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) **May 15, 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 2.02. Results of Operations and Financial Condition.

On May 15, 2023, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 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 May 15, 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: May 15, 2023

Exhibit 99.1

Cara Therapeutics Reports First Quarter 2023 Financial Results

– 1Q23 total revenue of $6.2M including collaborative revenue of $2.8M from the Company's share of profit of KORSUVA® (difelikefalin) injection –

– Acceleration in demand for KORSUVA injection as evidenced by total vial sales more than doubling quarter to quarter –

– Three late-stage oral difelikefalin clinical programs progressing with internal readout of Part A of KIND 1 AD trial on track for 4Q23 –

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

STAMFORD, Conn., May 15, 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 financial results and operational highlights for the first quarter ended March 31, 2023.

"The U.S. and global launches of KORSUVA® (difelikefalin) injection / Kapruvia® gained momentum in the first quarter of 2023. Trends in vial shipments indicate a significant acceleration in demand, and feedback from providers and patients continues to be positive," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "On the clinical development front, our three ongoing late-stage oral difelikefalin programs across our nephrology and dermatology franchises are progressing well. We are acutely focused on the execution of our clinical programs and committed to maximizing the potential of difelikefalin to address the unmet need for an oral therapy to treat moderate-to-severe chronic pruritus associated with advanced chronic kidney disease, atopic dermatitis, and notalgia paresthetica. Looking ahead, we expect the internal readout from Part A of our KIND 1 atopic dermatitis trial in the fourth quarter of 2023 and will continue to build on our positive momentum to drive long-term growth."

1Q23 and Recent Highlights

- Kapruvia launched in France, Finland, the Netherlands, and Switzerland
- Enrollment continued in the KIND Phase 3 program in atopic dermatitis with the internal readout from Part A expected in 4Q23 and final topline results for the program expected in 1H25
- Enrollment continued in the KICK Phase 3 program in advanced chronic kidney disease (CKD) with topline results expected in 2H24
- Results from the KOMFORT Phase 2 trial of oral difelikefalin in notalgia paresthetica (NP) were published in the *New England Journal of Medicine*

- Initiation of the KOURAGE Phase 2/3 program of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with NP; internal readout from Part A expected in 2H24 and final topline results for the program expected in 1H26
- Results from the Phase 2 trial of oral difelikefalin in CKD patients with moderate-to-severe pruritus were published in the *Journal of the American Academy of Dermatology*
- The Company released its inaugural Environmental, Social, and Governance (ESG) report

KORSUVA Injection Launch Update: 1Q23

In the first quarter of 2023, KORSUVA injection generated net sales of $5.7 million and the Company recorded collaborative revenue of $2.8 million, which represented the Company's share of the profit from sales of KORSUVA injection.

Wholesalers shipped 45,720 vials to dialysis centers, the majority of which were Fresenius clinics, during the first quarter of 2023. Vial orders more than doubled quarter to quarter, signifying an acceleration in patient demand.

In the first quarter of 2023, Kapruvia generated $1.2 million in net sales and the Company recorded $125,000 in royalty revenue associated with Kapruvia sales in Europe. Kapruvia launched in four additional countries in Europe, namely France, Finland, the Netherlands, and Switzerland. The Company expects additional launches to commence over the next 12-18 months.

The Company continues to expect its licensing partner Maruishi Pharmaceutical Co., Ltd. to receive a regulatory decision from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan in the second half of 2023.

Upcoming Meeting Activities

The Company expects to present at the following upcoming conferences:

- Jefferies Healthcare Conference, June 7-9
- Stifel Boston Bus Tour, June 21

First Quarter 2023 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2023 totaled $123.4 million compared to $156.7 million at December 31, 2022. The decrease in the balance primarily resulted from $34.6 million of cash used in operating activities.

For the first quarter of 2023, net loss was $26.7 million, or $(0.49) per basic and diluted share, compared to net loss of $27.7 million, or ($0.52) per basic and diluted share, for the same period in 2022.

Revenues: Total revenue was $6.2 million and $4.8 million for the three months ended March 31, 2023 and 2022, respectively. Revenue primarily consisted of:

- $2.8 million of collaborative revenue related to our share of the profit from CSL Vifor's sales of KORSUVA injection to third parties during the three months ended March 31, 2023. There was no collaborative revenue during the three months ended March 31, 2022.
- $3.2 million and $4.8 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor during the three months ended March 31, 2023 and 2022, respectively.
- Approximately $125,000 of royalty revenue related to our royalties on the net sales of Kapruvia in Europe and other countries during the three months ended March 31, 2023. There was no royalty revenue during the three months ended March 31, 2022.

