

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 05, 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 August 8, 2024, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release reporting its financial results for the period ended June 30, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 5, 2024, Marc Wilson notified the Company of his decision to step down from his position as Chief Financial Officer of the Company. Mr. Wilson intends to remain in his position until his replacement has been on-boarded with the Company. The Company has initiated a search for a replacement Chief Financial Officer. Mr. Wilson is departing for personal reasons, not because of any disagreement with the Company on any matter relating to the Company’s operations, policies or practices.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated August 8, 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: August 8, 2024

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 2024 Financial Results and Provides Business Update

Paltusotine NDA Submission in Acromegaly On Track for 2024

Topline Results from Phase 2 Studies of Atumelnant in Congenital Adrenal Hyperplasia and Additional Data for Phase 2 for ACTH-Dependent Cushing's Syndrome Expected by End of 2024

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

SAN DIEGO – August 8, 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 second quarter ended June 30, 2024.

“The second quarter of 2024 has been yet another successful period of executing our strategy to become the world’s premier endocrine company,” said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. “Our strong presence at the ENDO 2024 meeting in June showcased the breadth and depth of our pipeline. Our second internally-developed candidate atumelnant* showed profoundly positive initial results in the treatment of both congenital adrenal hyperplasia and Cushing’s disease. We anticipate reporting additional data in both indications later in 2024. Data presentations from the paltusotine program continue to demonstrate clinical benefits for patients, providing even more compelling support for its potential to treat people with acromegaly. We remain on track for our planned paltusotine NDA filing in acromegaly later this year, and multiple workstreams are underway in anticipation of an expected market launch in 2025.”

Crinetics today also announced that Marc Wilson will be transitioning from his role as Chief Financial Officer for personal reasons and the Company has initiated a search for a successor. Mr. Wilson will continue to serve at full capacity until a successor is named and will provide all necessary support to ensure a seamless transition.

“Marc has been an invaluable member of the Crinetics team over the last six years and we thank him for his outstanding contributions,” said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. “His leadership has been instrumental in the success of our capital markets activities, the build-out of our finance and corporate affairs functions, and the maturation of our organization and culture. During his tenure, we have successfully raised a significant amount of capital to fund development of our differentiated pipeline, our rapidly growing clinical and research programs, and our anticipated commercial launch.”

“I am proud of what Crinetics has accomplished, and it has been a privilege to work with such a talented and dedicated team over the last six years,” said Mr. Wilson. “The company is in a strong financial position to invest across its deep pipeline, and I have unwavering confidence in the team’s ability to continue discovering new, meaningful therapies and advance them through the clinic to reach as many patients as possible. I will continue to support the company through this transition and look forward to following the company’s continued success.”

Second Quarter 2024 and Recent Highlights:



- **Presented positive initial results from atumelnant studies at the Endocrine Society’s Annual Meeting (ENDO 2024).** In June, Crinetics presented positive initial results from its ongoing, open-label studies of atumelnant for the treatment of ACTH-dependent Cushing’s syndrome and congenital adrenal hyperplasia (CAH) at ENDO 2024 in Boston.
- **Presented data from paltusotine development program at ENDO 2024.** In June, Crinetics presented findings from its paltusotine development program in acromegaly. Data presented included results of the Phase 3 PATHFNDR-2 trial, a new analysis of patient reported outcome data from the Phase 3 PATHFNDR-1 trial, and interim long-term efficacy and safety results at 42 months from the open-label ACROBAT Advance extension study.
- **Selected development candidates in two programs.** Crinetics has identified an oral parathyroid hormone antagonist development candidate for the treatment of hyperparathyroidism and IND-enabling studies have commenced. In addition, a development candidate in the SST3 agonist program was selected for the treatment of autosomal dominant polycystic kidney disease.
- **Scott Struthers, Ph.D., founder and chief executive officer of Crinetics, was named an Entrepreneur of The Year® 2024 Pacific Southwest Award winner.**
- **Strengthened scientific leadership team.** In April, Crinetics appointed Lise Kjems, M.D., Ph.D. as Senior Vice President of Endocrinology Clinical Research, and in May, Crinetics appointed Robert M. Cuddihy, M.D., as Senior Vice President of Medical Affairs.

