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 11, 2022

Larimar Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36510**	**20-3857670**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Three Bala Plaza East **Bala Cynwyd, Pennsylvania** **(Address of Principal Executive Offices)**	**19004** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (844) 511-9056

(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	lrmr	NASDAQ Global 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 2.02 Results of Operations and Financial Condition.

On August 11, 2022, Larimar Therapeutics, Inc. (the "***Company***") announced its financial results and operational highlights for the second quarter ended June 30, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1 attached hereto, is intended to be furnished and 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 incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On August 11, 2022, the Company posted on its website an updated slide presentation, which is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the presentation in various meetings with investors, analysts and other parties from time to time.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits
Below is a list of exhibits included with this Current Report on Form 8-K.

Exhibit No.	Document
99.1	Press Release issued by Larimar Therapeutics, Inc. on August 11, 2022*
99.2	Larimar Therapeutics, Inc. Corporate Presentation, dated August 11, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith

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 thereunto duly authorized.

Larimar Therapeutics, Inc.

Date: August 11, 2022

By: /s/ Carole S. Ben-Maimon, M.D.
Name: Carole S. Ben-Maimon, M.D.
Title: President and Chief Executive Officer

Exhibit 99.1

Larimar Therapeutics Provides Updates on CTI-1601 Clinical Program Following a Type C Meeting with the U.S. Food and Drug Administration and Reports Second Quarter 2022 Operating and Financial Results

- *Larimar plans to submit a complete response to CTI-1601's clinical hold in the third quarter of 2022*
- *In conjunction with the complete response, Larimar is proposing a Phase 2, four-week dose exploration study in Friedreich's ataxia (FA) patients as CTI-1601's next clinical trial*
- *Cash and marketable debt securities at June 30, 2022 of $54.9 million provides projected cash runway through the third quarter of 2023*

Bala Cynwyd, PA, August 11, 2022 – Larimar Therapeutics, Inc. ("Larimar") (Nasdaq: LRMR), a clinical-stage biotechnology company focused on developing treatments for complex rare diseases, today announced that it has received meeting minutes from the U.S. Food and Drug Administration (FDA) following a recent Type C Meeting with the Agency and reported its second quarter 2022 operating and financial results.

The purpose of the Type C Meeting was to obtain FDA feedback on the information needed to resolve CTI-1601's current clinical hold in full or in part, as well as to discuss a proposed change in CTI-1601's clinical development plan to introduce a Phase 2 dose exploration study to precede initiation of an open label extension study.

The Company plans to submit a complete response to the CTI-1601 clinical hold in the third quarter of 2022. In conjunction with the complete response, Larimar is proposing as CTI-1601's next clinical trial a Phase 2, four-week dose exploration study in FA patients starting at the lower dose levels tested in the Company's Phase 1 multiple-ascending dose clinical trial. This study will provide data on extended dosing of lower doses of CTI-1601, including additional data on safety and tolerability as well as whether lower doses for longer periods of time can increase frataxin levels while maintaining acceptable exposures.

Carole Ben-Maimon, MD, President and Chief Executive Officer of Larimar, commented, "We would like to thank the FDA for a productive Type C Meeting, which informed the preparation and planned submission of a complete response that we believe will enable CTI-1601's return to the clinic. We look forward to receiving FDA feedback on the complete response and our proposed Phase 2 dose exploration study. The proposed study has been designed to provide additional information on CTI-1601's safety profile as well as pharmacokinetic and pharmacodynamic profiles, which we believe will allow us to select appropriate doses for future long-term dosing. It will also enable us to build on our prior Phase 1 results, which provided clinical proof-of-concept for CTI-1601 by demonstrating its ability to increase frataxin levels in peripheral tissues. Given FA's root cause is the inability of patients to produce sufficient amounts of frataxin, we believe these data highlight CTI-1601's potential to address the urgent need for disease-modifying treatments that go beyond just symptom management."

The CTI-1601 program was placed on clinical hold by the FDA in May 2021 following the Company's notification to the Agency of mortalities which occurred at the highest dose levels in a 26-week non-human primate (NHP) toxicology study that was designed to support extended dosing of patients with CTI-1601. At the time of the notice, Larimar had no interventional clinical trials with patients enrolled or enrolling.

Data from Phase 1 single- and multiple-ascending dose (MAD) clinical trials indicated that repeated subcutaneous injections of CTI-1601 were generally well tolerated at doses up to 100 mg administered daily for up to 13 days. No serious adverse events, important medical events, or treatment-related severe adverse events were reported in the trials and the number and severity of adverse events did not increase with increasing exposure to CTI-1601. The most common adverse events were mild and moderate injection site

reactions. Data from cohorts 2 and 3 of the MAD trial also showed that subcutaneous injections of 50 or 100 mg of CTI-1601, administered daily for at least seven days, resulted in frataxin levels in peripheral tissues (buccal cells) that were at or in excess of those that would be expected in phenotypically normal heterozygous carriers. Cohort 1 of the MAD trial, which evaluated a 25 mg dose, explored a daily dosing regimen for only four days.

Second Quarter 2022 Financial Results

As of June 30, 2022, the Company had cash and marketable debt securities totaling $54.9 million which provides projected cash runway through the third quarter of 2023.

The Company reported a net loss for the second quarter of 2022 of $8.7 million, or $0.47 per share, compared to a net loss of $12.6 million, or $0.79 per share, for the second quarter of 2021.

Research and development expenses for the second quarter of 2022 were $5.6 million compared to $9.1 million for the second quarter of 2021. The decrease in research and development expenses compared to the prior year period was primarily driven by a decrease in nonclinical costs of $2.5 million and a decrease of $1.1 million in clinical trial costs partially offset by an increase of $0.2 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022.

General and administrative expenses for the second quarter of 2022 were $3.0 million compared to $3.4 million for the second quarter of 2021. The decrease in general and administrative expenses compared to the prior year period was primarily driven by a decrease in professional fees associated with legal and accounting services of $0.5 million partially offset by an increase of $0.1 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022.

The Company reported a net loss for the first half of 2022 of $17.6 million, or $0.96 per share, compared to a net loss of $24.7 million, or $1.54 per share, for the first half of 2021.

Research and development expenses for the first half of 2022 were $11.5 million compared to $18.1 million for the first half of 2021. The decrease in research and development expenses compared to the prior year period was primarily driven by a decrease of $3.0 million in clinical trial costs, a decrease in clinical supply manufacturing costs of $2.3 million, and a decrease in nonclinical costs of $2.3 million partially offset by an increase of $0.4 million in personnel related costs due to annual compensation increases and an increase of $0.4 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022.

General and administrative expenses for the first half of 2022 were $6.1 million compared to $6.6 million for the first half of 2021. The decrease in general and administrative expenses compared to the prior year period was primarily driven by a decrease in professional fees associated with legal and accounting services of $0.6 million, a decrease in operational expenses of $0.3 million and partially offset by an increase of $0.4 million in stock-based compensation expense associated with stock option grants made in 2021 and 2022.

About CTI-1601
CTI-1601 is a recombinant fusion protein intended to deliver human frataxin to the mitochondria of patients with Friedreich’s ataxia who are unable to produce enough of this essential protein. CTI-1601 has been granted Rare Pediatric Disease designation, Fast Track designation and Orphan Drug designation by the U.S. Food and Drug Administration (FDA), Orphan Drug Designation by the European Commission, and a PRIME designation by the European Medicines Agency.

About Larimar Therapeutics
Larimar Therapeutics, Inc. (Nasdaq: LRMR), is a clinical-stage biotechnology company focused on developing treatments for complex rare diseases. Larimar’s lead compound, CTI-1601, is being developed as a potential treatment for Friedreich's ataxia. Larimar also plans to use its intracellular delivery platform to design other fusion proteins to target additional rare diseases characterized by deficiencies in intracellular bioactive compounds. For more information, please visit: https://larimartx.com.

