
**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) March 10, 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.)

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

06484
(Zip Code)

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

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 March 10, 2016 announcing its financial results for the fourth quarter and year ended December 31, 2015. 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 March 10, 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: March 10, 2016



**Cara Therapeutics Reports Fourth Quarter and Full Year 2015
Financial Results**

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

SHELTON, CONN., March 10, 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 kappa opioid receptors, today announced financial results for the fourth quarter and full year ended December 31, 2015.

“2015 was full of important development milestones, as we initiated an adaptive pivotal trial of I.V. CR845 in acute postoperative pain following abdominal surgery, met the primary endpoint in our Phase 2 study of I.V. CR845 in uremic pruritus, and demonstrated positive Phase 2a data on Oral CR845 in osteoarthritis patients,” said Derek Chalmers, Ph.D., D.Sc. President and Chief Executive Officer of Cara Therapeutics.

“We look forward to promptly resolving the IND clinical hold on our CLIN3001 trial in postoperative pain. Furthermore, we believe our strong balance sheet enables us to continue to execute on all of our planned clinical development activities for I.V. and Oral CR845.”

Fourth Quarter and Recent Business Highlights

- In February 2016, announced that the FDA had placed the Company’s CLIN3001 adaptive pivotal trial of I.V. CR845 in postoperative pain on clinical hold following the observation of rises in serum sodium in four patients in the highest dose group of the trial, which triggered a stopping rule and pre-specified safety review. No CR845-associated serious adverse events have been observed to date, and all four patients were asymptomatic with sodium levels resolving to normal levels within 24 hours post-dosing with standard fluid management.
- In February 2016, presented a poster at the American Academy of Pain Medicine’s 32nd Annual Meeting detailing data from Cara’s human abuse liability study of I.V. CR845.
- In December 2015, completed a guidance meeting with the U.S. Food and Drug Administration (FDA) to inform the design of a registration program for I.V. CR845 for the treatment of uremic pruritus.
- In December 2015, presented a poster at the American Society of Health-System Pharmacists (ASHP) 2015 Midyear Clinical Meeting, which included positive postoperative nausea and vomiting results seen in Cara’s Phase 2 studies of I.V. CR845 in acute postoperative pain.

- In December 2015, reported positive top-line results from Phase 2a trial of Oral CR845 in osteoarthritis (OA) patients with a dose-related reduction observed in the mean baseline pain score of up to 34 percent after two weeks, with a statistically significant reduction in mean rescue medication for the top 5.0 mg dose. All four tablet strengths were observed to be safe and well tolerated.
- In November 2015, presented a late-breaking poster at Kidney Week 2015, the American Society of Nephrology's Annual Meeting, on the Company's positive Phase 2 results for I.V. CR845 in uremic pruritus.

Expected Upcoming Milestones

- Type A meeting with FDA to discuss CLIN3001 trial in postoperative pain and address current IND clinical hold during the second quarter of 2016.
- Initiation of a registration program for CR845 in dialysis patients suffering from uremic pruritus during the first half of 2016.
- Initiation of a Phase 2b trial of Oral CR845 in chronic pain during the second half of 2016.

Fourth Quarter 2015 Financial Results

Net Loss: The Company reported a net loss of \$9.5 million, or \$0.35 per basic and diluted share, for the fourth quarter of 2015 compared to a net loss of \$4.2 million, or \$0.18 per basic and diluted share, for the same period of 2014.

Revenues: The Company did not recognize any revenues during the fourth quarter of 2015. For the fourth quarter of 2014, collaborative revenue was \$399,000, comprising revenue that had been deferred upon entry into the license agreement with Maruishi Pharmaceutical Company Ltd. and clinical compound revenue was \$515,000 from the sale of clinical compound to Maruishi.

Research and Development (R&D) Expenses: R&D expenses were \$7.6 million in the fourth quarter of 2015 compared to \$3.5 million in the same period of 2014. The higher R&D expenses in the fourth quarter of 2015 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, and an increase in payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were \$2.2 million in the fourth quarter of 2015 compared to \$1.8 million in the same period of 2014. The increase in the fourth quarter of 2015 was primarily due to increases in payroll and related costs and stock option expense. Those increases in costs were partially offset by decreases in professional and consultant fees.

Full Year 2015 Financial Results

Net Loss: The Company reported a net loss of \$24.7 million, or \$1.00 per basic and diluted share, for 2015 compared to a net loss of \$17.7 million, or \$0.85 per basic and diluted share for 2014.

