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 12, 2019

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 March 12, 2019, Cara Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 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	Press Release dated March 12, 2019

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: March 12, 2019

Cara Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results

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

STAMFORD, Conn., March 12, 2019 – Cara Therapeutics, Inc. (Nasdaq: CARA), a biopharmaceutical company focused on developing and commercializing new chemical entities with a primary focus on pruritus as well as pain by selectively targeting peripheral kappa opioid receptors, today announced financial results and operational highlights for the fourth quarter and full year ended December 31, 2018.

"During 2018, we made significant clinical and corporate advancements with our late-stage pruritus programs, including the initiation of both Phase 3 pivotal trials with KORSUVA™ Injection for chronic kidney disease-associated pruritus, or CKD-aP, in hemodialysis patients. Additionally, the execution of our Licensing Agreement with VFMCRP, a joint company of Vifor Pharma Group and Fresenius Medical Care, the world's largest dialysis company, will help provide momentum for the commercial launch of KORSUVA™ Injection in the U.S. and Europe, if approved," said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. "We anticipate 2019 to be a transformative year for the Company with significant clinical readouts expected from both pivotal Phase 3 trials of KORSUVA™ Injection, and from our Phase 2 trial of Oral KORSUVA™ in pre-dialysis patients with CKD-aP. We also expect to broaden our clinical pruritus program for Oral KORSUVA™ with the initiation of Phase 2 trials in both liver disease and dermatological conditions, including atopic dermatitis."

2018 & Recent Highlights and Outlook

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

- In January 2019, based on the recommendation of the Independent Data Monitoring Committee, the Company announced that its pivotal KALM-1 Phase 3 trial of KORSUVA™ (CR845/difelikefalin) Injection will continue as planned with no changes to the original enrollment target of 350 hemodialysis patients with moderate-to-severe CKD-aP. The pre-specified interim conditional power assessment was conducted after approximately half of the targeted number of patients completed the designated 12-week treatment period.
- The Company also announced the completion of enrollment in the KALM-1 Phase 3 trial. Top-line data from this trial are expected in the second quarter of 2019.

- In August 2018, the Company announced the dosing of the first patient in KALM-2, the second Phase 3 efficacy trial of KORSUVA Injection, which is similar in design to the KALM-1 trial and will facilitate regulatory filings worldwide. KALM-2 is an international trial that will enroll patients in the United States, Europe and Asia Pacific. Based on current patient enrollment projections, the Company expects top-line data from this trial in the second half of 2019.

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

- In July 2018, the Company announced the dosing of the first patient in the 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. Top-line data from this trial are expected in the second half of 2019.

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

- The Company completed a Phase 1 trial of Oral KORSUVA™ at multiple tablet strengths in patients with chronic liver disease in the first quarter of 2019. The pharmacokinetic parameters were dose-proportional and Oral KORSUVA™ was generally well tolerated with no unexpected safety signals reported. The Company expects to initiate a Phase 2 trial in chronic liver disease patients with moderate-to-severe pruritus in the second quarter of 2019.

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

- 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.

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., or VFMCRP, under which VFMCRP has the exclusive rights to commercialize KORSUVA™ Injection for the treatment of CKD-aP in dialysis patients outside of the United States, 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 United States, except in the dialysis clinics of Fresenius Medical Care North America, or FMCNA, where VFMCRP and the Company will promote KORSUVA™ Injection under a profit-sharing arrangement.

- Under the agreement, the Company received an upfront payment of $50.0 million in cash and Vifor (International) Ltd. made an equity investment of $20.0 million. The Company is also eligible to receive $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.

Appointments:

- **Chief Medical Officer -** In the fourth quarter of 2018, Cara announced the appointment of Joana Goncalves, M.D., as Chief Medical Officer, or CMO. The Company's former CMO, Dr. Joseph Stauffer, D.O., has transitioned to a consulting role for the Company.

Expected 2019 Clinical Milestones

- Top-line 12-week efficacy and safety data from the KALM-1 and KALM-2 Phase 3 trials of KORSUVA™ Injection in hemodialysis patients with moderate-to-severe CKD-aP are expected in the second quarter and second half of 2019, respectively.
- Top-line data from the Phase 2 trial of Oral KORSUVA™ in Stage III—V CKD patients (moderate-to-severe) CKD-aP are expected in the second half of 2019.
- Initiation of the Phase 2 trial of Oral KORSUVA™ in patients with CLD-aP is expected in the second quarter of 2019.
- Initiation of the Phase 2 trial of Oral KORSUVA™ in atopic dermatitis patients with moderate-to-severe pruritus is expected around mid-year 2019.

Upcoming Meeting Activities

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

- Needham & Company's Annual Healthcare Conference, April 9-10
- Bank of America Merrill Lynch Healthcare Conference, May 14-16
- Jefferies 2019 Healthcare Conference, June 4-7

Fourth Quarter and Full Year 2018 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2018 totaled $182.8 million compared to $92.6 million at December 31, 2017. The increase in the balance resulted primarily from $92.1 million of net proceeds raised in a follow-on offering of the Company's common stock in July 2018, as well as proceeds of $70.0 million related to the license agreement with VFMCRP, partially offset by cash used in operations.

