# 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): December 09, 2024**

# 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.)** |
| **6055 Lusk Boulevard 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 8.01 Other Events.**

On December 9, 2024, Crinetics Pharmaceuticals, Inc. (the "Company," "Crinetics," "we," "us," or "our") issued a press release announcing that the U.S. Food and Drug Administration accepted its New Drug Application for investigational candidate paltusotine for the treatment and long-term maintenance therapy of acromegaly in adults. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The press release is also available under the "Investors" section of the Company's website.

**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. 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, the 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 quarterly reports on Form 10-Q for the quarters ended March 31, 2024, June 30, 2024 and September 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.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated December 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 hereunto duly authorized.

Crinetics Pharmaceuticals, Inc.

Date: December 9, 2024

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

**EXHIBIT 99.1**

# Crinetics Announces FDA Acceptance of New Drug Application for Paltusotine for Adult Patients with Acromegaly

*FDA Assigns a Prescription Drug User Fee Act Target Action Date of September 25, 2025*

**SAN DIEGO – December 9, 2024** – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today announced the U.S. Food and Drug Administration (FDA) accepted its New Drug Application (NDA) for investigational candidate paltusotine for the treatment and long-term maintenance therapy of acromegaly in adults. If approved, paltusotine will be the first and only once-daily, oral, selective somatostatin receptor type 2 nonpeptide agonist available for adults living with acromegaly.

"With our patient-centered clinical development of paltusotine, we were guided by an unwavering ambition to deliver a new generation of treatment that provides a once-daily, oral alternative to the currently marketed peptide analog drugs," said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. "We look forward to working with the FDA throughout the review of our new drug application, as we also prepare for a potential commercial launch by building out our infrastructure and engaging with payers and the endocrinology community."

The NDA submission for once-daily, oral paltusotine included data from the PATHFNDR-1 (NCT04837040) and PATHFNDR-2 (NCT05192382) Phase 3 clinical trials, which evaluated paltusotine's safety and efficacy in previously treated and medically untreated adults, respectively. The FDA has set a Prescription Drug User Fee target action date of September 25, 2025, for completing review of the NDA. The FDA also confirmed that an advisory committee meeting is not anticipated as part of the application's review.

Paltusotine was granted Orphan Drug Designation for the treatment of acromegaly by the FDA in July 2020. This designation is provided to drugs defined as being intended for the safe and effective treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 people in the United States.

**ABOUT PALTUSOTINE**
Crinetics' lead development candidate, paltusotine, is the first investigational once-daily, oral, selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist that has completed Phase 3 clinical development for acromegaly and is initiating Phase 3 clinical development for carcinoid syndrome associated with neuroendocrine tumors. It was designed to be a once daily oral option for the control of acromegaly and the symptoms related to carcinoid syndrome. In Phase 3 studies, once-daily, oral paltusotine maintained IGF-1 levels and symptom control in patients with acromegaly who were switched from monthly injectable medications (PATHFNDR-1) and rapidly decreased IGF-1 levels and symptom burden in medically untreated acromegaly patients (PATHFNDR-2). IGF-1 is the primary biomarker endocrinologists use to manage acromegaly patients. Results from a Phase 2 study in carcinoid syndrome demonstrated rapid and sustained reductions in flushing episodes and bowel movement frequency, which are the most common symptoms of carcinoid syndrome. Crinetics is preparing to initiate a Phase 3 trial for control of symptoms associated with carcinoid syndrome in patients with neuroendocrine tumors.

**ABOUT ACROMEGALY**
Acromegaly is a serious rare disease generally caused by a benign pituitary adenoma (tumor) that secretes excess growth hormone (GH). Excess GH secretion causes excess secretion of insulin-like growth factor-1 (IGF-1) from the liver. Prolonged exposure to increased levels of IGF-1 and GH leads to progressive and serious systemic complications, often resulting in bone, joint, cardiovascular, metabolic, cerebrovascular, or respiratory disease. Acromegaly symptoms include headache, joint aches, fatigue, sleep apnea, severe

sweating, hyperhidrosis/oily skin, bone and cartilage overgrowth, abnormal growth of hands and feet, enlargement of heart, liver and other organs and alteration of facial features. Uncontrolled acromegaly results in increased mortality and has a debilitating impact on daily functioning and quality of life.

Monthly depot injections of peptide somatostatin receptor ligands are the most common pharmacologic treatment for people suffering with acromegaly. However, these depots typically require many months to achieve the correct dose level. People suffering with acromegaly often experience a return of symptoms towards the end of the monthly injection cycle and many must adjust their injection frequency to more often than monthly[1]. Further, these depots are difficult to administer and employ large gauge needles that are commonly associated with pain, injection site reactions and an increased burden on the lives of patients.

**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 the first investigational once-daily, oral, selective somatostatin receptor type 2 (SST2) nonpeptide agonist that is in clinical development for acromegaly and carcinoid syndrome associated with neuroendocrine tumors. Crinetics is also developing atumelnant 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 NDA review process and the expected timing of the completion of the FDA's review of the NDA for paltusotine for the treatment or maintenance of treatment of acromegaly in the United States, the therapeutic potential and clinical benefits or safety profile of paltusotine for patients with acromegaly and carcinoid syndrome, the plans and timelines for the commercial launch paltusotine for acromegaly, if approved, the expected timing of initiation of a Phase 3 program of paltusotine for carcinoid syndrome or the pathway for regulatory approval, the clinical development of atumelnant, including the therapeutic potential and clinical benefits or safety profile thereof, and the potential of our other research, discovery, and clinical trial programs. 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, the expected timing of additional data and topline results from studies of atumelnant in CAH and Cushing's syndrome; the possibility of unfavorable new clinical data and further analyses of existing clinical data; potential delays in the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; 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*

[1] Data on file.

*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; 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; 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, June 30, 2024 and September 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.*

**Investors:**
Gayathri Diwakar
Head of Investor Relations
gdiwakar@crinetics.com
(858) 345-6340

**Media:**
Natalie Badillo
Head of Corporate Communications
nbadillo@crinetics.com
(858) 345-6075