NEWS RELEASE

Crinetics Pharmaceuticals Reports Second Quarter 2025 Financial Results and Provides Business Update

2025-08-07

Regulatory Interactions and Commercial, Medical and Corporate Preparations On-Track for PALSONIFY™ (paltusotine) New Drug Application with September 25, 2025 PDUFA Date

Continued Progress on the Global Development Program for Atumelnant Across Multiple Trials, Including the BALANCE-CAH Phase 2/3 Study for the Treatment of Children with Congenital Adrenal Hyperplasia Expected to Initiate this Year

$1.2B in Cash, Cash Equivalents, and Investment Securities as of June 30, 2025 Anticipated to Provide Runway into 2029

Management Hosting Conference Call at 4:30 p.m. ET Today

SAN DIEGO, Aug. 07, 2025 (GLOBE NEWSWIRE) -- **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX), a global pharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for endocrine diseases and endocrine-related tumors, today reported financial results for the second quarter ended June 30, 2025.

“We continue to make significant progress towards our goal of becoming a fully-integrated, commercial-stage company and delivering on our commitment to help people living with acromegaly,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. “As we approach our PDUFA date, our interactions with the FDA remain on track. In addition to our world-class drug discovery and development capabilities, we have now nearly

completed the build-out of a premier commercial organization. We are committed to rapidly making PALSONIFY™ available as the new level of care for patients upon approval. At the same time, we remain dedicated to the execution of early- and late-stage trials across our pipeline. I am excited to see the ramp of our late-stage trials in carcinoid syndrome and CAH (both adult and pediatric), as well as initiation of the Phase 1/2 trial of our first nonpeptide drug-conjugate, CRN09682, for SST2-expressing solid tumors. Overall, Crinetics is in the strongest position in its history, with unprecedented momentum across our clinical programs, multiple new candidates approaching the clinic, a solid financial foundation, and a clear path toward delivering transformative therapies to patients."

Second Quarter 2025 and Recent Highlights:

- The review process for paltusotine's New Drug Application (NDA) for acromegaly remains on track with consistent and productive engagement with the Food & Drug Administration (FDA).
- Marketing Authorization Application (MAA) validated by the European Medicines Agency (EMA) for paltusotine for the treatment of acromegaly, consistent with a timeline for potential EMA decision in the first half of 2026.
- Continued progress on the global development program for atumelnant across multiple trials, including enrollment completion of Cohort 4 of the adult Phase 2 study with data expected early in 2026.
- The Phase 2/3 BALANCE-CAH pediatric study is seamlessly designed to expedite development with the goal of demonstrating atumelnant's potential ability to normalize androstenedione (A4) levels with physiological glucocorticoid (GC) replacement.
- Presented two abstracts at the American Association of Clinical Endocrinology (AACE) Annual Meeting 2025 which showed treatment with investigational PALSONIFY resulted in rapid and durable IGF-1 control in surgically naïve acromegaly patients and additional research on symptom burden and standard-of-care discontinuation rates.
- Eight abstracts from Crinetics' novel clinical development programs, including oral presentations featuring lead investigational drug candidate, paltusotine, investigational candidate atumelnant, and CRN12755, the early-stage development program in Graves' hyperthyroidism and orbitopathy, were presented at the Endocrine Society's Annual Meeting, ENDO 2025.

Key Upcoming Milestones:

- FDA PDUFA target action date of September 25, 2025 for paltusotine NDA for the treatment of acromegaly.
- Crinetics expects to initiate the CAREFNDR Phase 3 trial of paltusotine in carcinoid syndrome in the second half of 2025.
- Crinetics expects to initiate the CALM-CAH Phase 3 study in adults with CAH and the BALANCE-CAH Phase 2/3 study in pediatrics in the second half of 2025.

- Planning, including regulatory interactions, for the next study of atumelnant in ACTH-dependent Cushing's syndrome is underway. Initiation of the Phase 2/3 study is expected to begin in the first half of 2026.
- Crinetics expects to initiate a Phase 1/2 dose escalation study for CRN09682, the first candidate from the nonpeptide drug conjugate (NDC) platform with an expansion phase for the treatment of metastatic or locally advanced SST2-positive neuroendocrine tumors (NETs) and other SST2-expressing solid tumors.
- IND-enabling activities for the TSH antagonist continue as expected, and development of the SST3 agonist and PTH antagonist is ongoing.

