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): November 5, 2021

Crinetics Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38583**	**26-3744114**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

10222 Barnes Canyon Road, Bldg #2
San Diego, California 92121
(858) 450-6464

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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 (17 CFR § 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR § 240.12b-2).

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 November 5, 2021, Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") issued a press release reporting its financial results for the quarter ended September 30, 2021. 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.

Forward-Looking Statements

Crinetics cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential benefits of paltusotine for patients with acromegaly or neuroendocrine tumors complicated by carcinoid syndrome; the potential benefits of CRN04984 for patients with conditions of ACTH excess, including Cushing's disease and congenital adrenal hyperplasia; the potential benefits of CRN04777 for patients with congenital hyperinsulinism; the timing of data from the Phase 1 clinical trials of CRN04984 and CRN04777; plans to advance other pipeline product candidates and to invest in the small molecule discovery approach; Radionetics' ability to develop and advance its oncology pipeline; the potential benefits of nonpeptide radiopharmaceutical agents for the treatment of a broad range of oncology indications; the potential for Crinetics and its stockholders to obtain value from Crinetics' equity interest in Radionetics; and Crinetics' potential to receive future milestone and royalty payments from Radionetics. The inclusion of forward-looking statements should not be regarded as a representation by Crinetics that any of its plans will be achieved. Actual results may differ from those set forth in this current report due to the risks and uncertainties inherent in Crinetics' business, including, without limitation: data that we report may change following a more comprehensive review of the data related to the clinical trials and such data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory authorities may not agree with our interpretation of such results; advancement of CRN04894 and CRN04777 into later stage trials is dependent on and subject to the receipt of further feedback from the FDA and other regulatory agencies; 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; the COVID-19 pandemic may disrupt Crinetics' business and that of the third parties on which it depends, including delaying or otherwise disrupting its clinical trials and preclinical studies, manufacturing and supply chain, or impairing employee productivity; the company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the success of Crinetics' clinical trials and nonclinical studies for paltusotine, CRN04894, CRN04777, and its other product candidates; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of the company's product candidates that may limit their development, regulatory approval and/or commercialization; Crinetics may use its capital resources sooner than it expects; Radionetics will need additional funds to advance its pipeline and Crinetics' ownership interest may be diminished in connection with future capital raising; Crinetics' ability to receive milestone or royalty payments from Radionetics will depend on Radionetics ability to advance the pipeline through clinical development, regulatory approval and ultimately commercial sales, all of which will take significant time, will be subject to inherent risks in drug development and may be impacted by changes in regulatory requirements, healthcare reform measures and competitive dynamics; the technology platform is novel and unproven and may never lead to approved products of commercial value; clinical trials 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' or Radionetics' drug candidates may not advance in development or be approved for marketing; Crinetics and Radionetics may use their capital resources sooner than expected; and other risks described under the heading "Risk Factors" in documents the Company files from time to time with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Crinetics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No	Description
99.1	Press Release dated November 5, 2021.
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.

Date: November 5, 2021

Crinetics Pharmaceuticals, Inc.

/s/ R. Scott Struthers, Ph.D.

R. Scott Struthers, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Crinetics Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Corporate Update

– Pipeline Includes Three New Chemical Entities with Clinical Proof-of-concept Following CRN04894 and CRN04777 Phase 1 Readouts –

– Advancing a Parathyroid Hormone Receptor Antagonist Program Using the Drug Development Blueprint Followed by Paltusotine, CRN04894, and CRN04777 –

– Co-founded Radionetics Oncology with $30 million in Initial Financing from 5AM Ventures and Frazier Healthcare Partners –

SAN DIEGO – November 5, 2021 – Crinetics Pharmaceuticals, Inc. (Nasdaq: CRNX), a clinical stage pharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors, today announced financial results for the third quarter ended September 30, 2021 and provided a corporate update.

