

**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): January 8, 2024

Crinetics Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38583
(Commission
File Number)

26-3744114
(IRS Employer
Identification No.)

6055 Lusk Boulevard
San Diego, California
(Address of Principal Executive Offices)

92121
(Zip Code)

Registrant's Telephone Number, Including Area Code: (858) 450-6464

(Former Name or Former Address, if Changed Since Last Report)

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

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 7.01 Regulation FD Disclosure.

During the week of January 8, 2024, Crinetics Pharmaceuticals, Inc. (the “Company,” “Crinetics,” “we,” “us,” or “our”) will be attending meetings with investors, analysts and others at the 42nd annual J.P. Morgan Healthcare Conference, which is taking place in San Francisco, CA from January 8-11, 2024. Scott Struthers, Ph.D., Founder & Chief Executive Officer of Crinetics, will present a company update on Tuesday, January 9th at 3:45 pm Pacific Time. A live audio webcast of Dr. Struthers’ presentation may be accessed on the Events section of the Company’s website or directly on the J.P. Morgan virtual meeting platform. During the presentation, the Company will reference the corporate slide presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which is incorporated herein by reference.

The presentation will feature an overview of Crinetics’ key priorities and anticipated milestones for 2024. These include:

- The continued advancement of the Phase 3 PATHFNDR-2 trial of once-daily oral paltusotine in acromegaly. The trial remains on track for topline data readouts in the first quarter of 2024. If successful, Crinetics plans to submit data from its Phase 3 program to regulatory authorities in support of applications seeking approval for the use of paltusotine for all acromegaly patients who require pharmacotherapy, including untreated patients and those switching from other therapies.
- Efforts to further increase commercial readiness so that the Company can rapidly provide patients in the United States with acromegaly with broad access to once-daily oral paltusotine, if the new drug application is submitted and approved.
- The continued advancement of the Phase 2 trial of paltusotine in carcinoid syndrome, which remains on track for complete topline data in the first half of 2024 and the initiation of a Phase 3 program in the second half of 2024.
- The continued advancement of the Phase 2 trials of CRN04894, an investigational adrenocorticotrophic hormone (ACTH) antagonist, for congenital adrenal hyperplasia (CAH) and Cushing’s disease, with initial data expected in the second quarter of 2024.
- The continued preclinical evaluation of investigational, oral small molecules for hyperparathyroidism, polycystic kidney disease, Graves’ disease, thyroid eye disease, diabetes, and obesity.

The Company’s updated corporate presentation has been posted to the Company’s website, www.crinetics.com. The Company plans to use its website to disseminate future updates to its corporate presentation and does not intend to file or furnish a Form 8-K alerting investors each time the presentation is updated.

The information contained in this Item 7.01, including in Exhibit 99.1 hereto, is being “furnished” and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, is not subject to the liabilities of that section and is not deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

By filing this Current Report on Form 8-K and furnishing the information in this Item 7.01, the Company makes no admission as to the materiality of Item 7.01 in this report or the presentation available on the Company’s website. The information contained in the presentation is summary information that is intended to be considered in the context of the Company’s filings with the Securities and Exchange Commission (the “SEC”) and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate or as required by applicable law. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, by updating the Company’s website or through other public disclosure.

Forward-Looking Statements

This report 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 report are forward-looking statements, including statements regarding the plans and timelines for the clinical development of paltusotine, including the therapeutic potential and clinical benefits or safety profile thereof; the expected timing of topline data from the Phase 3 PATHFNDR-2 study of paltusotine in acromegaly and the Phase 2 study of paltusotine in carcinoid syndrome; plans and expected timing of Phase 3 trials of paltusotine in carcinoid syndrome; plans to submit data from the ongoing Phase 3 clinical studies of paltusotine in acromegaly to regulators in support of applications seeking approval for the use of paltusotine in acromegaly patients; the expected timing of a new drug application submission for paltusotine for the treatment or maintenance of treatment of acromegaly in the United States; the potential market opportunity for paltusotine in acromegaly and carcinoid syndrome; the expected timing of initial data from studies of CRN04894 in CAH and Cushing’s disease; the potential for any of our ongoing clinical studies to show safety or efficacy. These forward-looking statements speak only as of the date of this report and are subject to a number of known and unknown risks, uncertainties, assumptions, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, without limitation, initial findings and topline results that we report may change following 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, the possibility of unfavorable new clinical data and further analyses of existing clinical data, and the FDA and other regulatory authorities may not agree with our interpretation of such results; and the other risks and uncertainties described in the company’s periodic filings with the 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, 2022. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation
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: January 8, 2024

