

**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 5, 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, 9<sup>th</sup> 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  x

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 5, 2019, Cara Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated November 5, 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**  
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Mani Mohindru, Ph.D.  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: November 5, 2019



## Cara Therapeutics Reports Third Quarter 2019 Financial Results

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

**STAMFORD, Conn., November 5, 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 third quarter ended September 30, 2019.

“During the quarter, we completed several key clinical, financing and licensing objectives that position the Company well to continue to achieve our clinical, regulatory and commercial goals for later this year and next year,” said Derek Chalmers, Ph.D., DSc., President and Chief Executive Officer of Cara Therapeutics. “Based on the recent interim statistical analysis of our KALM-2 Phase 3 global trial and the continued progress with our two open-label safety trials, we continue to maintain our projected timeline for the submission of our first New Drug Application, or NDA, for KORSUVA Injection in dialysis patients with chronic kidney disease-associated pruritus, or CKD-aP, in the second half of 2020. In addition, our Phase 2 trial of Oral KORSUVA in non-hemodialysis patients with CKD-aP remains on track to read out top-line data before year-end.”

### Third Quarter and Recent Developments:

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

In October 2019, the Company announced the completion of an interim statistical assessment and a small increase in target enrollment for its pivotal KALM-2 Phase 3 global trial of KORSUVA Injection. Based on the recommendation of the Independent Data Monitoring Committee, or IDMC, the size of the trial will be increased from an original enrollment target of 350 patients to 430 patients. The prespecified interim conditional power assessment was conducted after approximately 50% of the targeted 350 patients completed the designated 12-week treatment period. The Company expects the trial to be fully enrolled in the fourth quarter of 2019 and remains on track to file the NDA for KORSUVA Injection in the second half of 2020.

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

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Company's long-term, 52-week open-label Phase 3 safety trial continues to progress, with approximately 185 patients having completed at least 6 months of treatment and over 100 of these patients having completed 1 year of treatment. The Company's 12-week open-label safety trial, launched in the second quarter of 2019, is expected to enroll up to 250 patients.

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

In July 2019, based on the recommendation of the IDMC, 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 pruritus. 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 initiated 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. Top-line data from this trial are expected in 2020.

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

The Company continues to screen patients in the ongoing 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. We aim to have top-line data from this trial in 2020.

#### **Enteris BioPharma, Inc. License Agreement**

In August 2019, the Company entered into a non-exclusive commercial license agreement with Enteris BioPharma, Inc., or Enteris, for oral formulation rights to Enteris' Peptelligence® Technology to develop and commercialize Oral KORSUVA in any indication worldwide, excluding South Korea and Japan. Under the terms of the agreement, the Company paid an upfront fee equal to \$8.0 million, consisting of \$4.0 million in cash and \$4.0 million in shares of the Company's common stock. The Company is also obligated to pay Enteris certain development, regulatory and tiered commercial milestone payments, as well as low, single-digit royalties based on net sales in the licensed territory. Until the second anniversary of the entry into the License Agreement, the Company has the right, but not the obligation, to terminate its obligation to pay any royalties under the License Agreement in exchange for a lump sum payment.

## 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 at \$23.00 per share, including the full exercise of the underwriters' option to purchase 825,000 additional shares of common stock. The Company received net proceeds of approximately \$136.5 million after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company.

## Upcoming Activities

The Company expects to make presentations at the following conferences:

- Kidney Week 2019, November 5-10, 2019 (late breaking oral presentation of pivotal Phase 3 KALM-1 trial results)
- World Congress of Itch, November 17-19, 2019
- Stifel Healthcare Conference, November 19-20, 2019
- Jefferies Global Healthcare Conference, November 20-21, 2019
- Piper Jaffray Healthcare Conference, December 3-5, 2019

## Third Quarter 2019 Financial Results

*Net Loss:* The Company reported a net loss of \$32.8 million, or \$0.74 per basic and diluted share, for the third quarter of 2019 compared to a net loss of \$19.4 million, or \$0.51 per basic and diluted share, for the third quarter of 2018.

*Revenues:* Total revenue of \$5.8 million for the three months ended September 30, 2019 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, or Vifor.

