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): February 28, 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 February 28, 2023, Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") issued a press release reporting its financial results for the period ended December 31, 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

Exhibit No.	Description
99.1	Press Release dated February 28, 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: February 28, 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 Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

- Paltusotine's Phase 3 PATHFNDR-1 study enrollment complete and topline data expected in 3Q 2023

- Paltusotine's Phase 3 PATHFNDR-2 study enrollment ongoing with topline data now expected in 1Q 2024

- Pending a successful outcome from the PATHFNDR studies, an NDA submission in acromegaly is expected in 2024

- Paltusotine's Phase 2 study in carcinoid syndrome on track for data in 2H 2023

- CRN04894's studies in Cushing's disease and congenital adrenal hyperplasia commenced in 1Q 2023

SAN DIEGO – February 28, 2023 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today reported financial results for the fourth quarter and year ended December 31, 2022.

"We continue to make great progress in our vision to build a premier fully integrated endocrine company that can sustainably innovate pioneering therapies for our patients around the world," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "In 2022, we demonstrated pharmacologic proof-of-concept for CRN04894 and CRN04777, established global clinical study capabilities with our Phase 3 PATHFNDR program for paltusotine in acromegaly, and began laying groundwork for a potential commercial launch."

Dr. Struthers continued, "Looking forward, we believe our efforts in acromegaly position us for success not only in this program, but also in additional indications with our multiple oral small molecule drug candidates. Going into 2023, I am especially proud of our discovery team who continues to bring innovative opportunities forward in the areas of hyperparathyroidism, polycystic kidney disease, Graves' disease, including thyroid eye disease, and metabolic diseases including diabetes and obesity."

Key Corporate Updates:

- **Phase 3 PATHFNDR-1 study enrollment complete.** PATHFNDR-1 is one of two ongoing, placebo-controlled Phase 3 clinical studies of oral paltusotine in participants with acromegaly. The study enrolled participants with acromegaly who were biochemically controlled (IGF-1 ≤ 1.0x upper limit of normal) on octreotide or lanreotide depot monotherapy. Topline data from PATHFNDR-1 are expected in the third quarter of 2023.
- **Phase 3 PATHFNDR-2 study enrollment ongoing.** PATHFNDR-2 is the second placebo-controlled Phase 3 clinical study of oral paltusotine in participants with acromegaly. The study is enrolling participants with acromegaly with elevated IGF-1 levels who are either medication naïve or who are not being treated with pharmacotherapy. Enrollment is ongoing in the study and the company is aggressively navigating prolonged pandemic-related and geopolitical disruptions in certain key study regions. Momentum and interest in the study continue to build despite these disruptions, however, based on current enrollment projections, the company's anticipated timeline for topline results from the study now extends into the first quarter of 2024.
- **Paltusotine NDA Submission.** Pending a successful outcome from the PATHFNDR studies, Crinetics plans to seek regulatory approval for paltusotine for the treatment of acromegaly in the United States with an anticipated submission of a new drug application (NDA) in 2024.
- **Phase 2 open-label study of paltusotine in carcinoid syndrome ongoing.** Paltusotine is also being studied in a Phase 2 open-label study in carcinoid syndrome associated with neuroendocrine tumors. Enrollment is ongoing and data from the study are expected in the second half of 2023.

- **CRN04894 studies in Cushing's disease and congenital adrenal hyperplasia.** Based on successful Phase 1 studies demonstrating pharmacologic proof-of-concept, Crinetics is advancing CRN04894 into clinical studies in Cushing's disease and congenital adrenal hyperplasia. Start-up activities for studies in each of these indications began in the first quarter of 2023.
- **CRN04777 progress.** In November 2022, the U.S. Food and Drug Administration (FDA) informed Crinetics that the company's planned Phase 2 study of CRN04777 in a pediatric population was not yet permitted to proceed. Crinetics is in the process of collecting additional information and data to submit to the FDA, with the goal of gaining allowance to proceed with the 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.

Full Year 2022 Highlights:

- **Reported long-term safety and efficacy data from ACROBAT Advance open-label extension study of paltusotine in acromegaly.** Once-daily oral paltusotine was shown to lower and maintain IGF-1 at levels comparable to prior injected somatostatin receptor ligand (SRL) therapy for up to 103 weeks. In addition, paltusotine was well tolerated and 89% of study participants surveyed selected paltusotine as their preferred treatment option over injected SRLs.
- **Reported positive topline results from multiple-ascending dose (MAD) cohorts of the CRN04894 Phase 1 study in healthy adult volunteers.** Pharmacodynamic data from the Phase 1 study's MAD cohorts demonstrated pharmacologic proof-of-concept for CRN04894, an adrenocorticotropic hormone (ACTH) antagonist being developed as a treatment for conditions of ACTH-excess. Pharmacokinetic data demonstrated CRN04894's oral bioavailability. No serious adverse events nor study drug discontinuations due to treatment-related adverse events were observed.
- **Reported positive topline results from MAD cohorts of the CRN04777 Phase 1 study in healthy adult volunteers.** Pharmacodynamic data from the Phase 1 study's MAD cohorts demonstrated pharmacologic proof-of-concept for CRN04777, a somatostatin receptor type 5 (SST5) agonist being developed as a treatment for congenital hyperinsulinism. Pharmacokinetic data indicated CRN04777 was orally bioavailable and support a once daily dosing schedule. No serious adverse events nor discontinuations due to adverse events were reported in the Phase 1 study, which was conducted under a Clinical Trial Application in Germany.
- **Received UK Medicines and Healthcare products Regulatory Agency (MHRA) Innovation Passport for CRN04777 for the treatment of congenital hyperinsulinism.** The Innovation Passport enables sponsors to access the Innovative Licensing and Access Pathway (ILAP), which was launched in 2021 with the goal of reducing the time to market for designated medicines. The ILAP is designed to achieve this goal by enabling enhanced coordination between sponsors and the MHRA leading up to Marketing Authorization Application (MAA) submissions and by providing the opportunity for accelerated MAA reviews.
- **Entered into strategic licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd. (Sanwa) for the development and commercialization of paltusotine in Japan.** Per the agreement, Crinetics received $13 million upfront and is also eligible to receive development, regulatory and commercial milestones, as well as tiered royalties on net product sales should paltusotine receive marketing approval in Japan. In exchange, Sanwa was granted an exclusive right to develop and commercialize paltusotine in Japan. Sanwa will assume all costs associated with clinical studies and regulatory applications in Japan. Crinetics retains all rights to develop and commercialize paltusotine in territories other than Japan.
- **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 approximately $125 million.

