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): April 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
(Address of principal executive offices) (Zip Code)

(858) 450-6464
(Registrant's telephone number, include area code)

N/A
(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 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))

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.

The slides attached as Exhibit 99.1 to this Current Report contain certain additional information related to the clinical data results discussed in Item 8.01 below. Crinetics Pharmaceuticals, Inc. (the "Company" or "Crinetics") intends to present the slides during a conference call and live webcast with the investment community on April 7, 2020, at 8:00 a.m. EDT.

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.

Item 8.01 Other Events.

On April 6, 2020, the Company announced interim results from the ongoing ACROBAT Edge Phase 2 clinical trial. Results as of a February 23, 2020 data cutoff showed that acromegaly patients switching from injectable depot therapy to once daily oral paltusotine (formerly CRN00808) maintained IGF-1 levels previously achieved with commercially available depot injections of somatostatin receptor ligands (SRLs).

Interim results from an exploratory analysis of the first 13 patients who entered the Edge trial on octreotide or lanreotide depot monotherapy (group 1) showed that, as of the cutoff date, switching to once daily oral paltusotine maintained patient IGF-1 levels at those achieved with prior depot therapy [mean change from baseline = -0.015 x ULN (95% CI = -0.123, +0.092)]. Ten of the 11 (91%) patients in group 1 who completed paltusotine treatment maintained IGF-1 levels within 15% of their respective baseline levels at week 13. No patient required "rescue therapy" with prior injected peptide acromegaly therapy after switching to paltusotine. Of the 12 patients in whom IGF-1 levels were measured two weeks after paltusotine withdrawal, the mean increase of IGF-1 from baseline was 0.74 x ULN ((95% CI = 0.394, 1.083), $p<0.001$). Paltusotine washed out in a time frame consistent with the approximately 2-day half-life previously measured in a healthy volunteer study. The rapid mean rise in IGF-1 after washout of paltusotine indicated a lack of suppressive effects by remnants of prior depot injected medication. Additionally, paltusotine was well tolerated and there were no discontinuations due to drug-related adverse events. The most common treatment emergent adverse events among patients in group 1 (>10%) were headache, arthralgia, peripheral swelling, back pain and hyperhidrosis. One serious adverse event (headache) was observed in the overall trial as of the data cutoff and determined to be non-treatment related.

The Company also provided additional updates on its development programs as follows:

- New enrollment in the ACROBAT Evolve study has been discontinued. The 12 patients already enrolled will continue in the study. The Company believes that this interim data from Edge alone is supportive of moving forward into Phase 3. Rather than waiting for Evolve to complete enrollment in the current environment, stopping enrollment now enables data from those patients already enrolled in the study to be available for end of Phase 2 regulatory interactions on the same timeline as data from Edge.
- Phase 1 data for CRN01941 in healthy volunteers showed that the compound did not represent an improvement over paltusotine. Therefore, the Company has discontinued its development in order to focus resources on development of paltusotine for both acromegaly and NETs. We believe that the acceleration and increased efficiency offered by focusing on paltusotine offers the best path forward for our sst2 franchise.
- First-in-human enabling activities are ongoing for both the oral nonpeptide ACTH antagonist for the treatment of Cushing's disease and congenital adrenal hyperplasia, and the oral nonpeptide sst5 agonist for the treatment of hyperinsulinism. The start of Phase 1 clinical trials is planned for late 2020 or early 2021 and if successful, the Company anticipates PK/PD data from these human proof-of-concept studies in the first half of 2021.
- Management has updated its cash runway guidance to extend into 2022 based on these development program updates.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Slide Presentation entitled "Interim Results from the Open Label ACROBAT Edge Phase 2 Study and Corporate Update"

Forward-Looking Statements

Crinetics cautions you that statements contained in this Current Report on Form 8-K 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 for interim data results to be consistent with final results, once available; the potential for any ongoing clinical trials to show safety or efficacy; the potential benefits of paltusotine for acromegaly patients; 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 patients with NETs and the expected timing thereof; the anticipated timing of topline data for EDGE and PK/PD data for its other development programs and initiation of trials thereafter; and the Company's anticipated cash runway. 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 Current Report on Form 8-K 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 U.S. Food and Drug Administration (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; 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.