Forward-Looking Statements
This press release contains forward-looking statements that are based on Larimar’s management’s beliefs and assumptions and on information currently available to management. All statements contained in this release

other than statements of historical fact are forward-looking statements, including but not limited to Larimar's expectations regarding its ability to resolve the clinical hold imposed by the FDA related to CTI-1601, Larimar's ability to develop and commercialize CTI-1601 and other planned product candidates, Larimar's planned research and development efforts, including the timing of its CTI-1601 clinical development plan and other matters regarding Larimar's business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, among others, Larimar's ability to successfully engage with the FDA and satisfactorily respond to requests from the FDA for further information and data regarding CTI-1601, FDA's acceptance of our proposed four-week dose exploration study and any modifications thereto, and any requests for additional toxicology studies, the timing and outcome of Larimar's planned interactions with the FDA concerning the clinical hold on CTI-1601, the success, cost and timing of Larimar's product development activities, nonclinical studies and clinical trials, including CTI-1601 clinical milestones; that preliminary clinical trial results may differ from final clinical trial results, that earlier non-clinical and clinical data and testing of CTI-1601 may not be predictive of the results or success of later clinical trials, and assessments; the ongoing impact of the COVID-19 pandemic on Larimar's future clinical trials, manufacturing, regulatory, nonclinical study timelines and operations, and the potential impact of the Russian invasion of Ukraine on Larimar's ability to raise additional capital and general economic conditions; Larimar's ability and the ability of third-party manufacturers Larimar engages, to optimize and scale CTI-1601's manufacturing process; Larimar's ability to obtain regulatory approvals for CTI-1601 and future product candidates; Larimar's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators, and to successfully commercialize any approved product candidates; Larimar's ability to raise the necessary capital to conduct its product development activities; and other risks described in the filings made by Larimar with the Securities and Exchange Commission (SEC), including but not limited to Larimar's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. These forward-looking statements are based on a combination of facts and factors currently known by Larimar and its projections of the future, about which it cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent Larimar's management's views only as of the date hereof. Larimar undertakes no obligation to update any forward-looking statements for any reason, except as required by law.

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Larimar Therapeutics, Inc.
Condensed Consolidated Balance Sheet
(Unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 19,736	$ 70,097
Marketable debt securities	35,188	—
Prepaid expenses and other current assets	1,820	2,107
Total current assets	56,744	72,204
Property and equipment, net	986	1,049
Operating lease right-of-use assets	3,134	3,406
Restricted cash	1,339	1,339
Other assets	649	669
Total assets	$ 62,852	$ 78,667
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 425	$ 1,660
Accrued expenses	6,656	6,592
Operating lease liabilities, current	638	594
Total current liabilities	7,719	8,846
Operating lease liabilities	5,077	5,408
Total liabilities	12,796	14,254
Commitments and contingencies (See Note 8)		
Stockholders' equity:		
Preferred stock; $0.001 par value per share; 5,000,000 shares authorized as of June 30, 2022 and December 31, 2021; no shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value per share; 115,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 17,710,450 shares issued and outstanding as of June 30, 2022 and December 31, 2021	18	18
Additional paid-in capital	183,955	180,645
Accumulated deficit	(133,860)	(116,250)
Accumulated other comprehensive loss	(57)	—
Total stockholders' equity	50,056	64,413
Total liabilities and stockholders' equity	$ 62,852	$ 78,667

Larimar Therapeutics, Inc.

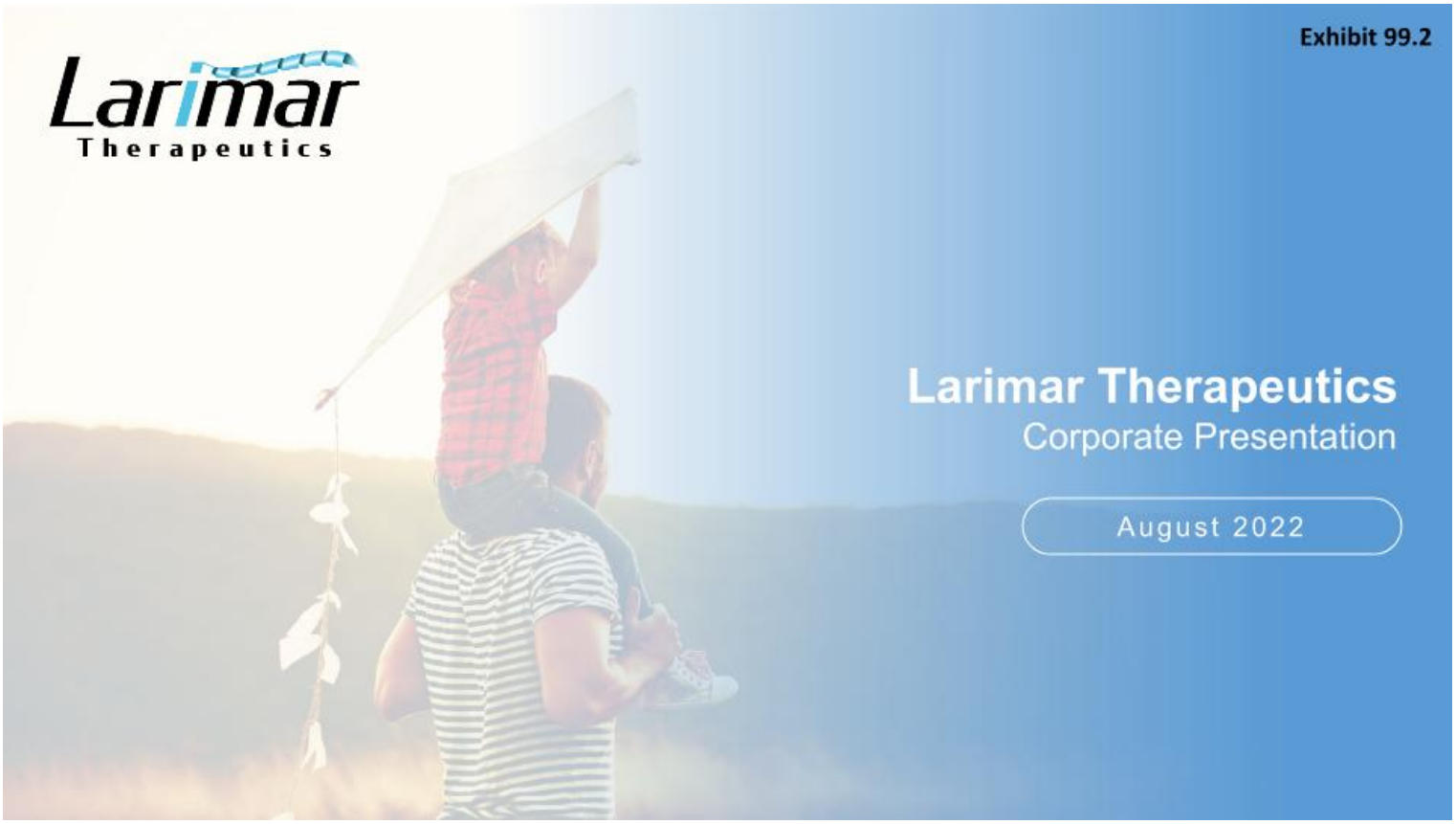
Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 5,644	$ 9,102	$ 11,450	$ 18,076
General and administrative	3,043	3,441	6,124	6,573
Total operating expenses	8,687	12,543	17,574	24,649
Loss from operations	(8,687)	(12,543)	(17,574)	(24,649)
Other income (expense), net	20	(66)	(36)	(48)
Net loss and Total comprehensive loss	$ (8,667)	$ (12,609)	$ (17,610)	$ (24,697)
Net loss per share, basic and diluted	$ (0.47)	$ (0.79)	$ (0.96)	$ (1.54)
Weighted average common shares outstanding, basic and diluted	18,338,853	15,996,133	18,338,853	15,996,133
Comprehensive loss:				
Net loss and Total comprehensive loss	$ (8,667)	$ (12,609)	$ (17,610)	$ (24,697)
Other comprehensive loss:				
Unrealized gain (loss) on marketable debt securities	(57)	—	(57)	—
Total other comprehensive loss	(57)	—	(57)	—
Total comprehensive loss	$ (8,724)	$ (12,609)	$ (17,667)	$ (24,697)

