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 6, 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** (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 2.02. Results of Operations and Financial Condition.

On March 6, 2023, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022. 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 6, 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: March 6, 2023

Exhibit 99.1

Cara Therapeutics Announces Fourth Quarter and Full Year 2022 Financial Results

– 4Q22 total revenue was $3.3 million including collaborative revenue of $1.1 million from the Company's share of profit of KORSUVA®(difelikefalin) injection; FY22 revenue was $41.9 million including collaborative revenue of $16.6 million –

– Positive momentum across first four EU launches; Global rollout to accelerate with most EU countries launching in 2023 –

– Phase 2/3 clinical program of oral difelikefalin in NP initiated in 2023; NDD CKD and AD programs tracking to expectations with internal readout from KIND 1 Part A expected in 2H23 –

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

STAMFORD, Conn., Mar. 6, 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 fourth quarter and full year ended December 31, 2022.

"As the U.S. launch of KORSUVA® (difelikefalin) injection continues to progress, we are encouraged by the positive feedback from providers and patients. During the fourth quarter of 2022, we saw both new clinic and repeat orders driving product uptake, bolstering our confidence in KORSUVA's long-term potential," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "The rollout of Kapruvia® in Europe has continued to gain momentum and we look forward to the acceleration of global launches throughout 2023. In addition, we continue to expect a regulatory decision from the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan in the second half of 2023."

Mr. Posner continued, "With the recent initiation of our Phase 2/3 clinical program of oral difelikefalin for moderate-to-severe pruritus in patients with notalgia paresthetica (NP), we now have three ongoing late-stage programs. As we focus on maximizing the potential of difelikefalin for the treatment of chronic pruritus associated with multiple indications, we are confident that our pipeline in a product together with our strong financial foundation will drive long-term growth across our nephrology and dermatology franchises and create significant value for our shareholders."

2022 and Recent Highlights

- KORSUVA injection launched in the U.S. by the Company's commercial partner CSL Vifor
- Kapruvia approved for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD) in adult hemodialysis patients by the European Commission, the UK Medicines and Healthcare products Regulatory Agency, and regulatory agencies in Canada, Australia, Singapore, and Switzerland
- Kapruvia launched in Austria, Germany, Sweden, and Denmark
- New Drug Application submitted by the Company's licensing partner, Maruishi Pharmaceutical Co., Ltd., to the PMDA for approval of difelikefalin for the treatment of pruritus in hemodialysis patients in Japan
- KIND and KICK Phase 3 programs of oral difelikefalin initiated for the treatment of pruritus in patients with atopic dermatitis (AD) and advanced non-dialysis dependent CKD, respectively
- KOMFORT Phase 2 trial of oral difelikefalin met primary endpoint in NP and the results were published in the *New England Journal of Medicine*
- KOURAGE Phase 2/3 program of oral difelikefalin initiated for the treatment of moderate-to-severe pruritus in patients with NP
- Vifor Fresenius Medical Care Renal Pharma and Winhealth Pharma signed long-term exclusive licensing agreement for co-development and commercialization of KORSUVA injection in China

KORSUVA Injection Launch Update: 4Q22 & FY22

In the fourth quarter of 2022, KORSUVA injection generated net sales of $2.3 million and the Company recorded collaborative revenue of $1.1 million, which represented the Company's share of the profit from sales of KORSUVA injection. The Company also recorded $72,000 in royalty revenue associated with Kapruvia sales in Europe. For the full year 2022, KORSUVA injection generated net sales of $35.3 million and the Company recorded collaborative revenue of $16.6 million.

In the fourth quarter of 2022, wholesalers shipped 20,844 vials to dialysis centers following initial inventory building in the third quarter of 2022, predominantly at Fresenius clinics. For the full year 2022, wholesalers shipped 207,096 vials to dialysis centers.

The Company expects launches in countries in Europe to continue in 2023, following launches of Kapruvia in Austria, Germany, and Sweden during the fourth quarter of 2022.

