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 7, 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 November 7, 2022, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 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 November 7, 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/ RYAN MAYNARD
Ryan Maynard
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 7, 2022

Exhibit 99.1

Cara Therapeutics Reports Third Quarter 2022 Financial Results

– Net revenue was $16.2M for 3Q22 including profit-sharing revenue of $7.4M from KORSUVA® (difelikefalin) injection –

– Strong demand for KORSUVA injection driven by large dialysis organizations with ~180,000 vials shipped –

– FDA meeting scheduled in 4Q22 to discuss potential pivotal program in notalgia paresthetica –

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

STAMFORD, Conn., Nov. 7, 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 third quarter ended September 30, 2022.

“Demand for KORSUVA® (difelikefalin) injection in the U.S. accelerated in the third quarter, reflecting the strong launch performance and our product’s value proposition for chronic kidney disease (CKD) patients undergoing hemodialysis who are suffering from pruritus,” said Christopher Posner, President and Chief Executive Officer of Cara Therapeutics. “Positive momentum has also been building internationally with the European launches in Austria and Germany, as well as approvals in Canada, Singapore and Switzerland during the third quarter. In addition, we are pleased that our partner in Japan has submitted a New Drug Application for the approval of difelikefalin injection, with a decision expected in the second half of 2023.”

Mr. Posner continued, “On the clinical development front, we continue to enroll patients in our two Phase 3 oral difelikefalin programs. We also look forward to our meeting with the FDA to discuss a potential pivotal program in notalgia paresthetica. As a result of slow enrollment due primarily to Covid-19, we made the strategic decision to discontinue our proof-of-concept Phase 2 study in pruritus associated with primary biliary cholangitis (PBC). Although we did not observe anything in this study that would preclude us from moving forward in this indication, we plan to focus our resources on maximizing the potential of our promising nephrology and dermatology franchises. With the strong traction we achieved during the third quarter, we believe we are well positioned to drive long-term growth and establish Cara Therapeutics as the leader in the treatment of chronic pruritus.”

Third Quarter and Recent Developments:

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus: Hemodialysis

KORSUVA injection generated net sales of $16.2 million and the Company recorded profit-sharing revenue of $7.4 million in the third quarter of 2022. Wholesaler shipments to dialysis centers increased from 1,812 vials in the second quarter of 2022 to 184,440 vials in the third quarter of 2022, driven primarily by large dialysis organizations.

During the third quarter of 2022, the Company's partner CSL Vifor commenced the European launch of Kapruvia® starting with Austria and Germany. In addition, KORSUVA was approved by Health Canada and the Health Sciences Authority in Singapore. It was also approved by the Swiss Agency for Therapeutic Products under the brand name Kapruvia. Approval is expected in Australia within the coming months.

In September 2022, the Company's licensing partner Maruishi Pharmaceutical Co., Ltd. submitted a New Drug Application in Japan for the approval of difelikefalin injection for the treatment of pruritus in hemodialysis patients. A final decision on the application is expected in the second half of 2023.

Oral Difelikefalin: Notalgia Paresthetica

New data from the Company's Phase 2 trial of oral difelikefalin for the treatment of moderate-to-severe pruritus in notalgia paresthetica (NP) were presented during a late-breaking news session at the 31st European Academy of Dermatology and Venereology (EADV) Congress in September 2022, as well as the Company's virtual NP event in September 2022. The data demonstrate that the onset of action with oral difelikefalin is as early as Day 1 and the duration of effect is sustained throughout the active extension period to Week 12.

The Company is scheduled to meet with the U.S. Food and Drug Administration (FDA) this month to discuss next steps toward a potential pivotal program for oral difelikefalin in NP.

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

Based on slow enrollment due primarily to Covid-19, the Company made a strategic decision to discontinue and unblind the proof-of-concept Phase 2 clinical trial of oral difelikefalin for the treatment of pruritus in patients with primary biliary cholangitis (PBC). The unblinded data showed no unexpected adverse events. However, the low number of patients (N=14) limits the ability to draw a meaningful conclusion regarding the efficacy (WI-NRS change from baseline at 16 weeks: DFK -3.8 vs. placebo -3.0) of difelikefalin in this patient population.

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

The Phase 3 program of oral difelikefalin is enrolling 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. The Company expects to report topline results in the second half of 2024.

Oral Difelikefalin: Atopic Dermatitis

The Phase 3 program of oral difelikefalin as an adjunctive therapy to topical corticosteroids is enrolling atopic dermatitis (AD) patients with moderate-to-severe pruritus. The program is comprised of two studies, known as KIND 1 (Part A and Part B) and KIND 2. At the end of the KIND 1 Part A 12-week treatment period, the Company expects to have an internal data readout to inform the dose and sample size to initiate KIND 1 Part B and KIND 2. KIND 1 Part B and KIND 2 are both double-blind, controlled, 12-week studies with patients allowed to roll over to 52-week open-label safety extensions. The internal readout for KIND 1 Part A is expected in the second half of 2023 and topline results for both KIND 1 Part B and KIND 2 are expected in the first half of 2025.

Appointments

In September 2022, the Company announced the appointment of Ryan Maynard as Chief Financial Officer.

