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 23, 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 7.01 Regulation FD Disclosure.

On May 23, 2018, Cara Pharmaceuticals, Inc. (the "Company") issued a press release announcing its entry into a license agreement with Vifor Fresenius Medical Care Renal Pharma Ltd, and the Company's related conference call to be held at 8:30 a.m. EDT on May 23, 2018. Copies of the press release and the presentation to be discussed on the conference call are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated by reference. The information furnished under this Item 7.01, including Exhibit 99.1 and Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	
99.1	Press release dated May 23, 2018.
99.2	Presentation dated May 23, 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 and Chief Strategy Officer
(Principal Financial and Accounting Officer)

Date: May 23, 2018

Exhibit 99.1

Cara Therapeutics and Vifor Fresenius Medical Care Renal Pharma (VFMCRP) Enter into Ex-U.S. Licensing Agreement to Commercialize KORSUVA™ Injection in Dialysis Patients with Pruritus

Cara receives upfront payment of $50 million in cash and an equity investment of $20 million

Cara eligible for up to $470 million in regulatory and commercial milestones

VFMCRP to commercialize KORSUVA injection worldwide except in the U.S., Japan and South Korea

Cara to commercialize KORSUVA injection in the U.S & co-promote with VFMCRP in U.S. Fresenius Medical Care (FMC) North America Dialysis Clinics

- Cara to Host Conference Call Today at 8:30 a.m. EDT -

STAMFORD, Conn., May 23, 2018 – Cara Therapeutics, Inc. (Nasdaq:CARA), a U.S. 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 that it has licensed worldwide rights, except in the U.S., Japan and South Korea, to commercialize KORSUVA (CR845/difelikefalin) injection for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in dialysis patients to Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP), a joint company of Vifor Pharma Group (SIX:VIFN) and Fresenius Medical Care (NYSE:FMS) that specializes in treatments for CKD. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to KORSUVA injection for this indication, for which there are currently no approved therapies in the U.S. or E.U.

“As a global leader in providing treatment for chronic kidney disease patients, VFMCRP is an ideal partner to bring KORSUVA injection to dialysis patients across Europe and other licensed territories,” said Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics. “Additionally, we believe the ability to leverage VFMCRP’s nephrology-focused commercial expertise in our co-promotion partnership for U.S. Fresenius Medical Care dialysis facilities will provide significant momentum for adoption of KORSUVA injection, if approved in the U.S. Importantly, we continue to retain all rights to KORSUVA/CR845 in other indications.”

“CR845 injection is a first-in-class, innovative investigational medicine for treating a highly debilitating disease. It is a natural fit to our leading product portfolio in nephrology, and we look forward to making it available to patients who urgently need better therapy,” said Stefan Schulze, Vifor Pharma President of the Executive Committee and COO. “Sixty to 70% of dialysis patients experience CKD-aP. Nearly 20% suffer from a very severe form, which is associated with much lower survival. And despite this clear unmet medical need, there is no approved treatment for CKD-aP in Europe or the U.S. CR845 does not penetrate the brain and so bypasses unwanted side-effects like opioid addiction. It has significant potential for setting new standards in providing relief, both from CKD- induced itching and post-operative pain.”

Summary of License Agreement

Under the terms of the Agreement, Cara will receive an upfront payment in the amount of $50 million in cash and an equity investment of $20 million to acquire Cara common stock at a price of approximately $17/share. Cara will also be eligible to receive additional payments of up to $470 million, which includes $30 million in regulatory and up to $440 million in tiered commercial milestones that are all sales related. Cara is also eligible to receive tiered royalties based on net sales of KORSUVA injection in the licensed territories. VFMCRP will have the exclusive rights to commercialize KORSUVA injection for the treatment of CKD-aP in dialysis patients ex-U.S. except in Japan and South Korea. Cara 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 Cara will promote KORSUVA injection under a profit-sharing arrangement based on net FMCNA clinic sales recorded by Cara. FMCNA is the largest kidney dialysis provider in the U.S. and treated approximately 38% of U.S. dialysis patients in 2017. Cara will solely promote KORSUVA injection in all non-FMC clinics in the U.S. and retain all profits from those sales.

KORSUVA (CR845/difelikefalin) Injection for CKD-aP in Dialysis Patients

In January 2018, based on positive data from Phase 2 clinical trials1 and after completion of the End-of-Phase 2 meeting with the FDA, Cara initiated the first pivotal Phase 3 trial of KORSUVA injection (KALM-1 trial) in hemodialysis patients suffering from moderate-to-severe CKD-aP in the United States (additional information about the study can be found at www.clinicaltrials.gov, ID: NCT03422653). Cara also expects to initiate a global Phase 3 clinical trial of KORSUVA injection for the treatment of CKD-aP in hemodialysis patients in multiple countries later this year. Data from these studies are expected to support filings for regulatory approvals in the U.S. and other markets.

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.

