

**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): August 12, 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 August 12, 2022, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended June 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 August 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: August 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 Second Quarter 2022 Financial Results and Provides Corporate Update

Paltusotine's Phase 3 PATHFNDR Program in Acromegaly and Phase 2 Program in Carcinoid Syndrome Remain on Track for Top-Line Data in 2023

CRN04894 Phase 1 Data Demonstrated Pharmacologic Proof-of-Concept for Further Development in Both Cushing's Disease and Congenital Adrenal Hyperplasia

CRN04777 and CRN04894 Phase 2 Studies Expected to Commence Following Finalization of Study Protocols with Global Regulators

SAN DIEGO – August 12, 2022 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today reported financial results for the second quarter ended June 30, 2022.

“Enrollment is on-track in our Phase 3 PATHFNDR program for paltusotine in acromegaly and our Phase 2 study in carcinoid syndrome, with results from these studies expected in 2023,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. “We continue to validate the unique early de-risking efficiency of our endocrine drug development paradigm. CRN04894 is now our third program to successfully demonstrate pharmacologic proof-of-concept in Phase 1. We are now working with global regulators to align on clinical plans for both CRN04777 and CRN04894 with the goal of initiating clinical studies in congenital HI, Cushing's Disease, and CAH.”

Second Quarter 2022 and Recent Highlights

- **Reported positive top-line results from multiple-ascending dose (MAD) cohorts of the CRN04894 Phase 1 study.** In May 2022, Crinetics announced positive data from the MAD cohorts of a Phase 1 healthy volunteer study of CRN04894, the company's adrenocorticotrophic hormone (ACTH) antagonist being developed as a treatment for Cushing's disease, congenital adrenal hyperplasia (CAH) and other conditions of ACTH excess. Pharmacodynamic data from the trial demonstrated pharmacologic proof-of-concept for CRN04894, while pharmacokinetic data demonstrated its oral bioavailability and support a once-daily dosing schedule. No serious adverse events nor study drug discontinuations due to treatment-related adverse events were observed.
- **Presented clinical and research results at the ENDO 2022 Annual Conference.** Presentations included an oral presentation featuring results from the Phase 1 study of CRN04894, a poster presentation featuring results from a Phase 1 study of CRN04777, the company's somatostatin receptor type 5 (SST5) agonist being developed as a treatment for congenital hyperinsulinism (HI), and a late-breaking poster presentation on the company's preclinical parathyroid hormone (PTH) receptor antagonist program.
- **Strengthened balance sheet with successful \$125 million common stock offering.** In April 2022, Crinetics successfully completed an underwritten follow-on offering of its common stock raising gross proceeds of \$125 million. 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.

Second Quarter 2022 Financial Results

- Research and development expenses were \$33.0 million for the three months ended June 30, 2022, compared to \$20.5 million for the same period in 2021. The increase was primarily attributable to an increase spending on manufacturing and development activities of \$7.6 million associated with
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clinical and nonclinical activities for paltusotine, CRN04777, CRN04894 and other preclinical programs, and an increase in personnel costs of \$3.9 million.

- General and administrative expenses were \$10.5 million for the three months ended June 30, 2022, compared to \$5.6 million for the same period in 2021. The increase was primarily attributable to an increase in personnel costs of \$3.1 million.
- Net loss for the three months ended June 30, 2022, was \$42.4 million, compared to a net loss of \$26.1 million for the same period in 2021.
- Revenues were \$0.4 million for the three months ended June 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 \$408.5 million as of June 30, 2022, compared to \$333.7 million as of December 31, 2021.
- The company had 53,752,778 common shares outstanding as of August 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, a 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 for congenital hyperinsulinism, and for CRN04894, an investigational, oral 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 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 data from the ongoing Phase 3 clinical trials of paltusotine in acromegaly and Phase 2 clinical trial of paltusotine in carcinoid syndrome; Crinetics' plans to advance CRN04777 and CRN04894 into Phase 2 clinical trials and the timing thereof; plans to meet with regulators and to advance CRN04894 into a clinical program in patients for the treatment of Cushing's disease and congenital adrenal hyperplasia and to advance CRN04777 into a clinical program in patients for the treatment of congenital hyperinsulinism and the timing thereof; 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, top-line 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; 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.

STATEMENTS OF OPERATIONS DATA:	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
License revenues	\$ 439	\$ —	\$ 3,570	\$ —
Operating expenses:				
Research and development	32,995	20,487	61,247	38,071
General and administrative	10,489	5,602	19,195	10,936
Total operating expenses	43,484	26,089	80,442	49,007
Loss from operations	(43,045)	(26,089)	(76,872)	(49,007)
Total other income (expense), net	670	(6)	880	11
Loss before equity method investment			(75,992)	(48,996)
Loss on equity method investment	—	—	(1,010)	—
Net loss	\$ (42,375)	\$ (26,095)	\$ (77,002)	\$ (48,996)
Net loss per share - basic and diluted	\$ (0.81)	\$ (0.70)	\$ (1.54)	\$ (1.40)
Weighted-average shares - basic and diluted	52,522	37,061	50,130	35,048

BALANCE SHEET DATA:	June 30, 2022	December 31, 2021
Cash, cash equivalents and investments	\$ 408,506	\$ 333,707
Working capital	\$ 390,170	\$ 328,725
Total assets	\$ 421,733	\$ 351,015
Total liabilities	\$ 35,568	\$ 19,071
Accumulated deficit	\$ (352,257)	\$ (275,255)
Total stockholders' equity	\$ 386,165	\$ 331,944

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