In November 2022, the Company announced the appointment of Lisa von Moltke, M.D., to its Board of Directors.

Upcoming Meeting Activities:

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

Stifel Healthcare Conference, November 15-16
Jefferies London Healthcare Conference, November 15-17
Evercore ISI Healthcare Conference, November 29-December 1
Piper Sandler Healthcare Conference, November 29-December 1

Third Quarter 2022 Financial Results

Cash, cash equivalents and marketable securities on September 30, 2022 totaled $179.5 million compared to $236.8 million at December 31, 2021. The decrease in the balance primarily resulted from $55.2 million of cash used in operating activities.

For the third quarter of 2022, net loss was $23.2 million, or $(0.43) per basic and diluted share, compared to net loss of $1.0 million, or ($0.02) per basic and diluted share, for the same period in 2021.

Revenues: Total revenue was $10.8 million and $20.3 million for the three months ended September 30, 2022 and 2021, respectively. Revenue consisted of:

- $7.4 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 September 30, 2022. There was no collaborative revenue during the three months ended September 30, 2021.
- There was no license and milestone fees revenue during the three months ended September 30, 2022. $20.0 million of license and milestone fees revenue related to the milestone payments the Company earned from Vifor during the three months ended September 30, 2021 that was allocated to the license fee performance obligation under the Vifor 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.
- $3.4 million of commercial supply revenue related to sales of KORSUVA injection to Vifor during the three months ended September 30, 2022. There was no commercial supply revenue during the three months ended September 30, 2021.
- There was no clinical compound revenue during the three months ended September 30, 2022. There was $0.2 million of clinical compound revenue related to sales of clinical compound to Vifor during the three months ended September 30, 2021.

Cost of Goods Sold: Cost of goods sold of $3.1 million related to commercial supply revenue for KORSUVA injection sales to Vifor during the three months ended September 30, 2022. There was no cost of goods sold during the three months ended September 30, 2021, as commercialization of KORSUVA injection began in April 2022.

Research and Development (R&D) Expenses: R&D expenses were $24.7 million for the three months ended September 30, 2022 compared to $15.5 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 a $5.0 million milestone payment due to Enteris Biopharma, Inc. during the three months ended September 30, 2022.

General and Administrative (G&A) Expenses: G&A expenses were $6.9 million for the three months ended September 30, 2022 compared to $5.9 million in the same period of 2021. The higher G&A expenses in 2022 were principally due to increases in accounting and auditing fees and payroll related costs, partially offset by a decrease in stock-based compensation expense.

Other Income, net: Other income, net was $0.7 million for the three months ended September 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 September 30, 2022, and a decrease in net amortization expense of available-for-sale securities during the three months ended September 30, 2022.

Financial Guidance

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 plan into the first half of 2024. This guidance assumes KORSUVA revenue profit share contribution consistent with what the Company has reported for the quarter ended September 30, 2022.

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 its 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 a Phase 2 proof-of-concept trial 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, timing of future regulatory and development milestones for the Company's product candidates, the future development of oral difelikefalin in pruritus associated with PBC, and the Company's potential to become the established leader in the treatment of chronic pruritus. 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, 2021, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and its other documents subsequently filed with or furnished to the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 42,806	$ 13,453
Marketable securities	112,806	153,582
Accounts receivable, net - related party	9,623	-
Inventory, net	1,835	2,584
Income tax receivable	697	697
Other receivables	451	455
Prepaid expenses	18,562	2,519
Total current assets	186,780	173,290
Operating lease right-of-use assets	1,918	2,973
Marketable securities, non-current	23,916	69,754
Property and equipment, net	487	631
Restricted cash	408	408
Total assets	$ 213,509	$ 247,056
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 26,316	$ 15,861
Operating lease liabilities, current	1,876	1,755
Total current liabilities	28,192	17,616
Operating lease liabilities, non-current	497	1,918
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock	-	-
Common stock	53	53
Additional paid-in capital	722,808	708,585
Accumulated deficit	(535,893)	(480,758)
Accumulated other comprehensive loss	(2,148)	(358)
Total stockholders' equity	184,820	227,522
Total liabilities and stockholders' equity	$ 213,509	$ 247,056

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,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Collaborative revenue	$ 7,443	$ -	$ 15,446	$ 706
License and milestone fees	-	20,031	15,000	21,223
Commercial supply revenue	3,370	-	8,160	-
Clinical compound revenue	-	241	-	278
Total revenue	10,813	20,272	38,606	22,207
Operating expenses:				
Cost of goods sold	3,055	-	5,136	-
Research and development	24,691	15,514	65,869	59,870
General and administrative	6,912	5,882	23,829	17,898
Total operating expenses	34,658	21,396	94,834	77,768
Operating loss	(23,845)	(1,124)	(56,228)	(55,561)
Other income, net	665	111	1,093	502
Net loss	$ (23,180)	$ (1,013)	$ (55,135)	$ (55,059)
Net loss per share:				
Basic and Diluted	$ (0.43)	$ (0.02)	$ (1.03)	$ (1.10)
Weighted average shares:				
Basic and Diluted	53,726,123	50,114,710	53,616,753	50,031,615

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