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): May 12, 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 2.02 Results of Operations and Financial Condition.

On May 12, 2022, Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") issued a press release reporting its financial results for the period ended March 31, 2022. 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 12, 2022.
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 thereunto duly authorized.

Crinetics Pharmaceuticals, Inc.

Date: May 12, 2022

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

Crinetics Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update

- *Phase 1 Multiple-Ascending Dose Data for CRN04894 Expected in 2Q22*
- *Paltusotine's Phase 3 PATHFNDR Trials in Acromegaly Advancing Towards Anticipated Top-Line Data Readouts in 2023*
- *Clinical Trial of CRN04777 in Congenital Hyperinsulinism Patients Planned to Begin in 2H22 Following Our Previous Announcement of Positive Top-Line Data from Phase 1 Multiple-Ascending Dose Cohorts*
- *Strengthened Balance Sheet by Raising Gross Proceeds of $125 Million in Successful Common Stock Offering*

SAN DIEGO – May 12, 2022 – 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 reported financial results for the first quarter ended March 31, 2022.

"We continue to build the foundation needed to establish Crinetics as the world's leading endocrine company, as recent progress has strengthened our clinical dataset, balance sheet and leadership team," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "This is highlighted by CRN04777's recent Phase 1 top-line results, which further demonstrated the molecule's dose-dependent effects on biomarkers that are critically important to the pathophysiology and medical management of hyperinsulinism. Later this quarter, we expect to report data from a healthy volunteer study designed to evaluate CRN04894's potential to counteract the effects of excess ACTH with a novel mechanism of action. The pharmacologic proof-of-concept these Phase 1 studies aim to achieve highlights the unique efficiency of our endocrine drug development paradigm. Looking forward, we will continue to combine the advantages of this paradigm with the efforts of our deeply talented drug discovery team to thoughtfully expand our pipeline as we work to advance our current clinical-stage candidates towards registration."

First Quarter 2022 and Recent Highlights

- **Reported positive top-line results from multiple-ascending dose (MAD) cohorts of the CRN04777 Phase 1 study.** In March 2022, Crinetics announced positive data from the MAD cohorts of a Phase 1 study of CRN04777, a somatostatin receptor type 5 (SST5) agonist being developed as a treatment for congenital and syndromic hyperinsulinisms. The results built upon previously reported pharmacologic proof-of-concept data from the trial's single-ascending dose (SAD) cohorts, as they showed strong dose-dependent suppression of fasting insulin as well as dose-dependent suppression of sulfonylurea-induced insulin secretion. Pharmacokinetic data indicated CRN04777 was orally bioavailable and supported a once daily dosing schedule. CRN04777 was shown to be well tolerated in the Phase 1 trial, with no dose discontinuations due to adverse events. Crinetics plans to initiate a Phase 2 study of CRN04777 in congenital hyperinsulinism patients in the second half of 2022, following discussions with global regulators.
- **Entered into strategic licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd. ("Sanwa") for the development and commercialization of paltusotine in Japan.** Crinetics received $13 million upfront in connection with the license agreement and is also eligible to receive payments related to development, regulatory, and commercial milestones. In addition, Crinetics will be eligible to receive tiered royalties on net product sales in Japan should paltusotine receive marketing approval in Japan. In exchange, Sanwa was granted an exclusive right to develop and commercialize paltusotine in Japan and will assume all costs associated with clinical trials and regulatory applications in the territory. Crinetics retains all rights to develop and commercialize paltusotine outside of Japan.

- **Strengthened balance sheet with successful $125 million common stock offering.** In April 2022, Crinetics completed an underwritten follow-on offering of 5,625,563 shares of its common stock at a price to the public of $22.22 per share, raising gross proceeds of approximately $125.0 million.
- **Strengthened company leadership with appointments to management team and Board of Directors**. In the first quarter of 2022, Crinetics built upon its strong leadership and scientific expertise by appointing James Hassard to the role of chief commercial officer, Chris Robillard to the role of chief business officer, and Dr. Rogério Vivaldi Coelho and Caren Deardorf to the Board of Directors.

