



NEWS RELEASE

# CRINETICS PHARMACEUTICALS REPORTS FIRST QUARTER 2025 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

2025-05-08

Regulatory Interactions and Commercial, Medical, and Corporate Preparations On-Track for Paltusotine New Drug Application with September 25, 2025 PDUFA Date

CALM-CAH Phase 3 Study of Atumelnant for the Treatment of Adults with Congenital Adrenal Hyperplasia to Initiate with Uncompromising Primary Endpoint to Normalize Androstenedione Levels with Physiologic Glucocorticoid Replacement

R&D Day Scheduled for June 26 to Share Early-Stage Pipeline Strategy and Data

\$1.3B in Cash, Cash Equivalents, and Investment Securities as of March 31, 2025 Anticipated to Provide Runway into 2029

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

SAN DIEGO – May 8, 2025 – **Crinetics Pharmaceuticals, Inc.** (Nasdaq: CRNX), a clinical stage 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 first quarter ended March 31, 2025.

“Crinetics is stronger than we have ever been,” said Scott Struthers, Ph.D., founder and chief executive officer of Crinetics. “We are approaching a pivotal moment in our company’s history. We are on-track with the FDA review

and preparations for the anticipated launch of paltusotine for acromegaly, while also moving forward with multiple late-stage studies. We are excited to unveil our Phase 3 study for adult CAH patients aimed at demonstrating normalization of androstenedione levels with physiological glucocorticoid replacement to define an uncompromising standard of care in CAH. We're also excited to start the clinical development program for CRN09682, the first candidate from our nonpeptide drug conjugate platform. We look forward to sharing more about this and our other early programs at our upcoming R&D Day. With a robust financial foundation and strong momentum across clinical, regulatory, and commercial fronts, we are poised to deliver on our mission of advancing innovative therapeutics to improve the lives of patients with endocrine diseases around the world.”

#### First Quarter 2025 and Recent Highlights:

- The review process for paltusotine’s New Drug Application (NDA) for acromegaly appears to be on track with productive and consistent engagement with the Food & Drug Administration (FDA).
- Launch of CrinetiCARE™ patient support services platform and a patient-focused disease state education website.
- 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. The EMA also granted Orphan Drug Designation (ODD) for paltusotine for the treatment of acromegaly, further highlighting the level of unmet need, and the potential for paltusotine to offer significant benefit to patients.
- Phase 2 TouCAHn open-label study of atumelnant in congenital adrenal hyperplasia (CAH) reported positive results. Atumelnant administration was shown to result in rapid, substantial and sustained statistically significant reduction in androstenedione (A4) levels, the key biomarker for disease control. Atumelnant was well-tolerated and demonstrated significant clinical improvements. We have also initiated an open-label extension study.
- Phase 3 CALM-CAH study is designed with an uncompromising primary endpoint to demonstrate atumelnant’s potential ability to normalize androstenedione (A4) levels with physiological glucocorticoid (GC) replacement.
- IND clearance for CRN09682, the first candidate from the nonpeptide drug conjugate (NDC) platform. A “Study May Proceed” letter has been received to allow us to begin a Phase 1/2 dose escalation study of CRN09682 with an expansion phase for the treatment of metastatic or locally advanced SST2-positive neuroendocrine tumors and other SST2-expressing solid tumors.

#### Key Upcoming Milestones

- FDA PDUFA target action date of September 25, 2025 for paltusotine NDA for the treatment and maintenance therapy of acromegaly.
- R&D Day scheduled for June 26, 2025, where Crinetics will provide updates on its early-stage pipeline, with a

focus on CRN09682 for neuroendocrine tumors and other SST2+ tumors, TSH antagonist for Graves' disease and thyroid eye disease, and SST3 agonist for autosomal dominant polycystic kidney disease.

- 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 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 second half of 2025.
- IND-enabling activities for the TSH antagonist continue as expected, and the SST3 agonist development is ongoing.
- Based on emerging data from IND-enabling studies, our PTH antagonist candidate in preclinical development has been substituted with another candidate expected to exhibit an improved profile. This new candidate is in IND-enabling studies, which we intend to complete next year.

#### First Quarter 2025 Financial Results

- Revenues were \$0.4 million for the quarter ended March 31, 2025, compared to \$0.6 million for the same period in 2024. Revenues were primarily derived from the paltusotine licensing agreement with Sanwa Kagaku Kenkyusho Co., Ltd.
- Research and development expenses were \$76.2 million for the three months ended March 31, 2025, compared to \$53.3 million for the same period in 2024. The increases were primarily attributable to an increase in personnel costs of \$13.3 million, increased manufacturing activities costs of \$2.5 million, and increased outside services costs of \$4.1 million, for the quarter ended March 31, 2025, respectively, all of which were driven by the advancement of our clinical programs and the expansion of our preclinical portfolio.
- Selling, general and administrative expenses were \$35.5 million for the three months ended March 31, 2025, compared to \$20.8 million for the same period in 2024. The increases were primarily driven by an increase in personnel costs of \$7.8 million and an increase in outside services costs of \$5.6 million for the quarter ended March 31, 2025, respectively, to support the continued overall growth of the Company and the planned commercial launch of paltusotine.
- Net loss for the three months ended March 31, 2025, was \$96.8 million, compared to a net loss of \$66.9 million for the same period in 2024.
- Cash, cash equivalents, and investments totaled \$1.3 billion as of March 31, 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 continue to anticipate our cash used in operations to be between \$340 and \$380 million.

#### Conference Call and Webcast Details

Management will hold a live conference call and webcast today, Thursday, May 8 at 4:30 p.m. ET. To participate, please dial 1-800-267-6316 (domestic) or 1-203-518-9783 (international) and refer to Conference ID CRNXQ4. 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](http://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, **paltusotine**, is the first investigational once-daily, oral, selective somatostatin receptor type 2 (SST2) nonpeptide agonist that is in clinical development for acromegaly and 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, 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; the success of Crinetics' clinical studies and nonclinical studies; regulatory developments 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; 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 March 31, 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.

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

Three months ended March 31

STATEMENTS OF OPERATIONS DATA:

2025

2024



Revenues	\$	361	\$	640
Operating expenses:				
Research and development		76,240		53,341
General and administrative		35,526		20,828
Total operating expenses		111,766		74,169
Loss from operations		(111,405)		(73,529)
Total other income, net		14,631		7,069
Loss before equity method investment		(96,774)		(66,460)
Loss on equity method investment		—		(470)
Net loss	\$	(96,774)	\$	(66,930)
Net loss per share – basic and diluted	\$	(1.04)	\$	(0.93)
Weighted-average shares – basic and diluted		93,102		72,289

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BALANCE SHEET DATA:

		March 31, 2025		December 31, 2024
Cash, cash equivalents and investments	\$	1,274,124	\$	1,354,069
Working capital	\$	1,233,744	\$	1,315,704
Total assets	\$	1,361,327	\$	1,434,592
Total liabilities	\$	107,327	\$	109,787
Accumulated deficit	\$	(1,048,884)	\$	(952,110)
Total stockholders' equity	\$	1,254,000	\$	1,324,805

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Source: Crinetics Pharmaceuticals, Inc.