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 10, 2021**

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 May 10, 2021, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2021. 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 10, 2021
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 10, 2021

Exhibit 99.1

Cara Therapeutics Reports First Quarter 2021 Financial Results

– U.S. Food and Drug Administration (FDA) Accepts New Drug Application (NDA) Filing and Grants Priority Review for KORSUVA™ Injection in CKD-aP –

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

STAMFORD, Conn., May 10, 2021 – Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors (KORs), today announced financial results and operational highlights for the first quarter ended March 31, 2021.

"During the first quarter of the year, we were very pleased with the FDA acceptance, with Priority Review, of our first NDA filing for our lead product candidate, KORSUVA™ Injection, for the treatment of moderate-to-severe pruritus in hemodialysis patients. With an expected Prescription Drug User Fee Act (PDUFA) target action date of August 23, 2021, we remain focused, along with our commercial partner, Vifor Pharma, on preparation for the U.S. launch of KORSUVA Injection in the second half of 2021, if approved," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "In addition, we continue to progress our Oral KORSUVA programs across a number of late-stage trials in patient populations where effective treatment of pruritus remains a significant unmet need. Having now generated Phase 2 data in pre-dialysis CKD patients and, more recently in mild-to-moderate atopic dermatitis patients in our KARE Phase 2 trial, we hope to initiate Phase 3 programs in both clinical indications by year-end."

First Quarter and Recent Developments:

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Hemodialysis

In February 2021, the FDA accepted the filing of the NDA for KORSUVA Injection for the treatment of moderate-to-severe pruritus in hemodialysis patients. Shortly after this decision, the FDA granted Priority Review for the NDA filing of KORSUVA Injection in March 2021 with an expected PDUFA target action date of August 23, 2021. Following these decisions, the potential approval and U.S. commercial launch of KORSUVA Injection could take place in the second half of 2021. If approved, KORSUVA Injection would be the first treatment for CKD-aP in hemodialysis patients.

In October 2020, the Company entered into a license agreement with Vifor (International) Ltd. (Vifor) under which it granted Vifor an exclusive license to commercialize KORSUVA Injection for the treatment of pruritus in hemodialysis patients in the United States under a Cara 60%, Vifor 40% profit-sharing arrangement. Under the terms of the agreement, upon U.S. regulatory approval of KORSUVA Injection, the Company will be eligible to receive a $50.0 million common stock investment at a 20% premium to the 30-day trailing average price of the Company's common stock as of such date. In addition, the Company is eligible to receive payments of up to $240.0 million upon the achievement of certain sales-based milestones.

In March 2021, the Company and Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP) announced that the European Medicines Agency (EMA) accepted to review the Marketing Authorization Application (MAA) for difelikefalin injection for the treatment of pruritus associated with chronic kidney disease in hemodialysis patients. The EMA will review the application under the centralized marketing authorization procedure. If approved, difelikefalin would receive marketing authorization in all member states of the European Union (EU), as well as in Iceland, Liechtenstein, and Norway. The EMA is expected to render a decision on the EU MAA in the second quarter of 2022.

Oral KORSUVA: Non-Dialysis Dependent (NDD) CKD-aP

In April 2021, the Company held an End of Phase 2 Meeting with the FDA to discuss the results of the Phase 2 trial of Oral KORSUVA in NDD CKD-aP and the potential Phase 3 program. The FDA indicated the acceptability of Stage 5 pre-dialysis CKD patients as a viable patient population for a Phase 3 trial. The FDA also indicated the potential to use data from Cara's previous trials of KORSUVA Injection in dialysis patients to support an approval based on a single Phase 3 clinical trial of Oral KORSUVA in the Stage 5 pre-dialysis population. The Company currently plans to initiate its Phase 3 program by year-end 2021. The Company also intends to continue discussions with the FDA on the potential inclusion of earlier stage CKD patients in the Phase 3 program.