Cost of Goods Sold: Cost of goods sold was $2.6 million and $2.1 million for the three months ended March 31, 2023 and 2022, respectively, related to commercial supply revenue for KORSUVA injection sales to CSL Vifor. There was no associated cost of goods sold recorded for commercial supply revenue of $2.3 million in January 2022 as all inventory costs were incurred prior to receipt of regulatory approval of KORSUVA injection, and accordingly, were expensed as incurred.

Research and Development (R&D) Expenses: R&D expenses were $24.3 million for the three months ended March 31, 2023 compared to $21.3 million in the same period of 2022. The higher R&D expenses in 2023 were primarily due to increases in direct clinical trial costs related to our three late-stage development programs.

General and Administrative (G&A) Expenses: G&A expenses were $6.9 million for the three months ended March 31, 2023 compared to $9.3 million in the same period of 2022. The lower G&A expenses in 2023 were primarily due to higher stock-based compensation expense recorded during the three months ended March 31, 2022 for the modification of our former CEO's equity awards, and certain performance-based restricted stock units that vested during the first quarter of 2022.

Other Income, net: Other income, net was approximately $985,000 for the three months ended March 31, 2023 compared to approximately $162,000 in the same period of 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 three months ended March 31, 2023, and an increase in accretion income from our available-for-sale marketable securities.

Financial Guidance

Cara expects that our current unrestricted cash and cash equivalents and available-for-sale marketable securities, including collaborative revenue from our share of the profit from KORSUVA injection, will be sufficient to fund our currently anticipated operating plan into the second half of 2024.

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 non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. In addition, the Company has initiated a 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 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 and its partners' ongoing commercialization of and ability to successfully commercialize KORSUVA injection and Kapruvia, future revenue and profit share from sales of KORSUVA and Kapruvia, planned future regulatory submissions and potential future regulatory approvals, potential for post-TDAPA reimbursement of KORSUVA, future product launches, the performance of the Company's commercial partners, including CSL Vifor, expected timing of the initiation, enrollment and data readouts from the Company's planned and ongoing clinical trials, the potential results of ongoing clinical trials, timing of future regulatory and development milestones for the Company's product candidates, the potential for the Company's product candidates to be alternatives in the therapeutic areas investigated and the potential for oral difelikefalin to address additional pruritic indications, the size and growth of the potential markets for pruritus management, and the Company's expected cash reach. 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, including CSL Vifor, 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 March 31, 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.
CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 47,391	$ 63,741
Marketable securities	66,892	81,658
Accounts receivable, net - related party	6,066	3,260
Inventory, net	3,515	2,383
Income tax receivable	697	697
Other receivables	495	496
Prepaid expenses	17,195	16,267
Restricted cash	408	408
Total current assets	142,659	168,910
Operating lease right-of-use assets	1,175	1,551
Marketable securities, non-current	9,074	11,350
Property and equipment, net	368	426
Total assets	$ 153,276	182,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,222	$ 21,540
Operating lease liabilities, current	1,456	1,918
Total current liabilities	16,678	23,458
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	54	53
Additional paid-in capital	730,542	726,630
Accumulated deficit	(592,897)	(566,232)
Accumulated other comprehensive loss	(1,101)	(1,672)
Total stockholders' equity	136,598	158,779
Total liabilities and stockholders' equity	$ 153,276	$ 182,237

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Collaborative revenue	$ 2,750	$ -
Commercial supply revenue	3,191	4,790
Royalty revenue	125	-
Clinical compound revenue	99	-
Total Revenue	6,165	4,790
Operating Expenses:		
Cost of goods sold	2,590	2,081
Research and development	24,334	21,273
General and administrative	6,891	9,347
Total Operating Expenses	33,815	32,701
Operating Loss	(27,650)	(27,911)
Other income, net	985	162
Net loss	$ (26,665)	$ (27,749)
Net loss per share:		
Basic and diluted	$ (0.49)	$ (0.52)
Weighted average shares:		
Basic and diluted	53,872,038	53,507,060

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