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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) May 5, 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.)

**1 Parrott Drive**  
**Shelton, Connecticut**  
(Address of principal executive offices)

**06484**  
(Zip Code)

**Registrant's telephone number, including area code (203) 567-1500**

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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 May 5, 2016 announcing its financial results for the first quarter ended March 31, 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

| <b>Exhibit No.</b> | <b>Description</b>              |
|--------------------|---------------------------------|
| 99.1               | Press Release dated May 5, 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: May 5, 2016



## Cara Therapeutics Reports First Quarter 2016 Financial Results

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

**SHELTON, CONN., May 5, 2016** – Cara Therapeutics, Inc. (NASDAQ: CARA), 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, today announced financial results for the first quarter ended March 31, 2016.

“We look forward to reinitiating our adaptive pivotal trial of I.V. CR845 for postoperative pain this month,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “We also remain on track to initiate our registration program for I.V. CR845 in hemodialysis patients suffering from uremic pruritus during the second quarter of 2016, and a Phase 2b trial of Oral CR845 in chronic pain in the second half of 2016. This will significantly expand our later-stage pipeline in indications in which we have already seen positive proof-of-concept data.”

### First Quarter and Recent Business Highlights

- In April 2016, announced removal of clinical hold on the adaptive pivotal trial of I.V. CR845 for postoperative pain (CLIN3001).
- In February 2016, presented a poster at the American Academy of Pain Medicine’s 32<sup>nd</sup> Annual Meeting detailing data from Cara’s human abuse liability study of I.V. CR845.

### Expected Upcoming Milestones

- Resumption of patient enrollment in the adaptive pivotal trial of I.V. CR845 for postoperative pain expected in May 2016. Based on a safety review and an analysis of efficacy trends from the first 90 patients dosed, the trial will continue as a three-arm trial, testing two doses of CR845 (1.0 ug/kg and 0.5 ug/kg) versus placebo.
- Initiation of a registration program for I.V. CR845 in hemodialysis patients suffering from moderate-to-severe uremic pruritus during the second quarter of 2016. The trial will be a two-part Phase 2/3 adaptive design:
  - Part A will be a randomized, double-blind, placebo-controlled trial in 160 patients of three doses of I.V. CR845 (anchored around 1.0 ug/kg) administered three times per week after dialysis over an eight-week period. Part B will be a randomized double-blind placebo-controlled trial in up to 240 patients of one optimized dose of I.V. CR845 administered three times per week after dialysis over a 12-week treatment period.

- The primary endpoint will be reduction in worst itching scores from baseline values measured on a standard Numeric Rating Scale alongside secondary quantitative quality of life endpoints.
- Initiation of a pharmacokinetic safety trial of multiple doses of Oral CR845 in hemodialysis patients to define bioequivalent tablet strengths to inform the Company's ability to develop an oral tablet formulation for moderate-to-severe uremic pruritus.
- Initiation of a Phase 2b trial of Oral CR845 in osteoarthritis patients during the second half of 2016:
  - The trial will be a double-blind, multiple-dose Phase 2b trial with twice-daily doses of Oral CR845 administered over an eight-week treatment period in osteoarthritis patients with moderate-to-severe pain.
  - The trial will include 330 patients randomized across three CR845 tablet strengths and a placebo arm at 15 sites across the United States.
- Presentations at the American Pain Society's 35<sup>th</sup> Annual Scientific Meeting in Austin, Texas, May 12 and 13, 2016. Leading experts will discuss the clinical progress and share acute and chronic pain management data from multiple studies of Oral and I.V. formulations of CR845.
- Platform Presentation titled "Kappa Opioid Receptor Agonists (KORAs), a Novel Pharmacology for the Treatment of Acute and Chronic Pain" at the International Conference on Opioids in Boston, MA, June 5, 2016.

### **First Quarter 2016 Financial Results**

*Net Loss:* The Company reported a net loss of \$10.7 million, or \$0.39 per basic and diluted share, for the first quarter of 2016 compared to a net loss of \$4.7 million, or \$0.21 per basic and diluted share, for the same period of 2015.

*Revenues:* The Company recognized \$7,000 of clinical compound revenue during the first quarter of 2016 from the sale of clinical compound to Maruishi Pharmaceutical Company Ltd. ("Maruishi"). For the first quarter of 2015, collaborative revenue was \$489,000, comprising revenue that had been deferred upon entry into the license agreement with Maruishi.

*Research and Development (R&D) Expenses:* R&D expenses were \$8.5 million in the first quarter of 2016 compared to \$3.4 million in the same period of 2015. The higher R&D expenses in the first quarter of 2016 were principally due to a net increase in direct preclinical studies and clinical trial costs, consultant services in support of preclinical studies and clinical trials, an increase in payroll and related costs for R&D personnel, the acceleration of amortization of the leasehold improvements at our Shelton, Connecticut facility prior to the relocation of our corporate headquarters to Stamford, Connecticut and increased rent.