With the approval of Kapruvia in Australia in the fourth quarter of 2022, all four Access Consortium countries have approved the product. The Company expects launches to commence in Canada, Singapore, Switzerland, and Australia over the next 12-18 months. The product is approved under the brand name KORSUVA in Canada and Singapore.

In Japan, the Company continues to expect its licensing partner Maruishi Pharmaceutical Co., Ltd. to receive a regulatory decision from the PMDA in the second half of 2023.

Upcoming Meeting Activities

The Company expects to present at the following upcoming conferences:

- 2023 American Academy of Dermatology Annual Meeting, March 17-23
- 22nd Annual Needham Virtual Healthcare Conference, April 17-20

Fourth Quarter and Full Year 2022 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2022 totaled $156.7 million compared to $236.8 million at December 31, 2021. The decrease in the balance primarily resulted from $78.7 million of cash used in operating activities.

For the fourth quarter of 2022, net loss was $30.3 million, or $(0.56) per basic and diluted share, compared to net loss of $33.4 million, or $(0.63) per basic and diluted share, for the same period in 2021.

Revenues: Total revenue was $3.3 million and $0.8 million for the three months ended December 31, 2022 and 2021, respectively. Revenue primarily consisted of:

- $1.1 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 December 31, 2022. There was no collaborative revenue during the three months ended December 31, 2021.
- $2.1 million and $0.7 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor during the three months ended December 31, 2022 and 2021, respectively.
- $72,000 of royalty revenue related to our royalties on the net sales of Kapruvia in Europe during the three months ended December 31, 2022. There was no royalty revenue during the three months ended December 31, 2021.

Cost of Goods Sold: 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. There was no cost of goods sold during the three months ended December 31, 2021, as commercialization of KORSUVA injection began in April 2022.

Research and Development (R&D) Expenses: R&D expenses were $26.0 million for the three months ended December 31, 2022 compared to $22.8 million in the same period of 2021. The higher R&D expenses in 2022 were principally due to increases in direct clinical trial costs and related consultants' costs, and increases in payroll and related costs. R&D expenses in the three months ended December 31, 2021 included a $5.0 million milestone paid to Enteris Biopharma, Inc., or Enteris.

General and Administrative (G&A) Expenses: G&A expenses were $6.4 million for the three months ended December 31, 2022 compared to $11.5 million in the same period of 2021. The lower G&A expenses in 2022 were principally due to a decrease in stock-based compensation expense as a result of expense relating to the modification of our former CEO's equity awards during the three months ended December 31, 2021.

Other Income, net: Other income, net was $1.0 million for the three months ended December 31, 2022 compared to $0.1 million in the same period of 2021. 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 December 31, 2022.

For the full year ended December 31, 2022, net loss was $85.5 million, or $(1.59) per basic and diluted share, compared to net loss of $88.4 million, or $(1.74) per basic and diluted share for the full year ended December 31, 2021.

Revenues: Total revenue was $41.9 million and $23.0 million for the full years ended December 31, 2022 and 2021, respectively. Revenue primarily consisted of:

- $16.6 million of collaborative revenue related to our share of the profit from CSL Vifor's sales of KORSUVA injection to third parties during the year ended December 31, 2022, compared to $0.7 million of collaborative revenue related to a portion of a milestone payment received from Maruishi during the year ended December 31, 2021.
- $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, compared to $21.2 million of license and milestone fees revenue for the year ended December 31, 2021 which was primarily related to a milestone payment we earned upon the regulatory approval of KORSUVA injection in August 2021.
- $10.2 million and $0.7 million of commercial supply revenue related to sales of KORSUVA injection to CSL Vifor for the years ended December 31, 2022 and 2021, respectively.
- $72,000 of royalty revenue related to our royalties on the net sales of Kapruvia in Europe during the year ended December 31, 2022. There was no royalty revenue during the year ended December 31, 2021.