For the fourth quarter of 2018, net loss was $20.7 million, or $0.52 per basic and diluted share, compared to a net loss of $14.2 million, or $0.43 per basic and diluted share, for the same period in 2017.

- *Revenues:* The Company recognized $5.5 million of license and milestone revenue during the fourth quarter of 2018 related to its collaboration agreement with VFMCRP. No revenue was recognized during the same period of 2017.
- *Research and Development (R&D) Expenses:* R&D expenses were $22.8 million in the fourth quarter of 2018 compared to $11.6 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.
- *General and Administrative (G&A) Expenses:* G&A expenses were $4.7 million during the fourth quarter of 2018 compared to $3.0 million in the same period of 2017. The increase in 2018 was primarily due to increases in stock compensation expense and payroll and related costs and consulting costs.
- *Other Income:* Other income was $1.2 million in the fourth quarter of 2018 compared to $368,000 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.

For the full year ended December 31, 2018, net loss was $74.0 million, or $2.06 per basic and diluted share, compared to a net loss of $58.1 million, or $1.86 per basic and diluted share, for the year ended 2017.

- *Revenues:* Total revenue was $13.5 million for the full year ended December 31, 2018 as compared to $911,000 for the year ended 2017. Total revenue consisted of:

  (1) License and milestone fees revenue of $13.4 million for the full year ended December 31, 2018 was recognized by the Company related to its license agreement with VFMCRP. The Company recognized license and milestone fees revenue of $530,000 in 2017 related to a sub-license fee received from Maruishi Pharmaceutical Co. Ltd., or Maruishi, in connection with its sub-license agreement with Kissei Pharmaceutical Co. Ltd.

  (2) There was no collaborative revenue recognized for the full year ended December 31, 2018. Collaborative revenue of $313,000 was recognized for the year ended 2017 related to a sub-license fee received from Maruishi.

  (3) The Company recognized $33,000 and $68,000 of clinical compound revenue during the full year ended December 31, 2018 and 2017, respectively, in connection with the sale of clinical compound to Maruishi.

- *Research and Development (R&D) Expenses:* R&D expenses were $75.5 million for the full year ended December 31, 2018 compared to $48.5 million for the year ended 2017. The higher R&D expenses in 2018 were principally due to a net increase in clinical trial costs, as well as increases in stock compensation expense and payroll and related costs.
- *General and Administrative (G&A) Expenses:* G&A expenses were $15.3 million for the full year ended December 31, 2018 compared to $11.9 million for the year ended 2017. The increase in 2018 was primarily due to increases in stock compensation expense, payroll and related costs, consultants' costs and legal fees. Those increases were partially offset by decreased rent, utilities and related costs.
- *Other Income:* Other income was $3.0 million for the full year ended December 31, 2018 compared to $1.2 million for the year ended 2017. The increase in 2018 was primarily due to a higher average balance of the Company's portfolio of investments in 2018.

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, 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 fourth quarter and full year 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 5381969. 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 with a primary focus on pruritus as well as 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 pruritus-related 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.

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 data readouts from the Company’s ongoing clinical trials, the expected timing for initiation 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, 2018 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,	
	2018	2017	2018	2017
Revenue:				
License and milestone fees	$ 5,533	$ —	$ 13,436	$ 530
Collaborative revenue	—	—	—	313
Clinical compound revenue	—	—	33	68
Total revenue	5,533	—	13,469	911
Operating expenses:				
Research and development	22,799	11,576	75,531	48,524
General and administrative	4,711	2,995	15,320	11,872
Total operating expenses	27,510	14,571	90,851	60,396
Operating loss	(21,977)	(14,571)	(77,382)	(59,485)
Other income	1,200	368	2,980	1,156
Loss before benefit from income taxes	(20,777)	(14,203)	(74,402)	(58,329)
Benefit from income taxes	125	26	389	204
Net loss	$ (20,652)	$ (14,177)	$ (74,013)	$ (58,125)
Net loss per share :				
Basic and Diluted	$ (0.52)	$ (0.43)	$ (2.06)	$ (1.86)
Weighted average shares:				
Basic and Diluted	39,441,640	32,635,706	35,892,786	31,202,842

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

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 15,081	$ 9,388
Marketable securities	146,302	83,181
Income tax receivable	664	731
Other receivables	926	123
Prepaid expenses	4,805	1,635
Restricted cash, current	361	—
Total current assets	168,139	95,058
Marketable securities, non-current	21,396	—
Property and equipment, net	880	1,177
Restricted cash	408	769
Total assets	$ 190,823	$ 97,004
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,622	$ 8,506
Current portion of deferred revenue	26,825	—
Total current liabilities	40,447	8,506
Deferred revenue, non-current	15,184	—
Deferred lease obligation	1,562	1,718
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	39	33
Additional paid-in capital	428,059	307,158
Accumulated deficit	(294,354)	(220,341)
Accumulated other comprehensive loss	(114)	(70)
Total stockholders' equity	133,630	86,780
Total liabilities and stockholders' equity	$ 190,823	$ 97,004

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