

CARA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/03/17 for the Period Ending 08/03/17

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| Address | 4 STAMFORD PLAZA 107 ELM STREET 9TH FLOOR STAMFORD, CT 06902 |
| Telephone | 203-406-3700 |
| CIK | 0001346830 |
| Symbol | CARA |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Medical Research |
| Sector | Healthcare |
| Fiscal Year | 12/31 |

**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 3, 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 August 3, 2017 announcing its financial results for the second quarter ended June 30, 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

| Exhibit No. | Description |
|--------------------|------------------------------------|
| 99.1 | Press Release dated August 3, 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: August 3, 2017



Cara Therapeutics Reports Second Quarter 2017 Financial Results

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

STAMFORD, CONN., August 3, 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 second quarter ended June 30, 2017.

“During the quarter, we continued to make good progress with our CR845 development programs in acute postoperative pain, chronic osteoarthritis pain and chronic kidney disease-associated pruritus. Importantly, we were very pleased to receive Breakthrough Therapy designation from the FDA for I.V. CR845 for the treatment of CKD-aP in hemodialysis patients, and expect to meet with the FDA in the third quarter of 2017 to finalize our pivotal program for this indication,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “We look forward to expanding our development activities in pruritus with Oral CR845 later this year through the initiation of a Phase 1 study in non-dialysis CKD patients and the submission of an IND application for the treatment of chronic liver disease-associated pruritus.”

Second Quarter and Recent Business Highlights

- In June 2017, reported the Independent Data Monitoring Committee’s recommendation that Cara continue testing both doses of I.V. CR845 in its Phase 3 trial for the treatment of postoperative pain following a pre-specified interim conditional power analysis.
- In June 2017, received Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for I.V. CR845 for the treatment of moderate-to-severe chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis patients.
- In June 2017, initiated a Phase 3, open-label, 52-week safety study evaluating the long-term safety of I.V. CR845 in 240 hemodialysis patients as part of the pivotal program in CKD-aP.
- In June 2017, reported top-line results from a Phase 2b trial of Oral CR845 in chronic pain patients with osteoarthritis of the hip or knee.
- In July 2017, reported summary data from a Phase 1 trial of Oral CR845 identifying tablet strengths exhibiting appropriate plasma levels for potential use in the non-hemodialysis CKD-aP population.

Expected Upcoming Milestones

- End of Phase 2 meeting with the FDA in the third quarter of 2017 to finalize pivotal program for I.V CR845 the treatment of CKD-aP in hemodialysis patients; initiation of a Phase 3 pivotal trial expected in the fourth quarter of 2017.
- Initiation of a Phase 1 trial of Oral CR845 in CKD-aP non-hemodialysis patients expected in fourth quarter of 2017.
- Investigational New Drug application submission for Oral CR845 in patients with chronic liver disease-associated pruritus expected in the fourth quarter of 2017.
- Completion of enrollment for CLIN-3001, the Company's ongoing adaptive pivotal Phase 3 trial of I.V. CR845 for the treatment of acute postoperative pain, expected in the fourth quarter of 2017.

Second Quarter 2017 Financial Results

Net Loss: The Company reported a net loss of \$9.3 million, or \$0.29 per basic and diluted share, for the second quarter of 2017 compared to a net loss of \$13.1 million, or \$0.48 per basic and diluted share, for the same period of 2016.

Revenues: The Company recognized \$79,000 from the sale of clinical compound to Maruishi Pharmaceutical Co. Ltd. during the second quarter of 2016. The Company did not recognize any revenue during the second quarter of 2017.

Research and Development (R&D) Expenses: R&D expenses were \$7.0 million in the second quarter of 2017 compared to \$10.8 million in the same period of 2016. The lower R&D expenses in the second quarter of 2017 were principally due to a net decrease in direct clinical trial costs, including a reduction of approximately \$1.5 million due to a change in estimate related to a clinical trial accrual that had been recorded in the first quarter of 2017, partially offset by an increase in payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were substantially unchanged at \$2.7 million for both the second quarter of 2017 and the same period of 2016. Increases in professional fees and public/investor relations costs, stock-based compensation and payroll and related costs were offset by decreases in depreciation and amortization expense and rent expense.

