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): February 25, 2022

Crinetics Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38583**	**26-3744114**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

10222 Barnes Canyon Road, Bldg. #2 **San Diego, California** **(Address of Principal Executive Offices)**	**92121** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (858) 450-6464

(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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	CRNX	NASDAQ Global Select Market

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.

On February 25, 2022, Crinetics Pharmaceuticals, Inc. ("Crinetics"), and Sanwa Kagaku Kenkyusho Co., Ltd. ("Sanwa"), an established, fully integrated pharmaceutical company headquartered in Nagoya, Japan, entered into a licensing agreement (the “Licensing Agreement”) for Sanwa to exclusively develop and commercialize paltusotine in Japan. Paltusotine is Crinetics’ investigational, orally available nonpeptide somatostatin receptor type 2 (SST2) agonist being evaluated as a treatment for acromegaly and neuroendocrine tumors (NETs), including NETs complicated by carcinoid syndrome.

Under the terms of the Licensing Agreement, Crinetics will receive $13.0 million upfront and will be eligible to receive up to an additional $25.5 million in milestone payments related to the achievement of certain development, regulatory and commercial goals. In addition, upon market approval of paltusotine in Japan, Crinetics will be eligible to receive tiered royalties, ranging from the low single digits to the high teens, based on net product sales. Sanwa will have an exclusive right to develop and commercialize the product in Japan and will be responsible for leading the development and commercialization of paltusotine for acromegaly and NETs in Japan. Also, Sanwa will assume all costs associated with clinical trials and regulatory applications associated with these processes. Crinetics retains all rights to develop and commercialize the product outside Japan.

There are approximately 10,000 acromegaly patients and 11,000 NETs patients in Japan and, as in the United States, somatostatin analogues are the first-line medical therapy for individuals for whom surgery is either not prescribed or is not curative.

Crinetics is currently enrolling patients in its Phase 3 PATHFNDR program, which is evaluating the safety and efficacy of once-daily oral paltusotine in a wide cross section of acromegaly patients in the United States and Europe. In Japan, Sanwa expects to initiate Phase 1 development with paltusotine in 2022.

The foregoing description of the Licensing Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Licensing Agreement, which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022. The Company intends to redact certain portions of the Licensing Agreement for confidentiality purposes.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding the potential benefits of paltusotine for patients with acromegaly or neuroendocrine tumors complicated by carcinoid syndrome; the potential benefits of, and results that may be achieved pursuant to, Crinetics’ licensing agreement with Sanwa; the payment of upfront and future milestones and royalties on future sales, as well as the total potential value of the licensing agreement; Crinetics’ enrollment efforts in its ongoing Phase 3 trials of paltusotine in acromegaly; and the potential to initiate a Phase 1 program of paltusotine in Japan and the expected timing thereof. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including risks and uncertainties inherent in Crinetics’ business, including unexpected adverse side effects or inadequate efficacy of the company’s product candidates that may limit their development, regulatory approval and/or commercialization, the company’s dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the success of Crinetics’ clinical trials and nonclinical studies; Sanwa may not pursue the development of paltusotine or those efforts may not be successful and the other risks and uncertainties described in the company’s periodic filings with the SEC. The events and circumstances reflected in the company’s forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Additional information on risks facing Crinetics can be found under the heading “Risk Factors” in Crinetics’ periodic reports, including its annual report on Form 10-K for the year ended December 31, 2020, filed with the SEC. Except as required by applicable law, Crinetics does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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 thereunto duly authorized.

Crinetics Pharmaceuticals, Inc.

Date: February 28, 2022

By: /s/ R. Scott Struthers, Ph.D.
R. Scott Struthers, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)