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): November 07, 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 November 7, 2023, Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") issued a press release reporting its financial results for the period ended September 30, 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 November 7, 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: November 7, 2023

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

R. Scott Struthers, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 99.1

Crinetics Pharmaceuticals Reports Third Quarter 2023 Financial Results and Provides Corporate Update

Phase 3 PATHFNDR-1 Study Met Primary and All Secondary Endpoints as Reported in September

Phase 3 PATHFNDR-2 Study Topline Data Expected in 1Q 2024

Initial Data from Phase 2 Study of Paltusotine in Carcinoid Syndrome Expected in December 2023

SAN DIEGO – November 7, 2023 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today reported financial results for the third quarter ended September 30, 2023.

"The resounding success of paltusotine in our PATHFNDR-1 Phase 3 study for acromegaly is a significant step toward fulfilling our strategic vision of building a premier, fully integrated endocrine company that can consistently create pioneering therapies for people around the world," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "We intend to build additional momentum around our investigational compound paltusotine in the next few months. In December, we plan to analyze initial data from approximately half of the study participants in our ongoing Phase 2 study in carcinoid syndrome that should provide a preliminary indication of pharmacokinetic exposure, safety, and efficacy in this important second indication. We anticipate the full Phase 2 dataset from carcinoid to be available in the first half of 2024 and we remain on track to announce Phase 3 data from the PATHFNDR-2 study in the first quarter of 2024. We are enthusiastic about these upcoming key milestones for the paltusotine franchise."

Third Quarter 2023 and Operating Highlights:

- **Phase 3 PATHFNDR-1 study met primary and all secondary endpoints.** In September 2023, Crinetics reported positive topline results from its placebo-controlled Phase 3 clinical study of paltusotine in participants with acromegaly switching from standard-of-care injected depot somatostatin analogs which is designed to support an indication for the maintenance of acromegaly treatment. The study met statistical significance ($p<0.0001$) on the primary endpoint, based on the proportion of participants taking paltusotine (83%) who maintained an insulin-like growth factor 1 (IGF-1) level ≤ 1.0 times the upper limit of normal (xULN) compared to those taking placebo (4%). All secondary endpoints also met statistical significance as compared to placebo: change from baseline in IGF-level ($p<0.0001$), change from baseline in acromegaly symptoms diary (ASD) total score ($p=0.02$), and proportion of participants who maintained growth hormone level of <1.0 ng/mL ($p=0.0003$).
- **Completed enrollment in paltusotine's Phase 3 PATHFNDR-2 study.** PATHFNDR-2 is a placebo-controlled Phase 3 clinical study of oral paltusotine in participants with acromegaly who are treatment-naïve or not currently receiving medical therapy, which is designed to support an indication for the treatment of acromegaly. The study completed enrollment of 112 participants with acromegaly who were either treatment-naïve or untreated for at least four months (Stratum 1: n=82), or who washed out of prior octreotide or lanreotide monotherapy (Stratum 2: n=30). Topline data from the study is expected in the first quarter of 2024.
- **Hosted Key Opinion Leader (KOL) webinar discussing acromegaly unmet need.** In August 2023, Crinetics hosted a webinar featuring presentations by KOLs Beverly MK Biller M.D. and Karen JP Liebert, R.N., BSN, both of Massachusetts General Hospital, who discussed the current landscape and unmet medical need in acromegaly, as well as the treatment burden associated with standard-of-care injectable somatostatin receptor ligands (SRLs). A replay of the webinar can be accessed here.
- **Paltusotine NDA submission anticipated in 2024.** Pending successful data from the PATHFNDR-2 study, Crinetics plans to submit a new drug application (NDA) to the Food and Drug

Administration seeking regulatory approval for both the treatment of acromegaly and maintenance of acromegaly treatment indications.

