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) **November 8, 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 November 8, 2021, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 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 November 8, 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: November 8, 2021

Exhibit 99.1

Cara Therapeutics Reports Third Quarter 2021 Financial Results

– KORSUVA™ (CR845/difelikefalin) injection Approved as First and Only Treatment for Chronic Kidney Disease-associated Pruritus (CKD-aP) in Adult Hemodialysis Patients by U.S. Food and Drug Administration (FDA) –

– Christopher Posner Appointed President and Chief Executive Officer Effective November 9th, 2021 –

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

STAMFORD, Conn., Nov. 8, 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 third quarter ended September 30, 2021.

"I am excited to be joining Cara at a transformational point for the Company as it prepares for the commercial launch of KORSUVA injection for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in hemodialysis patients in the first half of 2022," said Christopher Posner, Cara's newly appointed President and Chief Executive Officer. "As Cara continues to develop Oral KORSUVA across multiple patient populations, I believe the Company is well-positioned to become the leader in the treatment of itch-dominant medical conditions such as atopic dermatitis."

"In the third quarter of 2021, Cara made significant progress across our development programs, culminating with the FDA approval of KORSUVA injection for moderate-to-severe pruritus associated with chronic kidney disease in hemodialysis patients," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We are also making important clinical and regulatory progress with our Oral KORSUVA programs. Following recent guidance from the FDA, we aim to initiate Phase 3 programs with Oral Korsuva for the treatment of moderate to severe pruritus in both atopic dermatitis and non-dialysis dependent chronic kidney disease patients in the first quarter of 2022. Finally, I would like to welcome Chris as Cara's new President and CEO. Having worked closely with Chris as a Cara board member, I am confident in his ability to lead the Company through its next phase of development as an early commercial-stage biopharmaceutical company."

Third Quarter and Recent Developments:

Leadership Appointments

In November 2021, the Company announced the appointment of Christopher Posner as President and Chief Executive Officer of Cara Therapeutics, effective November 9, 2021. Mr. Posner joins the Company from LEO Pharma, Inc., the US affiliate of LEO Pharma A/S, a global leader in medical dermatology, where he was President and Chief Executive Officer. Mr. Posner succeeds Dr. Derek Chalmers, who will transition to a Senior Advisor Role to the Company.

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

In August 2021, the FDA approved KORSUVA injection for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis, making it the first and only therapy currently approved by the FDA for treatment of this indication. The New Drug Application for KORSUVA injection received Priority Review by the FDA, granted to therapies that, if approved, would offer significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications, and was supported by positive data from two pivotal Phase 3 trials and supportive data from an additional 32 clinical studies.

Following the FDA approval of KORSUVA injection, the Company has been collaborating with its commercial partner, Vifor Pharma, on the promotional launch of KORSUVA injection in the United States. In September 2021, Vifor Pharma and Cara submitted the required documentation to the U.S. Centers for Medicare and Medicaid Services (CMS) to secure reimbursement for KORSUVA injection. Vifor Pharma expects to initiate the commercial launch of KORSUVA injection in the first half of 2022, subject to CMS timelines.

In October 2020, Vifor Pharma and Cara agreed to an exclusive license to commercialize KORSUVA in the United States. That agreement features a Cara 60%, Vifor Pharma 40% profit-sharing arrangement in non-Fresenius Medical Care clinics in the U.S. Under the terms of this agreement, the Company received a $50.0 million common stock investment from Vifor in October 2021 at a 20% premium to the 30-day trailing average price of the Company's common stock for achievement of U.S. regulatory approval of KORSUVA injection. In addition, the Company is eligible to receive up to $240.0 million upon the achievement of certain sales-based milestones. Under another existing agreement, Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP) and the Company agreed to market KORSUVA injection to Fresenius Medical Care North America dialysis clinics in the U.S. under a Cara 50%, Vifor Pharma 50% profit-sharing arrangement. In October 2021, the Company received a $15.0 million cash payment based on the achievement of U.S. regulatory approval of KORSUVA injection.

In March 2021, the Company and 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: 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. While the study did not meet its primary endpoint, 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.

In the third quarter, the Company held an End-of-Phase 2 Meeting with the FDA to discuss the results from its Phase 2 KARE dose-ranging clinical trial of Oral KORSUVA for the treatment of moderate-to-severe pruritus in atopic dermatitis patients. Based on meeting guidance, the Company plans to initiate a Phase 3 program in AD patients in the first 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. Based on meeting guidance, the FDA indicated the acceptability of Stage 5 pre-dialysis CKD patients as a viable patient population for a Phase 3 trial.

In November 2021, the FDA provided written guidance indicating the patient population can be expanded to include the group of Stage 4 pre-dialysis patients with advanced CKD in a registration program consisting of two pivotal Phase 3 clinical trials. The Company expects to initiate this registration program in the first quarter of 2022.

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, primarily due to the ongoing effects of the COVID-19 pandemic on patient enrollment, currently expects to report top-line data in the first half of 2022.

Oral KORSUVA: Notalgia Paresthetica (NP)

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, in early 2021. The Phase 2 trial remains on track to be fully enrolled by year-end.

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 the commercial launch of KORSUVA injection and its ongoing and planned clinical trials.

