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 7, 2018

CARA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36279**	**75-3175693**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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.

On August 7, 2018, Cara Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2018. 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, including Exhibit 99.1, 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, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Earnings Press Release Q2 2018

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/ MANI MOHINDRU**
Mani Mohindru, Ph.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 7, 2018

Cara Therapeutics Reports Second Quarter 2018 Financial Results

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

STAMFORD, Conn., August 7, 2018 – Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus and pain by selectively targeting peripheral kappa opioid receptors, today announced financial results and operational highlights for the second quarter ended June 30, 2018.

“We are pleased with the progress we have made with our various pruritus programs, including the recent initiation of the second pivotal Phase 3 efficacy trial with KORSUVA injection in hemodialysis patients with chronic kidney disease-associated pruritus,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “In the remainder of the year, supported by the strength of our balance sheet, we expect to continue expanding KORSUVA’s clinical development to treat pruritus beyond hemodialysis patients into pre-dialysis CKD patients, as well as chronic liver disease and certain dermatologic patient populations.”

Second Quarter and Recent Developments:

Offering of Common Stock

In July 2018, the Company completed a public offering of 5,175,000 shares of its common stock, including the full exercise of the underwriters’ option to purchase additional shares at $19.00 per share, raising approximately $92.0 million in net proceeds after deducting underwriting discounts and commissions and estimated offering expenses.

Vifor Fresenius Medical Care Renal Pharma Ltd. License Agreement

In May 2018, the Company entered into a license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd. (VFMCRP), a joint company of Vifor Pharma Group and Fresenius Medical Care, under which VFMCRP has the exclusive rights to commercialize KORSUVA injection for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in dialysis patients outside the U.S., except in Japan and South Korea. The Company retains full development and commercialization rights for KORSUVA injection for the treatment of CKD-aP in the U.S., except in the dialysis clinics of Fresenius Medical Care North America (FMCNA), where VFMCRP and the Company will promote KORSUVA injection under a profit-sharing arrangement based on net FMCNA clinic sales recorded by the Company.

Under the agreement, the Company received an upfront payment of $50.0 million in cash and Vifor (International) Ltd. (Vifor) made an equity investment in the Company of $20.0 million at a premium. The Company is also eligible to receive up to $30.0 million in regulatory milestones, up to $440.0 million in tiered sales-based commercial milestones, and tiered royalties on net sales of KORSUVA injection in the licensed territories.

KORSUVA Injection: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Hemodialysis

In August 2018, the Company initiated the Global pivotal Phase 3 efficacy trial (KALM*TM*-2) of KORSUVA (CR845/difelikefalin) injection for the treatment of CKD-aP in patients undergoing hemodialysis. In addition, the Company is conducting a U.S. pivotal Phase 3 efficacy trial (KALM-1), as well as a 52-week Phase 3 safety study of KORSUVA (CR845/difelikefalin) injection in patients undergoing hemodialysis with CKD-aP.

Oral KORSUVA: Chronic Kidney Disease-Associated Pruritus (CKD-aP): Non-Hemodialysis

In July 2018, the Company announced the dosing of patients in a Phase 2 trial of Oral KORSUVA (CR845/difelikefalin) for the treatment of pruritus in stage III-V (moderate-to-severe) CKD patients, evaluating the safety and efficacy of three dose levels (0.25 mg, 0.5 mg and 1.0 mg, once daily) of Oral KORSUVA versus placebo.

I.V. CR845/Difelikefalin: Acute Post-Operative Pain

In June 2018, the Company reported positive top-line data from the adaptive Phase 2/3 trial of I.V. CR845 for the treatment of acute post-operative pain in patients undergoing abdominal surgery. At the 1.0 mcg/kg dose, I.V. CR845 achieved statistical significance for the primary endpoint of pain relief over the 0- to 24-hour period post-surgery. Additionally, I.V. CR845 treatment resulted in statistically significant reductions in the secondary endpoint of incidence of post-operative nausea and vomiting over the 24-hour period post-surgery for both 0.5 and 1.0 mcg/kg doses.

Upcoming Activities

The Company expects to make presentations at the following conferences through November 2018:

- European Academy of Dermatology & Venereology Congress, September 12-16
- Janney Montgomery Scott Healthcare Conference, September 17-18
- Cantor Fitzgerald Healthcare Conference, October 1-3
- Stifel Healthcare Conference, November 13-14
- Jefferies London Healthcare Conference, November 14-15
- 30th Annual Piper Jaffray Healthcare Conference, November 27-28
- Dermatology Drug Development Summit, November 27-28

Second Quarter 2018 Financial Results

Net Loss: The Company reported a net loss of $17.2 million, or $0.52 per basic and diluted share, for the second quarter of 2018 compared to a net loss of $9.3 million, or $0.29 per basic and diluted share, for the same quarter of 2017.