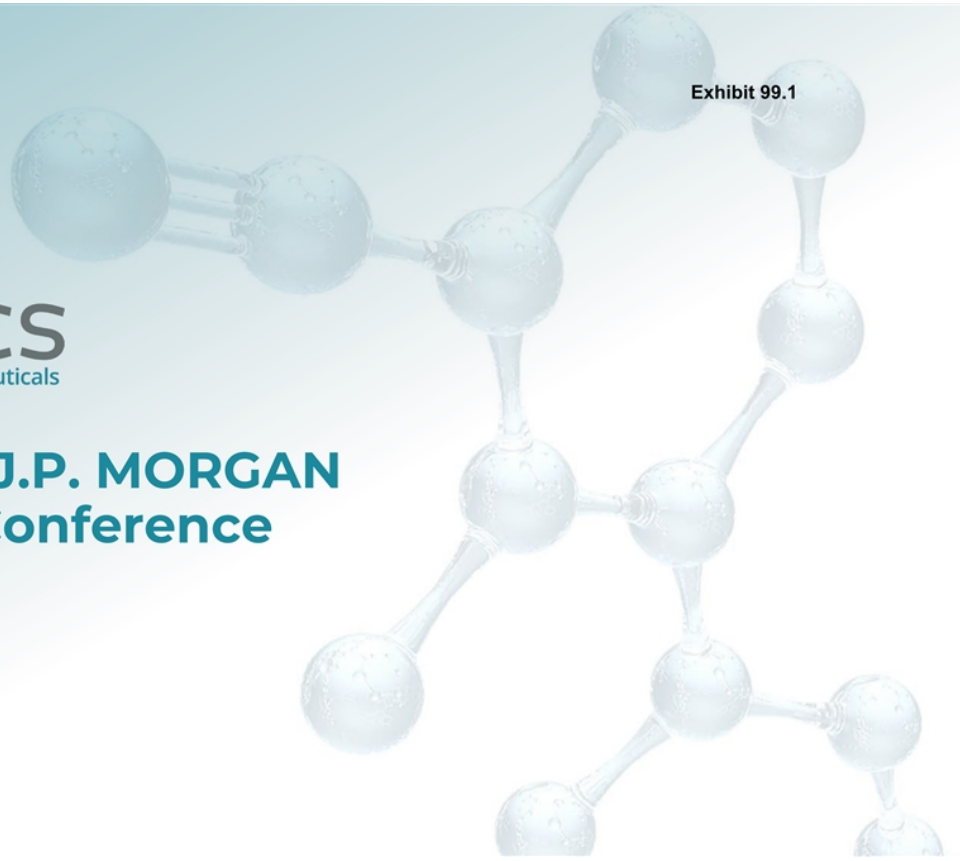
By: /s/ R. Scott Struthers, Ph. D.

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



42nd Annual J.P. MORGAN Healthcare Conference

JANUARY 9, 2024



Safe Harbor Statement

This presentation contains forward-looking statements. Crinetics Pharmaceuticals, Inc. ("Crinetics," the "company," "we," or "our") cautions you that statements contained in this presentation 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 and patients with carcinoid syndrome; the potential for the PATHFNDP program to support registration of paltusotine for all acromegaly patients who require pharmacotherapy; the plans and timelines for clinical development of paltusotine and CRN04894, including the therapeutic potential and clinical benefits or safety profile thereof; the expected timing of topline data and full results from the PATHFNDP-2 study and the Phase 2 study in patients with carcinoid syndrome and sharing the results with the FDA to align on and design a Phase 3 program; the expected timing of the submission of a new drug application for paltusotine for the treatment of acromegaly and related open label extension studies, and potential regulatory approval; the potential benefits of CRN04894 in patients with Cushing's disease or Congenital Adrenal Hyperplasia and the expected plans and timing for data from ongoing clinical studies; the potential benefits of PTH receptor antagonists for patients with hyperparathyroidism, the potential benefits of TSH antagonist for Graves' Disease or Thyroid eye disease; the potential for any of our ongoing clinical studies to show safety or efficacy; the potential of our ongoing discovery efforts to target future indications for polycystic kidney disease, or diabetes/obesity, and the expected plans and timing for candidate selection and clinical development of such candidates; our plans to identify and create new drug candidates for additional diseases; and our expected plans and timing for commercialization of paltusotine and other product candidates pending regulatory approval, including efforts in connection with prescribers, market research, payer engagement, and distribution channels. In some cases, you can identify forward-looking statements by terms such as "may," "believe," "anticipate," "could," "should," "estimate," "expect," "intend," "plan," "project," "will," "contemplate," "predict," "continue," "forecast," "laying the foundation," "leading to," "goal," "potential," "aspiring," "target," or the negative of and other similar terms.