Conference Call

Cara management will host a conference call today at 8:30 a.m. EDT to discuss the licensing agreement. To participate in the conference call, please dial (855) 445-2816 (domestic) or (484) 756-4300 (international) and refer to conference ID 2694637. 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 CKD-aP

CKD-aP is an intractable systemic itch condition that occurs with the high frequency and intensity in patients with chronic kidney disease undergoing hemodialysis and peritoneal dialysis. Pruritus has also been reported in patients with stage III-V CKD who are not on dialysis. Aggregate, longitudinal, multi-country studies estimate the weighted prevalence of CKD-aP to be approximately 40 percent in patients with end-stage renal disease (ESRD), with approximately 25 percent of patients reporting severe pruritus. The majority of dialysis patients (approximately 60-70 percent) report pruritus, with 30 to 40 percent reporting moderate or severe pruritus2,3. Recent data from the ITCH National Registry Study showed that among those with pruritus, approximately 59 percent experienced symptoms daily or nearly daily for more than a year. Given its association with CKD/ESRD, most afflicted patients will continue to have symptoms for months or years with currently employed antipruritic treatments, such as antihistamines and corticosteroids, unable to provide consistent adequate relief. Moderate-to-severe chronic pruritus has repeatedly been shown to directly decrease quality of life, contribute to symptoms that impair quality of life (such as poor sleep quality), and is associated with depression4. CKD-aP is also an independent predictor of mortality among hemodialysis patients, mainly related to increased risk of inflammation and infections.

References:

1. Data presentation at 2017 American Society of Nephrology’s Annual Meeting (Kidney Week 2017)
2. Pisoni RL, et al. Pruritus in haemodialysis patients: international results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Nephrol Dial Transplant. 2006; 21:3495-3505.
3. Ramakrishnan et al. Clinical characteristics and outcomes of end-stage renal disease patients with self-reported pruritus symptoms. International Journal of Nephrology and Renovascular Disease. 2014; 7: 1-12
4. Mathur V. et al. A longitudinal study of Uremic Pruritus in hemodialysis patients. Clin J Am Soc Nephrol. 2010; 5(8):1410-1419

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. 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 KORSUVA is currently being investigated in Phase 3 trials in hemodialysis patients with CKD-aP. Additionally, CR845/difelikefalin has demonstrated statistically significant pain relief in Phase 2 clinical trials conducted in patients with moderate-to-severe pain, without inducing many of the undesirable side effects typically associated with currently available opioid pain therapeutics.

About Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP)

VMCRP is a joint company of Vifor Pharma Group and Fresenius Medical Care, develops and commercialises innovative and high quality therapies to improve the life of patients suffering from chronic kidney disease (CKD) worldwide. The company was founded at the end of 2010 and is owned 55% by Vifor Pharma Group and 45% by Fresenius Medical Care. For more information about Vifor Fresenius Medical Care Renal Pharma and its parent companies, please visit www.vfmcrp.com, www.viforpharma.com and www.freseniusmedicalcare.com.

About Vifor Pharma Group

Vifor Pharma, formerly Galenica Group, is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is the partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma; Vifor Fresenius Medical Care Renal Pharma, a joint company with Fresenius Medical Care; Relypsa; and OM Pharma. Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit www.viforpharma.com.

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 plans, strategies and expectations for the future, including statements concerning the potential commercialization of KORSUVA in the licensed territories, the potential benefits of marketing KORSUVA in the United States through the promotion and profit share arrangement announced today, the potential of CR845 to set new standards in relief from CKD-induced itching and post-operative pain, the potential milestone and royalty payments payable to Cara pursuant to the agreement and the expected timelines for Cara’s planned clinical trials and regulatory submissions. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of these risks and uncertainties include, but are not limited to, those related to the initiation and conduct of clinical trials, the receipt of data sufficient to support regulatory submissions and required regulatory approvals of KORSUVA, and uncertainties regarding the rate and degree of market acceptance of KORSUVA, if approved for marketing, as well as those risks and uncertainties described more fully in Cara’s 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 undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Exhibit 99.2

Ex-US Licensing Agreement with VFMCRP for IV CR845 for Pruritus in Dialysis Patients

Cara and Vifor Fresenius Medical Care Renal Pharma (VFMCRP)

May 23rd, 2018

CARA THERAPEUTICS

Forward Looking Statements

This presentation contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “estimate,” “expect,” “objective,” “ongoing,” “plan,” “propose,” “potential,” or “upcoming” and/or the negative of these terms, or other comparable terminology intended to identify statements about the future. Examples of these forward-looking statements in this presentation include, among other things, statements concerning plans, strategies and expectations for the future, including statements concerning: the potential commercialization of KORSUVA in the licensed territories; the potential benefits of marketing KORSUVA in the United States through the promotion and profit share arrangement announced today; the potential milestone and royalty payments payable to Cara pursuant to the agreement; the expected timelines for Cara’s planned clinical trials and regulatory submissions; the shift in Cara’s focus toward expanding its pruritus programs; the potential future development of CR845 for pain indications, including the potential to develop CR845 with existing or new partners; results of ongoing and planned clinical trials; future regulatory and development milestones for Cara’s product candidates; and Cara’s expected cash reach.

