

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 08, 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 7.01 Regulation FD Disclosure.

On May 8, 2024, Crinetics Pharmaceuticals, Inc. (the “Company” or “Crinetics”) issued a press release announcing five abstracts from its clinical development program to be presented at the Endocrine Society’s annual meeting, ENDO 2024, which is taking place from June 1-4, 2024 in Boston, Massachusetts. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01, including in Exhibit 99.1 hereto, is being “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This report 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 report are forward-looking statements, including statements regarding plans to present updates and findings from the Company’s research and clinical trial programs. These forward-looking statements speak only as of the date of this report and are subject to a number of known and unknown risks, uncertainties and assumptions, including, without limitation, topline results 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, the possibility of unfavorable new clinical data and further analyses of existing clinical data, and the FDA and other regulatory authorities may not agree with our interpretation of such results; 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. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

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



Crinetics Pharmaceuticals to Present Advancements from Atumelnant (CRN04894) and Paltusotine Development Programs at ENDO 2024

Initial Data from Phase 2 Trial of Atumelnant in Congenital Adrenal Hyperplasia to be Presented, Along with Initial Findings from Phase 1b/2a ACTH-Dependent Cushing's Syndrome Trial

Data from Phase 3 PATHFNDR 1 and 2 Trials of Paltusotine in Acromegaly will be Presented, in Addition to New Long-Term Safety and Efficacy Findings

SAN DIEGO – May 8, 2024 – [Crinetics Pharmaceuticals, Inc.](#) (Nasdaq: CRNX) today announced five abstracts from its clinical development programs, including four late-breaking abstracts, will be presented at the Endocrine Society's annual meeting, [ENDO 2024](#), taking place June 1-4, 2024 in Boston, Massachusetts.

“This year’s Endocrine Society meeting represents a major milestone for Crinetics as we present initial findings from two clinical studies of atumelnant* (CRN04894), our investigational, once-daily oral ACTH receptor antagonist, in development for the treatment of people with classic congenital adrenal hyperplasia and ACTH-dependent Cushing’s syndrome, in addition to presentations featuring data from the acromegaly Phase 3 trials of our lead development candidate, paltusotine,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. “As we work toward submission of the new drug application for paltusotine later this year, and as our second clinical asset, atumelnant, advances through development, we are very pleased with the progress toward our vision of building the premier endocrine-focused pharmaceutical company.”

Two poster presentations will include clinical data for atumelnant, a novel, oral once-daily adrenocorticotrophic hormone (ACTH) receptor antagonist in development for classic congenital adrenal hyperplasia (CAH) and ACTH-dependent Cushing’s syndrome. One presentation will showcase initial safety and key biomarker efficacy findings in CAH, including rapid and profound reductions in androstenedione (A4) and 17-hydroxyprogesterone levels in participants, from the Phase 2 open label TouCAHn study. A second presentation includes data from a Phase 1b/2a open-label single center study of atumelnant in ACTH-dependent Cushing’s syndrome and will feature the first evidence of rapid and sustained cortisol reductions in participants.

Crinetics will also have a poster presentation with data from the Phase 3 PATHFNDR-2 study evaluating paltusotine in acromegaly patients who were medically untreated. Additionally, data from the Phase 3 PATHFNDR-1 study of previously treated acromegaly patients who switched to paltusotine from an injected somatostatin receptor ligand, including a new analysis of patient-reported symptoms, will be presented as a poster presentation. Data from the PATHFNDR program will be featured in a [Science and Innovation Theater](#) led by Dr. Kevin C.J. Yuen, of the Barrow Neurological Institute, on Saturday, June 1, 2024, titled “Paltusotine: A Novel, Investigational Oral Small Molecule Somatostatin Receptor Ligand for Acromegaly.” A third presentation from the paltusotine clinical program will be a poster showing long-term safety and efficacy updates from the Phase 2 ACROBAT Advance open-label extension study.

