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): January 6, 2021

Crinetics Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38583**	**26-3744114**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

10222 Barnes Canyon Road, Bldg #2
San Diego, California 92121
(858) 450-6464
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

N/A
(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 obligations 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 (17 CFR § 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR § 240.12b-2).

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 8.01 Other Events.

On January 6, 2021, Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") announced that Company management will participate in the 39th annual J.P. Morgan Healthcare Conference, which is taking place in a virtual format. Scott Struthers, Ph.D., Founder & CEO of Crinetics, will present a company update on Wednesday, January 13th at 1:30 pm Pacific Time. A live audio webcast of Dr. Struthers' presentation may be accessed on the Events section of the Company's website or directly on the J.P. Morgan virtual meeting platform.

During his presentation, Dr. Struthers will discuss Crinetics' key priorities and anticipated milestones for 2021, including initiating the Phase 3 program for paltusotine (formerly CRN00808) for the treatment of acromegaly, initiating clinical trials for paltusotine in patients with carcinoid syndrome as well as for two new drug candidates for congenital hyperinsulinism (CHI) and diseases of excess adrenocorticotropic hormone (ACTH). To support the Company's growing pipeline, Crinetics has expanded its development and medical teams with the appointments of several additional clinical endocrinology experts, increasing the company's total headcount to 90 with plans for continued hiring in 2021.

2020 Accomplishments

- Paltusotine for Acromegaly: In the fourth quarter of 2020, Crinetics reported positive top-line data from its Phase 2 program evaluating paltusotine for the treatment of acromegaly. These results demonstrated that individuals with acromegaly who switched from standard-of-care injected somatostatin receptor ligand (SRL) depots to once-daily oral paltusotine were able to maintain the level of insulin-like growth factor-1 (IGF-1) that was previously achieved on standard-of-care.
- Pipeline Programs Advanced Toward the Clinic: Crinetics selected CRN04894 as the company's lead ACTH antagonist and completed first-in-human-enabling manufacturing and toxicology studies. Such studies were also completed for its somatostatin receptor type 5 (SST5) agonist (CRN04777) drug candidate. After review of preclinical and manufacturing data, as well as Phase 1 study designs, the U.S. Investigational New Drug (IND) application for CRN04894 is now open and Germany's Federal Institute for Drugs and Medical Devices (BfArM) has approved the start of the Phase 1 trial for CRN04777.
- In-house Expertise: Throughout 2020, Crinetics bolstered its clinical and medical teams with the addition of experts in the development of therapeutics and management of clinical trials for endocrine diseases. These new hires include Drs. Alessandra Casagrande, Peter Trainer and Hjalmar Lagast, who join Drs. Alan Krasner and Christine Ferrara-Cook.

2021 Goals

- Paltusotine for Acromegaly: Crinetics expects to hold an end-of-Phase-2 meeting with the FDA in the first quarter of 2021 and start its Phase 3 program in the first half of 2021. Crinetics intends to use a new, improved tablet formulation of paltusotine in the Phase 3 program for acromegaly. This formulation is designed to provide convenient once-daily administration but enable a reduced fasting requirement (0.5 to 1 hour before eating) and improved dose-proportional exposure compared to the prior formulation. In addition, the new tablet formulation is designed to enable the administration of paltusotine with commonly used proton pump inhibitors.
- Paltusotine for Carcinoid Syndrome: Crinetics expects to advance paltusotine into a clinical study in patients with carcinoid syndrome due to neuroendocrine tumors (NETs). Injected SRLs are the standard of care for patients with carcinoid syndrome, but many patients become increasingly resistant to treatment over time, requiring increased dosage of depot preparations or the addition of short-acting analogs. Crinetics believes that an oral therapy with a long half-life and dose-proportional exposure would be a useful option for these patients, if approved.
- CRN04894: A Phase 1 study evaluating the ability of CRN04894 to suppress ACTH-stimulated cortisol secretion in healthy volunteers is planned to commence in January 2021. Data is expected in the first half of 2021 and, if positive, the results from this trial may provide proof-of-concept data supporting further evaluation of CRN04894 in the treatment of diseases associated with excess ACTH such as Cushing's disease and congenital adrenal hyperplasia (CAH). CRN04894 is an investigational, oral, selective ACTH antagonist designed to block the action of excess ACTH on the adrenal gland resulting in excess cortisol in Cushing's disease and excess adrenal androgens in CAH.
- CRN04777: A Phase 1 study evaluating the ability of CRN04777 to reduce stimulated insulin secretion in healthy volunteers is planned to commence in February 2021. Data is expected in mid-2021 and, if positive, the results of this trial may provide proof-of-concept data to support further evaluation of CRN04777 in the treatment of children with CHI. CRN04777 is an investigational, oral, selective non-peptide SST5 receptor agonist designed to reduce insulin secretion and thereby correct the life-threatening hypoglycemia (low blood glucose) that affects these children.
- In 2021, Crinetics expects to continue its drug discovery efforts with programs to identify drug candidates for hyperparathyroidism, nonfunctional pituitary adenomas and polycystic kidney disease, among other indications. This pipeline expansion is intended to drive continued growth and value for stakeholders.

Forward-Looking Statements

Crinetics cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential benefits of paltusotine for acromegaly patients and for patients with carcinoid syndrome; the potential to initiate a Phase 3 program of paltusotine in acromegaly and the expected timing thereof; Crinetics' plans to meet with the FDA in the first quarter of 2021; the benefits of Crinetics' improved tablet formulation of paltusotine; the potential to initiate a of paltusotine in patients with carcinoid syndrome due to NETs and the expected timing thereof; the potential to begin Phase 1 clinical development with CRN04894 and CRN04777 and the expected timing for the commencement thereof and the related generation of proof-of-concept data in healthy volunteers; Crinetics' plan to advance its programs into late-stage clinical trials and to create new drug candidates for additional diseases; and Crinetics' plans to identify and create new drug candidates for additional diseases, including hyperparathyroidism, nonfunctional pituitary adenomas and polycystic kidney disease, among other indications. The inclusion of forward-looking statements should not be regarded as a representation by Crinetics that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Crinetics' business, including, without limitation: advancement of paltusotine into a Phase 3 program for acromegaly or a trial for carcinoid syndrome and CRN04894 and CRN04777 into Phase 1 trials are dependent on and subject to the receipt of further feedback from the FDA; the COVID-19 pandemic may disrupt Crinetics' business and that of the third parties on which it depends, including delaying or otherwise disrupting its clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; 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 for paltusotine, CRN04894, CRN04777 and its other product candidates; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of the company's product candidates that may limit their development, regulatory approval and/or commercialization; Crinetics may use its capital resources sooner than it expects; and other risks described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Crinetics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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.

Crinetics Pharmaceuticals, Inc.

Date: January 6, 2021

/s/ R. Scott Struthers, Ph.D.
R. Scott Struthers, Ph.D.
President and Chief Executive Officer