These statements speak only as of the date of this presentation, involve known and unknown risks, uncertainties, assumptions, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, without limitation: topline and initial data that we report may change following 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; the risk that preliminary results of preclinical studies or clinical studies 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; the possibility of unfavorable new clinical data and further analyses of existing clinical data; potential delays in the commencement, enrollment and completion of clinical studies and the reporting of data therefrom; the FDA or other regulatory agencies may require additional clinical studies of paltusotine or suggest changes to our planned Phase 3 clinical studies prior to and in support of the approval of a New Drug Application or applicable foreign regulatory approval; international conflicts may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical studies and preclinical studies, manufacturing and supply chain, or impairing employee productivity; our dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the success of our clinical studies, nonclinical studies and preclinical studies for paltusotine, CRN04894, our discovery efforts for hyperparathyroidism, polycystic kidney, Graves' Disease & thyroid eye disease or diabetes/obesity product candidates; regulatory developments or price restrictions in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization; our ability to obtain and maintain intellectual property protection for our product candidates; we may use our capital resources sooner than we expect; and other risks described under the heading "Risk Factors" in documents we file from time to time with the Securities and Exchange Commission ("SEC"). Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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 and, except as required by applicable law, we do 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.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to addressable patients and addressable market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



Building a Premier **Fully
Integrated Endocrine-
focused Pharmaceutical
Company**

Strategic Approach to
Growing Long-term Value

2023 Laid the Foundation for a **Transformative** **2024-2025**

- ✓ Positive Phase 3 Results in Acromegaly for Paltusotine
- ✓ Positive Initial Phase 2 Results in Carcinoid Syndrome for Paltusotine
- ✓ Completed Enrollment in Second Phase 3 Study for Acromegaly
- ✓ Initiated Two Phase 2 Studies for Second Clinical Asset (CRN04894)
- ✓ \$350M Equity Offering

The Crinetics Way: Endocrinology for Health



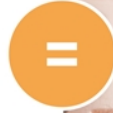
Deep roots in endocrinology



Commitment to transforming people's lives



World-class in-house R&D



Purposely crafted medicines



Deep Pipeline of Transformative Drug Candidates



6 | SST: somatostatin receptor type; ACTH: adrenocorticotropic hormone; PTH: parathyroid hormone; TSH: thyroid-stimulating hormone; TED: thyroid eye disease; GLP-1: glucagon-like peptide-1 receptor agonists; GIP: gastric inhibitory polypeptide



World-class Development Leading to Global Commercialization

Paltusotine: Lead Clinical Asset for
Acromegaly and Carcinoid Syndrome

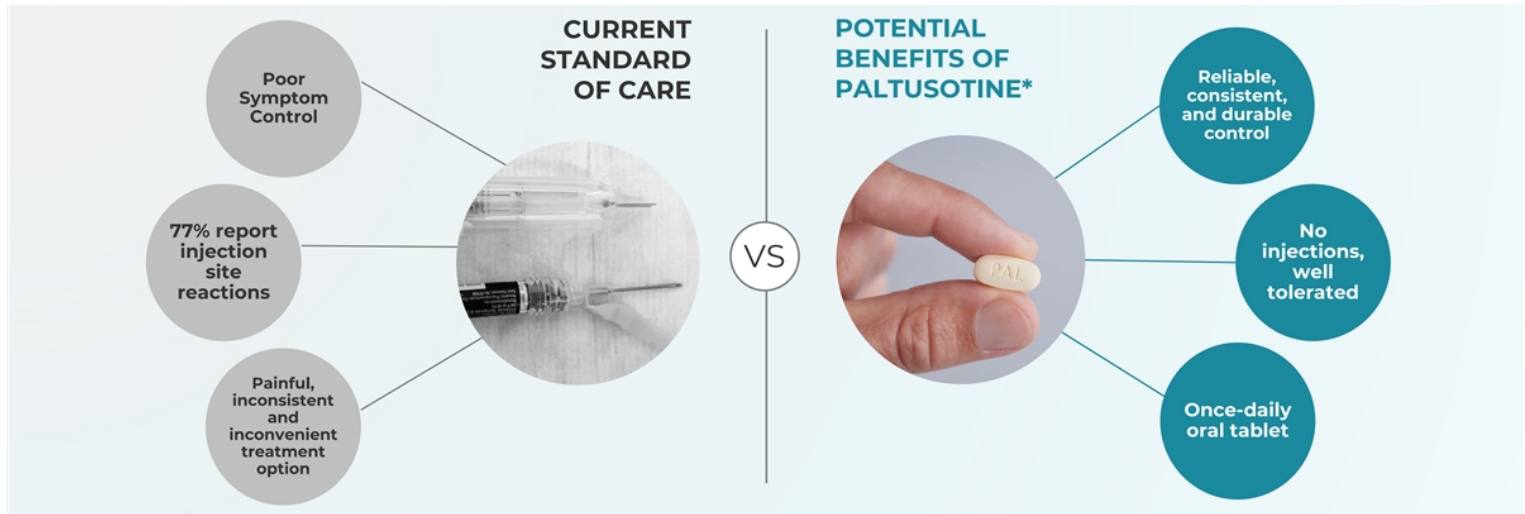


PATHFNR-1
PHASE 3 RESULTS



CARCINOID SYNDROME
PHASE 2 RESULTS

— Paltusotine: Designed to Allow People with Acromegaly and Carcinoid Syndrome to Focus on Living



***Pending receipt by paltusotine of regulatory approval. Clinical studies to support applications for regulatory approval are ongoing.**