*Proposed international nonproprietary name under review

Additional details on the presentations are shown below:



Title: Once Daily Oral Atumelnant (CRN04894) Induces Rapid and Profound Reductions of Androstenedione and 17-hydroxyprogesterone in Participants with Classical Congenital Adrenal Hyperplasia: Initial Results from a 12-Week, Phase 2, Open-Label Study

Date/Time: June 3rd from 12:00 – 1:30 pm ET

Location: Session P108 - Late-Breaking Poster Presentations - ENDOExpo PosterArea - BCEC

Title: Atumelnant (CRN04894) Induces Rapid And Sustained Reductions In Serum And Urine Cortisol In Patients With ACTH-dependent Cushing Syndrome During A Phase 1b/2a, Single Center, 10-day, Inpatient, Open-label Study

Date/Time: June 3rd from 12:00 – 1:30 pm ET

Location: Session P108 - Late-Breaking Poster Presentations - ENDOExpo PosterArea - BCEC

Title: Efficacy and Safety of Once-Daily Oral Paltusotine in Medically Untreated Patients With Acromegaly: Results from the Phase 3, Randomized, Placebo-Controlled PATHFNDR-2 Study

Date/Time: June 3rd from 12:00 – 1:30 pm ET

Location: Session P108 - Late-Breaking Poster Presentations - ENDOExpo PosterArea – BCEC

Title: Use of the Acromegaly Symptom Diary (ASD) in a Phase 3, Placebo-Controlled Study of Once-Daily, Oral Paltusotine in Patients With Acromegaly Switched From Injected Octreotide or Lanreotide

Date/Time: June 3rd from 12:00pm – 1:30 pm ET

Location: Neuroendocrinology and Pituitary: Pituitary Tumors IV - ENDOExpo PosterArea - BCEC

Title: Long-Term Safety and Efficacy of Once-Daily Oral Paltusotine in the Treatment of Patients With Acromegaly: Update From ACROBAT Advance

Date/Time: June 3rd from 12:00 – 1:30 pm ET

Location: Session P108 - Late-Breaking Poster Presentations - ENDOExpo PosterArea – BCEC

The poster presentations will be made available on the Crinetics website at the time of presentation in accordance with the ENDO embargo policy.

ABOUT ATUMELNANT (CRN04894)

Atumelnant, our second investigational compound, is the first once-daily, oral adrenocorticotropic hormone (ACTH) receptor antagonist that acts selectively at the melanocortin type 2 receptor (MC2R) on the adrenal glands. Diseases associated with excess ACTH can have significant impact on physical and mental health. Atumelnant has exhibited strong binding affinity for MC2R in preclinical models and has demonstrated suppression of adrenally derived glucocorticoids and androgens that are under the control of ACTH. Data in a Phase 1 healthy volunteer study demonstrated pharmacologic proof-of-concept for atumelnant, with reductions in both serum cortisol levels and 24-hour urine free cortisol excretion in the presence of sustained, disease-like ACTH concentrations. Atumelnant is currently in Phase 2 studies for Congenital Adrenal Hyperplasia and ACTH-dependent Cushing's syndrome.

ABOUT PALTUSOTINE

Paltusotine is the first oral, once-daily selectively-targeted somatostatin receptor type 2 (SST2) agonist, and has completed its randomized, controlled Phase 3 studies for acromegaly and a Phase 2 study for carcinoid syndrome. It was designed by the Crinetics' discovery team to provide an efficacious and convenient once-daily option for people living with acromegaly and carcinoid syndrome. In Phase 2



studies and the recently completed PATHFNDR-1 and PATHFNDR-2 Phase 3 studies, paltusotine maintained IGF-1 levels in patients with acromegaly who were switched from monthly injectable medications to paltusotine (PATHFNDR-1) and decreased IGF-1 levels in medically untreated patients (PATHFNDR-2). IGF-1 is the primary biomarker endocrinologists use to manage acromegaly patients. Results from the Phase 2 study in carcinoid syndrome further support paltusotine's potential use beyond acromegaly.

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 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; plans to submit a new drug application for paltusotine later this year; plans to develop atumelnant; and plans to present updates and findings from our research and clinical trial programs. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, without limitation, topline results 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, the possibility of unfavorable new clinical data and further analyses of existing clinical data, and the U.S. Food and Drug Administration and other regulatory authorities may not agree with our interpretation of such results; 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. 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.

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