

# CARA THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

Filed 11/02/17 for the Period Ending 11/02/17

Address	4 STAMFORD PLAZA 107 ELM STREET 9TH FLOOR STAMFORD, CT, 06902
Telephone	203-406-3700
CIK	0001346830
Symbol	CARA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 2, 2017**

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**CARA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**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))

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. .

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

Cara Therapeutics, Inc. (the “Company”) issued a press release on November 2, 2017 announcing its financial results for the third quarter ended September 30, 2017. 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 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, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing. Except as required by law, we undertake no duty or obligation to publicly update or revise the information so furnished.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated November 2, 2017</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: November 2, 2017



## **Cara Therapeutics Reports Third Quarter 2017 Financial Results**

*– Management to host conference call today at 4:30 p.m. ET –*

**STAMFORD, Conn., November 2, 2017** – Cara Therapeutics, Inc. (NASDAQ:CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors, today announced its financial results for the third quarter ended September 30, 2017.

“We are particularly pleased with the progress made in our pruritus program this quarter, including successful completion of our end-of-Phase 2 meeting with the FDA, supporting our plan to initiate our first pivotal Phase 3 efficacy trial of I.V. CR845 for the treatment of CKD-aP in hemodialysis patients in the U.S. by the end of 2017,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “We also recently initiated a Phase 1 study of Oral CR845 in patients with Stage III-V CKD which will inform dose selection and design of our planned Phase 2 trial in this patient population for early in 2018. We believe that CR845 has the potential to provide meaningful benefit to a range of patients suffering from pruritus, including patients with various stages of CKD as well as those with chronic liver disease. In addition, we continue towards full enrollment in the ongoing Phase 3 trial with I.V. CR845 for acute post-operative pain in patients undergoing abdominal surgery.”

### **Third Quarter and Recent Business Highlights**

#### **I.V. CR845: Chronic Kidney Disease Associated Pruritus (CKD-aP): Hemodialysis**

- In October 2017, the Company announced the successful completion of its End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA). The Company, in consultation with the FDA, has established the key elements of the Phase 3 registrational program for the treatment of moderate-to-severe CKD-aP in patients undergoing hemodialysis. The Company expects to initiate the first pivotal trial of I.V. CR845 in hemodialysis patients with CKD-aP in 4Q17.

#### **Oral CR845: Chronic Kidney Disease Associated Pruritus (CKD-aP): Non-Hemodialysis**

- In October 2017, the Company announced dosing of the first patient in a Phase 1 pharmacokinetic and safety trial of Oral CR845 tablets in patients with Stage III-V CKD who are not on dialysis. Data from the trial are expected to inform dose selection and design of the planned Phase 2 trial in non-hemodialysis patients with CKD-aP.

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## **I.V. CR845: Acute Post-Operative Pain**

- The ongoing adaptive Phase 3 trial of I.V. CR845 for the treatment of acute postoperative pain continues to enroll patients undergoing abdominal surgery, with enrollment completion expected by year end 2017 or early 2018.

## **Corporate Update**

- In August 2017, the Company announced the appointment of Mani Mohindru, Ph.D., as Chief Financial Officer and Chief Strategy Officer. Josef Schoell, who had held the CFO position at Cara for more than a decade, retired from the company.

## **Upcoming Activities**

The Company expects to make presentations at the following conferences through November 2017:

- Oral and poster presentation of Phase 2 I.V. CR845 data in CKD-aP at Kidney Week 2017, the American Society of Nephrology's Annual Meeting, on Friday, November 3 and Saturday, November 4, 2017 in New Orleans, LA.
- Late-breaking poster presentation of Phase 2b Oral CR845 data in patients with osteoarthritis of the hip or knee at the American College of Rheumatology ACR/ARHP Annual Meeting on Tuesday, November 7 in San Diego, CA.
- Stifel 2017 Healthcare Conference on Tuesday, November 14, 2017 in New York, NY.
- Jefferies 2017 London Healthcare Conference on Thursday, November 16, 2017 in London, UK.
- 29th Annual Piper Jaffray Healthcare Conference on Tuesday, November 28, 2017 in New York, NY.

## **Third Quarter 2017 Financial Results**

*Net Loss:* The Company reported a net loss of \$12.4 million, or \$0.38 per basic and diluted share, in the third quarter of 2017 compared to a net loss of \$11.5 million, or \$0.42 per basic and diluted share, in the same period of 2016.

*Revenues:* The Company did not recognize any revenue during the third quarter of 2017 or 2016.

