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) November 6, 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 November 6, 2018, Cara Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 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 Q3 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: November 6, 2018

Cara Therapeutics Reports Third Quarter 2018 Financial Results

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

STAMFORD, Conn., November 6, 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 third quarter ended September 30, 2018.

"In the past few months, we made significant clinical and corporate advancements, including the expanded pivotal Phase 3 development of KORSUVA™ Injection for chronic kidney disease-associated pruritus, or CKD-aP. We also strengthened our balance sheet with the successful completion of our follow-on offering and made key additions to our executive management team and board," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We expect 2019 to be a significant year for Cara, with anticipated readouts from both of our pivotal Phase 3 trials of KORSUVA™ Injection in dialysis patients with CKD-aP, and data from our ongoing Phase 2 trial of Oral KORSUVA™ in non-dialysis patients with CKD-aP. We also expect to initiate our clinical development program of Oral KORSUVA™ in dermatological conditions."

Third Quarter and Recent Developments

Appointments:

- **Chief Medical Officer -** In October 2018, the Company announced the appointment of Joana Goncalves, M.D., as Chief Medical Officer (CMO). The Company's former CMO, Dr. Joseph Stauffer, has transitioned to a consulting role for the Company.
- **Member, Board of Directors -** In August 2018, the Company announced the appointment of Christopher A. Posner to its Board of Directors. Mr. Posner currently serves as President and CEO of LEO Pharma, Inc., the U.S. subsidiary of LEO Pharma A/S, a global healthcare company specializing in dermatology and critical care.

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 $92.1 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.

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

In August 2018, the Company announced the dosing of the first patient in 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. Cara continues to enroll patients in the U.S. Phase 3 trial (KALM-1) and, based on current projections, anticipates completing the planned interim assessment by year-end or early 2019 and completing the trial's 12-week treatment period by the first half of 2019.

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.

Oral KORSUVA: Chronic Liver Disease-Associated Pruritus (CLD-aP)

The Phase 1 pharmacokinetic and safety trial of Oral KORSUVA in patients with CLD is fully enrolled and the Company plans to announce top-line data within the fourth quarter of 2018. Additionally, the Company expects to initiate a Phase 2 trial in patients with moderate-to-severe CLD-associated pruritus (CLD-aP) by year-end or early 2019.

Upcoming Meeting Activities

The Company expects to make presentations at the following upcoming conferences:

- Stifel 2018 Healthcare Conference, November 13-14
- Jefferies 2018 London Healthcare Conference, November 14-15
- Piper Jaffray 30th Annual Healthcare Conference, November 27-28
- Dermatology Drug Development Summit 2018, November 27-28

Third Quarter 2018 Financial Results

Net Loss: The Company reported a net loss of $19.4 million, or $0.51 per basic and diluted share, for the third quarter of 2018 compared to a net loss of $12.4 million, or $0.38 per basic and diluted share, for the same quarter of 2017.

Revenues: The Company recognized $5.0 million of license and milestone fee revenue during the third quarter of 2018 related to its license agreement with Vifor Fresenius Medical Care Renal Pharma (VFMCRP), a joint company of Vifor Pharma Group and Fresenius Medical Care. There was no license and milestone fee revenue recognized during the third quarter of 2017.

The Company recognized $33,000 of clinical compound revenue during the third quarter of 2018 in connection with the sale of clinical compound to Maruishi Pharmaceutical Co., Ltd. There was no clinical compound revenue recognized during the third quarter of 2017.

Research and Development (R&D) Expenses: R&D expenses were $22.3 million in the third quarter of 2018 compared to $9.2 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. Those increases were partially offset by lower costs associated with conferences.

General and Administrative (G&A) Expenses: G&A expenses were $3.2 million during the third quarter of 2018 compared to $3.8 million in the same period of 2017. The decrease in 2018 was primarily due to decreases in stock compensation expense, rent, utilities and related costs. Those decreases were partially offset by increased consultants' costs and legal fees.

Other Income: Other income was $1.0 million in the third quarter of 2018 compared to $367,000 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 September 30, 2018, cash and cash equivalents and marketable securities totaled $206.1 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 $92.1 million of net proceeds raised in a follow-on offering of 5,175,000 shares of the Company's common stock in July 2018, proceeds of $70.0 million related to the license agreement with VFMCRP (including upfront payment of $50.0 million in cash and $20.0 million of equity investment at premium), and $3.6 million from the exercise of stock options.

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 September 30, 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 third 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 8739658. 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 chronic kidney disease-associated pruritus (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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
License and milestone fees revenue	$ 5,029	$ —	$ 7,903	$ 530
Collaborative revenue	—	—	—	313
Clinical compound revenue	33	—	33	68
Total revenue	5,062	—	7,936	911
Operating expenses:				
Research and development	22,303	9,151	52,732	36,948
General and administrative	3,227	3,805	10,609	8,877
Total operating expenses	25,530	12,956	63,341	45,825
Operating loss	(20,468)	(12,956)	(55,405)	(44,914)
Other income	1,002	367	1,780	788
Loss before benefit from income taxes	(19,466)	(12,589)	(53,625)	(44,126)
Benefit from income taxes	66	145	264	178
Net loss	$ (19,400)	$ (12,444)	$ (53,361)	$ (43,948)
Net loss per share:				
Basic and Diluted	$ (0.51)	$ (0.38)	$ (1.54)	$ (1.43)
Weighted average shares:				
Basic and Diluted	38,034,216	32,591,550	34,696,835	30,729,752

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

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 96,729	$ 9,388
Marketable securities	109,348	83,181
Income tax receivable	539	731
Other receivables	193	123
Prepaid expenses	4,218	1,635
Restricted cash, current	361	—
Total current assets	211,388	95,058
Property and equipment, net	908	1,177
Restricted cash	408	769
Total assets	$ 212,704	$ 97,004
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,003	$ 8,506
Current portion of deferred revenue	29,242	—
Total current liabilities	43,245	8,506
Deferred revenue, non-current	18,300	—
Deferred lease obligation	1,629	1,718
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock	—	—
Common stock	39	33
Additional paid-in capital	423,180	307,158
Accumulated deficit	(273,702)	(220,341)
Accumulated other comprehensive income (loss)	13	(70)
Total stockholders' equity	149,530	86,780
Total liabilities and stockholders' equity	$ 212,704	$ 97,004

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