BID, 1.0 mg BID, 2.0 mg BID, placebo BID). The Company expects a data readout from the dose-finding portion of KOURAGE 1 in the third quarter of 2024. This readout will provide key information, specifically the dose and sample size to initiate the Phase 3 portions of the program – Part B of KOURAGE 1 and the second pivotal study KOURAGE 2.

Part B and KOURAGE 2 will be double-blind, placebo-controlled, 8-week studies with patients randomized 1:1 to either difelikefalin or matching placebo. The primary endpoint will be the proportion of patients with a ≥4-point improvement at Week 8 from baseline in the worst itch numeric rating scale. The Company expects final topline results from the first pivotal study by the end of 2025 with the second study by early 2026.

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, with an ongoing Phase 2/3 clinical program for patients with notalgia paresthetica, a neuropathic disorder characterized by chronic pruritus of the upper back for which there are no FDA-approved therapies. For more information, visit www.CaraTherapeutics.com and follow the company on X (Twitter), LinkedIn and Instagram.

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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 strategic plans to focus its resources on the development of oral difelikefalin for the treatment of pruritus associated with notalgia paresthetica and to discontinue the development of oral difelikefalin in advanced chronic kidney disease, the timing of enrollment and data readouts from the Company's planned and ongoing clinical trials, and the Company's cash runway. 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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