
**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, 2024

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.)

6055 Lusk Boulevard
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 February 28, 2024, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended December 31, 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 February 28, 2024.
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, 2024

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



Crinetics Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

Phase 3 PATHFNDR-2 Study Topline Results Expected in March 2024; Pending Results, NDA Submission in Acromegaly Anticipated 2H 2024

Phase 2 Study of Paltusotine in Carcinoid Syndrome Full Topline Results Expected 1H 2024

Announced a \$350 Million Private Placement Equity Financing

Management Hosting Conference Call and Webcast at 4:30 p.m. ET Today

SAN DIEGO – February 28, 2024 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today reported financial results for the fourth quarter and full year ended December 31, 2023.

“As we reflect on our achievements in 2023, this was a truly significant year for Crinetics, laying the foundation for our next phase of growth,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. “Our lead investigational compound, paltusotine, continues to demonstrate highly promising results, underscored by the success of the Phase 3 PATHFNDR-1 study in acromegaly and encouraging initial findings in the ongoing Phase 2 study in carcinoid syndrome. Pending results from our second Phase 3 PATHFNDR-2 study this quarter, we are on track to submit a New Drug Application (NDA) for paltusotine in acromegaly in the second half of 2024. We also expect full results from our Phase 2 study in carcinoid syndrome in the first half of this year. Looking ahead, 2024 and 2025 are poised to be transformational years as we advance our late-stage product candidate and prepare for a potential commercial launch, while also leveraging our world class in-house R&D expertise to enrich our pipeline with additional promising candidates in high-prevalence endocrine and metabolic indications. To support these growth activities, we announced a \$350 million private placement that is expected to extend our cash runway into 2028.”

Full Year 2023 and Recent Highlights:

- **Phase 3 PATHFNDR-1 study achieved 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.
 - **Reported positive initial data from Phase 2 study of paltusotine in carcinoid syndrome.** In December 2023, Crinetics reported an initial analysis of data from a subset of 27 patients. The study has completed enrollment.
 - **Completed enrollment in Phase 3 PATHFNDR-2 study of paltusotine.** PATHFNDR-2 is a placebo-controlled Phase 3 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.
 - **Presented clinical and preclinical data at the ENDO 2023 Annual Conference.** Presentations at the June 2023 conference featured results from *in vivo* studies of the company’s preclinical parathyroid hormone receptor type 1 (PTH1R) antagonist being developed for the treatment of primary
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hyperparathyroidism (PHPT), and the company's preclinical thyroid-stimulating hormone (TSH) receptor antagonist for the treatment of thyroid eye disease (orbitopathy) associated with Graves' disease. In addition, Scott Struthers, Ph.D., Crinetics' founder and CEO was awarded the John D. Baxter Prize for extraordinary achievement in endocrinology entrepreneurship at ENDO 2023.

- **Strengthened balance sheet with \$350 million private placement financing.** Earlier today, February 28, 2024, Crinetics announced a private placement equity financing for gross proceeds of approximately \$350 million. Additional details regarding the financing are available in the press release ([click here](#)).

Key Upcoming Milestones

- Topline results from the Phase 3 PATHFNDR-2 study of paltusotine are expected in March 2024.
- Topline results from the Phase 2 study of paltusotine in carcinoid syndrome are expected in the first half of 2024.
- Paltusotine NDA submission is anticipated in the second half of 2024. Pending successful data from the PATHFNDR-2 study, Crinetics plans to submit an NDA to the U.S. Food and Drug Administration (FDA) seeking regulatory approval for both the treatment of and maintenance of treatment of acromegaly indications.
- Initial results from ongoing Phase 2 study of oral CRN04894 in congenital adrenal hyperplasia (CAH) are expected in the second quarter of 2024. The Phase 2 study is an open-label, study evaluating the safety, efficacy and pharmacokinetics of different doses of CRN04894 in participants with CAH after 12 weeks of treatment.