*General and Administrative (G&A) Expenses:* G&A expenses were \$2.4 million in the first quarter of 2016 compared to \$1.8 million in the same period of 2015. The increase in the first quarter of 2016 was primarily due to increases in payroll and related costs, in investor relation costs and in professional and consultant fees, in franchise taxes and in rent and the acceleration of amortization of the leasehold improvements as noted above.

*Other Income (Expense), net:* Other income was \$149,000 of interest income and dividends earned on cash and cash equivalents and marketable securities during the first quarter of 2016 compared to \$14,000 of interest income during the same period in 2015. The increase in the first quarter ended March 31, 2016 was primarily due to an increase in interest income and dividends earned on a more diverse portfolio of investments in 2016, including marketable securities, as well as higher interest rates on a higher average balance of cash and cash equivalents and marketable securities in 2016 as a result of our follow-on offering of common stock, which closed in August 2015.

*Cash and Cash Equivalents and Marketable Securities Position:* As of March 31, 2016, cash and cash equivalents and marketable securities totaled \$96.2 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 \$9.8 million of cash used in operations and \$0.8 million of cash that was restricted to serve as collateral for the letter of credit issued to the landlord of our Stamford, Connecticut lease.

### **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, 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 first 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 1233026. 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.

### **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 timing of the resumption of the CLIN3001 trial, the expected timing and trial designs of the Company's other 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.**  
**STATEMENTS OF OPERATIONS**  
(amounts in thousands, except share and per share data)  
(unaudited)

|  | <b>Three Months Ended March 31,</b> |                   |
|--|-------------------------------------|-------------------|
|  | <b>2016</b>                         | <b>2015</b>       |
| <b>Revenue:</b>                              |                                     |                   |
| Collaborative revenue                        | \$ —                                | \$ 489            |
| Clinical compound revenue                    | 7                                   | —                 |
| <b>Total revenue</b>                         | <u>7</u>                            | <u>489</u>        |
| <b>Operating expenses:</b>                   |                                     |                   |
| Research and development                     | 8,546                               | 3,385             |
| General and administrative                   | 2,447                               | 1,822             |
| <b>Total operating expenses</b>              | <u>10,993</u>                       | <u>5,207</u>      |
| <b>Operating loss</b>                        | <u>(10,986)</u>                     | <u>(4,718)</u>    |
| Interest income                              | 149                                 | 14                |
| <b>Loss before benefit from income taxes</b> | <u>(10,837)</u>                     | <u>(4,704)</u>    |
| Benefit from income taxes                    | 145                                 | 15                |
| <b>Net loss</b>                              | <u>\$ (10,692)</u>                  | <u>\$ (4,689)</u> |
| <b>Loss per share:</b>                       |                                     |                   |
| Basic and Diluted                            | <u>\$ (0.39)</u>                    | <u>\$ (0.21)</u>  |
| <b>Weighted average shares:</b>              |                                     |                   |
| Basic and Diluted                            | 27,259,589                          | 22,808,479        |



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

|   | March 31,<br>2016 | December 31,<br>2015 |
|---|-------------------|----------------------|
| <b>Assets</b>                                 |                   |                      |
| Current assets:                               |                   |                      |
| Cash and cash equivalents                     | \$ 7,922          | \$ 15,101            |
| Marketable securities                         | 88,322            | 91,640               |
| Income tax receivable                         | 529               | 384                  |
| Other receivables                             | 128               | 80                   |
| Prepaid expenses                              | 2,573             | 1,729                |
| Total current assets                          | 99,474            | 108,934              |
| Property and equipment, net                   | 1,070             | 1,263                |
| Restricted cash                               | 1,469             | 700                  |
| Total assets                                  | <u>\$ 102,013</u> | <u>\$ 110,897</u>    |
| <b>Liabilities and stockholders' equity</b>   |                   |                      |
| Current liabilities:                          |                   |                      |
| Accounts payable and accrued expenses         | \$ 6,089          | \$ 5,268             |
| Total current liabilities                     | 6,089             | 5,268                |
| Deferred lease obligation                     | 997               | 585                  |
| Commitments and contingencies                 |                   |                      |
| Stockholders' equity:                         |                   |                      |
| Preferred stock                               | —                 | —                    |
| Common stock                                  | 27                | 27                   |
| Additional paid-in capital                    | 210,479           | 209,943              |
| Accumulated deficit                           | (115,583)         | (104,891)            |
| Accumulated other comprehensive income (loss) | 4                 | (35)                 |
| Total stockholders' equity                    | 94,927            | 105,044              |
| Total liabilities and stockholders' equity    | <u>\$ 102,013</u> | <u>\$ 110,897</u>    |

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