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 04, 2023

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	**92121**
(Address of Principal Executive Offices)	**(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 May4, 2023, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended March 31, 2023. 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 4, 2023.
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 4, 2023

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 2023 Financial Results and Provides Corporate Update

- *Phase 3 PATHFNDR-1 study topline data expected in 3Q 2023*
- *Phase 3 PATHFNDR-2 study topline data expected in 1Q 2024 and enrollment target increased to up to 98 per prespecified protocol criteria*
- *Paltusotine's Phase 2 study in carcinoid syndrome on track for preliminary data in 4Q 2023*

SAN DIEGO – May 4, 2023 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today reported financial results for the first quarter ended March 31, 2023.

"We plan to share topline results from PATHFNDR-1 next quarter, which should provide an important look at the impact that paltusotine may have on patients' lives," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "We designed the two PATHFNDR studies to address both treatment-naïve patients as well as patients who may switch from standard of care, the two patient populations specifically outlined in the recently released draft guidance from the FDA on Developing Drugs for Acromegaly Treatment."

Dr. Struthers continued, "Enrollment in PATHFNDR-2 has benefited from enthusiastic participation of treatment-naïve patients. This enables us to take advantage of a prespecified opportunity to increase the study's enrollment target while maintaining our estimated timeline of topline data in the first quarter of 2024. We anticipate this will provide an even clearer picture of paltusotine's potential to treat patients who have been recently diagnosed with acromegaly and could strengthen the competitive position of paltusotine from a market and payer perspective, if approved."

Clinical Program Updates:

- **Paltusotine's Phase 3 PATHFNDR-1 study: enrollment complete with topline data expected in 3Q 2023.** PATHFNDR-1 is a placebo-controlled Phase 3 clinical study of once-daily, oral paltusotine in participants with acromegaly switching from standard-of-care peptide depots. It is designed to support an indication for the maintenance of acromegaly treatment. The study enrolled participants with acromegaly who were biochemically controlled (IGF-1 ≤ 1.0x upper limit of normal) on octreotide or lanreotide depot monotherapy. The primary endpoint of the study is the proportion of participants who maintain biochemical control on paltusotine vs. placebo. Final study enrollment is 58 participants with topline data expected in the third quarter of 2023.
- **Paltusotine's Phase 3 PATHFNDR-2 study: enrollment ongoing with enrollment target increased to up to 98; topline data expected in 1Q 2024.** PATHFNDR-2 is a placebo-controlled Phase 3 clinical study designed to support an indication for the treatment of acromegaly. The study is enrolling participants with acromegaly with elevated IGF-1 levels who are either treatment-naïve or untreated for at least four months (Stratum 1), or who wash out of prior octreotide or lanreotide therapy (Stratum 2). The current enrollment has included a higher enrollment of participants in Stratum 1 as compared to Stratum 2. Accordingly, Crinetics has elected to adjust PATHFNDR-2's sample size to enable enrollment of up to 98 participants, which was an option prespecified in the study protocol. In addition to preserving statistical power to detect a difference on the primary endpoint, increasing the study's sample size may enable a statistical comparison of Stratum 1 participants receiving either paltusotine or placebo. Topline data from the study are expected in the first quarter of 2024, in line with prior guidance.
- **Paltusotine NDA Submission anticipated in 2024.** Pending a successful outcome from the PATHFNDR studies, Crinetics plans to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) seeking regulatory approval for paltusotine in acromegaly with both treatment and maintenance of treatment indications.

- **Phase 2 open-label study of paltusotine in carcinoid syndrome ongoing.** The Phase 2 open-label study of paltusotine in carcinoid syndrome associated with neuroendocrine tumors continues to enroll participants with preliminary data expected in the fourth quarter of 2023.
- **Advancing CRN04894 studies in Cushing's disease and congenital adrenal hyperplasia.** Based on successful Phase 1 studies demonstrating pharmacologic proof-of-concept, Crinetics is conducting clinical studies of CRN04894 in patients with Cushing's disease and congenital adrenal hyperplasia. Data from both studies is expected in 2024.
- **CRN04777 progress.** In November 2022, the FDA informed Crinetics that its planned Phase 2 study of CRN04777 in pediatric participants with congenital hyperinsulinism was not yet permitted to proceed. Crinetics plans to submit additional information and data to the FDA to support a release of the clinical hold on the planned Phase 2 study. The planned Phase 2 study is supported by pharmacologic proof-of-concept results from a successful Phase 1 study in healthy adult volunteers conducted under a Clinical Trial Application in Germany.

