

**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 7, 2019

CARA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36279
(Commission
File Number)

75-3175693
(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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 7, 2019, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2019. 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 7, 2019

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/ MANI MOHINDRU

Mani Mohindru, Ph.D.

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: August 7, 2019



Cara Therapeutics Reports Second Quarter 2019 Financial Results

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

STAMFORD, Conn., August 7, 2019 – 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, today announced financial results and operational highlights for the second quarter ended June 30, 2019.

“We were very pleased with the progress made across our late stage clinical pipeline this quarter, including positive top-line data from our KALM-1 pivotal Phase 3 trial of KORSUVA Injection for chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis patients, as well as the successful completion of the Interim Statistical Assessment of our Phase 2 trial of Oral KORSUVA™ for CKD-aP in non-hemodialysis patients,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “With a strengthened balance sheet from our recently completed follow-on offering, the Company is well positioned to deliver on a number of significant clinical milestones by year end, including top-line data from both our KALM-2 pivotal Phase 3 trial and Oral KORSUVA™ Phase 2 CKD-aP trial.”

Second Quarter and Recent Developments:

Follow-on Public Offering

In July 2019, the Company issued and sold 6,325,000 shares of its common stock in a follow-on public offering, which includes the full exercise of the underwriters’ option to purchase 825,000 additional shares of common stock at \$23.00 per share. The Company received net proceeds of approximately \$136.4 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

KORSUVA™ (CR845/difelikefalin) Injection Phase 3 Program: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Hemodialysis

In May 2019, the Company announced positive top-line data from the KALM-1 pivotal Phase 3 trial of KORSUVA Injection in hemodialysis patients with moderate-to-severe CKD-aP. The trial met the primary endpoint, with a statistically significant improvement in the proportion of patients on KORSUVA Injection achieving a three-point or greater improvement in the mean Worst Itching Intensity Numeric Rating Scale versus placebo (p=0.000019). In addition, the trial also met all secondary endpoints and was generally well-tolerated through 12 weeks of treatment with a safety profile consistent with prior clinical trials.

The Company continues to enroll patients in the United States, Europe and Asia Pacific in KALM-2, the global Phase 3 efficacy trial of KORSUVA Injection. Based on current patient enrollment projections, the Company expects top-line data from this trial in the fourth quarter of 2019.

Additionally, the Company continues to enroll two open-label safety trials, both of which are expected to support worldwide registration filings of KORSUVA Injection. The Company's long-term, 52-week open-label Phase 3 safety trial continues to progress, with approximately 165 patients having completed at least 6 months of treatment and over 50% of these patients having completed 1 year of treatment. The Company's 12-week open-label safety trial, launched this quarter, is expected to enroll up to 400 patients.

Oral KORSUVA: CKD-aP: Non-Hemodialysis

In July 2019, based on the recommendation of the Independent Data Monitoring Committee, the Company announced that the Phase 2 trial of Oral KORSUVA will continue as planned with no changes to the original enrollment target of 240 stage III-V CKD patients with moderate-to-severe CKD-aP. The prespecified interim conditional power assessment was conducted after approximately 50% of the 240 patients had completed the designated 12-week treatment period. The Company also announced the completion of enrollment in the Phase 2 trial and expects top-line data from this trial in the fourth quarter of 2019.

Oral KORSUVA: Atopic Dermatitis (AD)

In July 2019, the Company announced the initiation of a Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with AD, evaluating the safety and efficacy of three tablet strengths (0.25 mg, 0.5 mg and 1.0 mg, twice daily) of Oral KORSUVA versus placebo for 12 weeks, followed by a 4-week active extension phase.

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

In June 2019, the Company announced the initiation of 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 mg tablet, twice daily) versus placebo for 16 weeks.

Upcoming Activities

The Company expects to make presentations at the following conferences:

- Cantor Fitzgerald Global Healthcare Conference, October 2-4, 2019
- European Academy of Dermatology and Venereology, October 9-13, 2019
- Stifel Healthcare Conference, November 19-20, 2019
- Jefferies Global Healthcare Conference, November 20-21, 2019
- Piper Jaffray Health Care Conference, December 3-5, 2019

Second Quarter 2019 Financial Results

Net Loss: The Company reported a net loss of \$23.0 million, or \$0.58 per basic and diluted share, for the second quarter of 2019 compared to a net loss of \$17.2 million, or \$0.52 per basic and diluted share, for the second quarter of 2018.

Revenues: Total revenue of \$5.2 million and \$2.9 million for the three months ended June 30, 2019 and 2018, respectively, consisted of license and milestone fees revenue that was recognized by the Company related to its license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd.

Research and Development (R&D) Expenses: R&D expenses were \$24.4 million for the three months ended June 30, 2019 compared to \$17.0 million for the three months ended June 30, 2018. The higher R&D expenses in 2019 were primarily due to a net increase in clinical trial costs, as well as increases in stock-based compensation expense and payroll and related costs.

