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): **October 15, 2020**

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**	**06902**
(Address of principal executive offices)	(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	CARA	The Nasdaq Stock Market LLC

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 1.01 Entry into a Material Definitive Agreement.

License Agreement

On October 15, 2020, Cara Therapeutics, Inc. ("Cara") entered into a license agreement (the "Vifor Agreement") with Vifor (International) Ltd. ("Vifor Pharma"), under which Cara granted Vifor Pharma an exclusive license solely in the United States to use, distribute, offer for sale, promote, sell and otherwise commercialize Cara's product candidate KORSUVA Injection (CR845/difelikefalin) for all therapeutic uses relating to the inhibition, prevention or treatment of itch associated with pruritus in hemodialysis and peritoneal dialysis patients in the United States. Under the Vifor Agreement, Cara retains all rights with respect to the clinical development of, and activities to gain regulatory approvals of, KORSUVA Injection in the United States.

Under the terms of the Vifor Agreement, Cara will receive from Vifor Pharma an upfront payment of $100 million in cash and a $50 million investment in Cara's common stock at a price of $17.0094 per share. Upon U.S. regulatory approval of KORSUVA Injection, Cara will also be eligible to receive an additional $50 million common stock investment at a 20% premium to the 30-day trailing average price of Cara's common stock as of such date. In addition, pursuant to the Vifor Agreement, Cara is eligible to receive payments of up to $240 million upon the achievement of certain sales-based milestones. In connection with the Vifor Agreement, the parties entered into a securities purchase agreement (the "Purchase Agreement") dated October 15, 2020, governing the issuance of the common stock described herein.

The Vifor Agreement provides full commercialization rights in dialysis clinics to Vifor Pharma in the United States under a profit-sharing arrangement. Pursuant to the profit-sharing arrangement, Cara will generally be entitled to 60% of the net profits (as defined in the Vifor Agreement) from sales of KORSUVA Injection in the United States (excluding sales to Fresenius Medical Center dialysis clinics, compensation for which is governed by a separate license agreement dated May 17, 2018 between Cara and Vifor Fresenius Medical Care Renal Pharma Ltd. ("VFMCRP")) and Vifor Pharma is entitled to 40% of such net profits, subject to potential temporary adjustment in future years based on certain conditions. Under the Vifor Agreement, in consideration of Vifor Pharma's conduct of the marketing, promotion, selling and distribution of KORSUVA Injection in the United States, Cara will pay a marketing and distribution fee to Vifor Pharma based on the level of annual net sales. This fee will be deducted from product sales in calculating the net profits that are subject to the profit-sharing arrangement under the agreement. Vifor Pharma has simultaneously entered into an option agreement with VFMCRP pursuant to which the license may be transferred from Vifor Pharma to VFMCRP.

The Vifor Agreement shall continue in effect until its expiration upon the cessation of commercial sale of KORSUVA Injection in the United States by Vifor Pharma and its affiliates and sublicensees, or until the earlier termination of the Vifor Agreement.

In addition, upon the earlier of: (1) the acceptance for filing of a new drug application covering KORSUVA Injection submitted to the U.S. Federal Drug Administration ("FDA"); or (2) October 15, 2023, the Vifor Agreement may be terminated by Vifor Pharma in its entirety, with such termination effective upon 12 months' notice.

Securities Purchase Agreement

Pursuant to the Purchase Agreement, Vifor Pharma will not, and will not cause any direct or indirect affiliate to, during the period beginning on October 15, 2020 and ending at the close of business on the earlier of (A) October 15, 2022 and (B) the date that Cara publicly discloses the receipt of a complete response letter from the FDA with respect to Cara's NDA for KORSUVA Injection (such period, the "Restricted Period"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock of Cara or any securities convertible into or exercisable or exchangeable for common stock of Cara (including without limitation, common stock or such other securities which may be deemed to be beneficially owned by Vifor Pharma in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and securities which may be issued upon exercise of a stock option or warrant) owned by Vifor Pharma as of the date hereof or acquired prior to the end of the Restricted Period (collectively with the Common Stock, "Lock-Up Securities"), except any such sale, option or contract by and between Vifor Pharma and one of its affiliates (including Vifor Pharma Group Ltd. or VFMCRP), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise, (3) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities, or (4) publicly disclose the intention to do any of the foregoing.