References 1. Geer EB, Sisco J, Adelman DT, et al. Patient reported outcome data from acromegaly patients treated with injectable somatostatin receptor ligands (SRLs) in routine clinical practice. *BMC Endocr Disord.* 2020;20(1):117. doi:10.1186/s12902-020-00595-4; 2. Strasburger CJ, Karavitaki N, Störmann S, et al. Patient-reported outcomes of parenteral somatostatin analogue injections in 195 patients with acromegaly. *Eur J Endocrinol.* 2016;174(3):355-62. doi:10.1530/EJE-15-1042; 3. Fleseriu et al. *Frontiers in Endocrinology*; March 2021, Vol.12



Positive Phase 3 Results in Acromegaly Provide Strong Footing for First Commercial Launch* in 2025



PRIMARY ENDPOINT

83% of participants on paltusotine maintained IGF-1 \leq 1.0xULN vs 4% on placebo ($p < 0.0001$)



SECONDARY ENDPOINTS (paltusotine arm vs placebo)

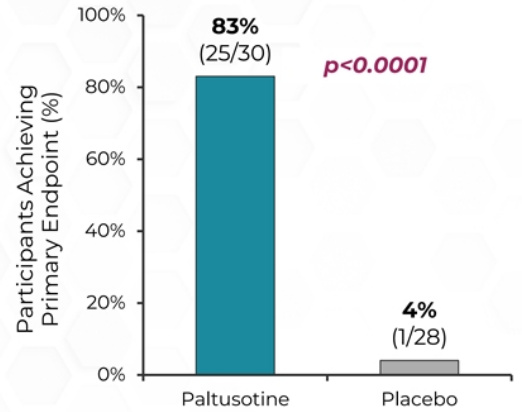
Change from baseline in IGF-1 ($p < 0.0001$)
Change from baseline in Acromegaly Symptoms Diary score ($p = 0.02$)
Proportion of participants who maintained GH < 1.0 ng/mL ($p = 0.0003$)



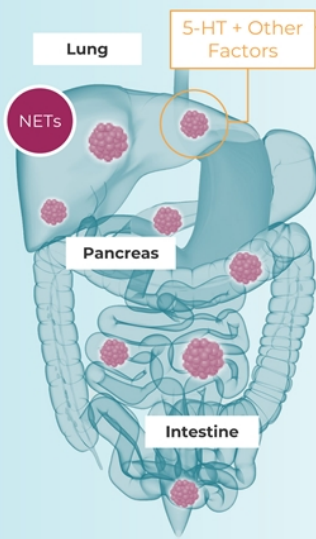
SAFETY

Paltusotine was well-tolerated with no severe or serious adverse events
Paltusotine demonstrated no new safety signals

Paltusotine is an investigational drug in clinical studies for the treatment of acromegaly and carcinoid syndrome



Paltusotine: Progressing Towards Phase 3 in a Second, More Prevalent Indication



Carcinoid Syndrome

~33,000 Patients Diagnosed with Carcinoid Syndrome (US)

Treatment Goals

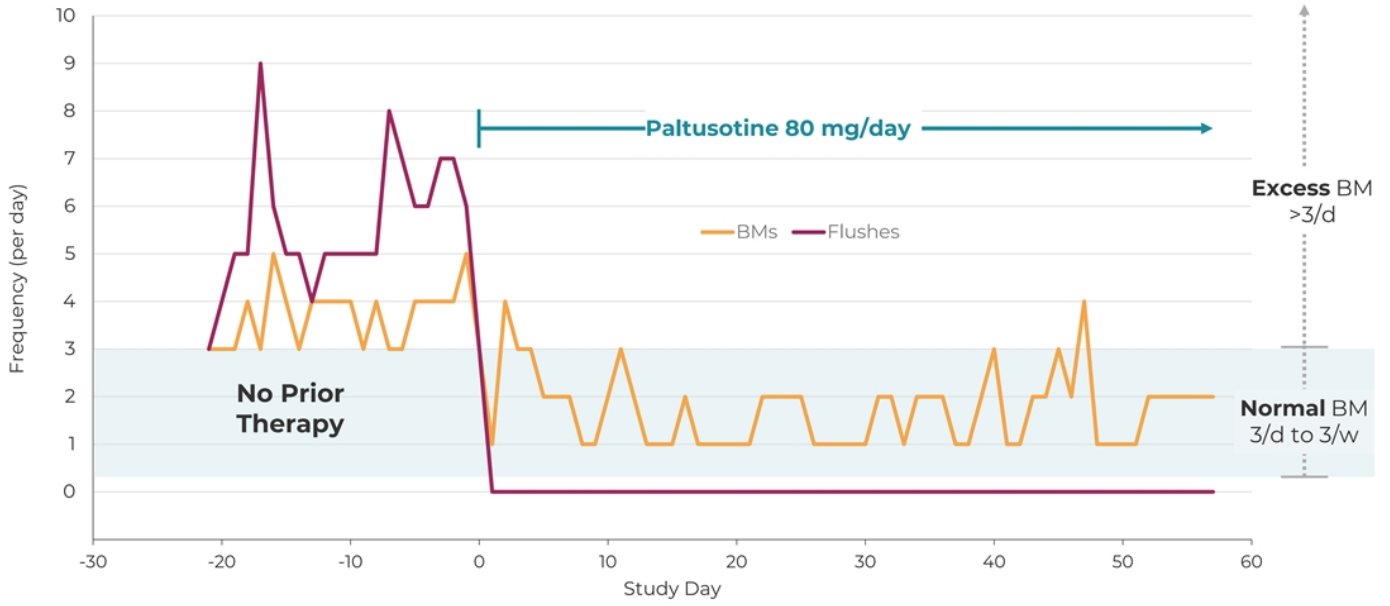
- ↓ Reduce frequency and urgency of highly disruptive excess bowel movements
- ↓ Reduce frequency and severity of severe flushing episodes which can be debilitating and potentially dangerous
- ⊗ Prevent severe complications from carcinoid heart disease (found in up to 50% of patients) & carcinoid crisis
- ⊗ Eliminate breakthrough of symptoms with injected SRLs and reduce a high burden of care

