
**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) August 4, 2016

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

Cara Therapeutics, Inc. (the “Company”) issued a press release on August 4, 2016 announcing its financial results for the second quarter ended June 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 August 4, 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: August 4, 2016



Cara Therapeutics Reports Second Quarter 2016 Financial Results

- Resumed patient enrollment in adaptive pivotal trial of I.V. CR845 in post-operative pain –
- Initiated adaptive Phase 2/3 trial for I.V. CR845 in dialysis patients with uremic pruritus –
- Initiation of Phase 2b trial of Oral CR845 in osteoarthritis patients expected in Q3, 2016 –
– Conference call today at 4:30 p.m. ET –

STAMFORD, CONN., August 4, 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 second quarter ended June 30, 2016.

“This quarter we were pleased to resume enrollment in the adaptive pivotal trial of I.V. CR845 for postoperative pain, as well as initiate our adaptive Phase 2/3 trial in dialysis patients suffering from moderate-to-severe uremic pruritus,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “With both studies enrolling on schedule and our Phase 2b trial of Oral CR845 in osteoarthritis expected to begin in the third quarter of this year, Cara will soon have three ongoing late-stage studies addressing distinct clinical populations.”

Second Quarter and Recent Business Highlights

- In June 2016, resumed patient enrollment for the adaptive Phase 3 trial of I.V. CR845 in postoperative pain. The trial continues as a three-arm trial testing two doses of CR845 (1.0 ug/kg and 0.5 ug/kg) versus placebo.
- In June 2016, initiated an adaptive Phase 2/3 trial of I.V. CR845 for the treatment of chronic kidney disease-associated, or uremic, pruritus, for which there are no approved therapies in the United States.

- Presented positive data from the Phase 2a study of the oral formulation of CR845 in osteoarthritis patients, as well as data from the human abuse liability study of I.V. CR845 showing low potential for human abuse at the 2016 International Conference on Opioids.

Expected Upcoming Milestones

- Initiation of a Phase 2b trial of Oral CR845 in osteoarthritis patients during the third quarter of 2016:
 - i 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 patients with moderate-to-severe osteoarthritis pain.
 - i The trial will include 15 trial sites across the United States, with 330 patients randomized across three CR845 tablet strengths and a placebo arm.
- Initiation of a pharmacokinetic safety trial of multiple doses of Oral CR845 in hemodialysis patients to define bioequivalent tablet strengths to inform our ability to develop an oral tablet formulation for moderate-to-severe uremic pruritus.

Second Quarter 2016 Financial Results

Net Loss: The Company reported a net loss of \$13.1 million, or \$0.48 per basic and diluted share, for the second quarter of 2016 compared to a net loss of \$5.7 million, or \$0.25 per basic and diluted share, for the same period of 2015.

Revenues: The Company recognized \$79,000 of clinical compound revenue during the second quarter of 2016 from the sale of clinical compound to Maruishi Pharmaceutical Company Ltd. (“Maruishi”). For the second quarter of 2015, collaborative revenue was \$874,000, comprising revenue that had been deferred upon entry into the license agreement with Maruishi.

Research and Development (R&D) Expenses: R&D expenses were \$10.8 million in the second quarter of 2016 compared to \$4.7 million in the same period of 2015. The higher R&D expenses in the second 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 the Company’s Shelton, Connecticut facility prior to the relocation of the Company’s corporate headquarters to Stamford, Connecticut in May 2016 and increased rent, including rent expense for the Stamford lease for the second quarter of 2016 and the remaining rent payments due for the Shelton lease through its term.

General and Administrative (G&A) Expenses: G&A expenses were \$2.6 million in the second quarter of 2016 compared to \$1.9 million in the same period of 2015. The increase in the second quarter of 2016 was primarily due to increases in payroll and related costs, in franchise taxes and in rent and the acceleration of amortization of the leasehold improvements, as noted above.

Other Income: Other income was \$172,000 of interest income and dividends earned on cash and cash equivalents and marketable securities during the second quarter of 2016 compared to \$13,000 of interest income during the same period in 2015. The increase in the second quarter ended June 30, 2016 was primarily due to our investments in marketable securities in the 2016 period but not in the 2015 period, 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 the Company's follow-on offering of common stock, which closed in August 2015.

Cash and Cash Equivalents and Marketable Securities Position: As of June 30, 2016, cash and cash equivalents and marketable securities totaled \$84.8 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 \$21.3 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 June 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 second 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 50082596. 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.

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 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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenue:				
Collaborative revenue	\$ —	\$ 874	\$ —	\$ 1,363
Clinical compound revenue	79	—	86	—
Total revenue	<u>79</u>	<u>874</u>	<u>86</u>	<u>1,363</u>
Operating expenses:				
Research and development	10,760	4,684	19,305	8,069
General and administrative	2,645	1,922	5,092	3,744
Total operating expenses	<u>13,405</u>	<u>6,606</u>	<u>24,397</u>	<u>11,813</u>
Operating loss	<u>(13,326)</u>	<u>(5,732)</u>	<u>(24,311)</u>	<u>(10,450)</u>
Interest income	172	13	321	27
Loss before benefit from income taxes	<u>(13,154)</u>	<u>(5,719)</u>	<u>(23,990)</u>	<u>(10,423)</u>
Benefit from income taxes	79	35	224	50
Net loss	<u>\$ (13,075)</u>	<u>\$ (5,684)</u>	<u>\$ (23,766)</u>	<u>\$ (10,373)</u>
Net loss per share:				
Basic and Diluted	<u>\$ (0.48)</u>	<u>\$ (0.25)</u>	<u>\$ (0.87)</u>	<u>\$ (0.45)</u>
Weighted average shares:				
Basic and Diluted	<u>27,282,863</u>	<u>22,828,612</u>	<u>27,271,226</u>	<u>22,818,601</u>

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

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,545	\$ 15,101
Marketable securities	81,219	91,640
Income tax receivable	608	384
Other receivables	373	80
Prepaid expenses	3,398	1,729
Total current assets	89,143	108,934
Property and equipment, net	1,433	1,263
Restricted cash	1,469	700
Total assets	\$ 92,045	\$ 110,897
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,168	\$ 5,268
Total current liabilities	8,168	5,268
Deferred lease obligation	1,289	585
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	27	27
Additional paid-in capital	211,177	209,943
Accumulated deficit	(128,657)	(104,891)
Accumulated other comprehensive income (loss)	41	(35)
Total stockholders' equity	82,588	105,044
Total liabilities and stockholders' equity	\$ 92,045	\$ 110,897

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