

**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 08, 2023**

**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 8, 2023, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended June 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release dated August 8, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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## 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 8, 2023

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

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

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**Crinetics Pharmaceuticals Reports Second Quarter 2023 Financial Results and Provides Corporate Update**

*Phase 3 PATHFNDR-1 Study Topline Data expected in September 2023*

*Enrollment Completed in Phase 3 PATHFNDR-2 Study with Topline Data Expected in 1Q 2024*

*Development of CRN04777 Suspended*

*Company Hosting KOL Webinar on Acromegaly Treatment Landscape Today at 12:00 pm ET*

**SAN DIEGO – August 8, 2023** – [Crinetics Pharmaceuticals, Inc.](#) (Nasdaq: CRNX) today reported financial results for the second quarter ended June 30, 2023.

“The [PATHFNDR program](#) for acromegaly continues to progress as expected. Topline results from our Phase 3 PATHFNDR-1 study are expected in September and should provide insight into paltusotine’s potential as an alternative to standard-of-care somatostatin receptor ligand depot injections. Enrollment in our Phase 3 PATHFNDR-2 study is also now complete and we anticipate topline results in the first quarter of 2024,” said [Scott Struthers, Ph.D., founder and chief executive officer](#) of Crinetics. “Unfortunately, we also suffered a setback with our CRN04777 program and made the difficult decision to wind down its development. We know that infants and children living with congenital hyperinsulinism are in desperate need of better treatment options and our hearts go out to them and their families. However, our recently evolved understanding of the nonclinical profile of CRN04777 suggests that it no longer meets the high standards to which we hold all drug candidates in our pipeline.”

**Second Quarter 2023 and Recent Highlights:**

- **Topline data from paltusotine’s Phase 3 PATHFNDR-1 study expected in September 2023.** PATHFNDR-1 is a placebo-controlled Phase 3 clinical study of [oral paltusotine](#) in participants with acromegaly switching from standard-of-care peptide depots. The study enrolled 58 participants with acromegaly whose average IGF-1 levels during screening were within the normal range (IGF-1  $\leq$  1.0x upper limit of normal) on octreotide or lanreotide depot monotherapy. The primary endpoint of the study is the proportion of participants whose average IGF-1 levels at weeks 34 and 36 are within the normal range after switching to paltusotine compared to placebo.
  - **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. 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.
  - **Paltusotine NDA submission anticipated in 2024.** Pending successful data from the PATHFNDR program, Crinetics plans to submit a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) seeking regulatory approval for the use of paltusotine in acromegaly with both treatment and maintenance of treatment indications.
  - **Clinical and preclinical data presented at the ENDO 2023 Annual Conference.** A [podium presentation featured results from the ACROBAT Advance open-label extension study of paltusotine in acromegaly](#). In addition, pre-clinical studies of the company’s [thyroid-stimulating hormone \(TSH\) receptor antagonist](#) for the treatment of thyroid eye disease (orbitopathy) associated with Graves’ disease and of the [parathyroid hormone receptor type 1 \(PTH1R\) antagonist](#) being developed for the
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treatment of primary hyperparathyroidism (PHPT) were presented as poster presentations. In addition, Scott Struthers, Ph.D., Crinetics' founder and CEO was awarded the John D. Baxter Prize to recognize extraordinary achievement in endocrinology entrepreneurship at ENDO 2023 and gave an award lecture on the history of discovering nonpeptide oral drugs acting at peptide hormone receptors.

- **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 is continuing to enroll participants, and preliminary data is anticipated in the fourth quarter of 2023.
- **CRN04894 studies in Cushing's disease and congenital adrenal hyperplasia are ongoing.** Based on successful Phase 1 studies demonstrating pharmacologic proof-of-concept, Crinetics is conducting clinical studies of CRN04894 in Cushing's disease and congenital adrenal hyperplasia. Data from both studies are expected in 2024.
- **CRN04777 update.** While developing our response to the clinical hold issued by the FDA, results from additional nonclinical studies became available. These studies uncovered findings at exposure levels that eroded anticipated therapeutic margins for CRN04777. These other findings are not related to those originally cited by the FDA for the clinical hold and, importantly, are not present in nonclinical studies that have been conducted with other Crinetics product candidates under development. We believe them to be specific to CRN04777 and not associated with its somatostatin receptor type 5 (SST5) mechanism of action. In light of these findings, the company has decided to suspend further significant investment into the molecule at this time.

