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) **March 4, 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 2.02. Results of Operations and Financial Condition.

On March 4, 2024, Cara Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023. 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 2.02.

The information furnished pursuant to this Item 2.02, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 4, 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: March 4, 2024

Exhibit 99.1

Cara Therapeutics Announces Fourth Quarter and Full Year 2023 Financial Results

–Announced prioritization of clinical programs to focus on late-stage development of oral difelikefalin for notalgia paresthetica (NP)–

–Completed enrollment of KOURAGE 1 Part A portion of NP pivotal program ahead of schedule; topline efficacy and safety results now expected in 3Q24–

–Extended cash runway into 2026 with clinical prioritization strategy and reduction in force–

–Conference call today at 4:30 p.m. EST–

STAMFORD, Conn., March 4, 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 financial results and operational highlights for the fourth quarter and full year ended December 31, 2023.

"Earlier this year, we announced the decision to focus all our resources on our late-stage notalgia paresthetica (NP) clinical program, which we believe puts us on the path to significant near-term value creation," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "We completed enrollment in KOURAGE 1 Part A, the dose-finding portion of our pivotal program, earlier than anticipated and now expect to report topline efficacy and safety results in the third quarter of 2024. With a sizeable patient population and no approved or effective therapies on the market, we are excited about the commercial potential for oral difelikefalin in NP. Importantly, our cash runway into 2026 gives us the resources necessary to reach all potential key value-inflection milestones in our NP clinical program."

2023 and Recent Highlights

- Completed enrollment in KOURAGE 1 Part A with 214 patients
- Prioritized late-stage NP clinical program, extending cash runway into 2026
- Entered into Royalty Purchase and Sale Agreement with HealthCare Royalty for up to $40 million and received $37.5 million, less $1.0 million of transaction costs and advisory fees, in 4Q23
- CY 2024 End Stage Renal Disease Prospective Payment System (ESRD PPS) final rule issued by CMS outlining post-TDAPA reimbursement
- Helen M. Boudreau appointed to the Company's Board of Directors and serving as Chair of the Audit Committee
- Results from the KOMFORT Phase 2 proof-of-concept study of oral difelikefalin in NP published in the *New England Journal of Medicine*

KOURAGE Update

In the first quarter of 2024, the Company completed enrollment in KOURAGE 1 Part A, the dose-finding portion of the Phase 2/3 clinical program evaluating oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with NP.

The Company enrolled 214 patients and expects topline efficacy and safety results from KOURAGE 1 Part A in the third quarter of 2024. Part A is not powered for statistical significance. This readout will provide key information, specifically the dose and sample size to initiate the Phase 3 pivotal portion of the program – Part B of KOURAGE 1 and the second study KOURAGE 2. Final topline results from the first pivotal study are expected by the end of 2025 with the second pivotal study results in early 2026.

On March 27, 2024, the Company will host a virtual event featuring a panel of leading dermatologists and key opinion leaders to discuss the unmet need in NP and the potential of oral difelikefalin. The Company will issue an announcement with more details.

4Q23 KORSUVA Injection U.S. Update

In the fourth quarter of 2023, KORSUVA® (difelikefalin) injection generated net sales of $5.0 million and the Company recorded collaborative revenue of $2.3 million, which represented the Company's share of the profit from sales of KORSUVA injection.

Wholesalers shipped 110,700 vials to dialysis centers during the fourth quarter of 2023 (an increase of 22% vs. the third quarter of 2023), the majority of which were vials reallocated within the Fresenius network of clinics.

On March 31, 2024, the Transitional Drug Add-On Payment Adjustment (TDAPA) period for KORSUVA injection will expire. After March 31, 2024, KORSUVA injection will be reimbursed through the ESRD PPS bundle.

Upcoming Meeting Activities

The Company expects to participate in the following upcoming events:

- Meet the NP Experts Virtual Event, March 27
- 23rd Annual Needham Virtual Healthcare Conference, April 8-11

Fourth Quarter and Full Year 2023 Financial Results

Royalty Purchase and Sale Agreement: During the three months ended December 31, 2023, the Company entered into a Purchase and Sale Agreement, or the HCR Agreement, with HCRX Investments Holdco, L.P. and Healthcare Royalty Partners IV, L.P., or collectively HCR, where HCR will receive future royalty and milestone payments for Kapruvia/KORSUVA (ex U.S. only) up to certain capped amounts in exchange for up to $40.0 million to the Company. The Company received proceeds of $37.5 million, less $1.0 million of transaction and advisory costs, both of which were recorded as a long-term liability as of December 31, 2023. This long-term debt balance will increase as imputed interest is calculated on the outstanding debt balance and will decrease as future royalty and milestone payments are paid to HCR over the period defined in the HCR Agreement.

Cash, cash equivalents and marketable securities at December 31, 2023 totaled $100.8 million compared to $156.7 million at December 31, 2022. The decrease in the balance primarily resulted from $92.1 million of cash used in operating activities, partially offset by $36.5 million of net proceeds received from the HCR Agreement.