Key Upcoming Milestones:

- Topline data and additional data from the ongoing Phase 2 studies of atumelnant in CAH and ACTH dependent Cushing’s syndrome, respectively, are anticipated by the end of 2024.
- 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 on track for the second half of 2024.
- Initiation of a Phase 3 program of paltusotine for carcinoid syndrome is expected by the end of 2024, following consultation with the FDA.
- Additional research pipeline updates are expected by the end of 2024.

Second Quarter 2024 Financial Results:

- Research and development expenses were \$58.3 million for the three months ended June 30, 2024, compared to \$40.6 million for the same period in 2023. The increase was primarily attributable to higher personnel costs and manufacturing and development activities, both of which were driven by the advancement of our clinical programs and the expansion of our preclinical portfolio.
 - General and administrative expenses were \$24.8 million for the three months June 30, 2024, compared to \$13.3 million for the same period in 2023. The increase was primarily driven by higher personnel and commercial planning costs.
 - Net loss for the three months ended June 30, 2024, was \$74.1 million, compared to a net loss of \$51.0 million for the same period in 2023.
 - Revenues were \$0.4 million for the three months ended June 30, 2024, compared to \$1.0 million for the same period in 2023. Revenues during the current year’s quarter were derived from the paltusotine licensing arrangement with our Japanese partner, Sanwa Kagaku Kenkyusho.
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- Unrestricted cash, cash equivalents, and investments totaled \$863.0 million as of June 30, 2024, compared to \$558.6 million as of December 31, 2023. Based on its current projections, Crinetics 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, Thursday, August 8, 2024 at 4:30 p.m. ET. To participate, please dial 1-800-267-6316 (domestic) or 1-203-518-9783 (international) and refer to Conference ID CRNXQ2. To access the webcast, [click here](#). Following the live event, a replay of the call will be available on the Investors section of the Company's website.

*Proposed international nonproprietary name under review.

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. Crinetics' lead development candidate, paltusotine, is an investigational, first-in-class, oral, once-daily somatostatin receptor type 2 (SST2) agonist 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 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 (including thyroid eye disease), diabetes, obesity and GPCR-targeted oncology indications.

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 to the FDA for paltusotine for the treatment or maintenance of treatment of acromegaly in the United States, and the plans and timelines for the commercial launch of paltusotine if approved; the expected timing of initiation of a Phase 3 program of paltusotine for carcinoid syndrome and FDA consultation; the expected timing of additional data and topline results from studies of atumelnant in CAH and Cushing's syndrome; the expected timing of additional research pipeline updates; 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, initial or topline data that we report may change following completion or 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 Securities and Exchange Commission (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 filings with the SEC, including its annual report on Form 10-K for the year ended December 31, 2023 and its Quarterly reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Revenues	\$ 399	\$ 988	\$ 1,039	\$ 3,667
Operating expenses:				
Research and development	58,344	40,640	111,685	79,108
General and administrative	24,838	13,343	45,666	25,532
Total operating expenses	83,182	53,983	157,351	104,640
Loss from operations	(82,783)	(52,995)	(156,312)	(100,973)
Total other income, net	8,728	2,016	15,797	3,999
Loss before equity method investment	(74,055)	(50,979)	(140,515)	(96,974)
Loss on equity method investment	—	—	(470)	—
Net loss	\$ (74,055)	\$ (50,979)	\$ (140,985)	\$ (96,974)
Net loss per share - basic and diluted	\$ (0.94)	\$ (0.94)	\$ (1.86)	\$ (1.79)
Weighted-average shares - basic and diluted	79,008	54,275	75,690	54,092

BALANCE SHEET DATA:	June 30,	December 31,
	2024	2023
Cash, cash equivalents and investments	\$ 862,953	\$ 558,555
Working capital	\$ 820,399	\$ 530,211
Total assets	\$ 935,535	\$ 635,353
Total liabilities	\$ 104,772	\$ 96,247
Accumulated deficit	\$ (794,687)	\$ (653,702)
Total stockholders' equity	\$ 830,763	\$ 539,106

Investors:

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