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 3, 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 February 3, 2021, Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") announced the initiation of a Phase 1 study of CRN04777, an oral, nonpeptide somatostatin receptor type 5 ("SST5") agonist being developed as a treatment for congenital hyperinsulinism ("HI"). Congenital HI is a rare genetic disease associated with dysregulated insulin production in which excess insulin produces life threatening hypoglycemia (low blood glucose) beginning at birth. The purpose of this study is to evaluate the safety and tolerability of CRN04777 in healthy adult volunteers, as well as to provide evidence of clinical proof-of-concept. In addition, the study is designed to test the mechanism of action of CRN04777 by measuring its ability to suppress insulin secretion in healthy volunteers following stimulation with either glucose or a sulfonylurea, an agent that increases the secretion of insulin. CRN04777 is a novel therapy under development that focuses on reducing insulin secretion, with a potential mechanism of action that we believe could treat all genetic forms of congenital HI.

About the CRN04777-01 Phase 1 Study
Crinetics anticipates enrolling up to 117 healthy volunteers, who will be randomized into cohorts to receive single-ascending doses ("SAD") or multiple-ascending doses ("MAD") of CRN04777. In the first part of the SAD phase, participants will receive IV glucose to stimulate insulin production and baseline plasma biomarker levels will be recorded. The following day, participants will receive CRN04777 or placebo followed by the IV glucose challenge, and a comparison will be made of plasma biomarker levels to baseline. In the second part of the SAD phase, participants will receive a sulfonylurea to stimulate insulin secretion in the setting of a euglycemic clamp, in which blood glucose levels are maintained ("clamped") via glucose infusion. Baseline plasma biomarker levels as well as the amount of IV glucose required to maintain euglycemia will be recorded. On the next day, participants will be administered CRN04777 or placebo, after which they will receive the sulfonylurea challenge, and a comparison will be made of plasma biomarker levels and IV glucose support to baseline levels. In the MAD phase, volunteers will undergo the sulfonylurea challenge in the setting of a euglycemic clamp at baseline after which they will be administered placebo or ascending doses of study drug daily for 10 days. Levels of IV glucose support, glucose, insulin and C-peptide will be measured after CRN04777 administration and compared to baselines to determine the degree to which CRN04777 can reduce insulin levels. Food effect, safety and tolerability will also be assessed.

In September 2020, it was announced that the U.S. Food and Drug Administration granted rare pediatric disease designation for CRN04777. A rare pediatric disease is defined as a serious or life-threatening disease, which primarily affects individuals aged from birth to 18 years and affects fewer than 200,000 people in the United States.

About Congenital Hyperinsulinism
Hyperinsulinism (HI) is a heterogeneous condition in which dangerously low blood sugar levels are caused by increased insulin secretion from pancreatic β-cells. Congenital HI is a severe form of hyperinsulinism driven by one of more than ten known genetic mutations in certain genes involved in regulating insulin secretion. The incidence of congenital HI is approximately 1 in 30,000 to 50,000 new births in the United States and it is estimated that there are between 2,000 and 4,000 congenital HI patients in the U.S. While this is a rare disease, congenital HI is a leading cause of persistent hypoglycemia in infants and children. Early diagnosis is vital to prevent neurological complications due to recurrent low blood sugar, which can result in apnea, seizures, developmental delays, learning disabilities and even death.

Forward-Looking Statements
Crinetics cautions you that statements contained in this report 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 initiation and enrollment of a Phase 1 clinical study in CRN04777 and the expected timing thereof; the potential to generate data regarding the safety, tolerability, food effects and mechanism of action of CRN04777 from such Phase 1 study in healthy volunteers and the expected timing thereof; the potential that such data will provide evidence of clinical proof-of-concept of CRN04777; and the potential of CRN04777 to treat all genetic forms of congenital HI. 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 report 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 program for carcinoid syndrome is 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, 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: February 3, 2021

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