Facial flushing in a patient with carcinoid syndrome

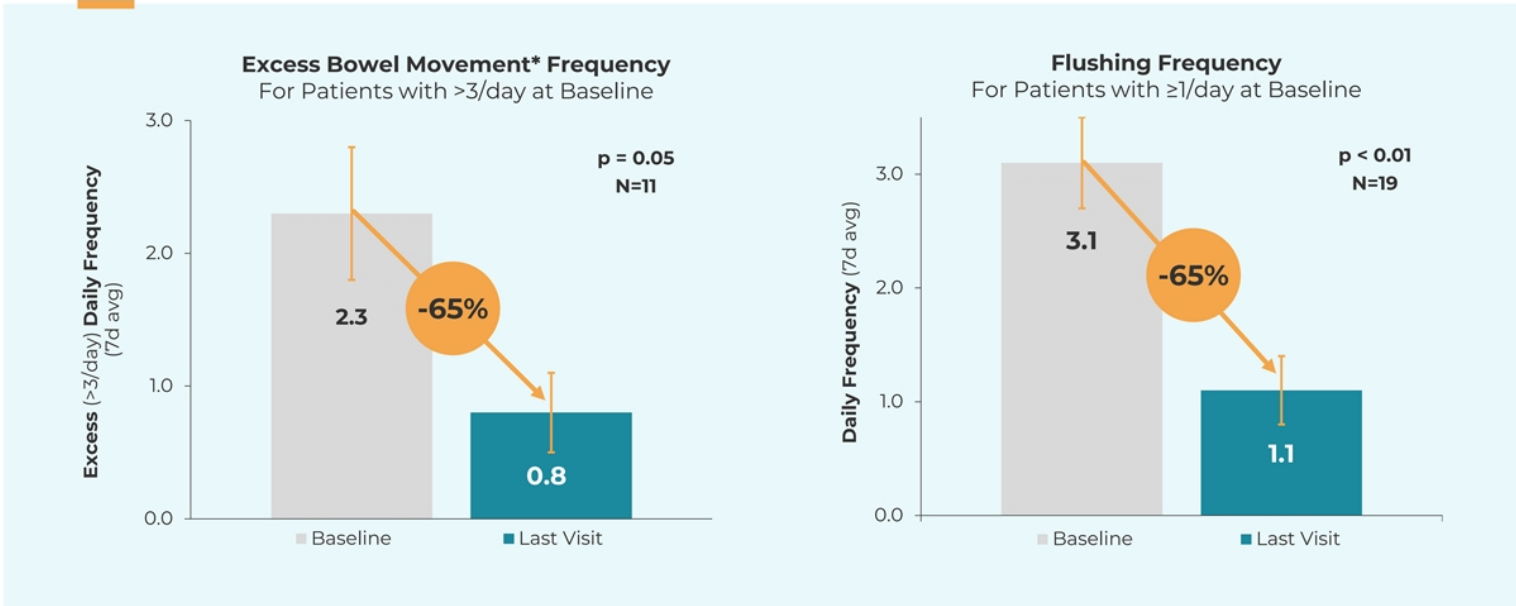


Courtesy of Stephen E Goldfinger, MD | UpToDate

Example Carcinoid Syndrome Study Participant: Elimination of Flushing and Normalization of BMs



Paltusotine Reduced the Frequency of Both Key Carcinoid Syndrome Core Symptoms: Excess BM and Flushing



12 *Excess bowel movements (BM) were defined as daily bowel movements above the upper limit of normal (3 per day)
Exploratory analysis of last visit prior to the preliminary data cut off includes 23 subjects: 15 subjects completed the week 8 visit, 4 subjects completed week 6 visit, 3 subjects completed week 4 visit and 1 subject completed week 2 visit.



