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): March 31, 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)

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 2.02 Results of Operations and Financial Condition.

On May 6, 2021, Crinetics Pharmaceuticals, Inc. issued a press release reporting its financial results for the quarter ended March 31, 2021. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information contained or incorporated herein, including the press release filed as Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No	Description
99.1	Press Release dated May 6, 2021.
104	Cover Page Interactive 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.

Crinetics Pharmaceuticals, Inc.

Date: May 6, 2021

/s/ R. Scott Struthers, Ph.D.

R. Scott Struthers, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

FOR IMMEDIATE RELEASE

Crinetics Pharmaceuticals Reports First Quarter 2021 Financial Results and Provides Corporate Update

Paltusotine Phase 3 PATHFNDR program in acromegaly initiated in 2Q 2021

Phase 1 data for CRN04894 and CRN04777 expected in mid-2021

SAN DIEGO – May 6, 2021 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX), a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors, today announced financial results for the first quarter ended March 31, 2021 and provided a corporate update.

"In the first quarter we achieved key clinical and regulatory milestones across our pipeline," said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. "Based on our interactions with the FDA and other regulators, we developed a robust Phase 3 program for paltusotine that is designed to support its approval for all acromegaly patients who require pharmacotherapy, including both untreated patients and those switching from injected standard of care. This progress was complemented by the advancement of CRN04894 and CRN04777 into Phase 1 trials in healthy volunteers, which are designed to generate safety, pharmacokinetic, and biomarker data that could establish clinical proof of concept and provide important dose guidance information for subsequent trials in patients. Looking ahead, we are on track for a steady cadence of catalysts through the remainder of the year, including data from both of our Phase 1 trials and the initiation of a clinical study in patients with neuroendocrine tumors complicated by carcinoid syndrome."

First Quarter and Subsequent Highlights

- **Announced the design of the Phase 3 program for paltusotine in acromegaly.** In March 2021, Crinetics announced plans to initiate two Phase 3 studies based on interactions with the U.S. Food and Drug Administration (FDA) and other regulators. The first of these studies, PATHFNDR-1, is a double-blind, placebo-controlled, nine-month clinical trial evaluating the safety and efficacy of paltusotine in acromegaly patients who are biochemically controlled (IGF-1 ≤ 1.0 × upper limit of normal [ULN]) and who are on stable doses of somatostatin receptor ligand monotherapy (octreotide LAR or lanreotide depot). The second study, PATHFNDR-2, is a double-blind, placebo-controlled, twelve-week trial in acromegaly patients with elevated IGF-1 levels who are medication naïve or who are not being treated with pharmacotherapy (untreated patients). If successful, Crinetics believes these trials could support registration of paltusotine in the United States and Europe for all acromegaly patients who require pharmacotherapy, including untreated patients and those switching from standard of care. The company initiated PATHFNDR-1 in April and expects to initiate PATHFNDR-2 in 2H 2021.

- **Showcased broad clinical-stage pipeline at ENDO 2021.** In March 2021, Crinetics gave presentations on its three clinical programs at the Endocrine Society's annual ENDO 2021 congress. Posters on the company's acromegaly program included a summary of the previously announced ACROBAT Edge Phase 2 results, as well as details of the new tablet formulation of paltusotine. Presentations related to the company's earlier stage clinical programs included a poster with preclinical data supporting the development of CRN04777 as a treatment for congenital hyperinsulinism (HI) and a live oral presentation with preclinical evidence supporting the further evaluation of CRN04894 in Cushing's disease and congenital adrenal hyperplasia (CAH).
- **Advanced ACTH antagonist CRN04894 into a Phase 1 study designed to provide clinical proof of concept.** In February 2021, Crinetics initiated a Phase 1 study of CRN04894, an investigational, oral, nonpeptide adrenocorticotropic hormone (ACTH) antagonist being developed for the treatment of diseases associated with excess ACTH such as

Cushing's disease and congenital adrenal hyperplasia (CAH). This study is designed to evaluate the safety and tolerability of CRN04894 in healthy volunteers, and to provide clinical proof-of-concept data by measuring the effect of CRN04894 on the suppression of endocrine biomarkers that are used as key endpoints in patient studies and reflect the ability of CRN04894 to block ACTH-stimulated adrenal function. This healthy volunteer trial is also expected to provide important information for dose selection and be predictive of efficacy in Cushing's disease and CAH patients. Crinetics expects preliminary safety, pharmacokinetic, and endocrine biomarker data in mid-2021.

