

**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): May 09, 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 May 9, 2024, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended March 31, 2024. 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 May 9, 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: May 9, 2024

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



Crinetics Pharmaceuticals Reports First Quarter 2024 Financial Results and Provides Business Update

Late-Breaking Presentations of Initial Results From Phase 2 Studies of Atumelnant (CRN04894) in Congenital Adrenal Hyperplasia and ACTH-Dependent Cushing's Syndrome Will be Presented at ENDO June 1-4, 2024

Following Second Positive Phase 3 Study (PATHFND-2), Paltusotine NDA Submission in Acromegaly Expected in 2H 2024

Following Positive Phase 2 Data, Plan to Initiate Paltusotine Phase 3 Study in Carcinoid Syndrome by End of 2024

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

SAN DIEGO – May 9, 2024 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX), a clinical stage pharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for endocrine diseases and endocrine-related tumors, today reported financial results for the first quarter ended March 31, 2024.

“Building on the positive momentum from the first PATHFND-2 readout in 2023, Crinetics began 2024 with continued strong performance. Our lead investigational compound, paltusotine, delivered positive data from two consecutive late-stage clinical trials in acromegaly and carcinoid syndrome. With our pivotal PATHFND-2 Phase 3 program in acromegaly now complete, we are working diligently to submit an NDA in the second half of 2024. We also intend to discuss the positive results from our Phase 2 study in carcinoid syndrome with the FDA in preparation for the Phase 3 program, which is expected to be initiated by the end of this year,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics.

“The clinical trials for the second compound in our pipeline, atumelnant, which is being developed for the treatment of CAH and Cushing's disease, continue to enroll patients. We plan to report initial results from a subset of patients from these trials in the second quarter,” continued Dr. Struthers. “In the first quarter, we strengthened our balance sheet to support commercial readiness for a potential paltusotine launch in acromegaly, as well as to fund the development of our deep clinical and preclinical pipeline. The progress made across our pipeline positions the Company for long-term success and towards achieving our objective to become a fully integrated pharmaceutical company.”

First Quarter 2024 and Recent Highlights:

- **Phase 3 PATHFND-2 study achieved primary and all secondary endpoints.** In March, Crinetics reported positive topline results from its placebo-controlled Phase 3 study of paltusotine in non-pharmacologically treated participants with acromegaly. PATHFND-2 was designed to support a treatment indication in those with uncontrolled acromegaly.
 - **Phase 2 study of paltusotine in carcinoid syndrome reported positive results.** In March, Crinetics reported positive topline results from its open-label Phase 2 study of paltusotine in participants with carcinoid syndrome. Paltusotine was shown to result in rapid and sustained reductions in frequency and severity of flushing episodes and bowel movements.
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- **Strengthened balance sheet with \$350 million private placement financing.** In February, Crinetics announced a private placement equity financing for gross proceeds of approximately \$350 million.

Key Upcoming Milestones:

- Initial results from the ongoing Phase 2 studies of atumelnant* in congenital adrenal hyperplasia (CAH) and ACTH-dependent Cushing's syndrome will be presented at the Endocrine Society's annual meeting, ENDO 2024, being held June 1-4, 2024 in Boston. The Phase 2 studies are evaluating the safety, efficacy and pharmacokinetics of different doses of atumelnant in participants with CAH and Cushing's disease.
- Submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking regulatory approval of paltusotine for the treatment of acromegaly is anticipated in the second half of 2024.
- Initiation of a Phase 3 program of paltusotine for carcinoid syndrome by the end of 2024, pending discussions with the FDA.

First Quarter 2024 Financial Results:

- Research and development expenses were \$53.3 million for the three months ended March 31, 2024, compared to \$38.5 million for the same period in 2023. The increases were primarily attributable to an increase in personnel costs of \$9.4 million, increased outside services and facilities costs of \$3.8 million, and increased spending on manufacturing and development activities of \$1.4 million.
- General and administrative expenses were \$20.8 million for the three months March 31, 2024, compared to \$12.2 million for the same period in 2023. The increases were primarily attributable to an increase in personnel costs of \$5.6 million.
- Net loss for the three months ended March 31, 2024, was \$66.9 million, compared to a net loss of \$46.0 million for the same period in 2023.
- Revenues were \$0.6 million for the three months ended March 31, 2024, compared to \$2.7 million for the same period in 2023. Revenues were derived from licensing arrangements for our paltusotine product candidate in 2024 and for paltusotine and CRN01941 product candidates in 2023.
- Unrestricted cash, cash equivalents, and investments totaled \$901.0 million as of March 31, 2024, compared to \$558.6 million as of December 31, 2023. 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.

*Proposed international nonproprietary name under review.

Conference Call and Webcast Details

Management will hold a live conference call and webcast today, Thursday, May 9, 2024 at 4:30 p.m. ET. To participate, please dial 1-888-886-7786 (domestic) or 1-416-764-8658 (international) and refer to Conference ID 71864759. 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 in Phase 2 clinical development for carcinoid syndrome associated with neuroendocrine tumors. Crinetics is also developing atumelnant (CRN04894), an investigational, first-in-class,



oral ACTH antagonist, that is currently completing Phase 2 clinical studies for the treatment of congenital adrenal hyperplasia (CAH) 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 atumelnant and paltusotine, including the therapeutic potential and clinical benefits or safety profile thereof; 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 initiation of a Phase 3 program of paltusotine for carcinoid syndrome; the expected timing of data from studies of atumelnant in congenital adrenal hyperplasia and Cushing's diseases; 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," "upcoming" 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 and its Quarterly report on Form 10-Q for the quarter ended March 31, 2024. 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 March 31,	
	2024	2023
Revenues	\$ 640	\$ 2,679
Operating expenses:		
Research and development	53,341	38,468
General and administrative	20,828	12,189
Total operating expenses	74,169	50,657
Loss from operations	(73,529)	(47,978)
Total other income, net	7,069	1,983
Loss before equity method investment	(66,460)	(45,995)
Loss on equity method investment	(470)	—
Net loss	\$ (66,930)	\$ (45,995)
Net loss per share - basic and diluted	\$ (0.93)	\$ (0.85)
Weighted-average shares - basic and diluted	72,289	53,908

BALANCE SHEET DATA:	March 31,	December 31,
	2024	2023
Cash, cash equivalents and investments	\$ 900,961	\$ 558,555
Working capital	\$ 865,461	\$ 530,211
Total assets	\$ 978,153	\$ 635,353
Total liabilities	\$ 103,220	\$ 96,247
Accumulated deficit	\$ (720,632)	\$ (653,702)
Total stockholders' equity	\$ 874,933	\$ 539,106

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