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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 3, 2016**

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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 9th Floor**  
**Stamford, Connecticut**  
(Address of principal executive offices)

**06902**  
(Zip Code)

Registrant's telephone number, including area code **(203) 406-3700**

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

Cara Therapeutics, Inc. (the “Company”) issued a press release on November 3, 2016 announcing its financial results for the third quarter ended September 30, 2016. 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

**Exhibit No. Description**

99.1 Press Release dated November 3, 2016

**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/ JOSEF SCHOELL**

Josef Schoell

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: November 3, 2016



## **Cara Therapeutics Reports Third Quarter 2016 Financial Results**

*– Currently enrolling three late stage studies with CR845 totaling over 900 patients –*

*– Top line data expected in 1H 2017 –*

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

**STAMFORD, CONN., November 3, 2016** – Cara Therapeutics, Inc. (Nasdaq:CARA), a biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors, today announced financial results for the third quarter ended September 30, 2016.

“We are pleased to be actively enrolling late stage studies with both IV and oral formulations of CR845 for three significant unmet medical indications,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “2017 will be an exciting and transformative year for the Company as we look forward to sharing top-line data from all three of our late-stage clinical programs.”

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

- In September 2016, announced the initiation of enrollment in a Phase 2b trial of Oral CR845 in approximately 330 patients for the treatment of pain associated with osteoarthritis (OA).
- In September 2016, presented positive data at PAINWeek from the Phase 2a study of Oral CR845 in OA.
- In September and October 2016, hosted industry symposia at PAINWeek and the Orthopaedic Trauma Association 2016 Annual Meeting, respectively, titled “Moving Beyond Mu with Kappa Opioid Receptor Agonists – Leaving the Baggage Behind”, which included data from our 2014 human abuse liability study of I.V. CR845 showing low potential for human abuse.
- In October 2016, initiated Phase 1 study with Oral CR845 in hemodialysis patients.

## Expected 2017 Milestones

- Top-line data expected in the first quarter of 2017 from Part A of the adaptive Phase 2/3 trial of I.V. CR845 in 160 dialysis patients suffering from moderate-to-severe uremic pruritus (UP), an intractable systemic itch condition in patients with chronic kidney disease (CKD), for which there are no approved therapies in the United States.
- Top-line data expected in the first quarter of 2017 from a pharmacokinetic safety trial of multiple doses of Oral CR845 in hemodialysis patients to define bioequivalent tablet strengths to inform the ability to develop an oral tablet formulation for moderate-to-severe UP.
- Top-line data expected in the first half of 2017 from the 330 patient Phase 2b trial of Oral CR845, for the treatment of pain associated with OA.
- Interim conditional power analysis expected in the first half of 2017 from CLIN-3001, Cara's 450 patient adaptive Phase 3 trial of I.V. CR845 in postoperative pain.

## Third Quarter 2016 Financial Results

*Net Loss:* The Company reported a net loss of \$11.5 million, or \$0.42 per basic and diluted share, for the third quarter of 2016 compared to a net loss of \$4.8 million, or \$0.19 per basic and diluted share, for the same period of 2015.

*Revenues:* The Company did not recognize any revenue during the third quarter of 2016. During the third quarter of 2015, total revenue recognized was \$2.4 million, including \$1.7 million of license and milestone fees revenue and \$730,000 of collaborative revenue, comprising revenue which was earned upon achievement of defined milestones under the license agreements with Maruishi Pharmaceutical Company Ltd. ("Maruishi") and Chong Kun Dang Pharmaceutical Company, as well as revenue that had been deferred upon entry into the license agreement with Maruishi.

*Research and Development (R&D) Expenses:* R&D expenses were \$9.7 million in the third quarter of 2016 compared to \$5.6 million in the same period of 2015. The higher R&D expenses in the third quarter of 2016 were principally due to a net increase in direct clinical trial costs, consultant services in support of clinical trials and an increase in payroll and related costs for R&D personnel.

*General and Administrative (G&A) Expenses:* G&A expenses were \$2.1 million in the third quarter of 2016 compared to \$1.9 million in the same period of 2015. The increase in the third quarter of 2016 was primarily due to increases in payroll and related costs and in franchise taxes.