First Quarter 2023 Financial Results

- Research and development expenses were $38.5 million for the three months ended March 31, 2023, compared to $28.3 million for the same period in 2022. The increase was primarily attributable to an increase in personnel costs of $7.0 million and increased consulting and outside services of $1.4 million to support paltusotine, CRN04894, CRN04777, and our preclinical programs.
- General and administrative expenses were $12.2 million for the three months ended March 31, 2023, compared to $8.7 million for the same period in 2022. The increase was primarily attributable to an increase in personnel costs of $2.7 million and an increase in other corporate expenditures of $0.8 million.
- Net loss for the three months ended March 31, 2023 was $46.0 million, compared to a net loss of $34.6 million for the same period in 2022.
- Revenues were $2.7 million for the three months ended March 31, 2023, compared to $3.1 million for the same period in 2022. Revenues in both periods were derived from out-licensing arrangements: for CRN01941 in March 2023 and paltusotine in February 2022.
- Unrestricted cash, cash equivalents, and investments totaled $296.1 million as of March 31, 2023, compared to $334.4 million as of December 31, 2022. Based on its current projections, the company expects that its cash, cash equivalents and short-term investments will fund its current operating plan through 2024.
- The company had 53,994,770 common shares outstanding as of May 1, 2023.

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. Paltusotine, an investigational, oral somatostatin receptor type 2 (SST2) agonist, is in Phase 3 clinical development for acromegaly and Phase 2 clinical development for carcinoid syndrome associated with neuroendocrine tumors. Crinetics has demonstrated pharmacologic proof-of-concept in Phase 1 clinical studies for CRN04777, an investigational, oral somatostatin receptor type 5 (SST5) agonist in development for congenital hyperinsulinism, and for CRN04894, an investigational, oral ACTH antagonist in development for the treatment of Cushing's disease, congenital adrenal hyperplasia, and other diseases of excess ACTH. All of the company's drug candidates are orally delivered, small molecule new chemical entities resulting from in-house drug discovery efforts.

EXHIBIT 99.1

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 plans and timelines for the clinical development of paltusotine, CRN04777 and CRN04894, including the therapeutic potential and clinical benefits thereof; the expected timing of topline data from the ongoing Phase 3 clinical studies of paltusotine in acromegaly and Phase 2 study of paltusotine in carcinoid syndrome; plans to submit data from the ongoing Phase 3 clinical studies of paltusotine in acromegaly to regulators in support of applications seeking approval for the use of paltusotine in acromegaly patients and the expected timing of an NDA submission for paltusotine for the treatment or maintenance of treatment of acromegaly in the United States; the potential effects of increasing the Phase 3 PATHFNDR-2 study's sample size; the expected timing of data from studies of CRN04894 in Cushing's disease and congenital adrenal hyperplasia; and plans to submit additional information and data to the FDA with the goal of gaining allowance to proceed with the Phase 2 study of CRN04777. 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, topline data that we report may change following a more comprehensive review of the data related to the clinical studies and such data may not accurately reflect the complete results of a clinical study, and the FDA and other regulatory authorities may not agree with our interpretation of such results; 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 and other geopolitical events may disrupt Crinetics' business and that of the third parties on which it depends, including delaying or otherwise disrupting its clinical studies 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 studies and nonclinical studies; regulatory developments in the United States and foreign countries; clinical studies 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; any future impacts to our business resulting from geopolitical developments outside our control; 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, 2022. 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.

EXHIBIT 99.1

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

STATEMENTS OF OPERATIONS DATA:	**Three months ended March 31,**	
	2023	**2022**
Revenues	$ 2,679	$ 3,131
Operating expenses:		
Research and development	38,468	28,252
General and administrative	12,189	8,706
Total operating expenses	50,657	36,958
Loss from operations	(47,978)	(33,827)
Total other income, net	1,983	210
Loss before equity method investment	(45,995)	(33,617)
Loss on equity method investment	—	(1,010)
Net loss	$ (45,995)	$ (34,627)
Net loss per share - basic and diluted	$ (0.85)	$ (0.73)
Weighted-average shares - basic and diluted	53,908	47,712

BALANCE SHEET DATA:	**March 31, 2023**	**December 31, 2022**
Cash, cash equivalents and investments	$ 296,122	$ 334,425
Working capital	$ 279,082	$ 317,461
Total assets	$ 314,009	$ 352,176
Total liabilities	$ 33,679	$ 35,848
Accumulated deficit	$ (485,168)	$ (439,173)
Total stockholders' equity	$ 280,330	$ 316,328

Contact:
Investor Relations
VP, IR & Corporate Communications
cschultz@crinetics.com
(858) 450-6464

Investors / Media:
Corey Davis
LifeSci Advisors, LLC
cdavis@lifesciadvisors.com
(212) 915-2577

Aline Sherwood
Scienta Communications
asherwood@scientapr.com
(312) 238-8957