For the fourth quarter of 2023, net loss was $32.3 million, or $(0.59) per basic and diluted share, compared to net loss of $30.3 million, or $(0.56) per basic and diluted share, for the same period in 2022.

Revenues: Total revenue was $3.0 million and $3.3 million for the three months ended December 31, 2023 and 2022, respectively. Revenue primarily consisted of:

- $2.3 million and $1.1 million of collaborative revenue related to our share of the profit from CSL Vifor's sales of KORSUVA injection in the U.S. to third parties during the three months ended December 31, 2023 and 2022, respectively.

- $2.1 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor during the three months ended December 31, 2022. There was no commercial supply revenue during the three months ended December 31, 2023.

- $0.7 million of other revenue related to royalties and milestone payments earned in conjunction with ex U.S. sales of KORSUVA/Kapruvia under agreements with CSL Vifor and Maruishi during the three months ended December 31, 2023, which were sold under the HCR Agreement and considered non-cash. There was no other revenue during the three months ended December 31, 2022.

Cost of Goods Sold: Cost of goods sold of $0.6 million primarily related to inventory adjustments during the three months ended December 31, 2023. Cost of goods sold of $2.1 million related to commercial supply revenue for KORSUVA injection sales to CSL Vifor during the three months ended December 31, 2022.

Research and Development (R&D) Expenses: R&D expenses were $28.4 million for the three months ended December 31, 2023 compared to $26.0 million in the same period of 2022. The higher R&D expenses in 2023 were primarily due to increases in clinical trial costs related to the Company's three late-stage development programs partially offset by a decrease in stock-based compensation expense. R&D expenses in the three months ended December 31, 2023 included a $1.7 million expense related to an agreement for manufacturing commitments that are no longer needed due to the reduced demand expectations of KORSUVA in the U.S.

General and Administrative (G&A) Expenses: G&A expenses were $6.6 million for the three months ended December 31, 2023 which were relatively flat compared to $6.4 million in the same period of 2022.

Other Income, net: Other income, net was $0.9 million for the three months ended December 31, 2023 compared to $1.0 million in the same period of 2022.

Non-cash interest expense on liability related to sales of future royalties and milestones: Non-cash interest expense was $0.6 million which represented imputed interest on the carrying value of the liability associated with the HCR Agreement and the amortization of the related issuance costs associated with the purchase and sale agreement for the three months ended December 31, 2023. There was no non-cash interest expense for the three months ended December 31, 2022.

For the full year ended December 31, 2023, net loss was $118.5 million, or $(2.19) per basic and diluted share, compared to net loss of $85.5 million, or $(1.59) per basic and diluted share for the full year ended December 31, 2022.

Revenues: Total revenue was $21.0 million and $41.9 million for the full years ended December 31, 2023 and 2022, respectively. Revenue primarily consisted of:

- $12.9 million and $16.6 million of collaborative revenue related to our share of the profit from CSL Vifor's sales of KORSUVA injection in the U.S. to third parties during the years ended December 31, 2023 and 2022, respectively. In addition, $0.5 million of collaborative revenue was recognized during the year ended December 31, 2023. This amount relates to an allocated portion of the regulatory milestone payment we earned in September 2023 from Maruishi Pharmaceuticals Co. Ltd., or Maruishi, for the marketing approval in Japan for KORSUVA injection.

- $5.8 million and $10.2 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor for the years ended December 31, 2023 and 2022, respectively.

- $0.9 million of license and milestone fees revenue for the year ended December 31, 2023 related to the remaining allocated portion of a regulatory milestone payment we earned in September 2023 from Maruishi for the marketing approval in Japan for KORSUVA injection, compared to $15.0 million of license and milestone fees revenue for the year ended December 31, 2022 related to the regulatory milestone payment for the approval of Kapruvia by the European Commission earned in April 2022.

- Approximately $415,000 and $72,000 of royalty revenue related to our royalties on the net sales of Kapruvia in Europe during the years ended December 31, 2023 and 2022, respectively.

- $0.7 million of other revenue related to royalties and milestone payments earned in conjunction with ex U.S. sales of KORSUVA/Kapruvia under agreements with CSL Vifor and Maruishi during the year ended December 31, 2023, which were sold under the HCR Agreement and considered non-cash. There was no other revenue during the year ended December 31, 2022.

Cost of Goods Sold: Cost of goods sold of $6.2 million and $7.3 million for the years ended December 31, 2023 and 2022, respectively, related to commercial supply revenue for KORSUVA injection sales to CSL Vifor.

Research and Development (R&D) Expenses: R&D expenses were $108.5 million for the full year ended December 31, 2023 compared to $91.9 million for the full year ended December 31, 2022. The higher R&D expenses in 2023 were primarily due to increases in clinical trial costs related to the Company's three late-stage development programs and increased payroll-related costs, partially offset by a decrease in stock-based compensation expense. R&D expenses in 2023 also included a $1.7 million expense related to an agreement for forecasted manufacturing commitments that are no longer needed due to the reduced demand expectations of KORSUVA in the United States, while R&D expenses in 2022 included the recognition of the $5.0 million milestone payment due to Enteris BioPharma, Inc.