Paltusotine: Initial Multi-billion Dollar U.S. Market Opportunity in Acromegaly and Carcinoid Syndrome

Diagnosed Prevalence (U.S. Patients)	Acromegaly 27,000	Carcinoid Syndrome 33,000
Addressable Patients Candidates for SRL	11,000 <i>Not cured surgically</i>	33,000
Current Patients On Endocrine Therapy*	10,000	10,000
Average Annual WAC** For Injectables	\$70K	\$100K
Current Market For Endocrine Therapy (U.S.)	\$700M	\$1,000M
Total Addressable Market For Endocrine Therapy (U.S.)	\$800M	\$3,300M

13

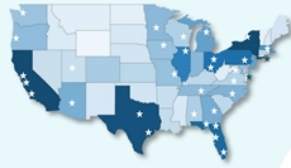
*Endocrine therapy includes SRLs, dopamine agonists, and growth hormone antagonists.
**WAC: Wholesale acquisition cost; Sources: Company data on file



Building the Base for Commercial Success in Multiple Indications for Paltusotine

Complete Prescribers Map

- 200 HCPs initiating 80% of acromegaly scripts
- 40 overlapping centers for both pituitary and NCCN
- Ad boards with top prescribers
- Expanding Med Affairs team



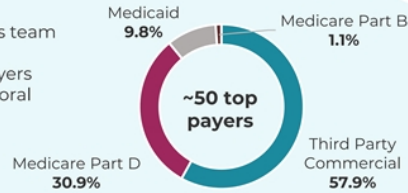
Market Research

- Backbone of marketing group in place
- Market research indicates burden of care is key to overcome inertia
- Compelling PATHFINDER-1 data is strengthening awareness



Payer Engagement

- Backbone of market access team in place.
- Engaged 50% of top US payers
- Payers appreciate value of oral option



Distribution Channel

- Finalized third party logistics vendor contract
- Negotiating specialty pharmacy network contracts
- Building Crinetics' Provider & Patient Services Hub

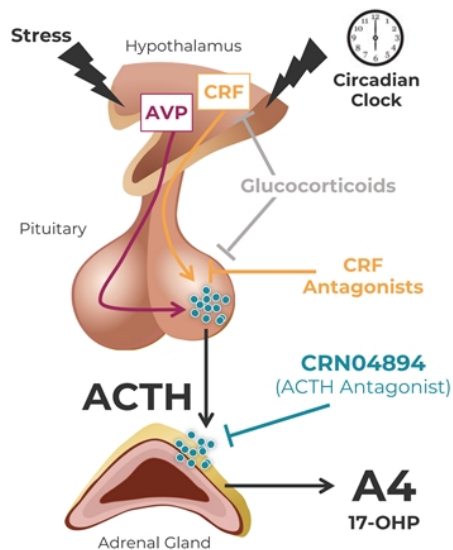


World-class Discovery to Grow the Clinical Pipeline

Following the Crinetics way to
create medicines to help increasingly
larger numbers of people



CRN04894: Second Clinical Asset In Late-Stage Development Skillfully Crafted to Help Patients Reach Their Treatment Goals



Lead Indication: Congenital Adrenal Hyperplasia (CAH)

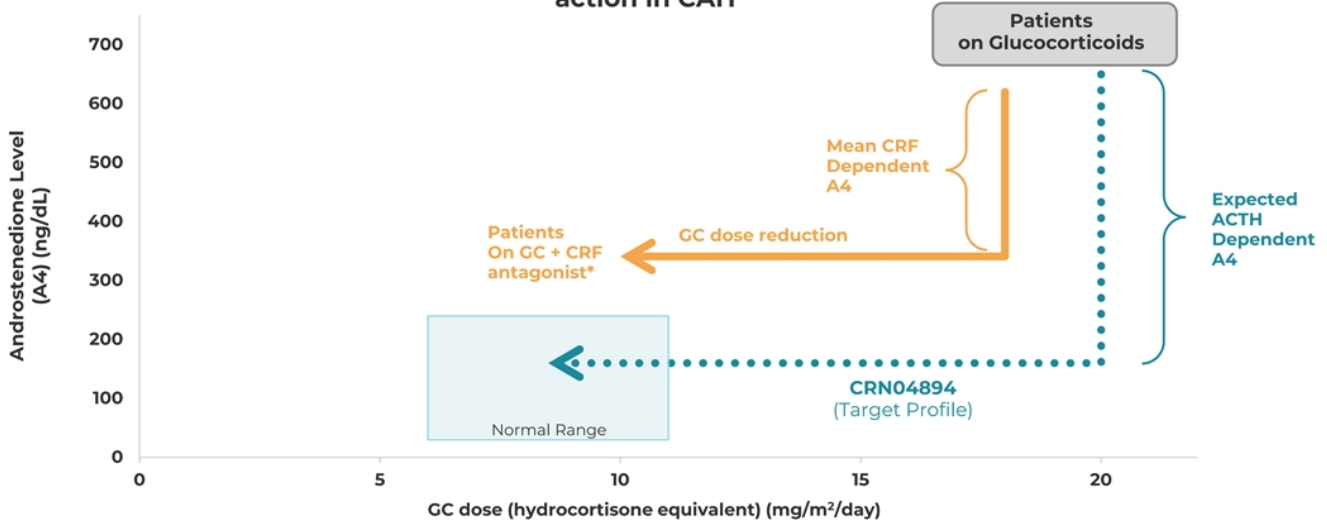
~27,000 Patients Prevalent/Diagnosed with Classical CAH (US)