Total revenue of \$5.1 million for the three months ended September 30, 2018 consisted of license and milestone fees revenue of \$5.0 million that was recognized by the Company related to its license agreement with Vifor as well as clinical compound revenue of \$33,000, which was related to the sale of clinical compound to Maruishi Pharmaceutical Co., Ltd.

*Research and Development (R&D) Expenses:* R&D expenses were \$36.0 million for the three months ended September 30, 2019 compared to \$22.3 million for the three months ended September 30, 2018. The higher R&D expenses in 2019 were primarily due to the \$8.0 million upfront payment made upon entering into the license agreement with Enteris, 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 \$4.2 million for the three months ended September 30, 2019 compared to \$3.2 million for the three months ended September 30, 2018. The increase in 2019 was primarily due to increased consultants' costs and accounting fees, as well as increases in stock-based compensation expense.

*Other Income:* Other income was \$1.3 million for the three months ended September 30, 2019 compared to \$1.0 million for the three months ended September 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 September 30, 2019, cash and cash equivalents and marketable securities totaled \$249.1 million compared to \$182.8 million at December 31, 2018. The increase in the balance of cash and cash equivalents and marketable securities primarily resulted from net proceeds of \$136.5 million from the sale of the Company's common stock in a follow-on public offering in July 2019 and proceeds of \$6.1 million from the exercise of stock options, partially offset by cash used in operations of \$78.1 million.

## **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 September 30, 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 third 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 9284479. 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 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 primary biliary cholangitis.

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 potential results of ongoing clinical trials, timing of future regulatory and development milestones for the Company’s product candidates, including the Company’s projected timeline for the submission of its first NDA, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
<b>Revenue:</b>				
License and milestone fees revenue	\$ 5,785	\$ 5,029	\$ 15,235	\$ 7,903
Clinical compound revenue	—	33	140	33
<b>Total revenue</b>	<b>5,785</b>	<b>5,062</b>	<b>15,375</b>	<b>7,936</b>
<b>Operating expenses:</b>				
Research and development	35,992	22,303	83,956	52,732
General and administrative	4,226	3,227	13,128	10,609
<b>Total operating expenses</b>	<b>40,218</b>	<b>25,530</b>	<b>97,084</b>	<b>63,341</b>
<b>Operating loss</b>	<b>(34,433)</b>	<b>(20,468)</b>	<b>(81,709)</b>	<b>(55,405)</b>
Other income	1,261	1,002	3,297	1,780
<b>Loss before benefit from income taxes</b>	<b>(33,172)</b>	<b>(19,466)</b>	<b>(78,412)</b>	<b>(53,625)</b>
Benefit from income taxes	330	66	650	264
<b>Net loss</b>	<b>\$ (32,842)</b>	<b>\$ (19,400)</b>	<b>\$ (77,762)</b>	<b>\$ (53,361)</b>
<b>Net loss per share:</b>				
Basic and Diluted	<b>\$ (0.74)</b>	<b>\$ (0.51)</b>	<b>\$ (1.88)</b>	<b>\$ (1.54)</b>
<b>Weighted average shares:</b>				
Basic and Diluted	<b>44,517,134</b>	<b>38,034,216</b>	<b>41,314,044</b>	<b>34,696,835</b>

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

	September 30, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 34,705	\$ 15,081
Marketable securities	158,384	146,302
Income tax receivable	1,033	664
Other receivables	784	926
Prepaid expenses	8,556	4,805
Restricted cash, current	—	361
Total current assets	<u>203,462</u>	<u>168,139</u>
Operating lease right-of-use asset	3,192	—
Marketable securities, non-current	55,985	21,396
Property and equipment, net	748	880
Restricted cash	408	408
Total assets	<u>\$ 263,795</u>	<u>\$ 190,823</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 20,581	\$ 13,622
Operating lease liability, current	945	—
Current portion of deferred revenue	26,773	26,825
Total current liabilities	<u>48,299</u>	<u>40,447</u>
Operating lease liability, non-current	3,602	—
Deferred revenue, non-current	—	15,184
Deferred lease obligation	—	1,562
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	46	39
Additional paid-in capital	583,811	428,059
Accumulated deficit	(372,116)	(294,354)
Accumulated other comprehensive income (loss)	153	(114)
Total stockholders' equity	<u>211,894</u>	<u>133,630</u>
Total liabilities and stockholders' equity	<u>\$ 263,795</u>	<u>\$ 190,823</u>

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