Fourth Quarter and Full Year 2023 Financial Results

- Research and development expenses were \$45.6 million and \$168.5 million for the three months and full year ended December 31, 2023, compared to \$37.0 million and \$130.2 million for the same period in 2022. The increases were primarily attributable to an increase in personnel costs of \$7.1 million for the quarter ended December 31, 2023 and \$29.3 million for the year ended December 31, 2023, and increased outside services of \$5.6 million for the year ended December 31, 2023.
 - General and administrative expenses were \$17.1 million and \$58.1 million for the three months and full year ended December 31, 2023, compared to \$11.3 million and \$42.4 million for the same period in 2022. The increases were primarily attributable to an increase in personnel costs of \$4.2 million for the quarter ended December 31, 2023 and \$12.8 million for the year ended December 31, 2023.
 - Net loss for the three months ended December 31, 2023, was \$60.1 million, compared to a net loss of \$45.0 million for the same period in 2022. For the year ended December 31, 2023, the company's net loss was \$214.5 million compared to a net loss of \$163.9 million for the year ended December 31, 2022. In addition to the financial results above, the company's net loss also included a loss on equity method investment of \$4.2 million and \$5.2 million for the three months and full year ended December 31, 2023, compared to no loss on equity method investment for the three months ended December 31, 2022 and \$1.0 million for the year ended December 31, 2022. This loss was derived from the company's investment in Radionetics Oncology, Inc.
 - Revenues were \$4.0 million for the full year ended December 31, 2023, compared to \$4.7 million for the same period in 2022. There were no revenues for the three months ended December 31, 2023, compared to \$0.7 million for the three months ended December 31, 2022. Revenues were derived from licensing arrangements for our paltusotine and CRN01941 product candidates.
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- Unrestricted cash, cash equivalents, and investments totaled \$558.6 million as of December 31, 2023, compared to \$334.4 million as of December 31, 2022. On February 28, 2024, the company announced a private placement equity financing for gross proceeds of approximately \$350 million. 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 2028.

Conference Call and Webcast Details

Management will hold a live conference call and webcast today, Wednesday, February 28, 2024 at 4:30 p.m. ET. To participate, please dial 1-888-886-7786 (domestic) or 1-416-764-8658 (international). To access the webcast, click [here](#). For instant telephone access, click the Call me™ link [here](#). Following the live event, a replay will be available on the Investors section of the Company's website.

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 congenital adrenal hyperplasia and Cushing's disease. 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, 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 congenital adrenal hyperplasia and Cushing's disease; our expected plans and timing for commercialization of paltusotine and other product candidates pending regulatory approval, including efforts to expand our commercial capabilities; 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; 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, 2023. 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 December 31,		Twelve months ended December 31,	
	2023	2022	2023	2022
Revenues	\$ —	\$ 709	\$ 4,013	\$ 4,737
Operating expenses:				
Research and development	45,580	36,991	168,527	130,225
General and administrative	17,078	11,274	58,094	42,394
Total operating expenses	62,658	48,265	226,621	172,619
Loss from operations	(62,658)	(47,556)	(222,608)	(167,882)
Total other income, net	6,762	2,565	13,277	4,974
Loss before equity method investment	(55,896)	(44,991)	(209,331)	(162,908)
Loss on equity method investment	(4,201)	—	(5,198)	(1,010)
Net loss	\$ (60,097)	\$ (44,991)	\$ (214,529)	\$ (163,918)
Net loss per share - basic and diluted	\$ (0.90)	\$ (0.84)	\$ (3.69)	\$ (3.15)
Weighted-average shares - basic and diluted	67,146	53,839	58,071	51,982

BALANCE SHEET DATA:	December 31,		December 31,	
	2023		2022	
Cash, cash equivalents and investments	\$	558,555	\$	334,425
Working capital	\$	530,211	\$	317,461
Total assets	\$	635,353	\$	352,176
Total liabilities	\$	96,247	\$	35,848
Accumulated deficit	\$	(653,702)	\$	(439,173)
Total stockholders' equity	\$	539,106	\$	316,328

Investors:
Corey Davis
LifeSci Advisors, LLC
cdavis@lifesciadvisors.com
(212) 915-2577

Media:
Natalie Badillo
Head of Corporate Communications
nbadillo@crinetics.com
(858) 450-6464