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: April 6, 2020

By: /s/ R. Scott Struthers, Ph.D.
R. Scott Struthers, Ph.D.
President and Chief Executive Officer

Exhibit 99.1

Crinetics Pharmaceuticals

Interim Results from the Open Label ACROBAT Edge Phase 2 Study and Corporate Update

SAFE HARBOR STATEMENT

This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation are forward-looking statements, including statements regarding: the potential for interim data results to be replicated or continue to show clinical efficacy as the ongoing trial continues; the potential benefits of paltusotine for acromegaly patients; the potential to initiate a pivotal Phase 3 trial of paltusotine in acromegaly based on interim results to date and the timing thereof; the planned expansion of the paltusotine development program to include the treatment of patients with NETs and the expected timing thereof; the anticipated timing of topline data for Edge and PK/PD data for its other development programs and initiation of trials thereafter; and the company's anticipated cash runway. In some cases, you can identify forward-looking statements by terms such as "may," "believe," "anticipate," "could," "should," "estimate," "expect," "intend," "plan," "project," "will," "forecast" and similar terms. These statements involve known and unknown risks, uncertainties 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: 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; the COVID-19 pandemic may disrupt our business and that of the third parties on which we depend, including delaying or otherwise disrupting our clinical trials 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 trials and nonclinical studies for paltusotine and our other product candidates; regulatory developments 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; 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. 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.

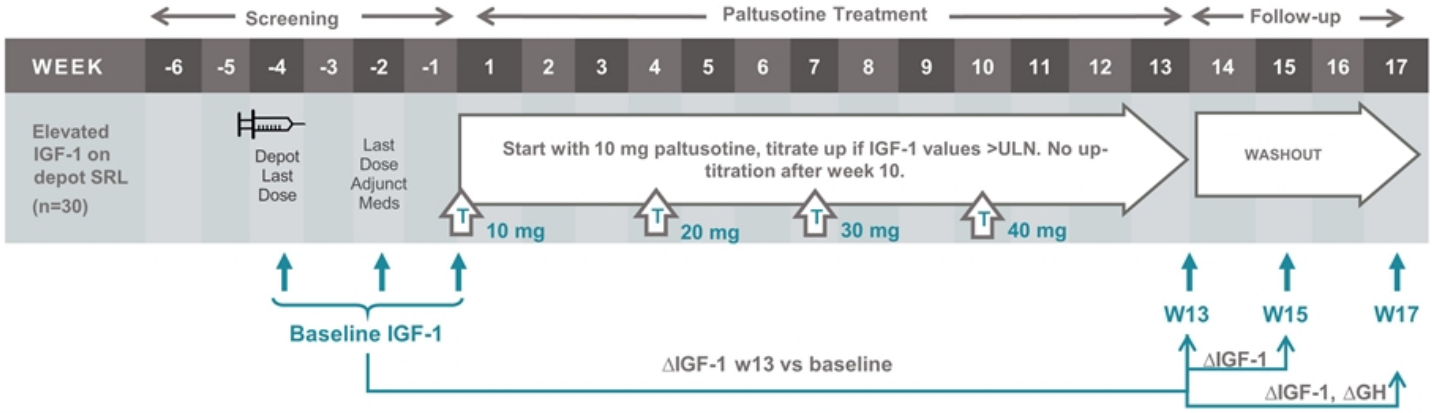
This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. 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.

