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): September 26, 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** **(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 8.01 Other Events.

On September 26, 2024, Crinetics Pharmaceuticals, Inc. (the "Company," "Crinetics," "we," "us," or "our") issued a press release announcing the submission of a New Drug Application to the U.S. Food and Drug Administration for paltusotine, the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist in development for the proposed treatment and long-term maintenance therapy of acromegaly. 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 will also be 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 26, 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: September 26, 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 Submits New Drug Application for Paltusotine for the Treatment of Acromegaly

SAN DIEGO – September 26, 2024 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for paltusotine, the first once-daily, oral, selectively-targeted somatostatin receptor type 2 nonpeptide agonist in development for the proposed treatment and long-term maintenance therapy of acromegaly.

"This NDA submission brings us one step closer to our goal of delivering a new generation of therapy that can help people living with acromegaly," said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. "Based on the comprehensive data from the Phase 3 PATHFNDR program, we are excited about the significance of this potential advancement for the acromegaly community, as well as what it represents to Crinetics as a company. Paltusotine is the leading candidate of a deep, innovative pipeline – the first of many therapeutic candidates that have been purposefully designed in-house to transform the lives of people impacted by a wide range of endocrine conditions."

The NDA is supported by data from 18 clinical trials, including two Phase 3 trials that evaluated paltusotine for the treatment of acromegaly in medically untreated and treated patients. All primary and secondary endpoints were met in both Phase 3 studies. Treatment with paltusotine was well-tolerated and resulted in biochemical control and patient reported symptom control compared to placebo.

Crinetics anticipates receiving notification from the FDA on the status of the NDA submission in December.

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 in Phase 2 clinical development for carcinoid syndrome associated with neuroendocrine tumors. It was designed by Crinetics with the goal of providing a once-daily, oral option for reliable and consistent control of acromegaly. 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 the Phase 2 study in carcinoid syndrome will provide an opportunity for paltusotine to potentially demonstrate utility in an investigational, Phase 3 trial for another important indication related to the treatment of symptoms in patients with neuroendocrine tumors.

ABOUT ACROMEGALY
Acromegaly is a serious rare disease generally caused by a pituitary adenoma, a benign tumor in the pituitary that secretes 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.

Surgical removal of pituitary adenomas, if possible, is the preferred initial treatment for most people with acromegaly. Pharmacotherapy is used for people who are not candidates for surgery, or when surgery is unsuccessful in achieving treatment goals. Approximately 50% of people with acromegaly prove to be

candidates for pharmacotherapy. Injectable somatostatin receptor ligands are the most common initial pharmacologic treatment; however, these drugs require monthly depot injections with 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, selectively-targeted somatostatin receptor type 2 (SST2) nonpeptide agonist that has completed Phase 3 clinical development for acromegaly and is 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 expected timing of notification from the FDA regarding the status of the NDA submission for paltusotine for the treatment or maintenance of treatment of acromegaly in the United States, and the plans and timelines for the commercial launch paltusotine, if approved or the potential pathway for regulatory approval for the use of paltusotine as a treatment for carcinoid syndrome. 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; 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; 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.

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