Exhibit 99.2



Larimar Therapeutics

Corporate Presentation

August 2022

Forward Looking Statements

This presentation contains forward-looking statements that are based on the beliefs and assumptions of Larimar Therapeutics, Inc. (the "Company") and on information currently available to management. All statements contained in this presentation other than statements of historical fact are forward-looking statements, including but not limited to statements regarding the expectations and assumptions regarding the future of the Company's business, including its ability to resolve the clinical hold by the FDA related to CTI-1601and the timing of such resolution, the Company's ability to develop and commercialize CTI-1601 and other planned product candidates, the Company's planned research and development efforts, and other matters regarding the Company's business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, among others, Larimar's ability to successfully engage with the FDA and satisfactorily respond to requests from the FDA for further information and data regarding CTI-1601, FDA's acceptance of our proposed four-week dose exploration study and any modifications thereto, and any requests for additional toxicology studies, the timing and outcome of Larimar's planned interactions with the FDA concerning the clinical hold on CTI-1601, the success, cost and timing of Larimar's product development activities, nonclinical studies and clinical trials, including CTI-1601 clinical milestones; that preliminary clinical trial results may differ from final clinical trial results, that earlier non-clinical and clinical data and testing of CTI-1601 may not be predictive of the results or success of later clinical trials, and assessments; the ongoing impact of the COVID-19 pandemic on Larimar's future clinical trials, manufacturing, regulatory, nonclinical study timelines and operations, and the potential impact of the Russian invasion of Ukraine on Larimar's ability to raise additional capital and general economic conditions; Larimar's ability and the ability of third-party manufacturers Larimar engages, to optimize and scale CTI-1601's manufacturing process; Larimar's ability to obtain regulatory approvals for CTI-1601 and future product candidates; Larimar's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators, and to successfully commercialize any approved product candidates; Larimar's ability to raise the necessary capital to conduct its product development activities; and other risks described in the filings made by Larimar with the Securities and Exchange Commission (SEC), including but not limited to Larimar's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. These forward-looking statements are based on a combination of facts and factors currently known by Larimar and its projections of the future, about which it cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent Larimar's management's views only as of the date hereof. Larimar undertakes no obligation to update any forward-looking statements for any reason, except as required by law.

Investment Highlights

Clinical-stage biotechnology company with a novel protein replacement therapy platform
Focused on addressing unmet needs in Friedreich's ataxia (FA) and other complex rare diseases based on a platform technology backed by a strong intellectual property portfolio

Lead candidate: CTI-1601, a recombinant fusion protein designed to deliver frataxin to mitochondria
Orphan Drug (US & EU), Rare Pediatric Disease (US), Fast Track (US), & PRIME (EU) designations for FA
Program placed on clinical hold following mortalities in a non-human primate toxicology study

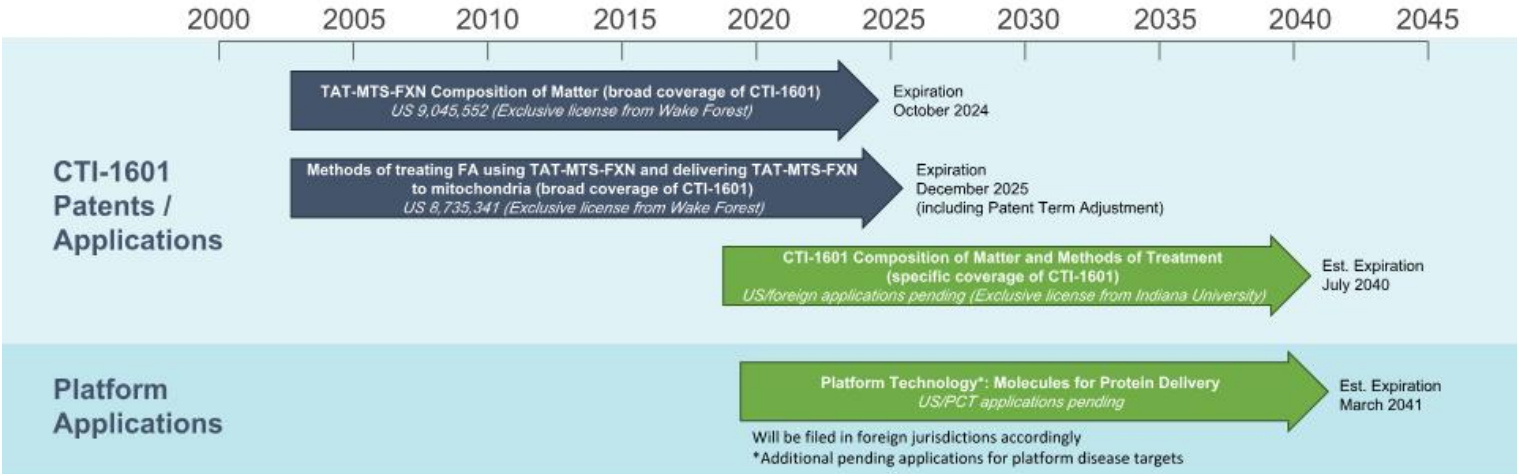
Double-blind, placebo-controlled Phase 1 proof-of-concept trials in FA patients complete
Data show dose dependent increases in frataxin (FXN) levels from baseline compared to placebo in all evaluated tissues with daily dosing & that CTI-1601 was generally well tolerated when dosed for up to 13 days

Plan to submit complete response incorporating Type C Meeting feedback regarding clinical hold
Plan to propose a Phase 2, four-week dose exploration study in FA patients as CTI-1601's next clinical trial
Plan to propose extended dosing at lower doses to provide additional data on safety/tolerability and evaluate increases in FXN levels with extended dosing while maintaining acceptable exposures

Strong financial foundation
High-quality institutional investor base includes founding investor Deerfield Management;
$54.9 million in cash/investments at 6/30/22 provides projected runway through the third quarter of 2023

Platform Technology is Supported by a Strong IP Portfolio

Pending CTI-1601 patent application, if issued, extends IP into 2040



Additional CTI-1601 IP protection

- CTI-1601 pending applications cover key biomarkers, analytical tools and quantification methods
- CTI-1601 is eligible for **12 years of market exclusivity** upon approval in the US (independent of patents) and at least **10 years of market exclusivity** upon approval in EU (independent of patents)

Larimar Therapeutics

Granted Pending

Friedreich's Ataxia (FA)

Rare and Progressive Disease

Caused by genetic defect resulting in low levels of frataxin

- Patients with FA only produce ~20-40% of normal frataxin levels depending on the tissue, sampling technique, and assay considered[1]
- Affects ~20,000 patients globally, with ~5,000 patients in the U.S. and majority of the remaining patients in the EU

>70% of patients present before age 14

- Initial symptoms may include unsteady posture, frequent falling and progressive difficulty in walking; By the time symptoms occur, heart damage may have already occurred. Progressive disease: Symptoms worsen and patients are eventually confined to a wheelchair with speech becoming hesitant and jerky (often referred to as "scanning of speech")

Life expectancy of 30-50 years

- Early death usually caused by heart disease

No approved therapies available

- Current treatment options are limited to symptom management

LRMR's strong relationship with Friedreich's Ataxia Research Alliance (FARA)

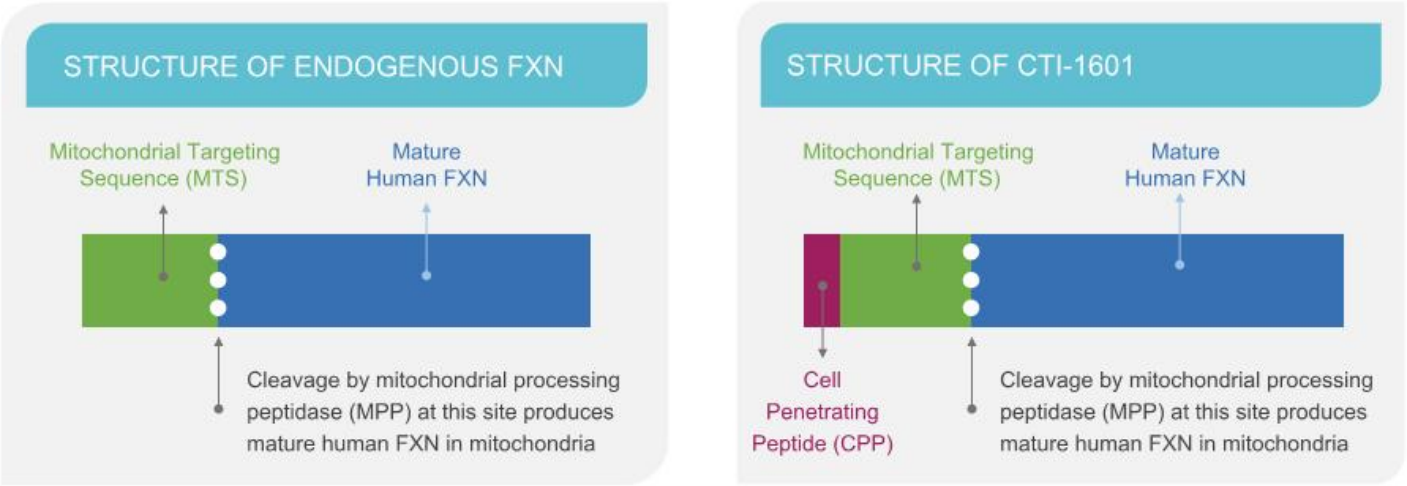
- Dedicated FA patient advocacy focused on treatments to cure FA