Under the Purchase Agreement, the parties also agreed that, in certain circumstances, upon the request of Vifor Pharma, the parties will enter into a registration rights agreement prior to the end of the Restricted Period that would provide Vifor Pharma (or its affiliate transferee) customary registration rights with respect to the shares of common stock issued pursuant to the Purchase Agreement following the expiration of the Restricted Period.

The descriptions of the Vifor Agreement and the Purchase Agreement contained herein do not purport to be complete and are qualified in their entirety by reference to the complete text of the Vifor Agreement and Purchase Agreement which will be filed as exhibits to Cara's Annual Report on Form 10-K for the fiscal year ending December 31, 2020.

Item 3.02 Unregistered Sale of Equity Securities.

The information in Item 1.01 above relating to issuance of shares of Cara's common stock to Vifor Pharma is incorporated by reference into this Item 3.02.

Neither Cara nor Vifor Pharma engaged any investment advisors with respect to the issuance of such shares and no finders' fees were paid to any party in connection therewith. The issuance of such shares was made in reliance on the exemption from registration contained in Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506(b) of Regulation D thereunder.

Neither this Current Report on Form 8-K nor any exhibit attached hereto is an offer to sell or the solicitation of an offer to buy shares of shares of common stock or other securities of Cara.

Item 7.01 Regulation FD Disclosure.

On October 20, 2020, Cara issued a press release announcing its entry into a license agreement with Vifor Pharma. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The information furnished under this Item 7.01, including Exhibit 99.1, 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 SEC made by Cara, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated October 20, 2020
104	Cover Page lnteractive Data File (embedded within the Inline XBRL document).

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/ Derek Chalmers, Ph.D., D.Sc.
Derek Chalmers, Ph.D., D.Sc.
President and Chief Executive Officer

Date: October 20, 2020

Press Release

Vifor Pharma and Cara Therapeutics sign US license agreement for IV Korsuva™* to treat dialysis patients with pruritus

- **Vifor Pharma secures commercial rights for IV Korsuva in non-Fresenius Medical Care dialysis clinics representing approximately 66% of the market, under a profit-sharing arrangement with Cara**
- **Cara will receive a USD 100 million upfront payment and an equity investment of USD 50 million**
- **IV Korsuva aims to address a significant unmet medical need for a highly debilitating disease**
- **NDA submission for IV Korsuva expected in Q4, 2020**

- Cara to Host Conference Call Today at 8:30am EDT -

Stamford, Conn. and St Gallen, October 20, 2020 – Vifor Pharma and Cara Therapeutics, Inc. (Nasdaq:CARA) today announced that both companies have signed a license agreement for commercialization of Korsuva (difelikefalin) Injection (IV Korsuva) for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in the US dialysis market for non-Fresenius Medical Care clinics under a Cara 60%, Vifor Pharma 40% profit-sharing arrangement.

“With an established fully dedicated nephrology sales force in the US, Vifor Pharma is an ideal commercialization partner to bring IV Korsuva to dialysis patients across the country,” said **Derek Chalmers, Ph.D., D.Sc., President and Chief Executive Officer of Cara Therapeutics**. “In addition, we believe Vifor Pharma’s existing relationships with US dialysis providers will provide significant momentum for the launch and adoption of IV Korsuva, if approved. As a result of this agreement, we expect to focus Cara’s internal resources on our clinical programs for Oral Korsuva in atopic dermatitis, pre-dialysis CKD and additional pruritic conditions.”

