
**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) May 4, 2017

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))

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.

Item 2.02. Results of Operations and Financial Condition.

Cara Therapeutics, Inc. (the “Company”) issued a press release on May 4, 2017 announcing its financial results for the first quarter ended March 31, 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	Press Release dated May 4, 2017

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 4, 2017



Cara Therapeutics Reports First Quarter 2017 Financial Results

- *Reported statistically significant positive top-line results from Part A of Phase 2/3 trial for I.V. CR845 in chronic kidney disease (CKD)-associated pruritus –*
- *Completed public offering of common stock, raising net proceeds of \$86.5 million –*
- *Conference call today at 4:30 p.m. ET –*

STAMFORD, CONN., May 4, 2017 – 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 first quarter ended March 31, 2017.

“During the quarter, we were pleased to announce positive data from Part A of our Phase 2/3 trial of I.V. CR845 in CKD-associated pruritus, where we observed sustained clinical benefit over the entire two-month treatment period, supporting the potential viability of I.V. CR845 as a long-term therapeutic approach for this unmet medical need,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “In addition to completing a successful follow on offering to support operations into 2019, our other late-stage trials continue to enroll well, and we look forward to completing an interim assessment in our adaptive Phase 3 postoperative pain trial of I.V. CR845, as well as reporting data from our Phase 2b chronic pain trial of Oral CR845 this quarter.”

First Quarter and Recent Business Highlights

- In March 2017, announced positive top-line data from Part A of Phase 2/3 trial of I.V. CR845 in chronic kidney disease (CKD)-associated pruritus, demonstrating improved symptoms and quality of life in 174 patients.
 - Met primary endpoint with 68 percent reduction in worst itching scores versus placebo after eight-week treatment period ($p < 0.0019$)
 - Met secondary endpoint with 100 percent improvement in quality of life domains versus placebo after eight-week treatment period ($p < 0.0007$)

- In April 2017, Cara completed a public offering of 5,117,500 shares of its common stock, including full exercise of the underwriters' option to purchase additional shares at \$18.00 per share, raising approximately \$86.5 million in net proceeds after deducting underwriting discounts and commissions, but before deducting estimated offering expenses payable by the Company.
- In April 2017, reported positive results from Phase a1 safety trial observing that I.V. CR845 did not significantly differ from placebo across three quantitative measures of respiratory drive in healthy individuals.

Expected Upcoming Milestones

- Top-line data expected in the second quarter of 2017 from the Phase 2b trial of Oral CR845, for the treatment of chronic pain associated with osteoarthritis.
- Interim conditional power analysis expected in the second quarter of 2017 from CLIN-3001, the Company's 450-patient adaptive Phase 3 trial of I.V. CR845 in postoperative pain.
- Data expected in the second 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 uremic pruritus.
- Initiation of an open-label 52-week safety study of I.V. CR845 in hemodialysis patients as part of the pivotal program in CKD-associated pruritus in the second quarter of 2017.
- Request an End of Phase 2 meeting with the U.S. Food and Drug Administration to discuss trial design for Part B of CKD-associated pruritus study.

First Quarter 2017 Financial Results

Net Loss: The Company reported a net loss of \$22.2 million, or \$0.81 per basic and diluted share, for the first quarter of 2017 compared to a net loss of \$10.7 million, or \$0.39 per basic and diluted share, for the same period of 2016.

Revenues: In the first quarter of 2017, the Company earned revenue of \$843 thousand in connection with the sub-license by Maruishi Pharmaceutical Co. Ltd., or Maruishi, of the Company's intellectual property related to CR845 for use in patients with uremic pruritus in Japan. Of that amount, \$530 thousand was recognized as milestone and license fees revenue and \$313 thousand as collaborative revenue. In addition, the Company recognized \$68 thousand and \$7 thousand from the sale of clinical compound to Maruishi during the first quarter of 2017 and 2016, respectively.

Research and Development (R&D) Expenses: R&D expenses were \$20.8 million in the first quarter of 2017 compared to \$8.5 million in the same period of 2016. The higher R&D expenses in the first quarter of 2017 were principally due to a net increase in direct clinical trial costs and an increase in payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were \$2.4 million in both the first quarter of 2017 and 2016, representing decreases in professional fees and public/investor relations costs and depreciation and amortization expense, which were offset by increases in stock-based compensation and payroll and related costs.

Other Income: Other income was \$90,000 in the first quarter of 2017 compared to \$149,000 in the first quarter of 2016. The decrease in 2017 was primarily due to lower dividend income earned on the lower average balance of our portfolio of investments.

Cash and Cash Equivalents and Marketable Securities Position: At March 31, 2017, cash and cash equivalents and marketable securities totaled \$36.8 million compared to \$58.3 million at December 31, 2016. The decrease in the balance of cash and cash equivalents and marketable securities primarily resulted from cash used in operations of \$21.6 million.

In April 2017, the Company completed a public offering of 5,117,500 shares of common stock, including full exercise of the underwriters' option to purchase additional shares at \$18.00 per share, raising approximately \$86.5 million in net proceeds after deducting underwriting discounts and commissions but before deducting estimated offering expenses payable by the Company.

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 first 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 10052639. 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, led by CR845, that target the body's peripheral nervous system and have demonstrated, in Phase 2 trials, preliminary efficacy in patients with moderate-to-severe pain and pruritus 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 of the Company’s 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, 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.
STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2017	2016
Revenue:		
License and milestone fees	\$ 530	\$ —
Collaborative revenue	313	—
Clinical compound revenue	68	7
Total revenue	911	7
Operating expenses:		
Research and development	20,836	8,546
General and administrative	2,400	2,447
Total operating expenses	23,236	10,993
Operating loss	(22,325)	(10,986)
Other income	90	149
Loss before benefit from income taxes	(22,235)	(10,837)
Benefit from income taxes	31	145
Net loss	<u>\$ (22,204)</u>	<u>\$ (10,692)</u>
Net loss per share :		
Basic and Diluted	\$ (0.81)	\$ (0.39)
Weighted average shares:		
Basic and Diluted	27,299,678	27,259,589

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

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,306	\$ 12,092
Marketable securities	31,504	46,184
Income tax receivable	558	852
Other receivables	984	87
Prepaid expenses	1,979	1,530
Restricted cash, current	700	700
Total current assets	<u>41,031</u>	<u>61,445</u>
Property and equipment, net	1,499	1,614
Restricted cash	769	769
Total assets	<u>\$ 43,299</u>	<u>\$ 63,828</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 12,512	\$ 11,533
Total current liabilities	12,512	11,533
Deferred lease obligation	1,518	1,570
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	27	27
Common stock subscribed in a follow-on offering	5	—
Additional paid-in capital	300,151	212,866
Subscriptions receivable	(86,518)	—
Accumulated deficit	(184,420)	(162,171)
Accumulated other comprehensive income	24	3
Total stockholders' equity	<u>29,269</u>	<u>50,725</u>
Total liabilities and stockholders' equity	<u>\$ 43,299</u>	<u>\$ 63,828</u>

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