Revenues: The Company recognized $2.9 million of license and milestone fee revenue during the second quarter of 2018 related to its license agreement with VFMCRP. There were no license and milestone fee revenue recognized during the second quarter of 2017.

Research and Development (R&D) Expenses: R&D expenses were $17.0 million in the second quarter of 2018 compared to $7.0 million in the same period of 2017. The higher R&D expenses in 2018 were principally due to a net increase in costs associated with clinical trials, as well as increases in stock compensation expense and payroll and related costs for R&D personnel.

General and Administrative (G&A) Expenses: G&A expenses were $3.7 million during the second quarter of 2018 compared to $2.7 million in the same period of 2017. The increase in 2018 was primarily due to increases in stock compensation expense, professional fees and payroll and related costs for G&A personnel.

Other Income: Other income was $467,000 in the second quarter of 2018 compared to $331,000 in the same period of 2017. The increase in 2018 was primarily due to a higher average balance of the Company's portfolio of investments in the 2018 period.

Cash and Cash Equivalents and Marketable Securities Position: At June 30, 2018, cash and cash equivalents and marketable securities totaled $132.0 million compared to $92.6 million at December 31, 2017. The increase in the balance of cash and cash equivalents and marketable securities primarily resulted from cash provided by operations of $22.6 million, which included cash received as an upfront payment from VFMCRP, proceeds of $14.6 million (excluding the premium) attributable to the sale of common stock in connection with the license agreement with VFMCRP and $1.7 million from the exercise of stock options.

Additionally, in July 2018, the Company raised approximately $92.0 million in net proceeds from a public offering of 5,175,000 shares of its common stock.

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, 2018, as well as approximately $92.0 million of net proceeds from the Company's public offering of common stock in July 2018, will be sufficient to fund its currently anticipated operating expenses and capital expenditures into 2021 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 2018 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 3364257. 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 pruritus and pain by selectively targeting peripheral kappa opioid receptors (KORs). Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (CR845/difelikefalin), a first-in-class KOR agonist that targets the body’s peripheral nervous system, as well as certain immune cells. In Phase 2 trials, KORSUVA injection has demonstrated statistically significant reductions in itch intensity and concomitant improvement in quality of life measures in hemodialysis patients with moderate-to-severe CKD-aP and is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, in a recently completed Phase 2/3 trial in post-operative patients, I.V. CR845/difelikefalin has demonstrated reduction in moderate-to-severe pain, while also reducing the incidence and intensity of nausea and vomiting throughout the post-operative period.

The FDA has conditionally accepted KORSUVA™ as the trade name for difelikefalin injection. CR845/difelikefalin is an investigational drug product, and its safety and efficacy have not been fully evaluated by any regulatory authority.

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, the potential for the Company’s product candidates to be alternatives in the therapeutic areas investigated, 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, 2017 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,	
	2018	2017	2018	2017
Revenue:				
License and milestone fees revenue	$ 2,874	$ —	$ 2,874	$ 530
Collaborative revenue	—	—	—	313
Clinical compound revenue	—	—	—	68
Total revenue	2,874	—	2,874	911
Operating expenses:				
Research and development	17,002	6,961	30,429	27,797
General and administrative	3,685	2,672	7,382	5,072
Total operating expenses	20,687	9,633	37,811	32,869
Operating loss	(17,813)	(9,633)	(34,937)	(31,958)
Other income	467	331	778	421
Loss before benefit from income taxes	(17,346)	(9,302)	(34,159)	(31,537)
Benefit from income taxes	152	2	198	33
Net loss	$ (17,194)	$ (9,300)	$ (33,961)	$ (31,504)
Net loss per share:				
Basic and Diluted	$ (0.52)	$ (0.29)	$ (1.03)	$ (1.06)
Weighted average shares:				
Basic and Diluted	33,315,809	32,239,877	33,000,487	29,783,424

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

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 17,802	$ 9,388
Marketable securities	114,159	83,181
Income tax receivable	473	731
Other receivables	116	123
Prepaid expenses	5,615	1,635
Restricted cash, current	361	—
Total current assets	138,526	95,058
Property and equipment, net	959	1,177
Restricted cash	408	769
Total assets	$ 139,893	$ 97,004
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,553	$ 8,506
Current portion of deferred revenue	22,270	—
Total current liabilities	34,823	8,506
Deferred revenue, non-current	30,299	—
Deferred lease obligation	1,695	1,718
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	34	33
Additional paid-in capital	327,401	307,158
Accumulated deficit	(254,302)	(220,341)
Accumulated other comprehensive loss	(57)	(70)
Total stockholders' equity	73,076	86,780
Total liabilities and stockholders' equity	$ 139,893	$ 97,004

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