*Other Income:* Other income was \$176,000 during the third quarter of 2016, which included interest income and dividends earned on cash and cash equivalents and marketable securities and realized gains on the sale of marketable securities, compared to \$22,000 of

interest income during the same period in 2015. The increase in the third quarter ended September 30, 2016 was primarily due to investments in marketable securities in the 2016 period but not in the 2015 period, as well as higher interest rates in 2016 on the Company's money market account balances compared with interest rates in 2015.

*Cash and Cash Equivalents and Marketable Securities Position:* As of September 30, 2016, cash and cash equivalents and marketable securities totaled \$71.4 million compared to \$106.7 million at December 31, 2015. The decrease in the balance of cash and cash equivalents and marketable securities primarily resulted from \$34.2 million of cash used in operating activities.

### **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, 2016 will be sufficient for the Company to fund its operating expenses and capital expenditure requirements through the end of the first quarter of 2018, 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 its third quarter 2016 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 90388150. 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 biotechnology company focused on developing and commercializing new chemical entities designed to alleviate pain and pruritus by selectively targeting peripheral kappa opioid receptors. Cara is developing a novel and proprietary class of product candidates that target the body's peripheral nervous system and have demonstrated initial efficacy in patients with moderate-to-severe pain without inducing many of the undesirable side effects typically associated with currently available pain therapeutics.

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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 and trial designs of the Company’s planned clinical trials, the potential results of ongoing and planned clinical trials, future development milestones for the Company’s product candidates 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, 2015 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,	
	2016	2015	2016	2015
Revenue:				
License and milestone fees revenue	\$ —	\$ 1,710	\$ —	\$ 1,710
Collaborative revenue	—	730	—	2,093
Clinical compound revenue	—	—	86	—
Total revenue	<u>—</u>	<u>2,440</u>	<u>86</u>	<u>3,803</u>
Operating expenses:				
Research and development	9,671	5,584	28,976	13,653
General and administrative	2,102	1,865	7,195	5,609
Total operating expenses	<u>11,773</u>	<u>7,449</u>	<u>36,171</u>	<u>19,262</u>
Operating loss	(11,773)	(5,009)	(36,085)	(15,459)
Other income	176	22	498	49
Loss before benefit from income taxes	(11,597)	(4,987)	(35,587)	(15,410)
Benefit from income taxes	55	200	279	250
Net loss	<u>\$ (11,542)</u>	<u>\$ (4,787)</u>	<u>\$ (35,308)</u>	<u>\$ (15,160)</u>
Net loss per share:				
Basic and Diluted	<u>\$ (0.42)</u>	<u>\$ (0.19)</u>	<u>\$ (1.29)</u>	<u>\$ (0.64)</u>
Weighted average shares:				
Basic and Diluted	<u>27,282,863</u>	<u>25,545,164</u>	<u>27,275,133</u>	<u>23,737,443</u>



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

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 5,426	\$ 15,101
Marketable securities	65,994	91,640
Income tax receivable	663	384
Other receivables	115	80
Prepaid expenses	4,820	1,729
<b>Total current assets</b>	<b>77,018</b>	<b>108,934</b>
Property and equipment, net	1,665	1,263
Restricted cash	1,469	700
<b>Total assets</b>	<b><u>\$ 80,152</u></b>	<b><u>\$ 110,897</u></b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 6,825	\$ 5,268
<b>Total current liabilities</b>	<b>6,825</b>	<b>5,268</b>
Deferred lease obligation	1,525	585
<b>Commitments and contingencies</b>	<b>—</b>	<b>—</b>
<b>Stockholders' equity:</b>		
Preferred stock	—	—
Common stock	27	27
Additional paid-in capital	211,954	209,943
Accumulated deficit	(140,199)	(104,891)
Accumulated other comprehensive income (loss)	20	(35)
<b>Total stockholders' equity</b>	<b>71,802</b>	<b>105,044</b>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 80,152</u></b>	<b><u>\$ 110,897</u></b>

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