First Quarter 2022 Financial Results

- Research and development expenses were $28.3 million for the three months ended March 31, 2022, compared to $17.6 million for the same period in 2021. The increase was primarily attributable to increased spending on manufacturing and development activities of $7.0 million associated with our clinical and nonclinical activities for paltusotine and our other clinical and preclinical programs, and an increase in personnel costs of $3.0 million, of which stock based compensation was $1.4 million.
- General and administrative expenses were $8.7 million for the three months ended March 31, 2022, compared to $5.3 million for the same period in 2021. The increase was primarily attributable to an increase in personnel costs of $2.1 million, of which stock compensation was $1.0 million.
- Net loss for the three months ended March 31, 2022, was $34.6 million, compared to a net loss of $22.9 million for the same period in 2021.
- Revenues were $3.1 million for the three months ended March 31, 2022, consisting of license revenue recognized from the Sanwa license agreement.
- Unrestricted cash, cash equivalents and investments totaled $319.7 million as of March 31, 2022, compared to $333.7 million as of December 31, 2021. The $319.7 million in unrestricted cash, cash equivalents and investments does not include the $125.0 million in gross proceeds from the company's April 2022 common stock offering. Based on its current plans, the company expects that current cash, cash equivalents and short-term investments will fund its current operating plan into the second half of 2024.
- The company had 53,505,809 common shares outstanding as of May 9, 2022.

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, is an investigational, oral, selective nonpeptide somatostatin receptor type 2 (SST2) biased agonist for the treatment of acromegaly, an orphan disease affecting more than 26,000 people in the United States. A Phase 3 clinical program in acromegaly with paltusotine is underway. Crinetics Pharmaceuticals is also developing paltusotine for the treatment of carcinoid syndrome associated with neuroendocrine tumors. The company is developing CRN04777, an investigational, oral, nonpeptide somatostatin receptor type 5 (SST5) agonist for congenital and other forms of hyperinsulinism, as well as CRN04894, an investigational, oral, nonpeptide adrenocorticotropic hormone (ACTH) antagonist for the treatment of congenital adrenal hyperplasia, Cushing's disease and other diseases of excess ACTH. All of the company's drug candidates are new chemical entities resulting from in-house drug discovery efforts.

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 for Crinetics to be a leader in the design and development of novel small molecule drugs for endocrine diseases; the plans and timelines for the clinical development of paltusotine, CRN04777 and CRN04894, including the therapeutic potential and clinical benefits thereof; the expected timing of data from the Phase 1 clinical trial of

CRN04984 and Phase 3 clinical trials of paltusotine; Crinetics' plans to advance a Phase 2 clinical trial of CRN04777 and the timing thereof; Crinetics' potential to receive future milestone and royalty payments from Sanwa; Crinetics' anticipated cash runway and plans to advance other pipeline product candidates or discovery efforts. 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, without limitation, preliminary data that we report may change following a more comprehensive review of the data related to the clinical trials and such data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory authorities may not agree with our interpretation of such results; advancement of CRN04894 and CRN04777 into later stage trials is dependent on and subject to the receipt of further feedback from the FDA and other regulatory agencies; we may not be able to obtain, maintain and enforce our patents and other intellectual property rights, and it may be prohibitively difficult or costly to protect such rights; 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; 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; regulatory developments in the United States and foreign countries; Crinetics' ability to receive milestone or royalty payments from Sanwa will depend on Sanwa's ability to advance the pipeline through clinical development, regulatory approval and ultimately commercial sales, all of which will take significant time, will be subject to inherent risks in drug development and may be impacted by changes in regulatory requirements, healthcare reform measures and competitive dynamics; clinical trials and preclinical studies may not proceed at the time or in the manner expected, or at all; the timing and outcome of research, development and regulatory review is uncertain, and Crinetics' drug candidates may not advance in development or be approved for marketing; Crinetics may use its capital resources sooner than expected; 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, 2021, You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. 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.

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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,**	
	2022	**2021**
License revenues	$ 3,131	$ —
Operating expenses:		
Research and development	28,252	17,584
General and administrative	8,706	5,334
Total operating expenses	36,958	22,918
Loss from operations	(33,827)	(22,918)
Total other income (expense), net	210	17
Loss before equity method investment	(33,617)	(22,901)
Loss on equity method investment	(1,010)	—
Net loss	$ (34,627)	$ (22,901)
Net loss per share - basic and diluted	$ (0.73)	$ (0.69)
Weighted-average shares - basic and diluted	47,712	33,012

BALANCE SHEET DATA:	**March 31, 2022**	**December 31, 2021**
Cash, cash equivalents and investments	$ 319,725	$ 333,707
Working capital	$ 307,992	$ 328,725
Total assets	$ 333,286	$ 351,015
Total liabilities	$ 30,242	$ 19,071
Accumulated deficit	$ (309,882)	$ (275,255)
Total stockholders’ equity	$ 303,044	$ 331,944