Larimar Therapeutics

1. E.C. Deutsch et al. Molecular Genetics and Metabolism 101 (2010) 238–245

CTI-1601 is Designed to Deliver Additional Frataxin (FXN)

CTI-1601 Maintains the Cleavage Site Between the MTS and Mature Human FXN



The maintenance of the cleavage site allows the CPP and MTS to be removed by mitochondrial processing peptidase to produce mature human FXN in the mitochondria

Larimar Therapeutics

Phase 1 Topline Data Demonstrated POC for CTI-1601 in FA

Safety	CTI-1601 appears to be generally well tolerated at doses up to 100 mg administered daily for 13 days
Pharmacodynamics	Daily dosing of CTI-1601 resulted in dose-dependent increases in FXN levels from baseline compared to placebo controls in all evaluated tissues
Pharmacokinetics	Pharmacokinetic analyses support evaluating a once-daily dosing regimen for CTI-1601
Conclusion	Daily subcutaneous (SC) administration of 50mg and 100mg doses of CTI-1601 resulted in FXN levels in buccal cells that are at, or in excess of, those we would expect to see in phenotypically normal heterozygous carriers (who have FXN levels of ~50% of unaffected persons)

Larimar Therapeutics

POC: Proof-of-concept

CTI-1601: Phase 1 Clinical Program in Patients with FA

Program consisted of double-blind, placebo controlled single- and multiple-ascending dose trials

Phase 1 Development Plan

- Two double-blind, placebo-controlled dosing trials in patients with FA
- Patient dosing began December 2019
- Safety Review Committee assessed all blinded data between each cohort to ensure patient safety

Number of subjects: 28
Dose levels: 25 mg, 50 mg, 75 mg and 100 mg (subcutaneous administration)
Treatment Duration: 1 day
1º Endpoint: Safety and tolerability
2º Endpoints: PK; PD; FXN levels; multiple exploratory
Status: Complete

Eligible patients from SAD trial could enroll in MAD trial

Number of Subjects: 27
Dose Range: 25 mg, 50 mg, 100 mg (subcutaneous administration)
Treatment Regimen: Multiple increasing doses administered subcutaneously over 13 days
1º Endpoint: Safety and tolerability
2º Endpoints: PK; PD; FXN levels (buccal cells, platelets, optional skin biopsies); multiple exploratory
Status: Complete

Larimar Therapeutics

MAD Trial Patient Enrollment

16 out of 28 patients who participated in the SAD trial enrolled in the MAD trial

MAD Trial Patient Enrollment (n=27)		
Parameter	**Statistic**	**Overall**
Participated in SAD trial?		
Yes	n (%)	16 (59%)
No	n (%)	11 (41%)
Cohort 1 (25 mg) Active vs. Placebo		
Active	n (%)	6 (75%)
Placebo	n (%)	2 (25%)
Cohort 2 (50 mg) Active vs. Placebo		
Active	n (%)	7 (78%)
Placebo	n (%)	2 (22%)
Cohort 3 (100 mg) Active vs. Placebo		
Active	n (%)	7 (70%)
Placebo	n (%)	3 (30%)

Multiple Ascending Dose Study Design

Treatment Schedules for Each Cohort

Cohort 1 (25 mg; n = 8)

13-day Treatment Period

= Administration of CTI-1601 or placebo

= No Administration

Cohort 2 (50 mg; n = 9)

13-day Treatment Period

= Administration of CTI-1601 or placebo

= No Administration

Cohort 3 (100 mg n = 10)

13-day Treatment Period

= Administration of CTI-1601 or placebo

= No Administration

FXN Level Sampling Days Presented for Each Cohort

Cohort 1 Sampling Days	
Buccal Cells	Baseline, Day 4, Day 13
Skin	Baseline, Day 13
Platelets	Baseline, Day 4, Day 13

Cohort 2 Sampling Days	
Buccal Cells	Baseline, Day 7, Day 13
Skin	Baseline, Day 13
Platelets	Baseline, Day 7, Day 13

Cohort 3 Sampling Days	
Buccal Cells	Baseline, Day 7, Day 13
Skin	Baseline, Day 13
Platelets	Baseline, Day 7, Day 13

Larimar Therapeutics

Data Compare Favorably to FXN Levels Expected in Heterozygous Carriers

Achieved median FXN levels that were >60% of the median FXN levels observed in healthy controls

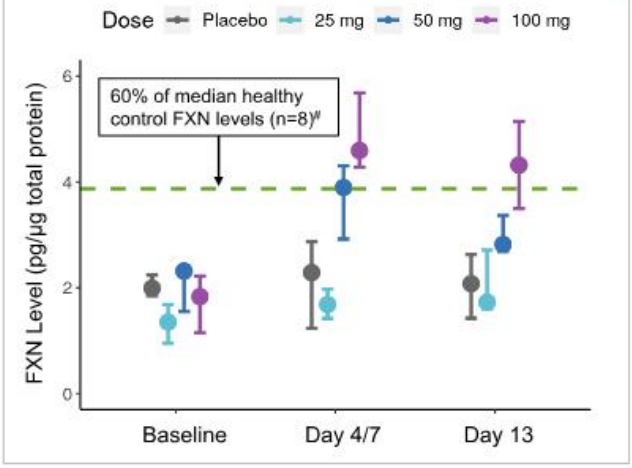
Benchmarking Clinical Relevance

- FXN levels in buccal cells and blood have been shown to correlate with neurological function in FA patients[1]
- Patients with FA only produce ~20-40% of normal frataxin levels depending on the tissue considered[2]
- Heterozygous carriers who show no signs of disease have FXN levels of ~50% of unaffected healthy persons[2]

Comparison to Healthy Controls

- FXN levels were measured in buccal cells from 8 healthy controls using the same assay and sampling technique employed in the Phase 1 MAD trial
- With daily administration, patients in Cohorts 2 & 3 of the Phase 1 MAD trial achieved median buccal cell FXN levels that were >60% of the median FXN levels observed in healthy controls
- Data from additional healthy control buccal cells, skin, and platelets will be collected in a separate non-interventional study

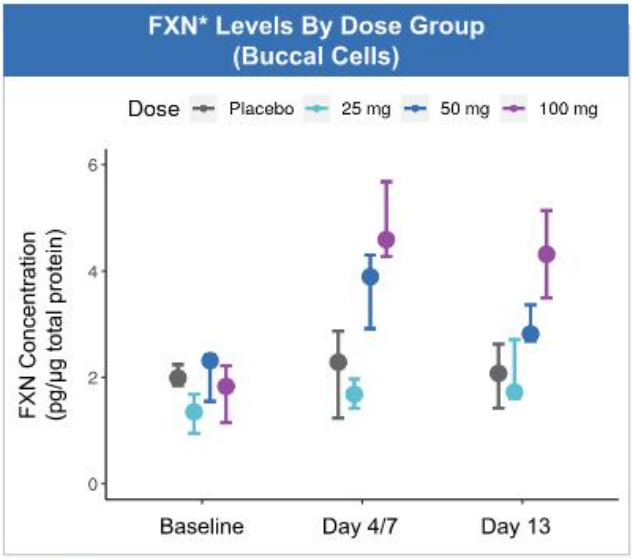
FXN* Levels By Dose Group (Buccal Cells)

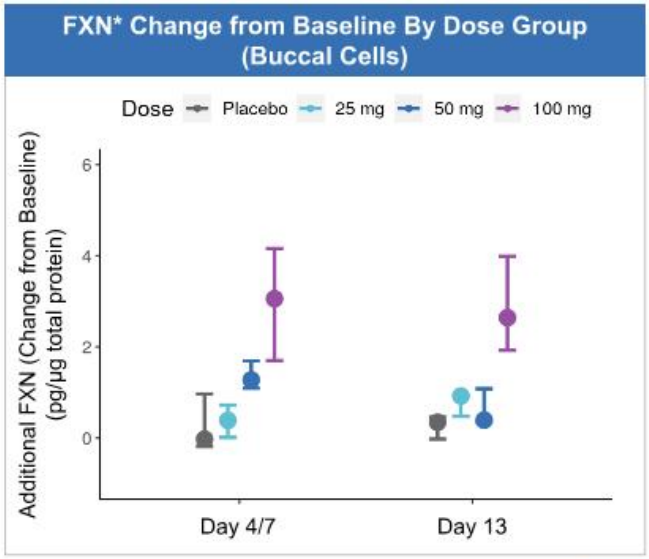


*FXN levels measured via detection of peptide derived from mature FXN; #Data on file; Data represent median and 25th and 75th percentiles ; FXN levels from baseline, Day 4, & Day 13 measurements are shown for data derived from the 25 mg cohort; FXN levels from baseline, Day 7 & Day 13 measurements are shown for data derived from the 50 & 100 mg cohorts; Sample collection days varied in each cohort per the trial protocol.1. Lazaropoulos et al. Ann Clin Transl Neurol. 2015 Aug; 2(8): 831–842; 2. E.C. Deutsch et al. Molecular Genetics and Metabolism 101 (2010) 238–245.