Corporate update

- Paltusotine Phase 2 acromegaly program achieves key milestones
  - Interim results from Edge patients who completed participation by Feb 23, 2020 showed that after 13 weeks, patients who were switched to once daily oral paltusotine maintained IGF-1 levels that were achieved with prior injected peptide octreotide or lanreotide depot monotherapy
  - Edge recruitment is now complete (topline data expected in 4Q2020)
  - New enrollment in the Evolve study has been discontinued. Patients already enrolled will continue in the study. Data from these patients are expected to be available for end of Phase 2 regulatory interactions at the same time as data from Edge.
- NETs development will proceed with paltusotine to accelerate the program and conserve resources. CRN01941 development has been discontinued.
- Cash runway guidance extended into 2022
- Acromegaly Phase 3 expected to start 1H2021 with to-be-marketed formulation of paltusotine
- ACTH antagonist and sst5 agonist programs continue with IND enabling activities with a goal of reporting of Phase 1 PK/PD proof-of-concept data in the first half of 2021

Crinetics Pharmaceuticals

ACROBAT Edge design



Group	Patient Groups	IGF-1 range	# of Patients
1	Octreotide LAR or lanreotide depot	> 1.0x ULN to ≤ 2.5x ULN	At least 30
2	Dopamine agonist + octreotide LAR or lanreotide depot	> 1.0x ULN to ≤ 2.5x ULN	
3	Dopamine agonist + octreotide LAR or lanreotide depot	≤ 1.0x ULN	Max 15
4	Pasireotide LAR	≤ 1.0x ULN	
5	Pegvisomant + octreotide LAR or lanreotide depot	≤ 1.0x ULN	

Key inclusion/rescue criteria

- Patients on stable approved monthly dose of SRL for at least 3 mo.
- 18 to 75 years of age
- Criteria for rescue with standard acromegaly medication: significant worsening of acromegaly symptoms

Crinetics Pharmaceuticals

EDGE interim data cut as of February 23, 2020

Data available for interim analysis

- As of February 23, 2020, 32 patients have enrolled in the study and either completed participation, or continue to receive paltusotine
- 17 patients have completed participation in the study.
  - 13 of these initial patients were treated with lanreotide depot (n=8) or octreotide LAR (n=5) monotherapy and entered the trial with IGF-1 above the upper limit of normal (Group 1)
- Efficacy Evaluation Set (n=13)
  - All available data from Group 1 patients who completed participation in the trial as of February 23, 2020
- Safety Evaluation Set (n=32)
  - All patients dosed in all subgroups as of February 23, 2020 (n=32) including those that had not yet completed the study

Patient baseline characteristics

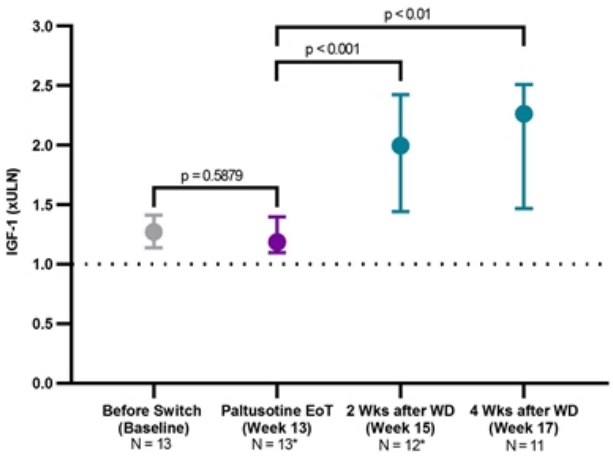
	Group 1 (N=13)	Total (N=32)
Median Age, years (Min, Max)	53.0 (34, 68)	51.5 (34, 70)
Sex		
Female	7 (53.8%)	19 (59.4%)
Male	6 (46.2%)	13 (40.6%)
Ethnicity		
Hispanic or Latino	0	6 (18.8%)
Not Hispanic or Latino	13 (100%)	26 (81.3%)
Race		
White	13 (100%)	29 (90.6%)
Black or African American	0	1 (3.1%)
Other	0	2 (6.3%)
Median Weight, kg (Min, Max)	97.9 (63, 155)	89.3 (57.3, 155)