- **Advanced SST5 agonist CRN04777 into a Phase 1 study designed to provide clinical proof of concept.** In February 2021, Crinetics initiated a Phase 1 study of CRN04777, an investigational, oral, nonpeptide somatostatin receptor type 5 (SST5) agonist. CRN04777 is being developed as a treatment for congenital HI, a rare genetic disease in which excess insulin secretion causes life-threatening hypoglycemia (low blood glucose). This study is designed to evaluate the safety and tolerability of CRN04777 in healthy volunteers and provide clinical proof-of-concept data by measuring both the ability of CRN04777 to inhibit glucose- and sulfonylurea-induced insulin secretion and the corresponding effects on blood glucose levels. These endocrine biomarkers are indicative of the ability of CRN04777 to prevent hypoglycemia and are expected to provide information for dose selection and be predictive of efficacy in patients with hyperinsulinism. Crinetics expects preliminary safety and pharmacological effect data in mid-2021.
- **Strengthened balance sheet with successful common stock offering.** In April 2021, Crinetics completed an underwritten follow-on offering and raised net proceeds of approximately $72.5 million.

First Quarter 2021 Financial Results

- Research and development expenses were $17.6 million for the three months ended March 31, 2021, compared to $13.9 million for the same period in 2020. The increase was primarily attributable to additional personnel costs and clinical development and manufacturing activities for paltusotine, CRN04894, and CRN04777 as well as the company's other preclinical programs.
- General and administrative expenses were $5.3 million for the three months ended March 31, 2021, compared to $4.0 million for the same period in 2020. The increase was primarily due to additional personnel costs to support the company's growth.
- Net loss for the three months ended March 31, 2021 was $22.9 million, compared to a net loss of $17.4 million for the three months ended March 31, 2020.
- Unrestricted cash, cash equivalents and investments totaled $150.7 million as of March 31, 2021, compared to $170.9 million as of December 31, 2020. The cash balance at the end of March does not include the $72.5 million of net proceeds from the follow-on offering completed in April.
- As of April 30, 2021, the company had 37,593,371 common shares outstanding.

About Crinetics Pharmaceuticals
Crinetics Pharmaceuticals is a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors. The company's lead product candidate, paltusotine (formerly CRN00808), is an investigational, oral, selective nonpeptide somatostatin receptor type 2 biased agonist for the treatment of acromegaly, an orphan disease affecting more than 26,000 people in the United States. A Phase 3 program in acromegaly with paltusotine is underway. Crinetics also plans to advance paltusotine into a Phase 2 trial for the treatment of carcinoid syndrome associated with neuroendocrine tumors. The company is also developing CRN04777, an investigational, oral, nonpeptide somatostatin receptor type 5 (SST5) agonist for congenital hyperinsulinism, as well as CRN04894, an investigational, oral, nonpeptide ACTH antagonist for the treatment of Cushing's disease, congenital adrenal hyperplasia, and other diseases of excess ACTH. All of the company's drug candidates are new chemical entities resulting from in-house drug discovery efforts and are wholly owned by the company.

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 initiation of the PATHFNDR-2 clinical trial of

paltusotine in acromegaly and a Phase 2 trial for the treatment of carcinoid syndrome associated with neuroendocrine tumors and the expected timing thereof; the potential for such Phase 3 program to support broad approval of paltusotine for all acromegaly patients who require pharmacotherapy; and the potential to generate safety, pharmacokinetic, and biomarker data from the Phase 1 studies in healthy volunteers with CRN04894 and CRN04777 that could establish clinical proof of concept and provide important dose guidance information for subsequent trials, and the expected timing thereof. 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: the FDA or other regulatory agencies may require one or more additional clinical trials of paltusotine or suggest changes to our planned Phase 3 clinical trials prior to and in support of the approval of a New Drug Application or applicable foreign regulatory approval; advancement of paltusotine into a Phase 2 trial 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, 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.

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CRINETICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENT DATA
(In thousands, except per share data)
(Unaudited)

STATEMENTS OF OPERATIONS DATA:	**Three months ended March 31, 2021**	**2020**
Grant revenues	$ -	$ 71
Operating expenses:		
Research and development	17,584	13,862
General and administrative	5,334	3,991
Total operating expenses	22,918	17,853
Loss from operations	(22,918)	(17,782)
Total other income (expense), net	17	422
Net loss	$ (22,901)	$ (17,360)
Net loss per share - basic and diluted	$ (0.69)	$ (0.71)
Weighted-average shares - basic and diluted	33,012	24,488

BALANCE SHEET DATA:	**March 31, 2021**	**December 31, 2020**
Cash, cash equivalents and investments	$ 150,665	$ 170,880
Working capital	$ 147,540	$ 167,003
Total assets	$ 163,550	$ 183,445
Total liabilities	$ 14,070	$ 14,526
Accumulated deficit	$ (190,515)	$ (167,614)
Total stockholders’ equity	$ 149,480	$ 168,919