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) **August 7, 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 August 7, 2023, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 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 August 7, 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: August 7, 2023

Exhibit 99.1

Cara Therapeutics Reports Second Quarter 2023 Financial Results

– 2Q23 total revenue of $6.9M including collaborative revenue of $5.4M from the Company's share of profit of KORSUVA® (difelikefalin) injection –

– Demand for KORSUVA injection accelerating with 46% increase in vial orders quarter to quarter –

– 2024 ESRD PPS proposed rule suggests additional funding for TDAPA-designated products in existing functional category; final rule expected in 4Q23 –

– Three late-stage oral difelikefalin clinical programs tracking to plan; Internal readout of Part A of KIND 1 atopic dermatitis trial expected in 4Q23 –

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

STAMFORD, Conn., August 7, 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 second quarter ended June 30, 2023.

"In the second quarter of 2023, the commercialization of KORSUVA® (difelikefalin) injection in the U.S. and Kapruvia® in countries around the world continued to make meaningful progress. We believe the increased vial shipments and reorder rates in the U.S., as well as the positive feedback from providers and patients globally, confirm the significant need for an anti-pruritic treatment for chronic kidney disease (CKD) patients," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "In June, CMS issued the CY2024 ESRD PPS proposed rule, providing clarity around the reimbursement of KORSUVA injection post its TDAPA period. While we were pleased that CMS included additional funding outside the bundle rate in the proposed rule, we will continue to work with CMS on refining the reimbursement methodology ahead of the release of the final rule, which is expected in the fourth quarter of 2023."

Mr. Posner continued, "On the development front, we are pleased with the progress of our late-stage oral difelikefalin programs for pruritus associated with atopic dermatitis (AD), advanced CKD and notalgia paresthetica (NP). All three trials are enrolling patients and the internal readout from Part A of our KIND Phase 3 program in AD is expected in the fourth quarter of 2023. As the key driver of our long-term value, we are focused on advancing the development of oral difelikefalin in our nephrology and medical dermatology franchises and remain steadfast in our commitment to establishing Cara Therapeutics as the leader in the treatment of chronic pruritus."

2Q23 and Recent Highlights

- England's National Institute for Health and Care Excellence (NICE) recommended Kapruvia® for the treatment of moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP) in adult patients on hemodialysis
- Enrollment continued in the KIND Phase 3 program in AD 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 CKD with topline results expected in 2H24
- KOURAGE Phase 2/3 program of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with NP is ongoing; internal readout from Part A is expected in 2H24 with final topline results for the program expected in 1H26

KORSUVA Injection Launch Update: 2Q23

United States

In the second quarter of 2023, KORSUVA injection generated net sales of $11.4 million and the Company recorded collaborative revenue of $5.4 million, which represented the Company's share of the profit from sales of KORSUVA injection.

Wholesalers shipped 66,852 vials to dialysis centers, the majority of which were Fresenius clinics, during the second quarter of 2023. Vial orders increased 46% quarter to quarter, indicating an acceleration in patient demand.

In June 2023, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule for the End Stage Renal Disease Prospective Payment System (ESRD PPS) for calendar year 2024, which addresses the reimbursement of KORSUVA injection after its Transitional Drug Add-On Payment Adjustment (TDAPA) period. The final rule is expected in the fourth quarter of 2023.

International

In the second quarter of 2023, Kapruvia generated $1.2 million in net sales and the Company recorded $123,000 in royalty revenue associated with Kapruvia sales in Europe.

Seven EU countries have launched Kapruvia to date, and the Company expects additional launches to commence over the coming months. In May 2023, England's NICE recommended Kapruvia for the treatment of moderate-to-severe CKD-aP in adult patients on hemodialysis.

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 investor conferences:

- Canaccord Genuity 43rd Annual Growth Conference, August 7-10
- Stifel Biotech Summer Summit, August 14-15
- H.C. Wainwright Global Investment Conference, September 11-13

Second Quarter 2023 Financial Results

Cash, cash equivalents and marketable securities at June 30, 2023 totaled $101.7 million compared to $156.7 million at December 31, 2022. The decrease in the balance primarily resulted from $55.1 million of cash used in operating activities.