Other Income: Other income was \$331,000 in the second quarter of 2017 compared to \$172,000 in the second quarter of 2016. The increase in 2017 was primarily due to higher dividend and interest income resulting from higher interest rates on a higher average balance of the Company's portfolio of investments in the 2017 period.

Cash and Cash Equivalents and Marketable Securities Position: At June 30, 2017, cash and cash equivalents and marketable securities totaled \$112.4 million compared to \$58.3 million at December 31, 2016. The increase in the balance of cash and cash equivalents and marketable securities primarily resulted from the net proceeds of \$86.2 million from the Company's second follow-on public offering of common stock and \$1.4 million received from the exercise of stock options, partially offset by cash used in operations of \$33.5 million.

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 second 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 57769313. 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 biopharmaceutical 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, led by CR845, that target the body’s peripheral nervous system. CR845 has 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. In patients with moderate-to-severe CKD-associated pruritus, CR845 has demonstrated its potential to reduce itch and improve quality of life.

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 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.
CONDENSED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(unaudited)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---------------------------------------|------------------------------------|--------------------|----------------------------------|--------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Revenue: | | | | |
| License and milestone fees revenue | \$ — | \$ — | \$ 530 | \$ — |
| Collaborative revenue | — | — | 313 | — |
| Clinical compound revenue | — | 79 | 68 | 86 |
| Total revenue | — | 79 | 911 | 86 |
| Operating expenses: | | | | |
| Research and development | 6,961 | 10,760 | 27,797 | 19,305 |
| General and administrative | 2,672 | 2,645 | 5,072 | 5,092 |
| Total operating expenses | 9,633 | 13,405 | 32,869 | 24,397 |
| Operating loss | (9,633) | (13,326) | (31,958) | (24,311) |
| Interest income | 331 | 172 | 421 | 321 |
| Loss before benefit from income taxes | (9,302) | (13,154) | (31,537) | (23,990) |
| Benefit from income taxes | 2 | 79 | 33 | 224 |
| Net loss | \$ (9,300) | \$ (13,075) | \$ (31,504) | \$ (23,766) |
| Net loss per share: | | | | |
| Basic and Diluted | \$ (0.29) | \$ (0.48) | \$ (1.06) | \$ (0.87) |
| Weighted average shares: | | | | |
| Basic and Diluted | 32,239,877 | 27,282,863 | 29,783,424 | 27,271,226 |

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

| | <u>June 30, 2017</u> | <u>December 31, 2016</u> |
|---|--------------------------|------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 9,416 | \$ 12,092 |
| Marketable securities | 103,020 | 46,184 |
| Income tax receivable | 560 | 852 |
| Other receivables | 175 | 87 |
| Prepaid expenses | 1,934 | 1,530 |
| Restricted cash, current | 700 | 700 |
| Total current assets | <u>115,805</u> | <u>61,445</u> |
| Property and equipment, net | 1,399 | 1,614 |
| Restricted cash | 769 | 769 |
| Total assets | <u>\$ 117,973</u> | <u>\$ 63,828</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 7,190 | \$ 11,533 |
| Total current liabilities | 7,190 | 11,533 |
| Deferred lease obligation | 1,563 | 1,570 |
| Commitments and contingencies | — | — |
| Stockholders' equity: | | |
| Preferred stock | — | — |
| Common stock | 33 | 27 |
| Additional paid-in capital | 302,920 | 212,866 |
| Accumulated deficit | (193,720) | (162,171) |
| Accumulated other comprehensive (loss) income | (13) | 3 |
| Total stockholders' equity | <u>109,220</u> | <u>50,725</u> |
| Total liabilities and stockholders' equity | <u>\$ 117,973</u> | <u>\$ 63,828</u> |

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