Upcoming Meeting Activities

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

- Stifel Healthcare Conference, November 15-17, 2021
- Jefferies Global Healthcare Conference, November 16-18, 2021
- Piper Sandler Health Care Conference, November 30-December 2, 2021
- J.P. Morgan Healthcare Conference, January 10-13, 2022
- 2022 Winter Clinical Dermatology Conference – Hawaii, January 14-19, 2022

Third Quarter 2021 Financial Results

Cash, cash equivalents and marketable securities at September 30, 2021 totaled $193.4 million compared to $251.5 million at December 31, 2020. The decrease in the balance primarily resulted from cash used in operating activities of $58.8 million, partially offset by proceeds of $1.3 million from the exercise of stock options.

For the three months ended September 30, 2021, net loss was $1.0 million, or $0.02 per basic and diluted share, compared to a net loss of $16.5 million, or $0.35 per basic and diluted share, for the same period in 2020.

Revenues: Revenue for the three months ended September 30, 2021 and 2020 was $20.3 million and $9.3 million, respectively. License and milestone fees revenue of $20.0 million for the three months ended September 30, 2021 was related to the milestone payments the Company earned from Vifor (International) Ltd. (Vifor) and VFMCRP that was allocated to the license fee performance obligation under the Vifor and VFMCRP agreements, as the variable consideration was deemed probable upon the regulatory approval of KORSUVA injection in August 2021. This included $5.0 million of the $50.0 million equity milestone investment under the agreement with Vifor. License and milestone fees revenue of $9.3 million for the three months ended September 30, 2020 was related to license fees earned by us in connection with the VFMCRP Agreement.

Research and Development (R&D) Expenses: R&D expenses were $15.5 million for the three months ended September 30, 2021 compared to $21.1 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 a $2.5 million milestone earned by Enteris Biopharma, Inc. during the three months ended September 30, 2020, partially offset by increases in stock compensation expense, payroll and related costs, and cost of compound sales.

General and Administrative (G&A) Expenses: G&A expenses were $5.9 million for the three months ended September 30, 2021 compared to $5.2 million in the same period of 2020. The higher G&A expenses in 2021 were principally due to an increase in stock compensation expense, consultants' costs, legal fees, and insurance costs, partially offset by decreases in commercial costs.

Other Income, net: Other income, net was $0.1 million for the three months ended September 30, 2021 compared to $0.4 million in the same period of 2020. The decrease in other income, net was primarily due to a decrease in interest income and an increase in net amortization expense of available-for-sale marketable securities 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 September 30, 2021, including the milestone payments received in October 2021 of $65.0 million from Vifor and VFMCRP, will be sufficient to fund its currently anticipated operating expenses and capital expenditures through 2023, without giving effect to any additional 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 third 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 1480703. 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 an early commercial-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 the body's peripheral nervous system, as well as certain immune cells. KORSUVA injection was approved by the FDA for the treatment of moderate-to-severe CKD-aP in adults undergoing hemodialysis on 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.

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 commercialize KORSUVA injection, including the timing of additional regulatory submissions and approvals, the Company's ability to obtain and maintain coverage and adequate reimbursement for KORSUVA injection, the performance of our 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 Company's expected cash reach, and the potential impact of COVID-19 on the Company's commercial launch, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
License and milestone fees	$ 20,031	$ 9,257	$ 21,223	$ 22,377
Collaborative revenue	-	-	706	-
Clinical compound revenue	241	9	278	616
Total revenue	20,272	9,266	22,207	22,993
Operating expenses:				
Research and development	15,514	21,067	59,870	80,711
General and administrative	5,882	5,219	17,898	15,187
Total operating expenses	21,396	26,286	77,768	95,898
Operating loss	(1,124)	(17,020)	(55,561)	(72,905)
Other income, net	111	379	502	1,970
Loss before benefit from income taxes	(1,013)	(16,641)	(55,059)	(70,935)
Benefit from income taxes	-	132	-	436
Net loss	$ (1,013)	$ (16,509)	$ (55,059)	$ (70,499)
Net loss per share:				
Basic and Diluted	$ (0.02)	$ (0.35)	$ (1.10)	$ (1.51)
Weighted average shares:				
Basic and Diluted	50,114,710	46,885,424	$ 50,031,615	46,803,659

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 22,991	$ 31,683
Marketable securities	121,203	149,242
Income tax receivable	697	1,507
Other receivables	20,350	557
Prepaid expenses	6,258	12,076
Total current assets	171,499	195,065
Operating lease right-of-use assets	3,310	4,279
Marketable securities, non-current	49,221	70,565
Property and equipment, net	654	840
Restricted cash	408	408
Total assets	$ 225,092	$ 271,157
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,812	$ 16,881
Operating lease liabilities, current	1,716	1,602
Total current liabilities	15,528	18,483
Operating lease liabilities, non-current	2,373	3,673
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	50	50
Common stock subscribed in Vifor stock purchase	3	-
Additional paid-in capital	699,482	641,195
Stock subscription receivable	(44,969)	-
Accumulated deficit	(447,376)	(392,317)
Accumulated other comprehensive income	1	73
Total stockholders' equity	207,191	249,001
Total liabilities and stockholders' equity	$ 225,092	$ 271,157

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