“Vifor Pharma has a strong market position and deep expertise in the nephrology space. This agreement further strengthens our US nephrology presence. The Vifor Pharma Group now has the commercialization rights for IV Korsuva in the full dialysis segment by adding all non-FMC dialysis clinics, representing approximately 66% of the US market,” said **Stefan Schulze, CEO of Vifor Pharma Group**. Moderate to severe haemodialysis-associated pruritus is a debilitating condition that impacts up to 40% of dialysis patients around the world and for which there is currently no approved treatment in the US or Europe. IV Korsuva is an important, innovative new therapeutic that has the potential to address this significant unmet need. We remain committed to making IV Korsuva available next year to dialysis patients, who urgently need an effective therapy.”

Under the terms of the agreement, Cara will receive an upfront payment of USD 100 million in cash and an equity investment of USD 50 million. In addition, Cara will be eligible to receive an additional equity investment upon US regulatory approval of IV Korsuva, as well as milestone payments dependent on achieving commercial targets, which together could total up to USD 290 million. Additional information regarding the terms of the agreements between Cara and Vifor announced today will be set forth in a Current Report on Form 8-K to be filed by Cara with the U.S. Securities and Exchange Commission on October 20, 2020.

In May 2018, Cara Therapeutics and Vifor Fresenius Medical Care Renal Pharma (VFMCRP) signed an initial agreement that granted the rights to develop and commercialize IV Korsuva for the treatment of chronic kidney disease-associated pruritus (CKD-aP) in hemodialysis and peritoneal dialysis patients worldwide, excluding the US, Japan and South Korea. At that time Cara retained full development and commercialization rights for IV Korsuva for the treatment of CKD-aP in the US except in the dialysis clinics of Fresenius Medical Care North America (FMCNA), where VFMCRP and Cara were to promote IV Korsuva under a profit-sharing arrangement based on net FMCNA clinic sales recorded by Cara. Under the agreement, Cara had sole responsibility to promote IV Korsuva in the US in non-Fresenius Medical Care clinics.

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Conference Call
Cara management will host a conference call today at 8:30 am 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 1891110. A live webcast of the call can be accessed under "Events and Presentations" in the News & Investors section of Cara's website at www.CaraTherapeutics.com. An archived webcast recording will be available on the Cara website beginning approximately two hours after the call.

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a 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 and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care).

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 viforpharma.com

Cara Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing new chemical entities designed to alleviate pruritus by selectively targeting peripheral kappa opioid receptors, or KORs. Cara is developing a novel and proprietary class of product candidates, led by KORSUVA™ (difelikefalin), a first-in-class KOR agonist that targets the body's peripheral nervous system, as well as certain immune cells. In two Phase 3 trials, IV KORSUVA 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). Cara has successfully completed its Phase 2 trial of Oral KORSUVA for the treatment of pruritus in patients with CKD and is currently conducting Phase 2 trials of Oral KORSUVA in atopic dermatitis and primary biliary cholangitis patients with moderate-to-severe pruritus.

CKD-aP is an intractable systemic itch condition that occurs with high frequency and intensity in patients with chronic kidney disease undergoing 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 on dialysis, 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 pruritus.[1,2] 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 depression.[3] CKD-aP is also an independent predictor of mortality among haemodialysis patients, mainly related to increased risk of inflammation and infections.

References:
1. 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.
2. Ramakrishnan K, et al. Clinical characteristics and outcomes of end-stage renal disease patients with selfreported pruritus symptoms. International Journal of Nephrology and Renovascular Disease. 2014; 7: 1-12.
3. Mathur VS, et al.

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 IV KORSUVA by Vifor Pharma, the potential benefits of Vifor Pharma's marketing IV KORSUVA in the United States through arrangement announced today, the potential of IV KORSUVA to address a significant unmet need, the potential equity investment, milestone and profit-sharing payments payable to Cara Therapeutics pursuant to the agreement and the expected timelines for planned 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 IV 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 Cara's Annual Report on Form 10-K for the year ended December 31, 2019, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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.

**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*.