For the second quarter of 2023, net loss was $31.5 million, or $(0.58) per basic and diluted share, compared to net loss of $4.2 million, or $(0.08) per basic and diluted share, for the same period in 2022.

Revenues: Total revenue was $6.9 million and $23.0 million for the three months ended June 30, 2023 and 2022, respectively. Revenue primarily consisted of:

- $5.4 million and $8.0 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 June 30, 2023 and 2022, respectively;

- $1.4 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor during the three months ended June 30, 2023. There was no commercial supply revenue during the three months ended June 30, 2022;

- Approximately $123,000 of royalty revenue related to our royalties on the net sales of Kapruvia in Europe during the three months ended June 30, 2023. There was no royalty revenue during the three months ended June 30, 2022; and

- There was no license and milestone revenue during the three months ended June 30, 2023. We recorded $15.0 million in milestone revenue related to the approval of Kapruvia by the European Commission in April 2022 during the three months ended June 30, 2022.

Cost of Goods Sold: Cost of goods sold was $1.4 million during the three months ended June 30, 2023, related to commercial supply revenue for KORSUVA injection sales to CSL Vifor. There was no associated cost of goods sold during the three months ended June 30, 2022 as there was no commercial supply revenue from CSL Vifor.

Research and Development (R&D) Expenses: R&D expenses were $30.3 million for the three months ended June 30, 2023 compared to $19.9 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 our three late-stage development programs partially offset by a decrease in stock-based compensation expense.

General and Administrative (G&A) Expenses: G&A expenses were essentially flat at $7.5 million for the three months ended June 30, 2023 compared to $7.6 million in the same period of 2022.

Other Income, net: Other income, net was approximately $861,000 for the three months ended June 30, 2023 compared to approximately $266,000 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 June 30, 2023.

Financial Guidance

We expect 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 for at least the next 12 months.

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 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 and timing of final rules related thereto, 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, the Company's participation in certain conferences 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 58,249	$ 63,741
Marketable securities	36,442	81,658
Accounts receivable, net - related party	10,124	3,260
Inventory, net	3,420	2,383
Income tax receivable	697	697
Other receivables	420	496
Prepaid expenses	14,976	16,267
Restricted cash	408	408
Total current assets	124,736	168,910
Operating lease right-of-use assets	792	1,551
Marketable securities, non-current	7,053	11,350
Property and equipment, net	308	426
Restricted cash, non-current	1,500	-
Total assets	$ 134,389	$ 182,237
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 24,475	$ 21,540
Operating lease liabilities, current	982	1,918
Total current liabilities	25,457	23,458
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	54	53
Additional paid-in capital	733,984	726,630
Accumulated deficit	(624,376)	(566,232)
Accumulated other comprehensive loss	(730)	(1,672)
Total stockholders' equity	108,932	158,779
Total liabilities and stockholders' equity	$ 134,389	$ 182,237

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Collaborative revenue	$ 5,410	$ 8,003	$ 8,160	$ 8,003
Commercial supply revenue	1,400	-	4,591	4,790
Royalty revenue	123	-	248	-
License and milestone fees	-	15,000	-	15,000
Clinical compound revenue	-	-	99	-
Total revenue	6,933	23,003	13,098	27,793
Operating expenses:				
Cost of goods sold	1,418	-	4,008	2,081
Research and development	30,310	19,905	54,644	41,178
General and administrative	7,545	7,570	14,436	16,917
Total operating expenses	39,273	27,475	73,088	60,176
Operating loss	(32,340)	(4,472)	(59,990)	(32,383)
Other income, net	861	266	1,846	428
Net loss	(31,479)	(4,206)	(58,144)	(31,955)
Net loss per share:				
Basic and Diluted	$ (0.58)	$ (0.08)	$ (1.08)	$ (0.60)
Weighted average shares:				
Basic and Diluted	54,002,988	53,614,668	53,937,875	53,561,161

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