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 9, 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 May 9, 2022, Cara Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 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 May 9, 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/ THOMAS REILLY
Thomas Reilly
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 9, 2022

Exhibit 99.1

Cara Therapeutics Reports First Quarter 2022 Financial Results

KORSUVA™ (difelikefalin) injection U.S. commercial launch began in April 2022 and is tracking to expectation

Kapruvia® (difelikefalin) approved by European Commission for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult hemodialysis patients, triggering $15M milestone payment to Cara

Top-line data from Phase 2 proof-of-concept trial of Oral KORSUVA (difelikefalin) in notalgia paresthetica expected in 2Q 2022

Oral KORSUVA (difelikefalin) Phase 3 pruritus programs in non-dialysis dependent advanced chronic kidney disease and atopic dermatitis underway

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

STAMFORD, Conn., May 9, 2022 – Cara Therapeutics, Inc. (Nasdaq: CARA), an early 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, 2022.

"We kicked off 2022 with substantial progress and execution of our mission to establish Cara Therapeutics as the leader in the treatment of chronic pruritus," said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. "In collaboration with our commercial partner Vifor Pharma, KORSUVA™ (difelikefalin) injection has launched in the U.S. and early performance indicators are in line with our expectations. Specifically, KORSUVA injection is available to be ordered by dialysis clinics nationwide, nephrologists are aware of KORSUVA injection and are ready and starting to prescribe, and patient outreach is expanding through additional channels. In April, the European Commission and the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization to Kapruvia® (difelikefalin), making it the first approved therapy in Europe for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult hemodialysis patients."

Mr. Posner continued, "We're also pleased with the progress across our Oral KORSUVA (difelikefalin) programs in multiple pruritus indications, which we believe represent significant market opportunities and tremendous patient needs. As discussed during our R&D Day, we initiated Phase 3 programs for pruritus associated with non-dialysis dependent advanced chronic kidney disease and atopic dermatitis. During this second quarter, we look forward to reporting top-line data from our Phase 2 proof-of-concept trial in notalgia paresthetica, in which we're looking for an efficacy signal. Lastly, we expect to have top-line data from our Phase 2 trial in primary biliary cholangitis in the second half of 2022. Our solid financial footing, first-of-its-kind commercial product in KORSUVA injection and Oral KORSUVA (difelikefalin) pipeline put us on the path to create significant value and future growth."

First Quarter and Recent Developments:

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus: Hemodialysis

In April 2022, the Company and its commercial partner, Vifor Pharma, commercially 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. Transitional Drug Add-On Payment Adjustment (TDAPA) and the J-code for KORSUVA injection were effective as of April 1, 2022. Vifor's field force of roughly 100 representatives has shifted its promotional efforts from patient identification to promoting KORSUVA injection. Furthermore, Vifor has shipped initial stocking orders of KORSUVA injection to the distribution channel.

In April 2022, the European Commission granted marketing authorization to Kapruvia® (difelikefalin) for the treatment of moderate-to-severe pruritus associated with CKD in adult hemodialysis patients. The marketing authorization approves Kapruvia for use in all member states of the European Union plus Iceland, Liechtenstein and Norway. Also in April, the Medicines and Healthcare products Regulatory Agency (MHRA) granted a UK Marketing Authorization. The first market launches in Europe are expected in the second half of 2022. This EU approval triggered a $15 million milestone payment to Cara.

Oral KORSUVA (difelikefalin): Pruritus Associated with Non-Dialysis Dependent Advanced Chronic Kidney Disease

The Company initiated a Phase 3 program of Oral KORSUVA (difelikefalin) in patients with advanced CKD stages 4 or 5 with moderate-to-severe pruritus who are not on dialysis. The Phase 3 program is comprised of two identical 12-week, double-blind, placebo-controlled studies, known as KICK 1 and KICK 2. Each study is expected to enroll approximately 400 patients who will be randomized 1:1 to either Oral KORSUVA (difelikefalin) 1 mg once daily or placebo. The primary endpoint is the proportion of patients with ≥4-point improvement at Week 12 from baseline in the Worst Itch Numeric Rating Scale (WI-NRS) score. The Company expects to report top-line results in the second half of 2024.

After the initial 12-week treatment period, patients are allowed to enter the safety extension. Patients will be re-randomized to either Oral KORSUVA (difelikefalin) or placebo for up to 52 weeks.

Oral KORSUVA (difelikefalin): Atopic Dermatitis

The Company initiated a Phase 3 program for Oral KORSUVA (difelikefalin) as an adjunctive therapy to topical corticosteroids (TCS) in atopic dermatitis patients with moderate-to-severe pruritus. 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. KIND 1 is composed of two parts, Part A and Part B. Part A is expected to include 280 patients who will be randomized equally to four arms – Oral KORSUVA (difelikefalin) 0.25 mg twice daily + TCS, Oral KORSVUA (difelikefalin) 0.5 mg twice daily + TCS, placebo twice daily + TCS, and placebo twice daily + vehicle. At the end of the 12-week treatment period in Part A, the Company expects to have an internal data readout in the second half of 2023, to inform the dose and sample size to initiate Part B and KIND 2.

Oral KORSUVA (difelikefalin): Notalgia Paresthetica

The Company is evaluating the efficacy and safety of Oral KORSUVA (difelikefalin) for moderate-to-severe pruritus in approximately 120 patients with notalgia paresthetica (NP) in a Phase 2 proof-of-concept trial. In this multicenter, randomized, double-blind, placebo-controlled 8-week trial, patients are randomized to receive Oral KORSUVA (difelikefalin) 2.0 mg twice daily versus placebo for 8 weeks, followed by a 4-week active extension period. The primary efficacy endpoint is the change from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 8 of the treatment period. Secondary endpoints include itch-related quality of life scores and sleep assessments. The Company expects to report top-line results from this trial in the second quarter of 2022.