Oral KORSUVA: Atopic Dermatitis (AD)

In April 2021, the Company announced top-line results from its Phase 2 KARE dose-ranging clinical trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in mild-to-severe atopic dermatitis patients. The study did not meet its primary endpoint of Worst Itch – Numeric Rating Scale (WI-NRS) change from baseline at week 12 or secondary endpoint of 4-point responder analysis in the intent to treat (ITT) patient population. However, in a pre-specified analysis of mild-to-moderate (BSA <10%) AD patients (64% of ITT patient population), the study met its primary endpoint of WI-NRS change and secondary endpoint of 4-point responder analysis in this patient population. Additionally, a statistically significant improvement was demonstrated in the 4-point responder analysis, which we expect will be the Phase 3 registrational endpoint, in mild-to-moderate AD patients, with 32% of KORSUVA-treated patients achieving a greater than 4-point reduction vs. 19% in placebo group (p=0.03). Oral KORSUVA was generally well-tolerated across all doses.

The Company intends to request an End of Phase 2 Meeting with the FDA to be held in the second half of 2021 and, subject to discussions with the FDA, aims to initiate a Phase 3 program by the end of the year.

Oral KORSUVA: Chronic Liver Disease-Associated Pruritus (CLD-aP): Primary Biliary Cholangitis (PBC)

The Company is currently conducting a Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with hepatic impairment due to PBC. The trial is evaluating the safety and efficacy of Oral KORSUVA (1.0 mg tablet, twice daily) versus placebo for 16 weeks. The Company continues to screen patients in this ongoing Phase 2 trial and aims to have top-line data in the second half of 2021.

Oral KORSUVA: Notalgia Paresthetica (NP)

In January 2021, the Company initiated a Phase 2 trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in patients suffering from NP, a nerve disorder characterized by chronic pruritus of the upper back. The Company is actively enrolling patients in this trial.

The Phase 2 multicenter, randomized, double-blind, placebo-controlled 8-week study is designed to evaluate the efficacy and safety of Oral KORSUVA for moderate-to-severe pruritus in approximately 120 subjects with NP. Subjects will be randomized to receive Oral KORSUVA 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 change from baseline in itch-related quality of life scores and a change from baseline in itch-related sleep disturbance subscale at the end of week 8.

COVID-19 Impacts and Business Operations

Due to the ongoing COVID-19 pandemic and in accordance with the FDA's updated guidance for conducting clinical trials, the Company has implemented numerous clinical and operational measures to prioritize the health and safety of patients, employees and study investigators and minimize potential disruptions to its ongoing clinical studies. The Company is working closely with its clinical and commercial manufacturing partners to continue to ensure sufficient supply of KORSUVA is available for its ongoing and planned clinical trials.

Based on guidelines from the Centers for Disease Control and Prevention and the State of Connecticut, all Cara employees continue to work remotely, and business travel has been restricted.

Upcoming Meeting Activities

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

- Bank of America Merrill Lynch Healthcare Conference, May 10-13, 2021
- Jefferies Healthcare Conference, June 1-4, 2021

First Quarter 2021 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2021 totaled $228.3 million compared to $251.5 million at December 31, 2020. The decrease in the balance primarily resulted from cash used in operating activities of $23.7 million, partially offset by proceeds of $0.7 million from the exercise of stock options.

For the three months ended March 31, 2021, net loss was $23.3 million, or $0.47 per basic and diluted share, compared to a net loss of $28.9 million, or $0.62 per basic and diluted share, for the same period in 2020.

Revenues: Total revenue was $1.9 million for the three months ended March 31, 2021, compared to $8.1 million during the same period of 2020. Total revenue primarily consisted of $1.9 million of license and milestone fees, and collaborative revenue during the three months ended March 31, 2021, which 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. The Company recognized $8.0 million of license and milestone fees revenue during the three months ended March 31, 2020, which related to the license fees earned in connection with the agreement with VFMCRP.

Research and Development (R&D) Expenses: R&D expenses were $19.1 million for the three months ended March 31, 2021 compared to $33.5 million in the same period of 2020. The lower R&D expenses in 2021 were principally due to a net decrease in costs associated with clinical trials and travel and related costs, partially offset by increases in payroll and related costs, and increases in stock compensation expense.

