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 8, 2022**

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 8, 2022, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 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 August 8, 2022
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/ RICHARD MAKARA
Richard Makara
Vice President, Head of Accounting & Controller
(Principal Financial and Accounting Officer)

Date: August 8, 2022

Exhibit 99.1

Cara Therapeutics Reports Second Quarter 2022 Financial Results

– Net revenue was $23M for 2Q 2022 comprised of profit-sharing revenue of $8M from KORSUVA™ (difelikefalin) injection and a $15M milestone payment from the European Commission approval of Kapruvia® (difelikefalin) –

– KOMFORT Phase 2 trial met primary endpoint in notalgia paresthetica, validating potential broad utility of oral difelikefalin across multiple disease categories; FDA meeting expected in 2H 2022 –

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

STAMFORD, Conn., August 8, 2022 – 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, 2022.

"During the second quarter of 2022, we made great strides toward establishing Cara Therapeutics as the leader in the treatment of chronic pruritus," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "The early U.S. launch of KORSUVA™ (difelikefalin) injection with our commercial partner Vifor has been progressing as expected, with independent and midsize dialysis organizations driving initial product uptake. We anticipate demand to accelerate in the coming months, driven by large dialysis organizations that started purchasing early in the third quarter."

Mr. Posner continued, "In June 2022, we were pleased to announce positive topline results from our KOMFORT Phase 2 proof-of-concept trial of oral difelikefalin for the treatment of pruritus in patients with notalgia paresthetica. We continue to deliver against our commitments associated with our three strategic priorities both on the commercial and development side of the business thereby driving long-term growth and value creation."

Second Quarter and Recent Developments:

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus: Hemodialysis

In April 2022, the Company and its commercial partner, Vifor, launched KORSUVA (difelikefalin) injection in the U.S. for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD) in adults undergoing hemodialysis. KORSUVA injection generated net sales of $16.8 million in the second quarter of 2022, translating into $8 million in profit-sharing revenue for Cara. Wholesalers shipped 1,812 vials driven by independent and midsize dialysis organizations.

In the second quarter, the Company received the $15 million regulatory milestone payment triggered by the April 2022 European Commission approval of Kapruvia® (difelikefalin) for the treatment of moderate-to-severe pruritus associated with CKD in adult hemodialysis patients. Also in April 2022, Kapruvia was approved in the UK. The Company expects the commercial launches of Kapruvia to commence in certain European markets in the second half of 2022.

Oral Difelikefalin: Notalgia Paresthetica

In June 2022, the Company announced positive topline results from the KOMFORT Phase 2 multicenter, randomized, double-blind, placebo-controlled, 8-week study evaluating the efficacy and safety of oral difelikefalin for moderate-to-severe pruritus in patients with notalgia paresthetica (NP). The Company has submitted the data for presentation at an upcoming medical meeting and plans to host an R&D Day focused on NP in the third quarter of 2022. In addition, the Company anticipates having a meeting with the U.S. Food and Drug Administration in the second half of 2022 to discuss next steps in the development of oral difelikefalin for the treatment of pruritus in patients with NP.

Oral Difelikefalin: Pruritus Associated with Non-Dialysis Dependent Advanced Chronic Kidney Disease

The Phase 3 program of oral difelikefalin in patients with advanced CKD stages 4 or 5 with moderate-to-severe pruritus who are not on dialysis is ongoing. The Phase 3 program is comprised of two identical 12-week, double-blind, placebo-controlled studies, known as KICK 1 and KICK 2. The Company expects to report topline results in the second half of 2024.

Oral Difelikefalin: Atopic Dermatitis

The Phase 3 program for oral difelikefalin as an adjunctive therapy to topical corticosteroids in atopic dermatitis (AD) patients with moderate-to-severe pruritus is ongoing. The program is comprised of two studies, known as KIND 1 and KIND 2. Both studies are double-blind, controlled, 12-week studies with patients allowed to roll over to 52-week open-label safety extensions. At the end of the 12-week treatment period in Part A of KIND 1, the Company expects to have an internal data readout to inform the dose and sample size to initiate Part B and KIND 2. The internal readout is expected for the second half of 2023.

Oral Difelikefalin: Chronic Liver Disease-Associated Pruritus: Primary Biliary Cholangitis

The Company is currently conducting a proof-of-concept Phase 2 clinical trial of oral difelikefalin for the treatment of pruritus in patients with hepatic impairment due to primary biliary cholangitis (PBC). The trial is evaluating the safety and efficacy of oral difelikefalin versus placebo for 16 weeks. The Company expects to report topline data in the second half of 2022.

Upcoming Meeting Activities:

The Company expects to present at the following upcoming investment conferences:

- Canaccord Genuity 42nd Annual Growth Conference, August 8-11
- H.C. Wainwright 24th Annual Global Investment Conference, September 12-14

Second Quarter 2022 Financial Results

Cash, cash equivalents and marketable securities at June 30, 2022 totaled $204.7 million compared to $236.8 million at December 31, 2021. The decrease in the balance primarily resulted from $30.0 million of cash used in operating activities.