Oral KORSUVA (difelikefalin): Chronic Liver Disease-Associated Pruritus: Primary Biliary Cholangitis

The Company is currently conducting a proof-of-concept Phase 2 clinical trial of Oral KORSUVA (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 KORSUVA (difelikefalin) (1.0 mg tablet, twice daily) versus placebo for 16 weeks. The Company expects to report top-line data in the second half of 2022.

Upcoming Meeting Activities:

The Company expects to make presentations at the following upcoming conferences:

- BofA Securities 2022 Healthcare Conference, May 10-12
- H.C. Wainwright Global Investment Conference, May 23-26
- Jefferies Healthcare Conference, June 8-10

First Quarter 2022 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2022 totaled $209.6 million compared to $236.8 million at December 31, 2021. The decrease in the balance primarily resulted from $25.5 million of cash used in operating activities.

For the first quarter of 2022, net loss was $27.7 million, or $(0.52) per basic and diluted share, compared to net loss of $23.3 million, or ($0.47) per basic and diluted share, for the same period in 2021.

Revenues: Total revenue was $4.8 million for the three months ended March 31, 2022, compared to $1.9 million during the same period of 2021. Revenue consisted of:

- $4.8 million of commercial supply revenue related to sales of KORSUVA injection to Vifor Pharma for the three months ended March 31, 2022. There was no commercial supply revenue for the same period in 2021.

- There was no license and milestone fees revenue or collaborative revenue for the three months ended March 31, 2022. $1.9 million of license and milestone fees revenue and collaborative revenue for the three months ended March 31, 2021 related to the milestone payment the Company earned from Maruishi Pharmaceutical Co. Ltd.'s (Maruishi) first initiation of a Phase 3 trial for uremic pruritus in Japan under the agreement with Maruishi.

Cost of Goods Sold (COGS): Through February 2022, the Company had not recorded any COGS related to its commercial supply revenue as all inventory costs were incurred prior to receipt of regulatory approval of KORSUVA injection and, accordingly, were expensed as incurred. In March 2022, the Company recorded commercial supply revenue of $2.5 million, with associated COGS of $2.1 million as these inventory costs were incurred subsequent to the receipt of regulatory approval of KORSUVA injection.

Research and Development (R&D) Expenses: R&D expenses were $21.3 million for the three months ended March 31, 2022 compared to $19.1 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 consultant costs and payroll related costs, partially offset by a decrease in stock-based compensation expense.

General and Administrative (G&A) Expenses: G&A expenses were $9.3 million for the three months ended March 31, 2022 compared to $6.4 million in the same period of 2021. The higher G&A expenses in 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 consultants' costs, legal fees, and payroll related costs.

Other Income, net: Other income, net was $0.2 million for the three months ended March 31, 2022 compared to $0.3 million in the same period of 2021. The decrease in other income, net was primarily due to an increase in net amortization expense of available-for-sale marketable securities and realized gains on sales of available-for-sale securities and property and equipment during the three months ended March 31, 2021, partially offset by an increase in interest income resulting from a higher yield on the Company's portfolio of investments in the 2022 period.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, Cara expects that its current unrestricted cash and cash equivalents and available-for-sale marketable securities, including the $15 million regulatory milestone payment earned in April 2022 upon European Commission approval of Kapruvia, will be sufficient to fund its currently anticipated operating expenses and capital requirements into the first half of 2024, without giving effect to any potential milestone payments under existing collaborations or product revenue from the commercialization of KORSUVA injection.

About Cara Therapeutics

Cara Therapeutics is an early 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. Phase 2 proof-of-concept trials of Oral KORSUVA (difelikefalin) are ongoing in notalgia paresthetica and primary biliary cholangitis patients with moderate-to-severe pruritus. 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, planned future regulatory submissions and potential future regulatory approvals, the Company's ability to obtain and maintain coverage and adequate reimbursement for KORSUVA injection, the performance of the Company's commercial partners, including Vifor Pharma, 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, the size and growth of the potential markets for pruritus management, the Company's expected cash reach, and the potential impact of COVID-19 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. 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.

Financial tables follow

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 21,362	$ 13,453
Marketable securities	119,749	153,582
Accounts receivable - related party	2,496	-
Inventory, net	1,907	2,584
Income tax receivable	697	697
Other receivables	438	455
Prepaid expenses	5,113	2,519
Total current assets	151,762	173,290
Operating lease right-of-use assets	2,629	2,973
Marketable securities, non-current	68,456	69,754
Property and equipment, net	611	631
Restricted cash	408	408
Total assets	$ 223,866	247,056
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 16,501	$ 15,861
Operating lease liabilities, current	1,795	1,755
Total current liabilities	18,296	17,616
Operating lease liabilities, non-current	1,455	1,918
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	53	53
Additional paid-in capital	714,292	708,585
Accumulated deficit	(508,507)	(480,758)
Accumulated other comprehensive loss	(1,723)	(358)
Total stockholders' equity	204,115	227,522
Total liabilities and stockholders' equity	$ 223,866	$ 247,056

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

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Commercial supply revenue	$ 4,790	$ -
License and milestone fees	-	1,192
Collaborative revenue	-	706
Clinical compound revenue	-	37
Total revenue	4,790	1,935
Operating expenses:		
Cost of goods sold	2,081	-
Research and development	21,273	19,131
General and administrative	9,347	6,365
Total operating expenses	32,701	25,496
Operating loss	(27,911)	(23,561)
Other income, net	162	260
Net loss	$ (27,749)	$ (23,301)
Net loss per share:		
Basic and diluted	$ (0.52)	$ (0.47)
Weighted average shares:		
Basic and diluted	53,507,060	49,917,990

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