General and Administrative (G&A) Expenses: G&A expenses were $6.4 million for the three months ended March 31, 2021 compared to $4.6 million in the same period of 2020. The higher G&A expenses in 2021 were principally due to increases in stock compensation expense, payroll and related costs, commercial costs, insurance costs and information technology related costs, partially offset by a decrease in consultants' costs.

Other Income, net: Other income, net was $0.3 million for the three months ended March 31, 2021 compared to $1.0 million in the same period of 2020. The decrease in other income, net was primarily due to a decrease in interest income resulting from a lower yield on the Company's portfolio of investments in the 2021 period.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, Cara expects that its existing unrestricted cash and cash equivalents and available-for-sale marketable securities as of March 31, 2021 will be sufficient to fund its currently anticipated operating expenses and capital expenditures into 2023, without giving effect to any potential milestone payments or potential product revenue under existing collaborations.

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss first quarter 2021 financial results and provide a business update.

To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 5789617. A live webcast of the call can be accessed under "Events and Presentations" in the News & Investors section of the Company's website at www.CaraTherapeutics.com.

An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

About Cara Therapeutics

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA (CR845/difelikefalin), a first-in-class KOR agonist that targets KORs located in the peripheral nervous system and on immune cells. In the Company's KALM^{TM}-1 and KALM-2 Phase 3 trials and two Phase 2 trials, KORSUVA Injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in pruritus-related quality of life measures in hemodialysis patients with moderate-to-severe CKD-aP. The FDA has accepted and granted Priority Review for the NDA for KORSUVA (difelikefalin) Injection for the treatment of moderate-to-severe pruritus in hemodialysis patients. The PDUFA target action date for KORSUVA is August 23, 2021. Oral KORSUVA has completed Phase 2 trials for the treatment of pruritus in patients with CKD and AD and is currently in Phase 2 trials in PBC and NP patients with moderate-to-severe pruritus.

The FDA has conditionally accepted KORSUVA as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product and its safety and efficacy have not been fully evaluated by any regulatory authority.

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 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 and potential commercialization of KORSUVA Injection for CKD-aP, the expected timeline for conducting meetings with the FDA concerning the Company's product candidates, including Oral KORSUVA for NDD CKD-aP and AD, the potential for the Company's product candidates to be alternatives in the therapeutic areas investigated, 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 most recent Annual Report on Form 10-K 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 STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		
License and milestone fees	$ 1,192	$ 8,021
Collaborative revenue	706	-
Clinical compound revenue	37	72
Total revenue	1,935	8,093
Operating expenses:		
Research and development	19,131	33,536
General and administrative	6,365	4,558
Total operating expenses	25,496	38,094
Operating loss	(23,561)	(30,001)
Other income, net	260	957
Loss before benefit from income taxes	(23,301)	(29,044)
Benefit from income taxes	-	122
Net Loss	$ (23,301)	$ (28,922)
Net Loss per share:		
Basic and diluted	$ (0.47)	$ (0.62)
Weighted average shares:		
Basic and diluted	49,917,990	46,724,951

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 22,519	$ 31,683
Marketable securities	149,063	149,242
Income tax receivable	1,507	1,507
Other receivables	2,244	557
Prepaid expenses	13,018	12,076
Total current assets	188,351	195,065
Operating lease right-of-use assets	3,963	4,279
Marketable securities, non-current	56,728	70,565
Property and equipment, net	778	840
Restricted cash	408	408
Total assets	$ 250,228	$ 271,157
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,880	$ 16,881
Operating lease liabilities, current	1,639	1,602
Total current liabilities	16,519	18,483
Operating lease liabilities, non-current	3,250	3,673
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	50	50
Additional paid-in capital	646,015	641,195
Accumulated deficit	(415,618)	(392,317)
Accumulated other comprehensive income	12	73
Total stockholders' equity	230,459	249,001
Total liabilities and stockholders' equity	$ 250,228	$ 271,157

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