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) **November 1, 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 1.01 Entry into a Material Definitive Agreement.

On November 1, 2023 (the "***Closing Date***"), Cara Therapeutics, Inc. (the "***Company***"), through its wholly-owned subsidiary Cara Royalty Sub, LLC, a Delaware limited liability company ("***Royalty Sub***"), entered into a Purchase and Sale Agreement (the "***Purchase and Sale Agreement***") with HCRX Investments Holdco, L.P., a Delaware limited partnership ("***HCRx***"), and Healthcare Royalty Partners IV, L.P., a Delaware limited partnership (collectively with HCRx, "***HCR***"). Pursuant to the Purchase and Sale Agreement, Royalty Sub sold, or agreed to sell, as applicable, to HCR certain of its rights to receive royalty payments (the "***Royalties***") due and payable to Royalty Sub, on or after October 1, 2023, until such time certain return thresholds are met as described below, under (a) that certain License Agreement, effective as of April 4, 2013, by and between the Company and Maruishi Pharmaceutical Co., Ltd., as amended from time to time and as assigned by the Company to Royalty Sub on the Closing Date (the "***Maruishi Agreement***") and (b) that certain License Agreement, dated May 17, 2018, by and between the Company and Vifor Fresenius Medical Care Renal Pharma Ltd., as amended from time to time and as assigned by the Company to Royalty Sub on the Closing Date (the "***Vifor Agreement***" and, collectively with the Maruishi Agreement, the "***Covered License Agreements***") in exchange for up to $40 million in cash. The Vifor Agreement and the Royalties thereunder shall be retained by the Company until the Company has received the First Milestone Payment (as defined below). Further, the Company has retained all of its right, title and interest in, to and under the Covered License Agreements that relate to any non-intravenous formulation of difelikefalin.

Under the terms of the Purchase and Sale Agreement, Royalty Sub will receive an upfront payment of $17.5 million, less certain expenses. The terms of the Purchase and Sale Agreement provide for an additional (a) $20 million milestone payment (the "***First Milestone Payment***") to Royalty Sub if, prior to December 31, 2023, pricing for Kapruvia® (difelikefalin) in Germany is approved above a certain threshold amount per dose and (b) $2.5 million milestone payment to Royalty Sub upon achievement of a 2024 sales milestone of KORSUVA in Japan.

The Purchase and Sale Agreement will automatically expire, and the payment of Royalties to HCR will cease, when HCR has received payments of Royalties equal to two times the aggregate amount of payments made by HCR under the agreement (the "***2029 Threshold***"), if the 2029 Threshold is achieved on or prior to December 31, 2029, or 2.8 times the aggregate amount of payments made by HCR under the agreement, if the 2029 Threshold is not achieved on or prior to December 31, 2029. After the Purchase and Sale Agreement expires, all rights to receive the Royalties return to Royalty Sub. The Purchase and Sale Agreement grants HCR the right to receive certain reports and other information relating to the Royalties and contains various representations and warranties, covenants, indemnification obligations and other provisions that are customary for a transaction of this nature.

On the Closing Date, the Company entered into (i) a Contribution and Servicing Agreement and (ii) a Pledge and Security Agreement. The Contribution and Servicing Agreement contains various representations and warranties, covenants, indemnification obligations and other provisions related to the contribution of the Covered License Agreement to Royalty Sub and the Company's maintenance and servicing obligations with respect to the Royalties and the Covered License Agreements. The Pledge and Security Agreement contains various representations, warranties and covenants, and includes a limited recourse guaranty of Royalty Sub's obligations under the Purchase and Sale Agreement which is secured by the pledge in favor of HCR all of the capital stock of Royalty Sub. HCR is entitled to foreclose on the capital stock of Royalty Sub following the occurrence of certain remedies events, including, without limitation, a bankruptcy of the Company or the failure of the Company to perform its obligations under the Contribution and Servicing Agreement.

The Company intends to use the proceeds from the Purchase and Sale Agreement to support the ongoing clinical development of its oral difelikefalin pipeline, including late-stage programs for pruritus associated with atopic dermatitis, advanced chronic kidney disease, and notalgia paresthetica.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the Purchase and Sale Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ending December 31, 2023.

Item 7.01 Regulation FD Disclosure.

On November 2, 2023, the Company issued a press release announcing the transaction with HCR. A copy of the press release is being furnished to the SEC as Exhibit 99.1 to this Form 8-K and is incorporated by reference to this Item 7.01.

The information furnished pursuant to 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 SEC 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated November 2, 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/ CHRISTOPHER POSNER
Christopher Posner
Chief Executive Officer

Date: November 2, 2023

Exhibit 99.1

Cara Therapeutics Announces up to $40.0 Million Non-Dilutive Financing Agreement with HealthCare Royalty

Transaction supports progression of late-stage oral difelikefalin clinical programs

Non-dilutive capital expected to extend cash runway into 2025

STAMFORD, Conn., November 2, 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 it has entered into a Royalty Interest Purchase and Sale Agreement (the agreement) with HealthCare Royalty (HCRx).

Cara intends to use the proceeds from the agreement to support the ongoing clinical development of its oral difelikefalin pipeline, including late-stage programs for pruritus associated with atopic dermatitis, advanced chronic kidney disease, and notalgia paresthetica.

“This non-dilutive capital strengthens our balance sheet and fuels the continued advancement of our three late-stage oral difelikefalin clinical programs,” said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. “Importantly, this financing is expected to extend our cash runway into 2025.”

Under the terms of the agreement, Cara will receive an initial payment of $17.5 million, less certain expenses. Cara will receive an additional payment of $20.0 million upon Kapruvia® (difelikefalin) receiving a certain minimum price in Germany, which is expected to occur this quarter. In addition, if KORSUVA achieves certain specified 2024 performance levels in Japan, Cara will receive a $2.5 million milestone payment. In exchange, HCRx will receive all royalties due to Cara from KORSUVA® (difelikefalin) injection / Kapruvia® ex-U.S. license agreements with CSL Vifor and Maruishi Pharmaceutical Co., Ltd. The arrangement with HCRx specifically excludes KORSUVA injection in the U.S. and all of Cara’s oral difelikefalin internal development programs.

The aggregate royalty payments to HCRx are capped at 2.0x the payments to Cara if received before the end of 2029. Otherwise, the payments are capped at 2.8x after which Cara will resume receiving all royalties from both CSL Vifor and Maruishi.

Armentum Partners served as financial advisor and Cooley LLP served as legal advisor to Cara. Morgan, Lewis & Bockius LLP acted as legal advisor to HCRx.

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 Phase 3 programs ongoing for the treatment of pruritus in patients with advanced chronic kidney disease and atopic dermatitis. In addition, the Company has an ongoing Phase 2/3 program of oral difelikefalin for the treatment of 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.

About HealthCare Royalty

HCRx is a leading royalty acquisition company focused on commercial or near-commercial stage biopharmaceutical products and has offices in Stamford (CT), San Francisco, Boston and London. For more information, visit www.hcrx.com. HEALTHCARE ROYALTY® and HCRx® are registered trademarks of HealthCare Royalty Management, LLC.

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 potential for the Company's product candidates to be alternatives in the therapeutic areas investigated, the potential benefits of the agreement with Healthcare Royalty, the Company's intended use of proceeds received from the agreement, potential for receipt of milestone payments based off of 2024 performance levels of KORSUVA in Japan, and the pricing for Kapruvia® (difelikefalin) in Germany and the timing thereof. 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 June 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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