Dose Dependent Increases in FXN Levels Observed in Buccal Cells

Daily SC injections of 100 mg CTI-1601 resulted in an ~2.5 fold increase in FXN levels from baseline

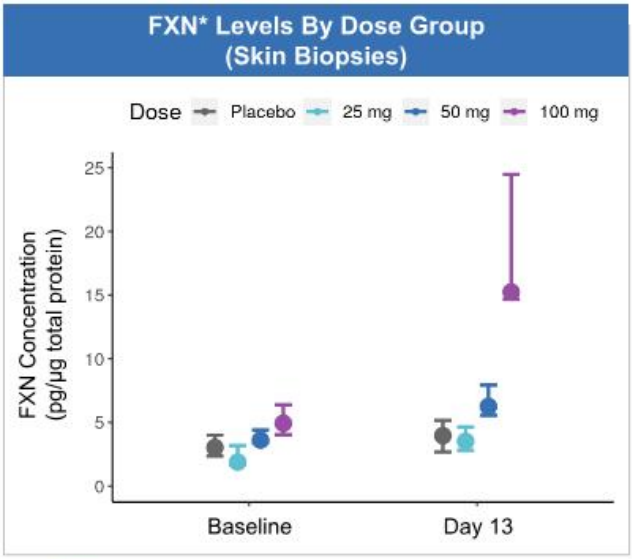


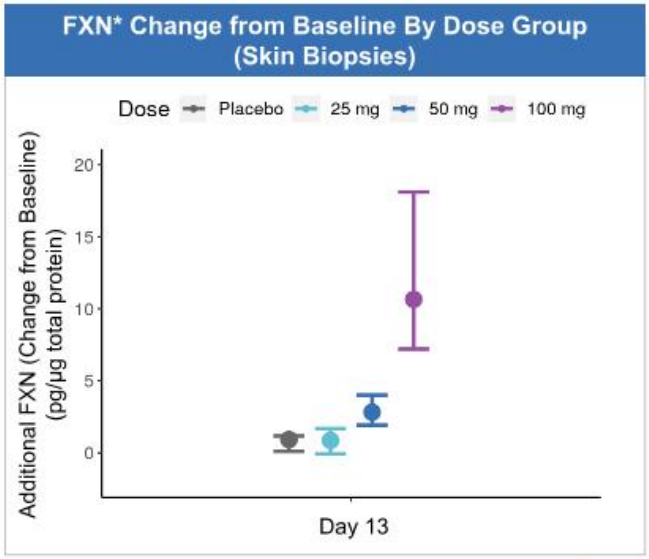


*FXN levels measured via detection of peptide derived from mature FXN; Data represent median and 25th and 75th percentiles; FXN levels from baseline, Day 4, & Day 13 measurements are shown for data derived from the 25 mg cohort; FXN levels from baseline, Day 7 & Day 13 measurements are shown for data derived from the 50 & 100 mg cohorts; Sample collection days varied in each cohort per the trial protocol

Dose Dependent Increases in FXN Levels Observed in Skin

Daily SC injections of 100 mg CTI-1601 resulted in an ~3 fold increase in FXN levels from baseline



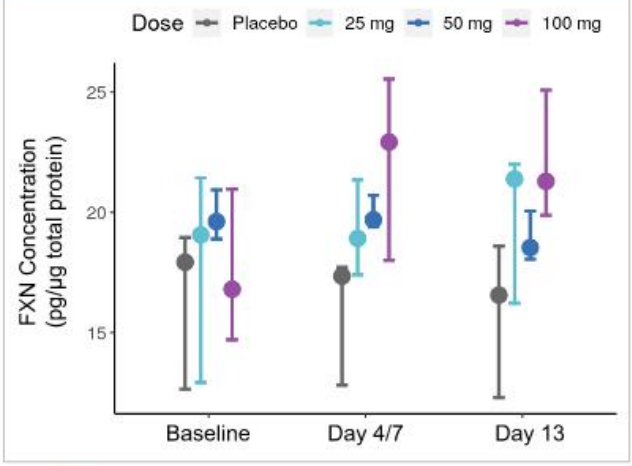


*FXN levels measured via detection of peptide derived from mature FXN; Data represent median and 25th and 75th percentiles

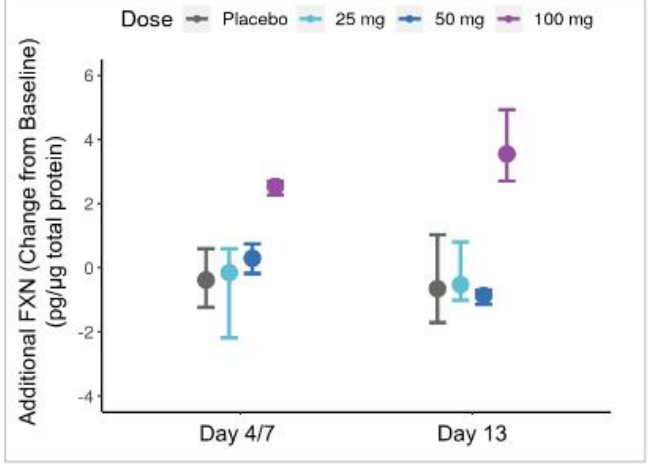
Dose Dependent Increases in FXN Levels Observed in Platelets with Daily Dosing

Daily SC injections of 100mg CTI-1601 resulted in increases in FXN levels from baseline compared to placebo

FXN* Levels By Dose Group (Platelets)



FXN* Change from Baseline By Dose Group (Platelets)



*FXN levels measured via detection of peptide derived from mature FXN; Data represent median and 25th and 75th percentiles; FXN levels from baseline, Day 4, & Day 13 measurements are shown for data derived from the 25 mg cohort; FXN levels from baseline, Day 7 & Day 13 measurements are shown for data derived from the 50 & 100 mg cohorts; Sample collection days varied in each cohort per the trial protocol

Repeated SC injections of CTI-1601 appear to be generally well tolerated at doses up to 100 mg administered daily for 13 days

Summary of MAD trial safety data:

Repeated doses (25 mg, 50 mg, and 100 mg) of CTI-1601 or placebo were administered subcutaneously. 27 patients were dosed in the trial. 26 patients completed the trial. 1 patient receiving CTI-1601 in Cohort 2 (50 mg) withdrew after experiencing mild/moderate symptoms (nausea and vomiting).