- **Made key additions to management team and Board of Directors.** Crinetics strengthened the company's leadership throughout 2022 by appointing James Hassard to the role of chief commercial officer, Chris Robillard to the role of chief business officer, Dana Pizzuti, M.D., to the role of chief development officer, and Rogério Vivaldi Coelho, M.D., M.B.A., and Caren Deardorf to the Board of Directors.

Fourth Quarter and Full Year 2022 Financial Results

- Research and development expenses were $37.0 million and $130.2 million for the three months and full year ended December 31, 2022, respectively, compared to $24.6 million and $84.3 million for the same periods in 2021. The increases were primarily attributable to an increase in supplies and spending on manufacturing and development activities of $5.6 million for the quarter ended December 31, 2022 and $25.3 million for the year ended December 31, 2022 associated with our clinical and nonclinical activities for paltusotine, CRN04777, CRN04894 and our preclinical programs and an increase in personnel costs of $5.0 million for the quarter ended December 31, 2022 and $16.2 million for the year ended December 31, 2022.
- General and administrative expenses were $11.3 million and $42.4 million for the three months and full year ended December 31, 2022, respectively, compared to $7.4 million and $24.5 million for the same periods in 2021. The increases were primarily attributable to an increase in personnel costs of $2.7 million for the quarter ended December 31, 2022 and $10.8 million for the year ended December 31, 2022.
- Net loss for the three months ended December 31, 2022, was $45.0 million, compared to a net loss of $30.8 million for the same period in 2021. For the year ended December 31, 2022, the company's net loss was $163.9 million compared to a net loss of $107.6 million for the year ended December 31, 2021.
- Revenues were $0.7 million and $4.7 million for the three months and full year ended December 31, 2022, respectively, primarily consisting of license revenue recognized from the license agreement entered into with Sanwa in February 2022.
- Unrestricted cash, cash equivalents, and investments totaled $334.4 million as of December 31, 2022, compared to $368.4 million as of September 30, 2022, and $333.7 million as of December 31, 2021. Based on its current projections, the company expects that current cash, cash equivalents and short-term investments will fund its current operating plan through 2024.
- The company had 53,908,865 common shares outstanding as of February 24, 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.

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 of acromegaly in the United States; the expected timing of the initiation of studies of CRN04894 in Cushing's disease and congenital adrenal hyperplasia; plans to generate and develop additional small molecule new chemical entities with the potential to address hyperparathyroidism, polycystic kidney disease, metabolic diseases, including diabetes and obesity, and Graves' Disease, including thyroid eye disease, or to advance them into clinical studies; 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; and Crinetics' potential to receive future milestone and royalty payments from Sanwa. 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 December 31,**		**Twelve months ended December 31,**	
	2022	**2021**	**2022**	**2021**
Revenues	$ 709	$ 1,078	$ 4,737	$ 1,078
Operating expenses:				
Research and development	36,991	24,604	130,225	84,255
General and administrative	11,274	7,362	42,394	24,525
Total operating expenses	48,265	31,966	172,619	108,780
Loss from operations	(47,556)	(30,888)	(167,882)	(107,702)
Total other income, net	2,565	94	4,974	61
Loss before equity method investment	(44,991)	(30,794)	(162,908)	(107,641)
Loss on equity method investment	—	—	(1,010)	—
Net loss	$ (44,991)	$ (30,794)	$ (163,918)	$ (107,641)
Net loss per share - basic and diluted	$ (0.84)	$ (0.68)	$ (3.15)	$ (2.80)
Weighted-average shares - basic and diluted	53,839	45,229	51,982	38,436

BALANCE SHEET DATA:	**December 31, 2022**	**December 31, 2021**
Cash, cash equivalents and investments	$ 334,425	$ 333,707
Working capital	$ 317,461	$ 328,725
Total assets	$ 352,176	$ 351,015
Total liabilities	$ 35,848	$ 19,071
Accumulated deficit	$ (439,173)	$ (275,255)
Total stockholders' equity	$ 316,328	$ 331,944

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