Treatment Goals:

- ↓ Normalize/eliminate adrenal androgen production
- ✓ Restore normal menstrual cycles and fertility in women
- ✓ Shrink testicular adrenal rest tumors, alleviate pain, restore fertility in men
- ⊗ Prevent consequences of excess androgens in children: atypical genitalia, precocious puberty, short stature, hirsutism
- ⊗ Avoid complications of glucocorticoid excess (weight gain, hypertension, bone disease...) and enable physiologic replacement levels

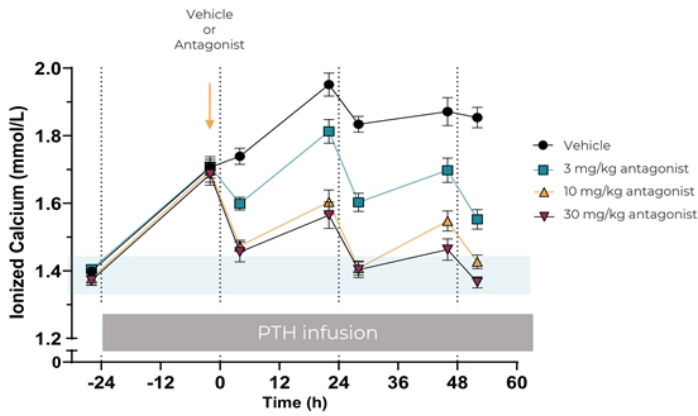
CRN04894: Targeting Mechanism Designed to Provide Maximum A4 Suppression. Initial Data Expected 2Q24

A4 suppression and steroid sparing expectations for different mechanisms of action in CAH



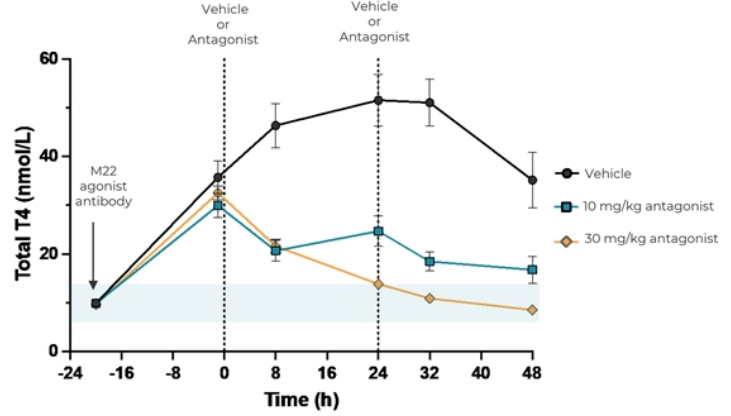
Two New Programs Anticipated to Begin First-in-human Enabling Studies in 2024