- No serious adverse events (SAEs), important medical events, or treatment-related severe adverse events
- The most common adverse events were mild and moderate injection site reactions (at least one injection site reaction was seen in 43% of placebo patients and in 100% of CTI-1601 patients)
- The number and severity of adverse events did not increase with increasing exposure to CTI-1601

PK analyses support evaluating a once-daily dosing regimen for CTI-1601

Summary of PK Analyses

- CTI-1601 was quickly absorbed after subcutaneous administration
- Dose-proportional increases in exposure observed with increasing doses of CTI-1601
- Mean half life of CTI-1601 in plasma was approximately 11 hours
- CTI-1601 appears to be at or close to steady state exposure after 13 days of dosing 100 mg once daily

Phase 1 Topline Data Demonstrated POC for CTI-1601 in FA

FXN levels in buccal cells & blood have been shown to correlate with disease severity in FA patients[1]

Safety Data

Repeated SC injections of CTI-1601 appear to be generally well tolerated at doses up to 100 mg administered daily for 13 days

The most common AEs were mild and moderate injection site reactions

No SAEs have been reported

Frataxin Measurements

Daily SC injections of CTI-1601 resulted in dose-dependent increases in FXN levels from baseline compared to placebo controls in all evaluated tissues

With daily dosing (50 mg and 100 mg), achieved median FXN levels that were >60% of the median FXN levels observed in healthy controls

Pharmacokinetic Data

CTI-1601 was quickly absorbed after subcutaneous administration

Dose-proportional increases in exposure observed with increasing doses of CTI-1601

Data support evaluating a once-daily dosing regimen for CTI-1601

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1. Lazaropoulos et al. Ann Clin Transl Neurol. 2015 Aug; 2(8): 831–842; POC: Proof-of-concept; OLE: Open label extension; AE: Adverse events

Upcoming CTI-1601 Trials and Regulatory Interactions

Additional analyses from the Phase 1 program planned for presentation at scientific meetings

Future Planned Trials and Regulatory Interactions Include:

Continued FDA interactions around the clinical hold, including planned submission of a complete response to the clinical hold and aligning with FDA on design of next proposed clinical trial.

Four-week Phase 2 dose exploration study to inform on long-term efficacious dose and dose regimen

Jive OLE trial for eligible patients who participated in SAD, MAD, and/or four-week dose exploration studies

MAD trial in patients 2 to 17 years of age. Participants eligible to screen for Jive OLE trial

Global double-blind placebo-controlled pivotal trial

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OLE: Open-label extension

Investment Highlights

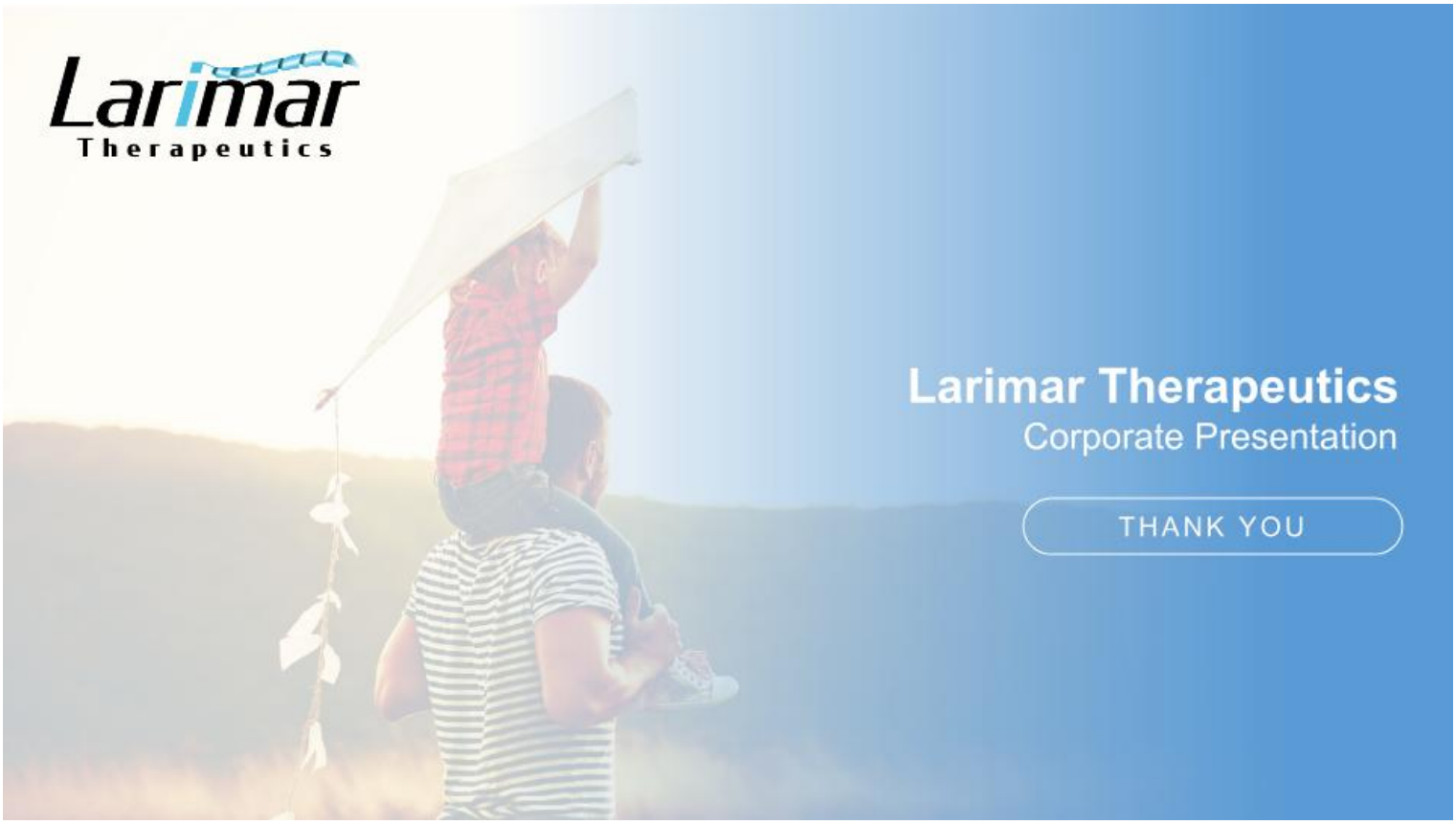
Clinical-stage biotechnology company with a novel protein replacement therapy platform
Focused on addressing unmet needs in Friedreich's ataxia (FA) and other complex rare diseases based on a platform technology backed by a strong intellectual property portfolio

Lead candidate: CTI-1601, a recombinant fusion protein designed to deliver frataxin to mitochondria
Orphan Drug (US & EU), Rare Pediatric Disease (US), Fast Track (US), & PRIME (EU) designations for FA
Program placed on clinical hold following mortalities in a non-human primate toxicology study

Double-blind, placebo-controlled Phase 1 proof-of-concept trials in FA patients complete
Data show dose dependent increases in frataxin (FXN) levels from baseline compared to placebo in all evaluated tissues with daily dosing & that CTI-1601 was generally well tolerated when dosed for up to 13 days

Plan to submit complete response incorporating Type C Meeting feedback regarding clinical hold
Plan to propose a Phase 2, four-week dose exploration study in FA patients as CTI-1601's next clinical trial
Plan to propose extended dosing at lower doses to provide additional data on safety/tolerability and evaluate increases in FXN levels with extended dosing while maintaining acceptable exposures

Strong financial foundation
High-quality institutional investor base includes founding investor Deerfield Management;
$54.9 million in cash/investments at 6/30/22 provides projected runway through the third quarter of 2023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Corporate Presentation
THANK YOU

Leadership Team

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Impax teva

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Nancy Ruiz, MD, FACP, FIDSA
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Schering-Plough MERCK

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teva Cell Pathways, Inc.

Noreen Scherer
VP, Clinical Operations

Shire Wyeth Pharmaceuticals

Francis Michael Conway
VP, Controller

TELA BIO stryker

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Recent and Upcoming Scientific Presentations

Conference Dates	Conference Name	Summary of Presentation(s)
Recent Presentations		
May 26 – 28, 2022	4th Pan American Parkinson's Disease and Movement Disorders Congress	Two abstracts accepted. Included safety, pharmacokinetic, and pharmacodynamic data from Phase 1 clinical program evaluating CTI-1601 in Friedreich's ataxia (FA) patients
June 8 – 11, 2022	United Mitochondrial Disease Foundation Mitochondrial Medicine 2022	Highlighted preclinical studies evaluating Frataxin and CTI-1601's effects on a model of neurodegeneration
June 12 – 15, 2022	XXIV World Congress International Society for Heart Research	Featured the findings of lipidomic studies in plasma from healthy individuals and from patients with FA that characterized dysregulated pathways in patients with FA. The ability of CTI-1601 to reverse the observed dyslipidemia in patients from Larimar's Phase 1 MAD study was presented and discussed in the context of FA
July 17 – 22, 2022	Gordon Research Conference on Mitochondria and Chloroplasts	Highlighted exploratory biomarker studies that identified genes that are differentially expressed between healthy individuals and those with FA
Aug. 7 – 12, 2022	Gordon Research Conference on the Neurobiology of Brain Disorders	Highlighted preclinical studies evaluating CTI-1601's effects on gene expression and neurodegeneration
Upcoming Presentations		
Sept. 4 – 7, 2022	62nd International Conference on the Bioscience of Lipids in Metabolic Health and Disease	Featuring findings on dyslipidemia in a number of mitochondrial diseases including in FA. Data on the effect of Larimar's CTI-1601 on reversing dyslipidemia in patients with FA in our Phase 1 MAD study were presented and discussed in the context of biomarker and efficacy marker characterization in mitochondrial diseases
Sept. 15 – 18, 2022	International Congress of Parkinson's Disease and Movement Disorders	Presentation will highlight findings from studies analyzing changes in expression of Frataxin Sensitive Gene Markers in patients with FA that were treated with CTI-1601 or placebo in Larimar's Phase 1 MAD study.