Crinetics Pharmaceuticals

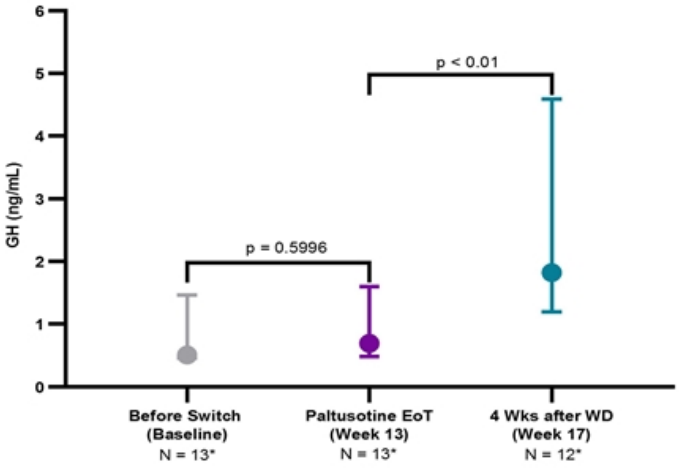
Paltusotine maintained baseline IGF-1 and integrated GH levels 13 weeks after switching from injected depot therapy

Both IGF-1 and GH levels promptly rose after paltusotine withdrawal

Serum IGF-1 changes at end of treatment and after withdrawal of paltusotine



Serum GH changes at end of treatment and after withdrawal of paltusotine



Average of 3 GH values drawn within 2 hours

Data shown are median (25th percentile, 75th percentile) for Group 1 patients

- *Data includes two early termination (ET) patients who discontinued for non-study drug related reasons: (1) use of prohibited concomitant medication and (2) inability to complete study visits. Their final treatment values were used for EoT. The 2 ET patients had 16 days (~2 weeks) and 23 days (~3 weeks) of paltusotine exposure. One ET patient had final assessment 2 weeks after EoT (GH data from this subject was included in the 4 wk GH WD data), the washout data for the other was not available
- p-values are based on non-parametric Wilcoxon Sign Rank test of whether the median change is different from zero.
- EoT=End of Treatment; WD=Withdrawal

Crinetics Pharmaceuticals

Exploratory statistical analysis of Group 1 patients

Efficacy Conclusions

1. IGF-1 and GH levels after 13 weeks of paltusotine treatment were not different than baseline (while treated with SRL depot)
2. IGF-1 rose significantly within 2 weeks of paltusotine withdrawal. GH hormone also rose significantly (GH measured only 4 weeks after withdrawal)

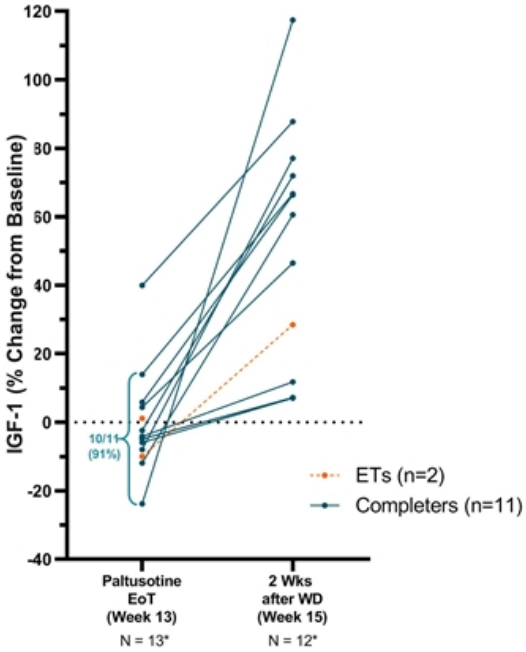
	Change in Serum Hormone Levels		
		Change from EoT to Post Withdrawal Visit	
Parameter (units)	Change from Baseline to EoT (Week 13)	2 Weeks	4 Weeks
IGF-1 (×ULN)	N=13	N=12	N=11
Mean (95% CI)	-0.015 (-0.123, 0.092)	0.739 (0.394, 1.083)	0.767 (0.379, 1.155)
Median (25th, 75th percentiles)	-0.047 (-0.102, 0.050)	0.574 (0.297, 1.083)	0.782 (0.371, 1.250)
p-value^	0.5879	< 0.001	< 0.01
GH (ng/mL)	N=13	Not Measured	N=12
Mean (95% CI)	0.054 (-0.285, 0.394)		1.612 (0.452, 2.772)
Median (25th, 75th percentiles)	0.011 (-0.100, 0.240)		0.891 (0.358, 2.716)
p-value^	0.5996		< 0.01