"Positive Phase 1 readouts from our CRN04894 and CRN04777 programs during the third quarter have us advancing a diverse pipeline that includes three wholly-owned new chemical entities (NCEs) with clinical proof-of-concept," said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. "The drug development blueprint followed by these NCEs, which aims for early de-risking through animal and healthy volunteer studies leveraging well-established endocrine biomarkers, is now being applied to our recently unveiled parathyroid hormone receptor antagonist program and other discovery efforts. We also continue to make strong progress in our efforts to develop paltusotine as a convenient, oral treatment for acromegaly and neuroendocrine tumors complicated by carcinoid syndrome. We also continue to make strong progress in our efforts to develop paltusotine as an oral treatment for acromegaly and neuroendocrine tumors complicated by carcinoid syndrome. With a strong financial foundation that was recently bolstered by our successful common stock offering, we believe we are well positioned to advance our pipeline programs and achieve a regular cadence of milestones."

Dr. Struthers continued, "Beyond our internal pipeline, our drug discovery platform has also generated exciting radiopharmaceutical candidates with the potential to treat a broad range of cancers. This led us to co-found Radionetics Oncology, which has positioned Crinetics to participate in the value of these assets while maintaining focus on our core mission of delivering much-needed therapies to patients with endocrine diseases."

Third Quarter and Subsequent Highlights

- **Reported positive data from single-ascending dose (SAD) cohorts of first-in-human study of CRN04777.** In September 2021, Crinetics announced preliminary data from the SAD cohorts of an ongoing Phase 1 study of CRN04777, its somatostatin receptor type 5 (SST5) agonist being developed as a treatment for congenital hyperinsulinism. The data provided evidence of clinically meaningful suppression of insulin secretion by showing dose-dependent reductions in glucose-stimulated insulin secretion and a dose-dependent reversal of sulfonylurea-induced insulin secretion in a pharmacologic model of congenital hyperinsulinism. In addition, the data suggest CRN04777 was orally bioavailable and demonstrated dose-proportional pharmacokinetics. Single doses of CRN04777 were well tolerated, as all adverse events were considered mild/moderate. Data from multiple-ascending dose (MAD) cohorts of the Phase 1 study are expected in the first quarter of 2022.

- **Reported positive data from SAD cohorts of first-in-human study of CRN04894.** In August 2021, Crinetics announced preliminary data from the SAD cohorts of an ongoing Phase 1 study of CRN04894, its adrenocorticotropic hormone (ACTH) antagonist being developed as a treatment for diseases of ACTH excess. The data provided evidence of clinically relevant cortisol suppression and showed dose-dependent reductions in

basal cortisol levels as well as suppression of cortisol following ACTH challenge. In addition, the data suggest that CRN04894 was orally bioavailable and demonstrated dose-proportional pharmacokinetics. Single doses of CRN04894 were well-tolerated, as all adverse events were considered mild. Data from the MAD cohorts of the Phase 1 study are expected in the first quarter of 2022.

- **Unveiled its parathyroid hormone receptor antagonist program.** In September 2021, Crinetics announced its intent to develop a nonpeptide oral parathyroid hormone (PTH) receptor antagonist for the treatment of hypercalcemia associated with hyperparathyroidism (HPT) and other diseases of PTH receptor type 1 (PTHR1) over-activation. Details on the preclinical efforts supporting the program were presented in a late-breaking poster at the annual meeting of the American Society for Bone and Mineral Research (ASBMR). More information on the program and a copy of the poster can be found here.

- **Co-founded Radionetics Oncology.** In October 2021, Crinetics, together with 5AM Ventures and Frazier Healthcare Partners, founded Radionetics Oncology, an independently operated company that aims to develop a deep pipeline of novel, targeted, nonpeptide radiopharmaceuticals for the treatment of a broad range of oncology indications. In conjunction with formation of the company, Radionetics received an exclusive world-wide license to a radiotherapeutics technology platform and intellectual property from Crinetics in exchange for equity, milestones in excess of $1 billion and single-digit royalties on net sales. Radionetics launched with a $30 million private financing with 5AM Ventures and Frazier Healthcare Partners as the sole investors.