Second Quarter 2025 Financial Results:

- Revenues were $1.0 million for the quarter ended June 30, 2025, compared to $0.4 million for the same period in 2024. Revenues were derived from the paltusotine licensing and supply agreements with Sanwa Kagaku Kenkyusho Co., Ltd.
- Research and development expenses were $80.3 million for the three months ended June 30, 2025, compared to $58.3 million for the same period in 2024. The increases were primarily attributable to an increase in personnel costs of $9.6 million and increased clinical and manufacturing activities costs of $7.9 million for the quarter ended June 30, 2025, respectively, driven by the advancement of our clinical programs and the expansion of our preclinical portfolio.
- Selling, general and administrative expenses were $49.8 million for the three months ended June 30, 2025, compared to $24.8 million for the same period in 2024. The increases were primarily driven by an increase in personnel costs of $12.0 million primarily due to the increase in headcount and an increase in outside services costs of $10.3 million primarily for commercial planning for the quarter ended June 30, 2025, respectively, to support our overall growth and the planned commercial launch of PALSONIFY
- Net loss for the three months ended June 30, 2025, was $115.6 million, compared to a net loss of $74.1 million for the same period in 2024.
- Cash, cash equivalents, and investments totaled $1.2 billion as of June 30, 2025, compared to $1.4 billion as of December 31, 2024. Based on current projections, Crinetics expects that its cash, cash equivalents and investments will be sufficient to fund its current operating plan into 2029. For 2025, we now anticipate our cash used in operations to be between $340 and $370 million.

Conference Call and Webcast Details

Management will hold a live conference call and webcast today, Thursday, August 7 at 4:30 p.m. ET. To participate, please dial 1-833-470-1428 (domestic) or 1-404-975-4839 (international) and refer to Access Code 899803. To access the webcast, the direct link (**here**) or visit the **Events** page of the Crinetics website. Following the live event, the

webcast will be archived on the Investor Relations section of **www.crinetics.com**.

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, PALSONIFY (paltusotine), is the first investigational once-daily, oral, selective somatostatin receptor type 2 (SST2) nonpeptide agonist that is in clinical development for acromegaly. Paltusotine is also in clinical development for carcinoid syndrome associated with neuroendocrine tumors. Atumelnant is currently in development for congenital adrenal hyperplasia and ACTH-dependent Cushing's syndrome. 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 plans and timelines for the clinical development of atumelnant and paltusotine, including the therapeutic potential and clinical benefits or safety profile thereof; the expected timing of the PDUFA target action date for our NDA submission to the FDA and of a potential EMA decision for our MAA for paltusotine for the treatment or maintenance of treatment of acromegaly in the United States and other applicable jurisdictions, and the plans and timelines for the commercial launch paltusotine if approved; the expected timing of initiation of a Phase 3 program for atumelnant for CAH and for a Phase 2/3 program of atumelnant for ACTH-dependent Cushing's syndrome; the therapeutic potential for our development candidates; the expected timing for IND-enabling studies and potential IND-filings in our development candidates to transition to clinical development; the expected timing of additional research pipeline updates; and the expected timing through which our cash, cash equivalents, and short-term investments will fund our operating plans. 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, data that we report may change following completion or a more comprehensive review of the data related to the clinical studies, 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; the success of Crinetics' clinical studies and nonclinical studies; regulatory developments or political changes, including policies related to pricing and pharmaceutical drug reimbursement, in the United States and foreign countries; clinical studies 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' drug candidates may not advance in development or be approved for marketing; Crinetics may use its capital resources sooner than expected or our cash burn rate may accelerate; 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, 2024 and quarterly report on Form 10-Q for the quarter ended June 30, 2025. 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.

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

STATEMENTS OF OPERATIONS DATA:	Three months ended June 30, 2025	Three months ended June 30, 2024	Six months ended June 30, 2025	Six months ended June 30, 2024
Revenues	$ 1,031	$ 399	$ 1,392	$ 1,039
Operating expenses:				
Research and development	80,301	58,344	156,541	111,685
Selling, general and administrative	49,842	24,838	85,368	45,666
Total operating expenses	130,143	83,182	241,909	157,351
Loss from operations	(129,112)	(82,783)	(240,517)	(156,312)
Total other income, net	13,475	8,728	28,106	15,797
Loss before equity method investment	(115,637)	(74,055)	(212,411)	(140,515)
Loss on equity method investment	—	—	—	(470)
Net loss	$ (115,637)	$ (74,055)	$ (212,411)	$ (140,985)
Net loss per share - basic and diluted	$ (1.23)	$ (0.94)	$ (2.27)	$ (1.86)
Weighted-average shares - basic and diluted	93,791	79,008	93,448	75,690

BALANCE SHEET DATA:	June 30, 2025	December 31, 2024
Cash, cash equivalents and investments	$ 1,196,360	$ 1,354,069
Working capital	$ 1,148,868	$ 1,315,704
Total assets	$ 1,289,574	$ 1,434,592
Total liabilities	$ 118,048	$ 109,787
Accumulated deficit	$ (1,164,521)	$ (952,110)
Total stockholders' equity	$ 1,171,526	$ 1,324,805

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