These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward-looking statements include the risks described in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2017, as well as those set forth from time to time in the Company’s other SEC filings, available at http://www.sec.gov. Any forward-looking statements speak only as of the date of this presentation.

The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise except as required by law.

Vifor Fresenius Medical Care Renal Pharma (VFMCRP)

VFMCRP: JV - Vifor Pharma Group & Fresenius Medical Care (FMC)

- **Vifor Pharma:** Leader in iron deficiency, nephrology & cardio-renal therapies
- **FMC:** Global leading provider of services for dialysis patients

VIFOR PHARMA

STRONG IRON AND PHARMA EXPERTISE

ferinject® · Venofer® IRON SUCROSE · MIRCERA® · Rayaldee® calcifediol ER capsules · Veltassa® · Biosimilar epoetin alfa[1] · Vadadustat[1] · Avacopan[1] · CCX140[1] · VELPHORO®

FRESENIUS MEDICAL CARE

GLOBAL LEADER IN DIALYSIS

55% Stake

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

45% Stake

[1] Pre-commercial products

CARA THERAPEUTICS

Summary of Agreement

- **Licensed Product:** IV CR845/ difelikefalin for Chronic Kidney Disease associated pruritus (CKD-aP) in dialysis patients
  - U.S. trade name: KORSUVA™ injection*
  - Breakthrough Designation by FDA for CKD-aP in hemodialysis patients
- **Licensed Territory:** Worldwide, excluding U.S., Japan & South Korea
  - VFMCRP and Cara to promote in U.S. Fresenius Medical Care dialysis clinics under a profit share agreement
  - Cara to solely promote in all non-Fresenius U.S. dialysis clinics and retain all profits
- **Field-of-use:** Prevention, inhibition or treatment of pruritus/ CKD-aP in hemodialysis/ peritoneal dialysis patients

* 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.

CARA THERAPEUTICS

Summary of Financial Terms

- **Up-Front: total $70 million**
  - $50 million in cash
  - Purchase of $20 million of Cara common stock at a price of ~$17 per share
- **Additional payments: up to $470 million**
  - Upon achievement of certain Regulatory ($30 million) & Commercial (up to $440 million) milestones
- **VFMCRP & Cara promotion and profit share arrangement** in U.S. FMC clinics
- **Royalty :** Tiered royalty based on net sales of I.V. CR845/ difelikefalin in licensed territory

CARA THERAPEUTICS

Strategic Partnership: Supports Cara's Long Term Goals

- **Strengthens Balance Sheet**
  - Minimally dilutive capital
  - Extends cash runway beyond key inflection points:
    - Data from ongoing Ph 3 trial of KORSUVA injection for CKD-aP in hemodialysis patients
    - Data from Ph 2 trial of Oral KORSUVA for CKD-aP in non-hemodialysis patients
- **Ideal partner for commercialization of I.V. CR845 in dialysis markets in the EU and other territories**
- **Will help build momentum for U.S. launch of KORSUVA Injection, if approved, with VFMCRP co-promotion in U.S. Fresenius dialysis clinics**
- **Validation for strategic focus on pruritus; enables Cara to expand development of Oral KORSUVA in multiple other pruritic indications:**
  - CKD-aP in pre-dialysis (Stage 3-5) patients, chronic liver disease associated pruritus, dermatological pruritic indications etc.

Development Pipeline Q2, 2018

Program	Indication	Stage of Development				Commercial Rights (ex-Japan and S. Korea)*
		Preclinical	Phase 1	Phase 2	Phase 3	
KORSUVA™ Injection	Pruritus CKD-HD**					US- Cara EU/Other-VFMCRP#
Oral KORSUVA™	Pruritus CKD-HD			*Ph 1 completed*		Cara
Oral KORSUVA™	Pruritus CKD (III-IV)					Cara
Oral KORSUVA™	Pruritus CLD					Cara
IV CR845	Post-op Pain					Cara
Oral CR845	Chronic Pain (OA)				*Ph 2b completed*	Cara

***Commercialization rights to CR845 in all indications - Japan: Maruishi Pharma ; South Korea: CKD Pharma**
 # VFMCRP and Cara have rights to promote in U.S. Fresenius Medical Care dialysis clinics under a profit share agreement

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

**Breakthrough Designation for IV CR385 for Pruritus CKD-HD

CKD-HD: Chronic Kidney Disease- Hemodialysis; **OA**: Osteoarthritis; CLD: Chronic Liver Disease

CARA THERAPEUTICS

Financial Highlights

As of March 31st, 2018

Cash and Marketable Securities	$74.5M
Net loss – Q1 2018	($16.8M)
Shares outstanding	32.7M
• Stock options	~3.9M

- *May, 2018*
  - *Additional Cash of $70M (VFMCRP agreement)*
  - *Additional shares (Vifor): 1,174,827*

CARA THERAPEUTICS