General and Administrative (G&A) Expenses: G&A expenses were $27.8 million for the full year ended December 31, 2023 compared to $30.3 million for the full year ended December 31, 2022. The decrease in 2023 was primarily related to a decrease in stock-based compensation expense.

Other Income, net: Other income, net was $3.6 million for the full year ended December 31, 2023 compared to $2.1 million for the full year ended December 31, 2022. The increase in other income, net was primarily due to an increase in interest income resulting from a higher yield on our portfolio of investments during the year ended December 31, 2023.

Non-cash interest expense on liability related to sales of future royalties and milestones: Non-cash interest expense was $0.6 million which represented imputed interest on the carrying value of the liability associated with the HCR Agreement and the amortization of the related issuance costs associated with the HCR Agreement for the year ended December 31, 2023. There was no non-cash interest expense for the year ended December 31, 2022.

Financial Guidance

Cara expects that our current unrestricted cash and cash equivalents and available-for-sale marketable securities will be sufficient to fund our currently anticipated operating plan into 2026. Our current operating plan reflects the impact of our prioritization announcement in January 2024 which includes costs related to our pivotal program in NP.

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) includes 214 patients who are randomized equally to four arms (0.25 mg BID, 1.0 mg BID, 2.0 mg BID, placebo BID). Part A is not powered for statistical significance.

Part B and KOURAGE 2 will likely be double-blind, placebo-controlled, 8-week studies with patients randomized 1:1 to either difelikefalin or matching placebo. The primary endpoint for both the dose-finding portion of KOURAGE 1 (Part A) and the two pivotal studies Part B and KOURAGE 2 will likely be the proportion of patients with a ≥4-point improvement at Week 8 from baseline in the worst itch numeric rating scale.

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 is developing an oral formulation of difelikefalin, a selective, peripherally acting, non-scheduled kappa opioid receptor agonist, for the treatment of chronic pruritus associated with notalgia paresthetica (NP), a common, underdiagnosed neuropathy affecting the upper back for which there are no FDA-approved therapies. The Company is conducting a Phase 2/3 clinical program in NP with topline results of the dose-finding portion expected in the third quarter of 2024. Cara Therapeutics also 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 Company's strategic plans to focus its resources on the development of oral difelikefalin for the treatment of pruritus associated with notalgia paresthetica, the timing of initiation, enrollment and data readouts from, and potential results of, the Company's planned and ongoing clinical trials, the potential for the Company's product candidate to be an alternative in the treatment of pruritus, the commercial potential of the Company's product candidate, the receipt of potential milestone payments pursuant to the Purchase and Sale Agreement with HealthCare Royalty, 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. Risks are described more fully in the Company's 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, 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.

Financial tables follow

CARA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 51,775	$ 63,741
Marketable securities	48,983	81,658
Accounts receivable, net - related party	2,765	3,260
Inventory, net	2,821	2,383
Income tax receivable	697	697
Other receivables	555	496
Prepaid expenses	8,154	16,267
Restricted cash	408	408
Total current assets	116,158	168,910
Operating lease right-of-use assets	4,864	1,551
Marketable securities, non-current	-	11,350
Property and equipment, net	3,322	426
Restricted cash, non-current	1,500	-
Total assets	$ 125,844	$ 182,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 25,592	$ 21,540
Operating lease liabilities, current	-	1,918
Total current liabilities	25,592	23,458
Liability related to sales of future royalties and milestones, net	37,079	-
Operating lease liabilities, non-current	6,088	-
Total liabilities	68,759	23,458
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	54	53
Additional paid-in capital	742,036	726,630
Accumulated deficit	(684,745)	(566,232)
Accumulated other comprehensive loss	(260)	(1,672)
Total stockholders' equity	57,085	158,779
Total liabilities and stockholders' equity	$ 125,844	$ 182,237

CARA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Collaborative revenue	$ 2,305	$ 1,126	$ 12,936	$ 16,572
Commercial supply revenue	-	2,063	5,843	10,223
License and milestone fees	-	-	910	15,000
Royalty revenue	-	72	415	72
Clinical compound revenue	-	-	165	-
Other revenue	699	-	699	-
Total revenue	3,004	3,261	20,968	41,867
Operating expenses:				
Cost of goods sold	608	2,130	6,174	7,266
Research and development	28,415	26,010	108,510	91,879
General and administrative	6,588	6,428	27,779	30,257
Total operating expenses	35,611	34,568	142,463	129,402
Operating loss	(32,607)	(31,307)	(121,495)	(87,535)
Other income, net	874	968	3,586	2,061
Non-cash interest expense on liability related to sales of future royalties and milestones	(604)	-	(604)	-
Net loss	$ (32,337)	$ (30,339)	$ (118,513)	$ (85,474)
Net loss per share:				
Basic and Diluted	$ (0.59)	$ (0.56)	$ (2.19)	$ (1.59)
Weighted average shares:				
Basic and Diluted	54,477,906	53,762,797	54,149,059	53,653,564

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