General and Administrative (G&A) Expenses: G&A expenses were \$5.0 million for the three months ended June 30, 2019 compared to \$3.7 million for the three months ended June 30, 2018. The increase in 2019 was primarily due to increases in stock-based compensation expense, payroll and related costs, and franchise taxes.

Other Income: Other income was \$947,000 for the three months ended June 30, 2019 compared to \$467,000 for the three months ended June 30, 2018. The increase in 2019 was due to an increase in interest and accretion income resulting from a higher average balance of the Company's portfolio of investments in the 2019 period.

Cash and Cash Equivalents and Marketable Securities Position: At June 30, 2019, cash and cash equivalents and marketable securities totaled \$135.6 million compared to \$182.8 million at December 31, 2018. The decrease in the balance of cash and cash equivalents and marketable securities primarily resulted from cash used in operations of \$52.4 million, partially offset by proceeds of \$4.2 million from the exercise of stock options.

Additionally, in July 2019, the Company raised approximately \$136.4 million in net proceeds from a public offering of 6,325,000 shares of its common stock.

Financial Guidance

Based on timing expectations and projected costs for current clinical development plans, Cara expects that its existing cash and cash equivalents and available-for-sale marketable securities as of June 30, 2019, as well as approximately \$136.4 million of net proceeds from the Company's public offering in July 2019, will be sufficient to fund its currently anticipated operating expenses and capital expenditures into the second half of 2021, without giving effect to any potential milestone payments under existing collaborations.

Conference Call

Cara management will host a conference call today at 4:30 p.m. ET to discuss second quarter 2019 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 6576266. A live webcast of the call can be accessed under “Events & 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 kappa opioid receptors, or 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 a Phase 3 and two Phase 2 trials, KORSUVA (CR845/difelikefalin) 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 and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Oral KORSUVA is in Phase 2 trials for the treatment of pruritus in patients with CKD, AD and PBC.

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 data readouts from the Company’s ongoing clinical trials, the expected timing for initiation of the Company’s planned clinical trials, the potential results of ongoing and planned clinical trials, 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, and the Company’s expected cash reach. 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 ended December 31, 2018 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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenue:				
License and milestone fees revenue	\$ 5,208	\$ 2,874	\$ 9,450	\$ 2,874
Clinical compound revenue	—	—	140	—
Total revenue	<u>5,208</u>	<u>2,874</u>	<u>9,590</u>	<u>2,874</u>
Operating expenses:				
Research and development	24,356	17,002	47,964	30,429
General and administrative	4,994	3,685	8,902	7,382
Total operating expenses	<u>29,350</u>	<u>20,687</u>	<u>56,866</u>	<u>37,811</u>
Operating loss	<u>(24,142)</u>	<u>(17,813)</u>	<u>(47,276)</u>	<u>(34,937)</u>
Other income	947	467	2,036	778
Loss before benefit from income taxes	<u>(23,195)</u>	<u>(17,346)</u>	<u>(45,240)</u>	<u>(34,159)</u>
Benefit from income taxes	235	152	320	198
Net loss	<u>\$ (22,960)</u>	<u>\$ (17,194)</u>	<u>\$ (44,920)</u>	<u>\$ (33,961)</u>
Net loss per share:				
Basic and Diluted	<u>\$ (0.58)</u>	<u>\$ (0.52)</u>	<u>\$ (1.13)</u>	<u>\$ (1.03)</u>
Weighted average shares:				
Basic and Diluted	<u>39,818,162</u>	<u>33,315,809</u>	<u>39,685,954</u>	<u>33,000,487</u>

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

	June 30,	December 31,
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,494	\$ 15,081
Marketable securities	96,815	146,302
Income tax receivable	984	664
Other receivables	605	926
Prepaid expenses	7,512	4,805
Restricted cash, current	361	361
Total current assets	124,771	168,139
Operating lease right-of-use asset	3,344	—
Marketable securities, non-current	20,320	21,396
Property and equipment, net	798	880
Restricted cash	408	408
Total assets	\$ 149,641	\$ 190,823
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 12,766	\$ 13,622
Operating lease liability, current	923	—
Current portion of deferred revenue	26,473	26,825
Total current liabilities	40,162	40,447
Operating lease liability, non-current	3,849	—
Deferred revenue, non-current	6,085	15,184
Deferred lease obligation	—	1,562
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	40	39
Additional paid-in capital	438,614	428,059
Accumulated deficit	(339,274)	(294,354)
Accumulated other comprehensive income (loss)	165	(114)
Total stockholders' equity	99,545	133,630
Total liabilities and stockholders' equity	\$ 149,641	\$ 190,823

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