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): September 21, 2020

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 September 21, 2020, Crinetics Pharmaceuticals, Inc. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") has granted rare pediatric disease designation for CRN04777, an investigational, orally available, nonpeptide somatostatin receptor type 5 ("SST5") agonist being developed as a treatment for congenital hyperinsulinism ("HI"). Congenital HI is a devastating rare disease in which infants are born with life-threatening hypoglycemia (low blood glucose) due to excess insulin secretion.

The Company believes CRN04777 is the first oral, selective nonpeptide SST5 receptor agonist designed to reduce insulin secretion and is designed to be a universal treatment for all patients with congenital HI. The Company plans to initiate a Phase 1 clinical study for CRN04777 in early 2021.

A rare pediatric disease is defined by the Federal Food, Drug, and Cosmetic Act to include 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 U.S. In an effort to address the challenges drug companies face when developing treatments for these unique patient populations, the FDA developed the Rare Pediatric Disease Priority Review Voucher ("PRV") Program. Under this program, companies are eligible to receive a priority review voucher following approval of a product with an RPD designation if the marketing application submitted for the product satisfies certain additional conditions, including approval no later than September 30, 2022 (unless this statutory sunset provision is modified by Congress). If issued, a sponsor may redeem a PRV for priority review of a subsequent marketing application for a different product candidate, or the PRV could be sold or transferred to another sponsor.

Forward-Looking Statements

The Company 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 Company's eligibility to receive a priority review voucher following approval of CRN04777 for the treatment of congenital HI; the potential to initiate Phase 1 trials of CRN04777 and the timing thereof; and the potential of CRN04777 to be an effective treatment option for congenital HI patients. The inclusion of forward-looking statements should not be regarded as a representation by the Company 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 the Company's business, including, without limitation: the Company may not meet the eligibility criteria for a priority review voucher; potential delays in the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; advancement of CRN04777 into a Phase 1 trial for congenital HI is dependent on and subject to the receipt of further feedback from the FDA; the COVID-19 pandemic may disrupt the Company's 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; unexpected adverse side effects or inadequate efficacy of the Company's product candidates that may limit their development, regulatory approval and/or commercialization; 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 the Company 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: September 21, 2020

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