

**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 14, 2022

Crinetics Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38583
(Commission File Number)

26-3744114
(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 November 14, 2022, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended September 30, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 14, 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: November 14, 2022

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

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

Paltusotine's Phase 3 PATHFNDR-1 trial in acromegaly fully enrolled and on track for topline data in Q3 2023

Paltusotine lowered and maintained IGF-1 at levels comparable to prior injected SRL therapy for up to 103 weeks in participants living with acromegaly participating in the ACROBAT Advance Long-term Extension Study

SAN DIEGO, November 14, 2022 -- Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today reported financial results for the third quarter ended September 30, 2022.

“This has been yet another successful quarter of executing our strategy to build a leading endocrinology company by advancing our clinical pipeline of internally discovered drug candidates and preparing to add to that pipeline with our highly productive drug discovery efforts. Progress includes completion of enrollment in the Phase 3 PATHFNDR-1 trial and reporting Phase 2 open-label extension data demonstrating maintenance of IGF-1 as well as a strong preference among acromegaly patients for oral paltusotine over the injected standard-of-care,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. “We remain on track for two Phase 3 readouts in acromegaly next year. Beyond acromegaly, we maintained strong momentum with our efforts to demonstrate paltusotine’s utility in carcinoid syndrome with a Phase 2 readout expected next year. We also continue to advance CRN04777 and CRN04894 toward patient trials based on the positive proof-of-pharmacology data we reported earlier this year.”

Third Quarter 2022 and Recent Highlights

- **Completed enrollment in Phase 3 PATHFNDR-1 study.** PATHFNDR-1 is one of two ongoing, placebo-controlled Phase 3 clinical trials evaluating the safety and efficacy of paltusotine in acromegaly patients. Topline data from PATHFNDR-1 are expected in the third quarter of 2023 and topline data from paltusotine’s second Phase 3 trial, PATHFNDR-2, are expected in the fourth quarter of 2023. If successful, Crinetics plans to submit data from the PATHFNDR trials to regulatory authorities in support of applications seeking approval for the broad use of paltusotine for all acromegaly patients who require pharmacotherapy, including untreated patients and those switching from other therapies.
 - **Reported new long-term safety and efficacy data from ACROBAT Advance open-label extension trial of paltusotine in acromegaly.** Results showed that once-daily oral paltusotine lowered and maintained IGF-1 at levels comparable to prior injected somatostatin receptor ligand (SRL) therapy for up to 103 weeks. In addition, paltusotine was well tolerated in the study and 89% of study participants surveyed selected paltusotine as their preferred treatment option over injected SRLs.
 - **Received a UK Medicines and Healthcare products Regulatory Agency (MHRA) Innovation Passport for CRN04777 for the treatment of congenital hyperinsulinism.** The Innovation Passport enables Crinetics to access the Innovative Licensing and Access Pathway (ILAP). The ILAP aims to reduce the time to market for designated medicines by enabling enhanced coordination between sponsors and MHRA leading up to Marketing Authorization Application (MAA) submissions and by providing the opportunity for accelerated MAA reviews.
 - **Reviewed analyses from preclinical and Phase 1 clinical studies of CRN04894 in an oral presentation at the 10th International Congress of Neuroendocrinology.** CRN04894 is an adrenocorticotrophic hormone (ACTH) antagonist being developed as a treatment for Cushing’s
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disease, congenital adrenal hyperplasia (CAH) and other conditions of ACTH excess. The presentation was delivered by the Crinetics' vice president of clinical endocrinology, Dr. Peter J. Trainer, and featured the results of a Phase 1 healthy volunteer study demonstrating pharmacologic proof-of-concept for CRN04894. These results showed dose-dependent increases in CRN04894 plasma concentrations as well as reductions of both basal cortisol and elevated cortisol following an ACTH challenge.

- **Strengthened leadership team with appointment of Dana Pizzuti, M.D. as chief development officer.** Dr. Pizzuti is a board-certified physician with more than 30 years of pharmaceutical industry experience in clinical development, pharmacovigilance, medical and regulatory affairs.

Third Quarter 2022 Financial Results

- Research and development expenses were \$32.0 million for the three months ended September 30, 2022, compared to \$21.6 million for the same period in 2021. The increase was primarily attributable to an increase in spending on manufacturing and development activities of \$5.2 million associated with our clinical and nonclinical activities for paltusotine, CRN04777, CRN04894 and our other clinical and preclinical programs and an increase in personnel costs of \$4.2 million.
- General and administrative expenses were \$11.9 million for the three months ended September 30, 2022, compared to \$6.2 million for the same period in 2021. The increase was primarily attributable to an increase in personnel costs of \$3.0 million.
- Net loss for the three months ended September 30, 2022, was \$41.9 million, compared to a net loss of \$27.9 million for the same period in 2021.
- Revenues were \$0.5 million for the three months ended September 30, 2022, consisting of license revenue recognized from the license agreement entered into with Sanwa Kagaku Kenkyusho Co., Ltd. in February 2022.
- Unrestricted cash, cash equivalents and investments totaled \$368.4 million as of September 30, 2022, compared to \$333.7 million as of December 31, 2021.
- The company had 53,810,476 common shares outstanding as of November 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. 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 CNR04894, 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.

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 trials of paltusotine in acromegaly and Phase 2 trial of paltusotine in carcinoid syndrome; plans to submit data from the ongoing Phase 3 clinical trials of paltusotine in

acromegaly to regulators in support of applications seeking approval for the use of paltusotine in acromegaly patients; the ability to gain access to an expedited review pathway in the United Kingdom for CRN04777; Crinetics' plans to advance CRN04777 and CRN04894 toward patient trials; and 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, topline 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; 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; 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; any future impacts to our business resulting from the conflict between Russia and Ukraine or other 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, 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.

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,	
	2022	2021	2022	2021
License revenues	\$ 458	\$ —	\$ 4,028	\$ —
Operating expenses:				
Research and development	31,987	21,580	93,234	59,651
General and administrative	11,925	6,227	31,120	17,163
Total operating expenses	43,912	27,807	124,354	76,814
Loss from operations	(43,454)	(27,807)	(120,326)	(76,814)
Total other income (expense), net	1,529	(44)	2,409	(33)
Loss before equity method investment			(117,917)	(76,847)
Loss on equity method investment	—	—	(1,010)	—
Net loss	\$ (41,925)	\$ (27,851)	\$ (118,927)	\$ (76,847)
Net loss per share - basic and diluted	\$ (0.78)	\$ (0.73)	\$ (2.32)	\$ (2.13)
Weighted-average shares - basic and diluted	53,768	38,309	51,356	36,147

BALANCE SHEET DATA:

	September 30, 2022	December 31, 2021
Cash, cash equivalents and investments	\$ 368,362	\$ 333,707
Working capital	\$ 353,767	\$ 328,725
Total assets	\$ 384,880	\$ 351,015
Total liabilities	\$ 33,508	\$ 19,071
Accumulated deficit	\$ (394,182)	\$ (275,255)
Total stockholders' equity	\$ 351,372	\$ 331,944

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