Revenues: License and milestone fees revenue was \$1.7 million for 2015 (representing \$1.1 million of the \$1.7 million milestone payment earned in September 2015 under the Maruishi License Agreement, which was attributable to the previously delivered license, and \$600,000 from the two milestone payments earned by the Company under the CKD License Agreement in July and September 2015) compared to \$302,000 for 2014 (representing the earned portion of the milestone payment received from Maruishi).

Collaborative revenue was \$2.1 million for 2015 (consisting of \$600,000 of the \$1.7 million milestone payment earned in September 2015 under the Maruishi License Agreement, which was attributable to the fully delivered R&D services deliverable, and \$1.5 million of revenue that had been deferred upon entry into the Maruishi License Agreement) compared to \$2.2 million for 2014 (comprising revenue that had been deferred upon entry into the Maruishi License Agreement).

Clinical compound revenue for 2015 and 2014 was \$0 and \$674,000, respectively, from the sale of clinical compound to Maruishi.

Research and Development (R&D) Expenses: R&D expenses were \$21.2 million in 2015 compared to \$15.1 million in 2014. The higher R&D expenses in 2015 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, and an increase in payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were \$7.8 million in 2015 compared to \$6.2 million in 2014. The increase in 2015 was primarily due to increases in payroll and related costs, mostly due to increases in headcount, public/investor relations costs, insurance costs, professional fees, including legal fees and accounting and audit fees and stock option expense. Those increases were partially offset by a decrease in consultant fees.

Other Income (Expense), net: Other income was \$101,000 of interest income and dividends earned on cash and cash equivalents, marketable securities and restricted cash in 2015 compared to \$126,000 of interest income in 2014. The decrease from the year ended December 31, 2014 was due to lower interest rates on a higher average balance in 2015.

Cash and Cash Equivalents and Marketable Securities Position: At December 31, 2015, cash and cash equivalents and marketable securities totaled \$106.7 million, compared to \$52.7 million at December 31, 2014. The increase in the balance of cash and cash equivalents and marketable securities resulted from the receipt of net proceeds of \$75.2 million from the Company's follow-on offering of common stock which closed in August 2015, cash received from the exercise of stock options of \$300,000, partially offset by \$21.5 million of cash used in operations.

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 December 31, 2015 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 fourth quarter and full year 2015 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 56780146. 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 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 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 for the Company’s holding of a Type A meeting with the FDA to discuss the IND clinical hold, the potential removal of the clinical hold and resumption of the CLIN3001 trial, the expected timing of the Company’s other planned clinical trials, the potential results of ongoing and planned clinical trials, future regulatory and 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Revenue:				
License and milestone fees	\$ —	\$ —	\$ 1,710	\$ 302
Collaborative revenue	—	399	2,093	2,201
Clinical compound revenue	—	515	—	674
Total revenue	—	914	3,803	3,177
Operating expenses:				
Research and development	7,568	3,459	21,221	15,068
General and administrative	2,161	1,791	7,770	6,181
Total operating expenses	9,729	5,250	28,991	21,249
Operating loss	(9,729)	(4,336)	(25,188)	(18,072)
Other income (expense), net	52	22	101	126
Loss before benefit from income taxes	(9,677)	(4,314)	(25,087)	(17,946)
Benefit from income taxes	147	142	397	201
Net loss	\$ (9,530)	\$ (4,172)	\$ (24,690)	\$ (17,745)
Net loss per share :				
Basic and Diluted	\$ (0.35)	\$ (0.18)	\$ (1.00)	\$ (0.85)
Weighted average shares:				
Basic and Diluted	27,240,369	22,790,676	24,620,372	20,965,935

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

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 15,101	\$ 52,663
Marketable securities	91,640	—
Income tax receivable	384	200
Interest receivable	80	—
Prepaid expenses	1,729	287
Total current assets	108,934	53,150
Property and equipment, net	1,263	2,084
Restricted cash	700	700
Total assets	<u>\$ 110,897</u>	<u>\$ 55,934</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,268	\$ 1,946
Deferred Revenue	—	1,452
Total current liabilities	5,268	3,398
Deferred lease obligation	585	874
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	27	23
Additional paid-in capital	209,943	131,840
Accumulated deficit	(104,891)	(80,201)
Accumulated other comprehensive loss	(35)	—
Total stockholders' equity	105,044	51,662
Total liabilities and stockholders' equity	<u>\$ 110,897</u>	<u>\$ 55,934</u>

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