Strong Relationship with FARA

Company has strong relationship with Friedreich's Ataxia Research Alliance (FARA)

- National, non-profit organization dedicated to the pursuit of scientific research leading to treatments and a cure for FA

FARA provides industry with several key items

- Assistance with patient recruitment and education
- Access to Global Patient Registry with demographic and clinical information on more than 1,000 FA patients
- Sponsored a Patient-Focused Drug Development Meeting in 2017 resulting in a publication titled "The Voice of the Patient"

FARA Friedreich's Ataxia Research Alliance

Scientific Advisory Board

Russell Clayton, DO (Chairman)

Former Chief Medical Officer at Alcresta Therapeutics, a medical device company

Former Senior Vice President of Research and Development at Discovery Labs, a pharmaceutical and medical device company

Giovanni Manfredi, MD, PhD

Finbar and Marianne Kenny Professor in Clinical and Research Neurology at Weill Cornell Medicine.

Professor of Neuroscience at Weill Cornell Medicine.

Mark Payne, MD

Co-founder of Chondrial Therapeutics, which became Larimar Therapeutics, Inc.

Professor of Pediatrics at Indiana University School of Medicine

Marni J. Falk, MD

Executive Director of the Mitochondrial Medicine Frontier Program at The Children's Hospital of Philadelphia (CHOP)

Professor in the Division of Human Genetics, Department of Pediatrics at University of Pennsylvania Perelman School of Medicine

Jill Ostrem, MD

Medical director and division chief of the University of California San Francisco (UCSF) Movement Disorders and Neuromodulation Center.

Carlin and Ellen Wiegner Endowed Professor of Neurology

MAD Trial Patient Demographics

Parameter	Statistic	All placebo (n=7)	25 mg CTI-1601 (n=6)	50 mg CTI-1601 (n=7)	100 mg CTI-1601 (n=7)	All CTI-1601 (n=20)	Overall (n=27)
Sex							
Male	n (%)	5 (71.4)	3 (50.0)	4 (57.1)	3 (42.9)	10 (50.0)	15 (55.6)
Female	n (%)	2 (28.6)	3 (50.0)	3 (42.9)	4 (57.1)	10 (50.0)	12 (44.4)
Age (years)							
	Mean	25.7	39.7	34.7	28.0	33.9	31.7
	SD	6.37	16.59	9.03	8.96	12.13	11.40
	Median	23	37	36	24	34	28
	Min, Max	20,36	21,65	19,47	20,44	19,65	19,65
Race							
White	n (%)	6 (85.7)	6 (100.0)	6 (85.7)	6 (85.7)	18 (90.0)	24 (88.9)
Asian	n (%)	0	0	1 (14.3)	1 (14.3)	2 (10.0)	2 (7.4)
American Indian	n (%)	1 (14.3)	0	0	0	0	1 (3.7)
Ethnicity							
Hispanic/Latino	n (%)	2 (28.6)	0	0	0	0	2 (7.4)
Not Hispanic/Latino	n (%)	5 (71.4)	6 (100.0)	7 (100.0)	7 (100.0)	20 (100.0)	25 (92.6)

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SD: Standard deviation

MAD Trial Patient Disease Characteristics

Parameter	Statistic	All placebo (n=7)	25 mg CTI-1601 (n=6)	50 mg CTI-1601 (n=7)	100 mg CTI-1601 (n=7)	All CTI-1601 (n=20)	Overall (n=27)
Age at Symptom Onset							
	Mean	14.1	24.0	19.3	11.9	18.1	17.1
	SD	5.34	14.48	6.21	6.72	10.37	9.39
	Median	15.0	18.0	19.0	10.0	18.0	16.0
	Min, Max	8,23	12,44	8,28	5,22	5,44	5,44
Age at Diagnosis							
	Mean	18.3	31.5	26.4	15.9	24.3	22.7
	SD	7.87	19.88	4.28	8.21	13.24	12.23
	Median	20.0	25.5	28.0	13.0	27.0	21.0
	Min, Max	9,32	14,64	17,30	5,27	5,64	5,64
Assistive Device							
Walker	n (%)	0	2 (33.3)	3 (42.9)	0	5 (25.0)	5 (18.5)
Wheelchair	n (%)	4 (57.1)	3 (50.0)	1 (14.3)	6 (85.7)	10 (50.0)	14 (51.9)
Other	n (%)	1 (14.3)	0	1(14.3)	0	1 (5.0)	2 (7.4)
None	n (%)	2 (28.6)	1 (16.7)	2 (28.6)	1 (14.3)	4 (20.0)	6 (22.2)

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SD: Standard deviation

CTI-1601: Positive Mouse Model Data Support Development

Proof-of-Concept Demonstrated In Mouse Models of FA

Cardiac Knock Out Mouse Model Studies
(MCK-Cre FXN KO Mouse)

- Extended survival
- Demonstrated ability to deliver hFXN to mitochondria
- Increased in a dose dependent manner, succinate dehydrogenase (SDH) activity. SDH is an FXN dependent enzyme, whose activity is indicative of mitochondrial function.
- Prevented left ventricle dilation and maintained function

Neurologic Knock Out Mouse Model Study
(Pvalb-CRE FXN KO Mouse)

- Prevented development of ataxic gait
- Showed that treated mice survive longer than untreated mice
- Demonstrated CNS penetration, as hFXN was present in brain, dorsal root ganglia & spinal cord

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CTI-1601 Extends Survival in FXN-deficient KO Mice

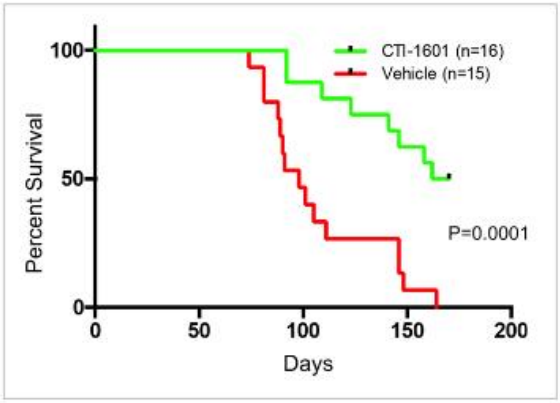
Initial Proof of Concept for FXN Replacement Therapy in Cardiac Mouse Model of FA

Median Survival of MCK-Cre FXN-KO Mice

- 166 days (CTI-1601) vs. 98 days (Vehicle)
- CTI-1601 was administered 10 mg/kg SC every other day

Survival beyond vehicle mean (107.5 days)

- 87.5% (CTI-1601) vs. 33% (Vehicle)
- Demonstrates that CTI-1601 is capable of delivering sufficient amounts of FXN to mitochondria



CTI-1601 rescues a severe disease phenotype in a well-characterized cardiac mouse model of FA

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CTI-1601 Prevents The Development of Ataxic Gait in KO mice

In-Vivo Efficacy Data in Neurologic KO Mouse Model

Pvalb-Cre FXN-KO mouse

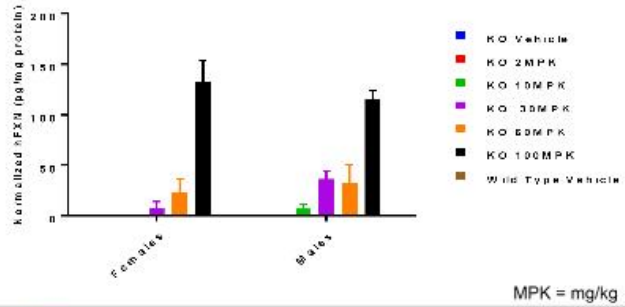
Single dose level: 10 mg/kg CTI-1601 or vehicle given intraperitoneally three times per week

