
**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): August 7, 2020

Crinetics Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

001-38583
(Commission File Number)

26-3744114
(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 August 7, 2020, Crinetics Pharmaceuticals, Inc. issued a press release reporting its financial results for the quarter ended June 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

<u>Exhibit No</u>	<u>Description</u>
99.1	Press Release dated August 7, 2020.

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: August 7, 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 Second Quarter 2020 Financial Results and Provides Corporate Update

Paltusotine received Orphan Drug Designation for the treatment of acromegaly

Half of the enrolled patients in the ongoing Phase 2 ACROBAT Edge clinical trial for paltusotine had completed the study as of June and topline data is expected in fourth quarter 2020

Reported positive interim results for the ACROBAT Edge Phase 2 trial of oral paltusotine for the treatment of acromegaly

Completed successful public offering raising net proceeds of \$107.9 million

SAN DIEGO – August 7, 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 second quarter ended June 30, 2020 and provided a corporate update.

“Crinetics has made significant progress in the second quarter of the year, which began with our positive interim data from the Phase 2 ACROBAT Edge trial, and Orphan Drug Designation for paltusotine for the treatment of acromegaly, both solidifying the confidence we have in our lead product to be an effective, orally available treatment for patients with this rare disease,” said Scott Struthers, Ph.D., Founder and Chief Executive Officer of Crinetics. “Looking ahead to the rest of the year, we see additional clinical milestones for the company with topline data from our ongoing Phase 2 trials expected to be presented in the fourth quarter of 2020. Additionally, with the capital from our April financing, we are well positioned to execute on our planned Phase 3 trial in acromegaly, a Phase 2 trial of paltusotine in carcinoid syndrome associated with neuroendocrine tumors, as well as the planned Phase 1 trials for our ACTH antagonist and SST5 agonist programs.”

Second Quarter and Subsequent Highlights

- **Received Orphan Drug Designation for paltusotine for the treatment of acromegaly.** In July 2020, the U.S. Food and Drug Administration (FDA) granted paltusotine Orphan Drug Designation for the treatment of acromegaly. Orphan Drug Designation qualifies Crinetics for certain development incentives, that may include exemption from FDA prescription drug user fees, financial incentives for qualified clinical development, and seven years of market exclusivity in the U.S. if the treatment is approved.
 - **Confirmed completion for half of the enrolled patients in the ongoing Phase 2 ACROBAT Edge clinical trial for paltusotine.** In June 2020, Crinetics announced that over 50% (28/47) of the patients enrolled in the ACROBAT Edge Phase 2 clinical trial have completed the study, which is investigating the effects of once daily oral paltusotine on IGF-1
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levels after switching patients from injectable depot therapy. Recruitment for the Edge and Evolve trials has been completed with 47 and 13 patients, respectively, and topline data is planned for the fourth quarter of 2020.

- **Reported positive interim results for the ACROBAT Edge Phase 2 trial of paltusotine in acromegaly patients.** In April 2020, Crinetics reported interim results from its ongoing ACROBAT Edge Phase 2 trial. Results as of the February 23, 2020 data cutoff showed that acromegaly patients switching from injectable depot therapy to once daily oral paltusotine maintained IGF-1 levels previously achieved with commercially available depot injections of somatostatin receptor ligands.
- **Successful public offering strengthens cash position.** In April 2020, Crinetics completed a public offering in which the company sold an aggregate of 8,222,500 shares of common stock at a price to the public of \$14.00 per share. Net proceeds from the public offering after deducting underwriting discounts, commissions and offering expenses, were approximately \$107.9 million.

Second Quarter 2020 Financial Results

- Research and development expenses were \$12.6 million for the three months ended June 30, 2020, compared to \$10.3 million for the same period in 2019. The increase was primarily attributable to development and manufacturing activities for paltusotine as well as the advancement of the company's preclinical programs and higher personnel costs.
- General and administrative expenses were \$4.3 million for the three months ended June 30, 2020, compared to \$3.1 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 June 30, 2020 was \$16.5 million, compared to a net loss of \$12.4 million for the three months ended June 30, 2019.
- Cash, cash equivalents and investments totaled \$205.2 million as of June 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 July 31, 2020, the company had 32,883,582 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 undergoing two Phase 2 clinical trials 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 trial in acromegaly and a Phase 2 trial for the treatment of carcinoid syndrome associated with neuroendocrine tumors in 2021. The company is also developing an oral nonpeptide somatostatin receptor type 5 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 of paltusotine to be an effective treatment option for acromegaly patients; the benefits Crinetics may obtain as a result of the Orphan Drug Designation for paltusotine; the potential to initiate a pivotal Phase 3 trial of paltusotine in acromegaly based on interim results obtained to date and the timing thereof; the planned expansion of the paltusotine development program to include the treatment of carcinoid syndrome in patients with neuroendocrine tumors and the expected timing thereof, including initiation of a Phase 2 trial in these patients; the anticipated timing of topline data for Edge and Evolve and the initiation of Phase 1 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: the risk that interim results of a clinical trial do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; potential delays in the commencement, enrollment and completion of clinical trials and the reporting of data therefrom; advancement of paltusotine into a Phase 3 trial is dependent on and subject to the receipt of further feedback from the FDA; 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; Crinetics may not be able to maintain the Orphan Drug Designation for paltusotine, and may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity; 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, or may result in recalls or product liability claims; Crinetics' ability to obtain and maintain intellectual property protection for its product candidates; 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.

Contacts:

Marc Wilson
Chief Financial Officer
IR@crinetics.com
(858) 450-6464

Robert H. Uhl
Westwicke ICR
robert.uhl@westwicke.com
(858) 356-5932

CRINETICS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED FINANCIAL STATEMENT DATA
(UNAUDITED)

STATEMENTS OF OPERATIONS DATA:	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Grant revenues	\$ -	\$ -	\$ 71	\$ 367
Operating expenses:				
Research and development	12,607	10,285	26,469	17,540
General and administrative	4,322	3,060	8,313	6,216
Total operating expenses	16,929	13,345	34,782	23,756
Loss from operations	(16,929)	(13,345)	(34,711)	(23,389)
Total other income (expense), net	438	918	860	1,946
 Net loss	 \$ (16,491)	 \$ (12,427)	 \$ (33,851)	 \$ (21,443)
 Net loss per share - basic and diluted	 \$ (0.53)	 \$ (0.51)	 \$ (1.21)	 \$ (0.89)
Weighted-average shares - basic and diluted	31,409	24,161	27,948	24,128
 BALANCE SHEET DATA:			June 30,	December 31,
			2020	2019
Cash, cash equivalents and investments			\$ 205,165	\$ 118,392
Working capital			\$ 200,740	\$ 114,999
Total assets			\$ 217,122	\$ 130,377
Total liabilities			\$ 14,348	\$ 13,238
Accumulated deficit			\$ (127,653)	\$ (93,802)
Total stockholders' equity			\$ 202,774	\$ 117,139