^p-values are based on non-parametric Wilcoxon Sign Rank test
EoT=End of Treatment;

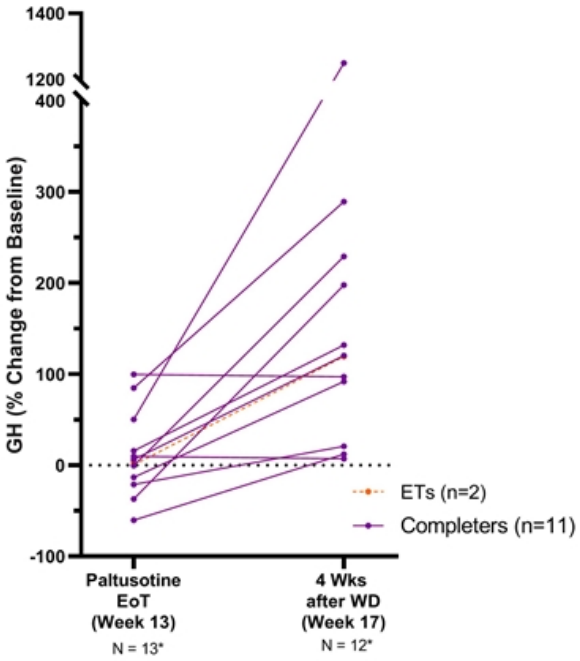
Crinetics Pharmaceuticals

Switching to once daily oral paltusotine from injected depot SRLs maintained IGF-1 levels in > 90% of Group 1 completers

Individual IGF-1 changes at end of treatment and 2 weeks after withdrawal of paltusotine



Individual GH changes at end of treatment and 4 weeks after withdrawal of paltusotine



- EoT=End of Treatment; WD=Withdrawal
- *Data includes two early termination (ET) patients who discontinued for non-study drug related reasons and had 16 days (~2 weeks) and 23 days (~3 weeks) of paltusotine exposure. 1 ET patient had final assessment 2 weeks after EoT (GH data from this subject was included in the 4 wk GH WD data), the washout data for the other was not available. These were not included in calculation of 91% who maintained IGF-1 levels within 15% of baseline values.
- Pre-trial therapy SRL median concentrations at W13 compared to baseline: [Lanreotide] ↓ by 70%; [Octreotide] ↓ by 100%; paltusotine median concentrations at W15 compared to W13 (last dose) were decreased by >99.9%

Crinetics Pharmaceuticals

Paltusotine was safe and well tolerated

Safety data in all patients dosed with paltusotine as of February 23, 2020 (n=32) in Edge

Adverse events on treatment regardless of causality in 2 or more patients

Preferred Term	Group 1 (N=13) n (%)	Total (N=32) n (%)
Number (%) of Patients with any TEAEs	9 (69%)	14 (44%)
Arthralgia	3 (23%)	6 (19%)
Headache	4 (31%)	5 (16%)
Abdominal discomfort	1 (8%)	3 (9%)
Peripheral swelling	2 (15%)	3 (9%)
Back pain	2 (15%)	2 (6%)
Diarrhoea	0	2 (6%)
Flatulence	0	2 (6%)
Hyperhidrosis	2 (15%)	2 (6%)
Palpitations	1 (8%)	2 (6%)

- No discontinuations due to adverse events
- No patients have required “rescue treatments” with standard acromegaly medications
- 1 SAE--Headache--non-treatment related (admission for diagnostic evaluation)
- No safety signals to date with vital signs, clinical safety laboratories (including amylase/lipase, fasting glucose, liver function tests), HbA1c, ECGs
- Acceptable safety and tolerability profile has also been shown in >100 healthy volunteers dosed with paltusotine to date

Crinetics Pharmaceuticals