- hFXN replacement with CTI-1601 **prevents the development of ataxic gait**
- CTI-1601-treated mice **survive longer** than untreated mice
- Human frataxin **present in brain, dorsal root ganglia and spinal cord** demonstrating central nervous system penetration

CTI-1601 Delivers hFXN to Mitochondria in KO Mice

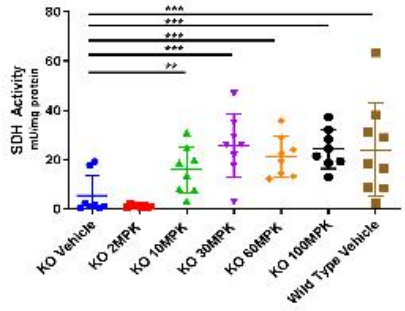
- hFXN concentration within mitochondria increases in a dose-dependent manner
- Given subcutaneously, CTI-1601 functionally replaces hFXN in mitochondria of KO mice
- Succinate dehydrogenase (SDH) activity, which is indicative of mitochondrial function, increases in a dose-dependent manner after administration of CTI-1601; activity plateaus at 30 mg/kg and is equivalent to activity in wild type animals
- Demonstrated normalization of gene expression in cardiac tissue

Normalized Mitochondrial FXN (Heart)



MPK = mg/kg

Normalized SDH Activity (Muscle)

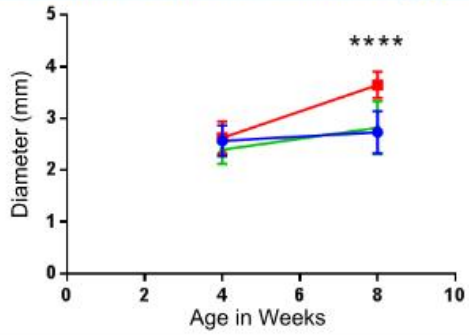


MPK = mg/kg

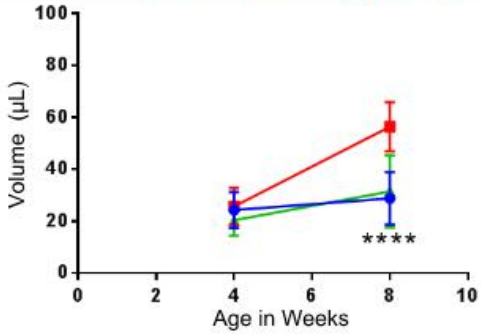
CTI-1601 Prevents Left Ventricle Dilation in KO Mice

- Left ventricular (LV) volume increases in systole in untreated mice by 8 weeks (after 4 weeks of dosing with vehicle), but remains similar to wildtype when treated with CTI-1601 (10 mg/kg every other day)
- CTI-1601-treated mice have similar LV volume as healthy controls; echocardiogram shows significant differences between vehicle and CTI-1601 treated (10 mg/kg every other day) KO mice

Left Ventricle Internal Diameter (Systole)



Left Ventricle Volume (Systole)



KO: CTI-1601 KO: Vehicle Wild-type: Vehicle

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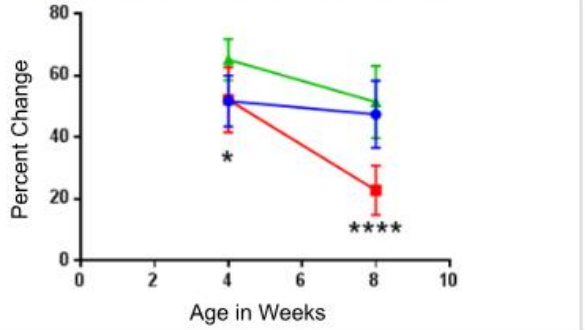
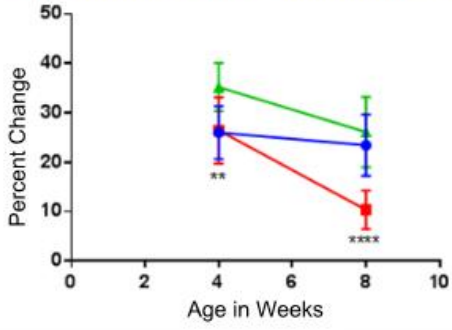
CTI-1601 Preserves Left Ventricle Function in KO Mice

- Left ventricular (LV) function drops significantly in vehicle treated mice by week 8
- CTI-1601-treated (10 mg/kg every other day) mice have similar LV as healthy controls; echocardiogram shows significant differences between vehicle and CTI-1601 treated KO mice

Left Ventricle Ejection Function



Left Ventricle Fractional Shortening



KO: CTI-1601 KO: Vehicle Wild-type: Vehicle

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Favorable PK/PD Profile in Healthy Cynomolgus Monkeys

Study Design (14-Days of CTI-1601 dosing)

6 healthy cynomolgus monkeys (3M / 3F)

Pre-dosed for 2 days with Vehicle

Pre-dose collection of platelets, cerebrospinal fluid, buccal swab, skin punch
Dosing starts 15 mg/kg SC BID

Day 10 (7 days dosing)

Collection of platelets, buccal swab, skin punch

Day 16 (following 14th day of dosing)

Collection of cerebrospinal fluid, platelets, buccal swab, skin punch

- CTI-1601 is bioavailable when given subcutaneously
- Sustained levels of hFXN are found in blood cells (platelets) and peripheral tissues (buccal cells, skin) as early as the 7th day and still present after 14 days
- Sustained levels of hFXN are found after 14 days in the cerebrospinal fluid of monkeys, suggesting CNS penetration

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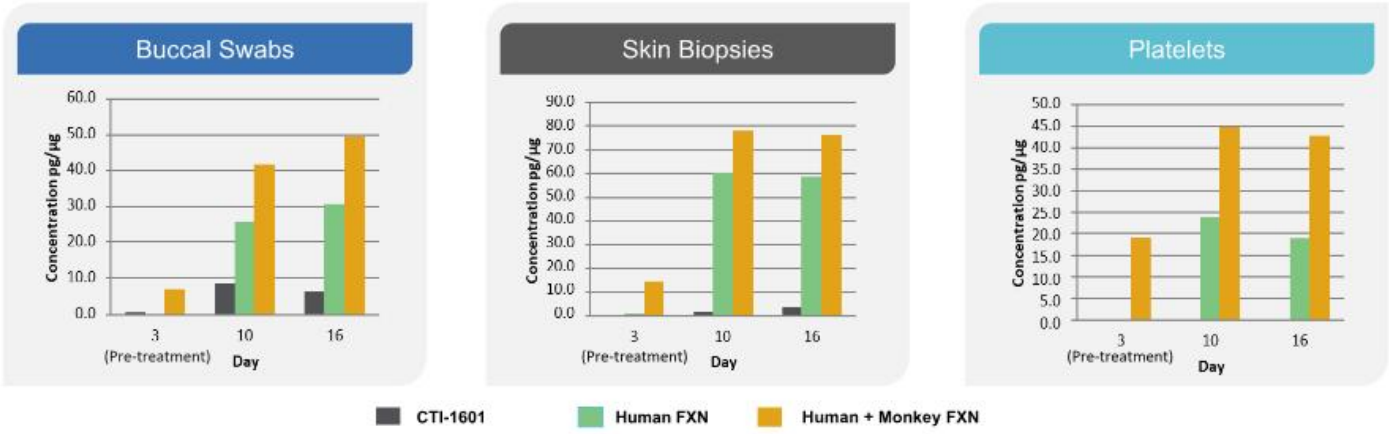
Biodistribution in Healthy Cynomolgus Monkeys

Sustained levels of human FXN (hFXN) in peripheral tissues after 14 days of CTI-1601 dosing



- Treatment of monkeys with CTI-1601 results in sustained levels of hFXN in peripheral tissues that are accessible in the clinic
- FXN levels increase ~4X or more following CTI-1601 administration
  - For comparison, FA patients show FXN levels that range from ~20-40% of normal FXN levels depending on the tissue considered[1]
    - Heterozygous carriers show no phenotype and display levels of FXN representing ~2-3X higher than most FA patients[1]

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1. E.C. Deutsch et al. Molecular Genetics and Metabolism 101 (2010) 238–245