### Second Quarter 2023 Financial Results

- Research and development expenses were \$40.6 million for the three months ended June 30, 2023, compared to \$33.0 million for the same period in 2022. The increase was primarily attributable to an increase in personnel costs of \$6.9 million, increased consulting and outside services of \$1.6 million, increased other expenditures of \$0.7 million, partially offset by decreased net spending on manufacturing and development activities of \$1.6 million associated with our clinical and nonclinical programs.
- General and administrative expenses were \$13.3 million for the three months ended June 30, 2023, compared to \$10.5 million for the same period in 2022. The increase was primarily attributable to an increase in personnel costs of \$2.7 million.
- Net loss for the three months ended June 30, 2023, was \$51.0 million, compared to a net loss of \$42.4 million for the same period in 2022.
- Revenues were \$1.0 million for the three months ended June 30, 2023, compared to \$0.4 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 \$264.5 million as of June 30, 2023, compared to \$334.4 million as of December 31, 2022.
- The company had 54,686,550 common shares outstanding as of August 4, 2023.

### Key Opinion Leader (KOL) Webinar on Acromegaly Current Treatment Landscape and Unmet Need

Crinetics is hosting a KOL webinar today, August 8, 2023 at 12:00 pm ET. The webinar will feature key opinion leaders Beverly MK Biller, M.D. and Karen JP Liebert, R.N., B.S.N, both of Massachusetts General Hospital, who will discuss 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). In addition, the Crinetics management team will discuss its pipeline of internally discovered oral small molecule drug candidates, with a focus on the Phase 3 PATHFINDER-1 study of paltusotine.

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A live question and answer session will follow the formal presentations. To register for the event, please [click here](#). If you would like to ask a question during the live Q&A, please submit your request to [questions@lifesciadvisors.com](mailto:questions@lifesciadvisors.com). A replay of the event will be available by [clicking here](#).

### **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 a Phase 1 clinical study for CRN04894, an investigational, oral ACTH antagonist in development 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.

### **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. 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*

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*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)

<b>STATEMENTS OF OPERATIONS DATA:</b>	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenues	\$ 988	\$ 439	\$ 3,667	\$ 3,570
Operating expenses:				
Research and development	40,640	32,995	79,108	61,247
General and administrative	13,343	10,489	25,532	19,195
<b>Total operating expenses</b>	<b>53,983</b>	<b>43,484</b>	<b>104,640</b>	<b>80,442</b>
Loss from operations	(52,995)	(43,045)	(100,973)	(76,872)
Total other income, net	2,016	670	3,999	880
Loss before equity method investment	(50,979)	(42,375)	(96,974)	(75,992)
Loss on equity method investment	—	—	—	(1,010)
<b>Net loss</b>	<b>\$ (50,979)</b>	<b>\$ (42,375)</b>	<b>\$ (96,974)</b>	<b>\$ (77,002)</b>
<b>Net loss per share - basic and diluted</b>	<b>\$ (0.94)</b>	<b>\$ (0.81)</b>	<b>\$ (1.79)</b>	<b>\$ (1.54)</b>
Weighted-average shares - basic and diluted	54,275	52,522	54,092	50,130

<b>BALANCE SHEET DATA:</b>	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	\$ 264,529	\$ 334,425
Working capital	\$ 252,200	\$ 317,461
<b>Total assets</b>	<b>\$ 293,254</b>	<b>\$ 352,176</b>
Total liabilities	\$ 39,138	\$ 35,848
Accumulated deficit	\$ (536,147)	\$ (439,173)
<b>Total stockholders' equity</b>	<b>\$ 254,116</b>	<b>\$ 316,328</b>

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