For the second quarter of 2022, net loss was $4.2 million, or $(0.08) per basic and diluted share, compared to net loss of $30.7 million, or ($0.61) per basic and diluted share, for the same period in 2021.

Revenues: Total revenue was $23.0 million for the three months ended June 30, 2022. There was no revenue during the same period of 2021. Revenue consisted of:

- $15.0 million of license and milestone fees revenue, related to the regulatory milestone payment for the approval of Kapruvia by the European Commission in April 2022 during the three months ended June 30, 2022; and
- $8.0 million of collaborative revenue, related to the profit-sharing revenue from Vifor's sales of KORSUVA injection to third parties during the three months ended June 30, 2022.

Cost of Goods Sold (COGS): There was no COGS during the three months ended June 30, 2022 or June 30, 2021, as there was no commercial supply revenue recognized for the period.

Research and Development (R&D) Expenses: R&D expenses were $19.9 million for the three months ended June 30, 2022 compared to $25.2 million in the same period of 2021. The lower R&D expenses in 2022 were principally due to a $10.0 million milestone earned by Enteris during the three months ended June 30, 2021, partially offset by increases in direct clinical trial costs and related consultant costs during the three months ended June 30, 2022.

General and Administrative (G&A) Expenses: G&A expenses were $7.6 million for the three months ended June 30, 2022 compared to $5.7 million in the same period of 2021. The higher G&A expenses for the three months ended June 30, 2022 were principally due to increases in stock-based compensation expense, which included additional compensation expense relating to the modification of the Company's former Chief Executive Officer's equity awards in November 2021, as well as increases in accounting and auditing fees and payroll related costs.

Other Income, net: Other income, net was $0.3 million for the three months ended June 30, 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 the Company's portfolio of investments during the three months ended June 30, 2022, partially offset by an increase in net amortization expense of available-for-sale securities during the three months ended June 30, 2022.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, which include conducting supportive Phase 1 trials, Phase 2 trials in PBC and NP, and Phase 3 trials in CKD and AD, Cara expects that its current unrestricted cash and cash equivalents and available-for-sale marketable securities will be sufficient to fund its currently anticipated operating expenses and capital requirements into the first half of 2024, without giving effect to product revenue the Company receives from the commercialization of KORSUVA injection or Kapruvia or any potential milestone payments or potential additional product revenue the Company may receive under collaboration agreements.

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 novel 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 initiated Phase 3 programs for the treatment of pruritus in patients with non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. The Company has completed the placebo-controlled phase of a Phase 2 proof-of-concept trial of oral difelikefalin for the treatment of moderate-to-severe pruritus in patients with notalgia paresthetica. A Phase 2 proof-of-concept trial in primary biliary cholangitis patients with moderate-to-severe pruritus is ongoing. 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 ability to successfully commercialize KORSUVA injection and Kapruvia, risks that KORSUVA injection and Kapruvia revenue, expenses and costs may not be as expected, planned future regulatory meetings and/or submissions and potential future regulatory approvals, the performance of the Company's commercial partners, including 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, including NP, 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 expected cash reach, and the potential impact of COVID-19, geopolitical tensions and macroeconomic conditions on the Company's clinical development and regulatory timelines and plans. 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 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, 2021 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, 2022. 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 46,718	$ 13,453
Marketable securities	110,794	153,582
Accounts receivable - related party	8,003	-
Inventory, net	3,460	2,584
Income tax receivable	697	697
Other receivables	468	455
Prepaid expenses	6,026	2,519
Total current assets	176,166	173,290
Operating lease right-of-use assets	2,278	2,973
Marketable securities, non-current	47,171	69,754
Property and equipment, net	549	631
Restricted cash	408	408
Total assets	$ 226,572	$ 247,056
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 19,332	$ 15,861
Operating lease liabilities, current	1,835	1,755
Total current liabilities	21,167	17,616
Operating lease liabilities, non-current	983	1,918
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	53	53
Additional paid-in capital	719,129	708,585
Accumulated deficit	(512,713)	(480,758)
Accumulated other comprehensive loss	(2,047)	(358)
Total stockholders' equity	204,422	227,522
Total liabilities and stockholders' equity	$ 226,572	$ 247,056

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,	
	2022	**2021**	**2022**	**2021**
Revenue:				
License and milestone fees	$ 15,000	$ -	$ 15,000	$ 1,192
Collaborative revenue	8,003	-	8,003	706
Commercial supply revenue	-	-	4,790	-
Clinical compound revenue	-	-	-	37
Total revenue	23,003	-	27,793	1,935
Operating expenses:				
Cost of goods sold	-	-	2,081	-
Research and development	19,905	25,225	41,178	44,356
General and administrative	7,570	5,651	16,917	12,016
Total operating expenses	27,475	30,876	60,176	56,372
Operating loss	(4,472)	(30,876)	(32,383)	(54,437)
Other income, net	266	131	428	391
Net loss	(4,206)	(30,745)	(31,955)	(54,046)
Net loss per share:				
Basic and Diluted	$ (0.08)	$ (0.61)	$ (0.60)	$ (1.08)
Weighted average shares:				
Basic and Diluted	53,614,668	50,059,984	53,561,161	49,989,379

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