*Research and Development (R&D) Expenses:* R&D expenses were \$9.2 million in the third quarter of 2017 compared to \$9.7 million in the same period of 2016. The marginally lower R&D expenses in the third quarter of 2017 were principally due to a net decrease in direct clinical trial costs, partially offset by increases in stock-based compensation and personnel-related costs.

*General and Administrative (G&A) Expenses:* G&A expenses were \$3.8 million in the third quarter of 2017 compared to \$2.1 million in the same period of 2016. The higher G&A expenses in the third quarter of 2017 were principally due to increases in stock-based compensation, personnel-related costs and professional fees.

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*Other Income:* Other income was \$367,000 in the third quarter of 2017 compared to \$176,000 in the third quarter of 2016. The increase in 2017 was primarily due to higher dividend and interest income resulting from higher interest rates on a higher average balance of the Company's portfolio of investments in the 2017 period.

*Cash and Cash Equivalents and Marketable Securities Position:* At September 30, 2017, cash and cash equivalents and marketable securities totaled \$103.0 million compared to \$58.3 million at December 31, 2016. The increase in the balance of cash and cash equivalents and marketable securities primarily resulted from the net proceeds of \$86.2 million from the Company's follow-on public offering of common stock in April 2017 and \$1.5 million received from the exercise of stock options, partially offset by cash used in operations of \$43.4 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 will be sufficient for the Company to fund its operating expenses and capital expenditure requirements into 2019, 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 2017 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 1853199. 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](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 pain and pruritus by selectively targeting peripheral kappa opioid receptors (KORS). Cara is developing a novel and proprietary class of product candidates, led by CR845, a first-in-class KOR agonist that targets the body's peripheral nervous system and certain immune cells. CR845 has demonstrated initial signs of efficacy in patients with moderate-to-severe pain, without inducing many of the undesirable side effects typically associated with currently available opioid pain therapeutics. In Phase 2 trials, CR845 has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in patients with moderate-to-severe chronic kidney disease-associated pruritus.

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**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 Company’s ongoing and planned clinical trials, the potential results of ongoing and planned clinical trials, expected industry and investor presentations 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, 2016 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)

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
<b>Revenue:</b>				
License and milestone fees revenue	\$ —	\$ —	\$ 530	\$ —
Collaborative revenue	—	—	313	—
Clinical compound revenue	—	—	68	86
<b>Total revenue</b>	<b>—</b>	<b>—</b>	<b>911</b>	<b>86</b>
<b>Operating expenses:</b>				
Research and development	9,151	9,671	36,948	28,976
General and administrative	3,805	2,102	8,877	7,195
<b>Total operating expenses</b>	<b>12,956</b>	<b>11,773</b>	<b>45,825</b>	<b>36,171</b>
<b>Operating loss</b>	<b>(12,956)</b>	<b>(11,773)</b>	<b>(44,914)</b>	<b>(36,085)</b>
Interest income	367	176	788	498
Loss before benefit from income taxes	(12,589)	(11,597)	(44,126)	(35,587)
Benefit from income taxes	145	55	178	279
<b>Net loss</b>	<b>\$ (12,444)</b>	<b>\$ (11,542)</b>	<b>\$ (43,948)</b>	<b>\$ (35,308)</b>
<b>Net loss per share:</b>				
Basic and Diluted	<b>\$ (0.38)</b>	<b>\$ (0.42)</b>	<b>\$ (1.43)</b>	<b>\$ (1.29)</b>
<b>Weighted average shares:</b>				
Basic and Diluted	<b>32,591,550</b>	<b>27,282,863</b>	<b>30,729,752</b>	<b>27,275,133</b>



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

	<u>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 11,792	\$ 12,092
Marketable securities	91,190	46,184
Income tax receivable	705	852
Other receivables	97	87
Prepaid expenses	1,492	1,530
Restricted cash, current	700	700
Total current assets	<u>105,976</u>	<u>61,445</u>
Property and equipment, net	1,302	1,614
Restricted cash	769	769
Total assets	<u>\$ 108,047</u>	<u>\$ 63,828</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 7,272	\$ 11,533
Total current liabilities	7,272	11,533
Deferred lease obligation	1,701	1,570
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	33	27
Additional paid-in capital	305,165	212,866
Accumulated deficit	(206,164)	(162,171)
Accumulated other comprehensive income	40	3
Total stockholders' equity	<u>99,074</u>	<u>50,725</u>
Total liabilities and stockholders' equity	<u>\$ 108,047</u>	<u>\$ 63,828</u>

**INVESTOR CONTACT:**

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