

**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 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))

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. .

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

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**Item 2.02. Results of Operations and Financial Condition.**

On May 7, 2019, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated May 7, 2019</a>

**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: May 7, 2019



## **Cara Therapeutics Reports First Quarter 2019 Financial Results**

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

**STAMFORD, Conn., May 7, 2019** – Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities with a primary focus on pruritus as well as pain by selectively targeting peripheral kappa opioid receptors, today announced financial results and operational highlights for the first quarter ended March 31, 2019.

“We are pleased with the progress made across our clinical pruritus programs in chronic kidney disease in the first quarter and remain on track to release top-line data from KALM-1, the first of our pivotal Phase 3 trials of KORSUVA Injection for chronic kidney disease-associated pruritus in hemodialysis patients, in the second quarter,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “Additionally, we look forward to broadening our clinical pruritus program for Oral KORSUVA with the initiation of Phase 2 trials in chronic liver disease and atopic dermatitis in the next few months.”

### **First Quarter and Recent Developments:**

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

In January 2019, based on the recommendation of the Independent Data Monitoring Committee, the Company announced that its pivotal KALM™-1 Phase 3 trial of KORSUVA Injection will continue as planned with no changes to the original enrollment target of 350 hemodialysis patients with moderate-to-severe CKD-aP. The pre-specified interim conditional power assessment was conducted after approximately half of the targeted number of patients completed the designated 12-week treatment period. The Company also announced the completion of enrollment in the KALM-1 trial, and it expects top-line data from this trial in the second quarter of 2019.

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 second half of 2019.

The Company's long term, 52-week open-label Phase 3 safety trial continues to progress. Approximately 150 patients have completed at least 6 months of treatment and approximately 40% of these patients have completed 1 year of treatment.

In the second quarter of 2019, the Company initiated an additional open-label safety trial of KORSUVA Injection that is expected to enroll up to 400 hemodialysis patients with CKD-aP for up to 12 weeks of treatment. Both of the safety trials are expected to support worldwide registration filings of KORSUVA Injection.

#### **Oral KORSUVA: CKD-aP: Non-Hemodialysis**

The Company continues to enroll patients in the Phase 2 trial of Oral KORSUVA for the treatment of pruritus in stage III – V (moderate-to-severe) chronic kidney disease, or CKD, patients. Based on current enrollment projections, the Company anticipates top-line data from this trial in the second half of 2019.

#### **Oral KORSUVA: Chronic Liver Disease-Associated Pruritus (CLD-aP)**

The Company recently completed a Phase 1 trial of Oral KORSUVA at multiple tablet strengths in patients with chronic liver disease, or CLD. The pharmacokinetic parameters were dose proportional and Oral KORSUVA was generally well tolerated with no unexpected safety signals reported. The Company expects to initiate a Phase 2 trial in CLD patients with moderate-to-severe pruritus in the second quarter of 2019.

#### **Oral KORSUVA: Atopic Dermatitis**

The Company plans to initiate a multi-dose, proof-of-concept Phase 2 trial of Oral KORSUVA in atopic dermatitis patients with moderate-to-severe pruritus around mid-year 2019.

#### **Upcoming Activities**

The Company expects to make presentations at the following conferences:

- Bank of America Merrill Lynch Health Care Conference 2019, May 14-16, 2019
- Jefferies 2019 Healthcare Conference, June 4-7, 2019
- European Academy of Dermatology and Venereology, October 9–13, 2019

#### **First Quarter 2019 Financial Results**

*Net Loss:* The Company reported a net loss of \$22.0 million, or \$0.56 per basic and diluted share, for the first quarter of 2019 compared to a net loss of \$16.8 million, or \$0.51 per basic and diluted share, for the first quarter of 2018.

*Revenues:* Total revenue was \$4.4 million for the three months ended March 31, 2019. There was no revenue during the three months ended March 31, 2018. Total revenue in 2019 consisted of:

- (1) License and milestone fees revenue of \$4.2 million that was recognized by the Company related to its license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd.
- (2) Clinical compound revenue of \$140,000 that was earned by the Company from the sale of clinical compound to Maruishi Pharmaceutical Co. Ltd.

*Research and Development (R&D) Expenses:* R&D expenses were \$23.6 million for the three months ended March 31, 2019 compared to \$13.4 million for the three months ended March 31, 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 compensation expense and payroll and related costs.

*General and Administrative (G&A) Expenses:* G&A expenses were \$3.9 million for the three months ended March 31, 2019 compared to \$3.7 million for the three months ended March 31, 2018. The increase in 2019 was primarily due to increases in legal, accounting and consultants' costs.

*Other Income:* Other income was \$1.1 million for the three months ended March 31, 2019 compared to \$311,000 for the three months ended March 31, 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 March 31, 2019, cash and cash equivalents and marketable securities totaled \$156.1 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 \$27.5 million, partially offset by proceeds of \$0.2 million from the exercise of stock options.

### **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 March 31, 2019 will be sufficient to fund its currently anticipated operating expenses and capital expenditures into the fourth quarter of 2020, 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 first 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 3027399. 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](http://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 with a primary focus on pruritus as well as pain by selectively targeting peripheral kappa opioid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVATM (CR845/difelikefalin), a first-in-class KOR agonist that targets the body’s peripheral nervous system, as well as certain immune cells. In 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 and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP.

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)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
License and milestone fees	\$ 4,242	\$ —
Clinical compound revenue	140	—
Total revenue	4,382	—
Operating expenses:		
Research and development	23,608	13,427
General and administrative	3,908	3,697
Total operating expenses	27,516	17,124
Operating loss	(23,134)	(17,124)
Other income	1,089	311
Loss before benefit from income taxes	(22,045)	(16,813)
Benefit from income taxes	85	46
Net loss	<u>\$ (21,960)</u>	<u>\$ (16,767)</u>
Net loss per share :		
Basic and Diluted	\$ (0.56)	\$ (0.51)
Weighted average shares:		
Basic and Diluted	39,552,277	32,681,661



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

	March 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,188	\$ 15,081
Marketable securities	120,265	146,302
Income tax receivable	749	664
Other receivables	1,019	926
Prepaid expenses	7,577	4,805
Restricted cash, current	361	361
Total current assets	144,159	168,139
Operating lease right-of-use asset	3,492	—
Marketable securities, non-current	21,687	21,396
Property and equipment, net	841	880
Restricted cash	408	408
Total assets	\$ 170,587	\$ 190,823
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 13,310	\$ 13,622
Operating lease liability, current	901	—
Current portion of deferred revenue	28,194	26,825
Total current liabilities	42,405	40,447
Operating lease liability, non-current	4,087	—
Deferred revenue, non-current	9,573	15,184
Deferred lease obligation	—	1,562
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	39	39
Additional paid-in capital	430,724	428,059
Accumulated deficit	(316,314)	(294,354)
Accumulated other comprehensive income (loss)	73	(114)
Total stockholders' equity	114,522	133,630
Total liabilities and stockholders' equity	\$ 170,587	\$ 190,823

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