- **Initial data from Phase 2 study of paltusotine in carcinoid syndrome expected December 2023.** The Phase 2 open-label study of paltusotine in carcinoid syndrome associated with neuroendocrine tumors is completing enrollment. A preliminary analysis from a subset of approximately half of the expected 30 participants is anticipated in December 2023. The study is designed primarily to assess the pharmacokinetic exposure and safety profile of paltusotine in participants with carcinoid syndrome. In addition, the study should provide descriptive efficacy information on the frequency of bowel movements and flushing episodes.
- **CRN04894 studies for Cushing's disease and congenital adrenal hyperplasia (CAH).** Based on successful Phase 1 studies demonstrating pharmacologic proof-of-concept, Crinetics is advancing clinical studies of CRN04894 in both Cushing's disease and congenital adrenal hyperplasia. Data from the ongoing studies are expected in the second half of 2024.
- **Strengthened balance sheet with $350 million public offering.** In September 2023, Crinetics announced the pricing of an upsized underwritten public offering of 11,441,648 shares of its common stock at $30.59 per share. Gross proceeds from the offering were $350.0 million.

Third Quarter 2023 Financial Results

- Research and development expenses were $43.8 million for the three months ended September 30, 2023, compared to $32.0 million for the same period in 2022. The change was primarily due to an increase in personnel costs of $8.3 million, increased net spending on manufacturing and development activities of $1.8 million associated with our clinical and nonclinical programs, and increased outside services of $1.2 million.
- General and administrative expenses were $15.5 million for the three months ended September 30, 2023, compared to $11.9 million for the same period in 2022. The change was primarily due to an increase in personnel costs of $3.2 million.
- Net loss for the three months ended September 30, 2023, was $57.5 million, compared to a net loss of $41.9 million for the same period in 2022.
- Revenues were $0.3 million for the three months ended September 30, 2023, compared to $0.5 million for the same period in 2022. Revenues in both periods were primarily derived from the paltusotine licensing arrangement with Sanwa Kagaku Kenkyusho Co., Ltd.
- Unrestricted cash, cash equivalents, and investments totaled $554.7 million as of September 30, 2023, compared to $334.4 million as of December 31, 2022. Based on its current projections, the company now expects that its cash, cash equivalents and short-term investments will be sufficient to fund its current operating plan into 2026.
- The company had 66,799,257 common shares outstanding as of October 31, 2023.

About Crinetics Pharmaceuticals

Crinetics Pharmaceuticals is a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for endocrine diseases and endocrine-related tumors. Paltusotine,an investigational, first-in-class, 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 a Phase 1 clinical study for CRN04894 a first-in-class, investigational, oral ACTH antagonist, that is currently in Phase 2 clinical studies for the treatment of Cushing's disease and congenital adrenal hyperplasia. All of the Company's drug candidates are orally delivered, small molecule new chemical entities resulting from in-house drug discovery efforts, including additional discovery programs addressing a variety of endocrine conditions such as

hyperparathyroidism, polycystic kidney disease, Graves' disease, thyroid eye disease, hyperinsulinism, diabetes and obesity.

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 and CRN04894, including the therapeutic potential and clinical benefits or safety profile 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 expected timing of data from studies of CRN04894 in Cushing's disease and congenital adrenal hyperplasia; and the expected timing through which our cash, cash equivalents, and short-term investments will fund our operating plans. 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.

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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 September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenues	$ 346	$ 458	$ 4,013	$ 4,028
Operating expenses:				
Research and development	43,839	31,987	122,947	93,234
General and administrative	15,484	11,925	41,016	31,120
Total operating expenses	59,323	43,912	163,963	124,354
Loss from operations	(58,977)	(43,454)	(159,950)	(120,326)
Total other income, net	2,516	1,529	6,515	2,409
Loss before equity method investment	(56,461)	(41,925)	(153,435)	(117,917)
Loss on equity method investment	(997)	—	(997)	(1,010)
Net loss	$ (57,458)	$ (41,925)	$ (154,432)	$ (118,927)
Net loss per share - basic and diluted	$ (1.01)	$ (0.78)	$ (2.81)	$ (2.32)
Weighted-average shares - basic and diluted	56,808	53,768	55,003	51,356

BALANCE SHEET DATA:	September 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 554,653	$ 334,425
Working capital	$ 535,297	$ 317,461
Total assets	$ 641,537	$ 352,176
Total liabilities	$ 93,789	$ 35,848
Accumulated deficit	$ (593,605)	$ (439,173)
Total stockholders' equity	$ 547,748	$ 316,328

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