Cost of Goods Sold: Cost of goods sold of $7.3 million related to commercial supply revenue for KORSUVA injection sales to CSL Vifor during the year ended December 31, 2022. There was no cost of goods sold during the year ended December 31, 2021, as commercialization of KORSUVA injection began in April 2022.

Research and Development (R&D) Expenses: R&D expenses were $91.9 million for the full year ended December 31, 2022 compared to $82.7 million for the full year ended December 31, 2021. The higher R&D expenses in 2022 were principally due to increases in direct clinical trial costs and related consultant costs, payroll and related costs, and travel costs. R&D expenses in the year ended December 31, 2022 and 2021 included milestones of $5.0 million and $15.0 million, respectively, earned by Enteris.

General and Administrative (G&A) Expenses: G&A expenses were $30.3 million for the full year ended December 31, 2022 compared to $29.4 million for the full year ended December 31, 2021. The increase in 2022 was primarily due to increases in payroll and related costs, accounting and auditing fees, and consultants' costs, partially offset by decreases in stock-based compensation expense as a result of expense relating to the modification of our former CEO's equity awards during the year ended December 31, 2021.

Other Income, net: Other income, net was $2.1 million for the full year ended December 31, 2022 compared to $0.6 million for the full year ended December 31, 2021. 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, 2022, and a decrease in net amortization expense of available-for-sale marketable securities during the year ended December 31, 2022.

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 at least the first 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 ongoing commercialization of KORSUVA injection and Kapruvia, planned future regulatory meetings and/or submissions and potential future regulatory approvals, the performance of the Company's commercial partners, including CSL Vifor, the 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, and the timing of future regulatory and development milestones for the Company's product candidates. 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. 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.
BALANCE SHEETS
(in thousands)
(unaudited)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 63,741	$ 13,453
Marketable securities	81,658	153,582
Accounts receivable, net - related party	3,260	-
Inventory, net	2,383	2,584
Income tax receivable	697	697
Other receivables	496	455
Prepaid expenses	16,267	2,519
Restricted cash	408	-
Total current assets	168,910	173,290
Operating lease right-of-use assets	1,551	2,973
Marketable securities, non-current	11,350	69,754
Property and equipment, net	426	631
Restricted cash, non-current	-	408
Total assets	$ 182,237	$ 247,056
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,540	$ 15,861
Operating lease liabilities, current	1,918	1,755
Total current liabilities	23,458	17,616
Operating lease liabilities, non-current	-	1,918
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	53	53
Additional paid-in capital	726,630	708,585
Accumulated deficit	(566,232)	(480,758)
Accumulated other comprehensive loss	(1,672)	(358)
Total stockholders' equity	158,779	227,522
Total liabilities and stockholders' equity	$ 182,237	$ 247,056

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Collaborative revenue	$ 1,126	$ -	$ 16,572	$ 706
License and milestone fees	-	-	15,000	21,223
Commercial supply revenue	2,063	701	10,223	701
Royalty revenue	72	-	72	-
Clinical compound revenue	-	120	-	398
Total revenue	3,261	821	41,867	23,028
Operating expenses:				
Cost of goods sold	2,130	-	7,266	-
Research and development	26,010	22,831	91,879	82,701
General and administrative	6,428	11,512	30,257	29,410
Total operating expenses	34,568	34,343	129,402	112,111
Operating loss	(31,307)	(33,522)	(87,535)	(89,083)
Other income, net	968	140	2,061	642
Net loss	$ (30,339)	$ (33,382)	$ (85,474)	$ (88,441)
Net loss per share:				
Basic	$ (0.56)	$ (0.63)	$ (1.59)	$ (1.74)
Diluted	$ (0.56)	$ (0.63)	$ (1.59)	$ (1.74)
Weighted average shares:				
Basic	53,762,797	52,757,808	53,653,564	50,718,765
Diluted	53,762,797	52,757,808	53,653,564	50,718,765

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