PTH Antagonist for Hyperparathyroidism



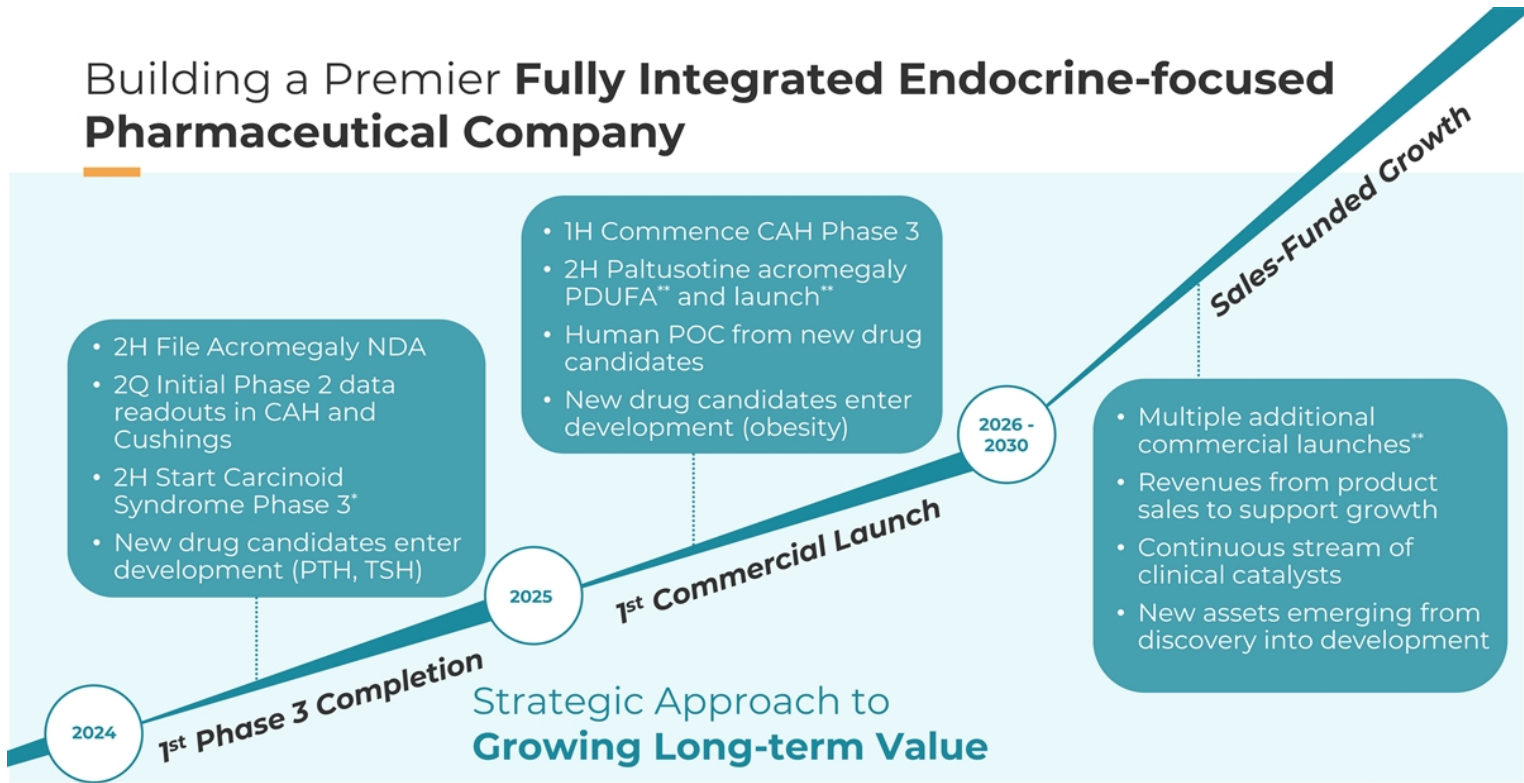
Preclinical efficacy data for potential candidate

TSH Antagonist for Graves' Disease and TED*



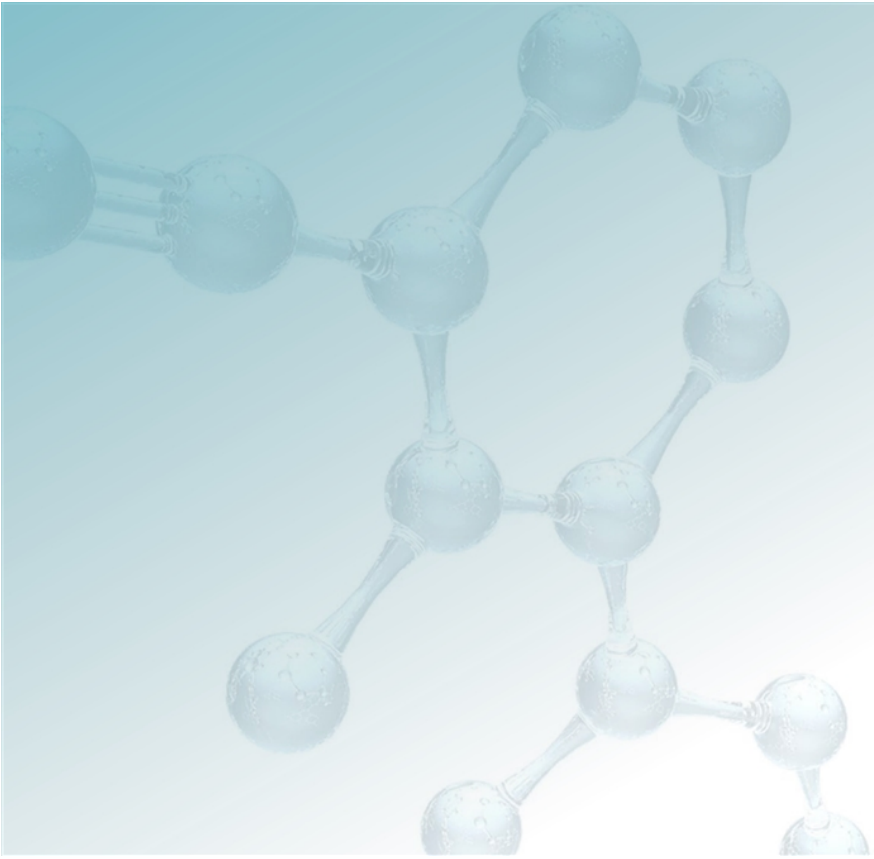
Preclinical efficacy data for potential lead candidate

Building a Premier **Fully Integrated Endocrine-focused Pharmaceutical Company**



*Pending alignment with FDA

**Pending NDA submission and regulatory approval



Thank You