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 6, 2020

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))

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. ☒

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

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2020, Crinetics Pharmaceuticals, Inc. issued a press release reporting its financial results for the quarter ended September 30, 2020. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No	Description
99.1	Press Release dated November 6, 2020.
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: November 6, 2020

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

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

FOR IMMEDIATE RELEASE

Crinetics Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Corporate Update

Reported positive topline results for the ACROBAT Edge and Evolve Phase 2 trials of oral paltusotine for the treatment of acromegaly

CRN04777 received Rare Pediatric Disease Designation for the treatment of congenital hyperinsulinism

SAN DIEGO – November 6, 2020 – 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, 2020 and provided a corporate update.

"Crinetics made significant progress in the third quarter, and we are excited by the recently reported positive topline ACROBAT Edge results showing that the study met its primary endpoint," said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. "With this data, we are well positioned for a productive end-of-Phase 2 meeting with regulatory authorities and we look forward to finalizing our Phase 3 program for paltusotine in the first half of next year. In addition, we are eager to initiate clinical studies for our ACTH antagonist and SST5 agonist programs in the coming months, as there is a high unmet need for the patients who can be served by these novel approaches. Like paltusotine, Phase 1 studies for these drug candidates are expected to produce key biomarker data that are intended to be predictive of efficacy and de-risk the clinical programs."

Third Quarter and Subsequent Highlights

- **Reported positive topline results for the ACROBAT Edge and Evolve Phase 2 trials of paltusotine in acromegaly patients.** In October 2020, Crinetics reported topline results from its ACROBAT Edge and Evolve Phase 2 trial. The prespecified primary endpoint in Edge was achieved, showing that once-daily oral paltusotine maintained insulin-like growth factor-1 (IGF-1) levels at Week 13 in acromegaly patients who were switched from an injected somatostatin receptor ligand (SRL) depot of either octreotide or lanreotide monotherapy. This data showed that acromegaly patients switching to once-daily oral paltusotine from first-line injected depot monotherapies maintained IGF-1 levels previously achieved with octreotide or lanreotide.

- **Received Rare Pediatric Disease Designation for CRN04777 for the treatment of congenital hyperinsulinism**. In September 2020, the U.S. Food and Drug Administration (FDA) granted CRN04777 Rare Pediatric Disease (RPD) Designation for the treatment of congenital hyperinsulinism. The FDA developed the Rare Pediatric Disease Priority Review Voucher (PRV) Program whereby companies are eligible to receive a priority review voucher following approval of a product with an RPD designation if the marketing application submitted for the product satisfies certain additional conditions. If issued, a sponsor may redeem a PRV for priority review of a subsequent marketing application for a different product candidate, or the PRV could be sold or transferred to another sponsor.

Third Quarter 2020 Financial Results

- Research and development expenses were $13.7 million for the three months ended September 30, 2020, compared to $11.8 million for the same period in 2019. The increase was primarily attributable to higher personnel costs and clinical and nonclinical development and manufacturing activities for the company's programs.
- General and administrative expenses were $4.8 million for the three months ended September 30, 2020, compared to $3.9 million for the same period in 2019. The increase was primarily due to personnel costs to support the company's growth.
- Net loss for the three months ended September 30, 2020 was $18.3 million, compared to a net loss of $14.4 million for the three months ended September 30, 2019.
- Cash, cash equivalents and investments totaled $186.8 million as of September 30, 2020, compared to $118.4 million as of December 31, 2019. The cash balance includes the $107.9 million of net proceeds from the public equity offering completed in April.
- As of October 31, 2020, the company had 32,922,328 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 oral selective nonpeptide somatostatin receptor type 2 biased agonist for the treatment of acromegaly, an orphan disease affecting more than 25,000 people in the United States. Crinetics plans to advance paltusotine into a Phase 3 program in acromegaly and a Phase 2 trial for the treatment of carcinoid syndrome associated with neuroendocrine tumors (NETs) in 2021. The company is also developing CRN04777, an oral nonpeptide somatostatin receptor type 5 (SST5) agonist for hyperinsulinism, as well as an 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. For more information, please visit www.crinetics.com.

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 acromegaly patients; the potential to initiate a Phase 3 program of paltusotine in acromegaly based on the Edge and Evolve topline results and the timing thereof; Crinetics' plans to meet with the FDA to finalize plans for a Phase 3 program for paltusotine; the planned expansion of the paltusotine development program to include the treatment of carcinoid syndrome in patients with NETs and the expected timing thereof, including initiation of a Phase 2 trial in these patients; Crinetics' eligibility to receive a priority review voucher following approval of CRN04777 for the treatment of congenital hyperinsulinism; the initiation of clinical trials for its other development programs; and expected cash runway and future capital needs. 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 press release due to the risks and uncertainties inherent in Crinetics' business, including, without limitation: topline data that Crinetics reports is based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trials and such topline data may not accurately reflect the complete results of a clinical trial, and the FDA and other regulatory authorities may not agree with Crinetics' interpretation of such results; advancement of paltusotine into a Phase 3 program for acromegaly or a Phase 2 trial for carcinoid syndrome and CRN04777 into a Phase 1 trial for congenital hyperinsulinism are dependent on and subject to the receipt of further feedback from the FDA; Crinetics may not meet the eligibility criteria for a PRV; 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 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;

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.

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CRINETICS PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED FINANCIAL STATEMENT DATA

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
STATEMENTS OF OPERATIONS DATA:	**2020**	**2019**	**2020**	**2019**
Grant revenues	$ -	$ 505	$ 71	$ 872
Operating expenses:				
Research and development	13,699	11,823	40,168	29,363
General and administrative	4,752	3,911	13,065	10,127
Total operating expenses	18,451	15,734	53,233	39,490
Loss from operations	(18,451)	(15,229)	(53,162)	(38,618)
Total other income (expense), net	131	799	991	2,745
Net loss	$ (18,320)	$ (14,430)	$ (52,171)	$ (35,873)
Net loss per share - basic and diluted	$ (0.56)	$ (0.60)	$ (1.76)	$ (1.49)
Weighted-average shares - basic and diluted	32,890	24,208	29,608	24,155

BALANCE SHEET DATA:	**September 30, 2020**	**December 31, 2019**
Cash, cash equivalents and investment securities	$ 186,824	$ 118,392
Working capital	$ 185,289	$ 114,999
Total assets	$ 200,317	$ 130,377
Total liabilities	$ 13,095	$ 13,238
Accumulated deficit	$ (145,973)	$ (93,802)
Total stockholders’ equity	$ 187,222	$ 117,139