- **Strengthened balance sheet with successful common stock offerings.** In July 2021, Crinetics entered into a securities purchase agreement with Frazier Healthcare Partners for the private placement of 851,306 shares at $17.62 per share, raising gross proceeds of $15.0 million. In October 2021, Crinetics completed an underwritten public offering of 8,712,400 shares of its common stock at a price to the public of $19.80 per share, raising gross proceeds of $172.5 million.

Third Quarter 2021 Financial Results

- Research and development expenses were $21.6 million for the three months ended September 30, 2021, compared to $13.7 million for the same period in 2020. The increase was primarily attributable to increased spending on manufacturing and development activities of $4.3 million associated with our clinical and nonclinical activities for paltusotine and our other clinical and preclinical programs, and an increase in personnel costs of $3.2 million, of which stock-based compensation was $1.2 million.
- General and administrative expenses were $6.2 million for the three months ended September 30, 2021, compared to $4.8 million for the same period in 2020. The increase was primarily due to additional personnel costs of $1.0 million, of which stock-based compensation was $0.6 million.
- Net loss for the three months ended September 30, 2021, was $27.9 million, compared to a net loss of $18.3 million for the three months ended September 30, 2020.
- Unrestricted cash, cash equivalents and investments totaled $193.3 million as of September 30, 2021, compared to $170.9 million as of December 31, 2020. The $193.3 million in unrestricted cash, cash equivalents and investments does not include the $172.5 million in gross proceeds from the Company's October 2021 common stock offering.
- As of October 31, 2021, the company had 47,499,886 common shares outstanding.

About Crinetics Pharmaceuticals

Crinetics Pharmaceuticals is a clinical stage pharmaceutical company focused on the discovery, development, and commercialization of novel therapeutics for rare endocrine diseases and endocrine-related tumors. The company's lead product candidate, paltusotine (formerly CRN00808), is an investigational, oral, selective nonpeptide somatostatin receptor type 2 biased agonist for the treatment of acromegaly, an orphan disease affecting more than 26,000 people in the United States. A Phase 3 program in acromegaly with paltusotine is underway. Crinetics also plans to advance paltusotine into a Phase 2 trial for the treatment of carcinoid syndrome associated with neuroendocrine tumors. The company is also developing CRN04777, an investigational, oral, nonpeptide somatostatin receptor type 5 (SST5) agonist for congenital

hyperinsulinism, as well as CRN04894, an investigational, oral, nonpeptide ACTH antagonist for the treatment of Cushing's disease, congenital adrenal hyperplasia and other diseases of excess ACTH. All of the company's drug candidates are new chemical entities resulting from in-house drug discovery efforts and are wholly owned by the company.

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CRINETICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENT DATA
(In thousands, except per share data)
(Unaudited)

	Three months ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
STATEMENTS OF OPERATIONS DATA:				
Grant revenues	$ -	$ -	$ -	$ 71
Operating expenses:				
Research and development	21,580	13,699	59,651	40,168
General and administrative	6,227	4,752	17,163	13,065
Total operating expenses	27,807	18,451	76,814	53,233
Loss from operations	(27,807)	(18,451)	(76,814)	(53,162)
Total other income (expense), net	(44)	131	(33)	991
Net loss	$ (27,851)	$ (18,320)	$ (76,847)	$ (52,171)
Net loss per share - basic and diluted	$ (0.73)	$ (0.56)	$ (2.13)	$ (1.76)
Weighted-average shares - basic and diluted	38,309	32,890	36,147	29,608

	September 30, 2021	December 31, 2020
BALANCE SHEET DATA:		
Cash, cash equivalents and investments	$ 193,325	$ 170,880
Working capital	$ 191,533	$ 167,003
Total assets	$ 209,359	$ 183,445
Total liabilities	$ 15,769	$ 14,526
Accumulated deficit	$ (244,461)	$ (167,614)
Total stockholders’ equity	$ 193,590	$ 168,919