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): May 3, 2023

Reneo Pharmaceuticals, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40315**	**47-2309515**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

18575 Jamboree Road, Suite 275-S **Irvine, California** **(Address of Principal Executive Offices)**	**92612** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 858 283-0280

(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 $0.0001 per share	RPHM	The Nasdaq Stock Market LLC

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 May 3, 2023, Reneo Pharmaceuticals, Inc. (the "Company") announced that, based upon preliminary and unaudited estimates and information available to the Company as of today, it expects to report that it had approximately $93.8 million of cash, cash equivalents and short-term investments as of March 31, 2023. The unaudited, estimated results as of the three months ended March 31, 2023 are preliminary and were prepared by the Company's management based upon its estimates, a number of assumptions and currently available information. This preliminary financial information is the responsibility of management and has been prepared in good faith on a consistent basis with prior periods. However, the Company has not yet completed its quarter-end financial close process for the quarter ended March 31, 2023. This estimate of the Company's cash, cash equivalents and short-term investments as of March 31, 2023 is preliminary, has not been audited and is subject to change upon completion of its financial statement closing procedures, and as a result should not be regarded as a representation by the Company and its management as to its actual cash, cash equivalents and short-term investments as of March 31, 2023. Additional information and disclosure would be required for a more complete understanding of the Company's financial position and results of operations as of March 31, 2023. The Company's independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to this preliminary result and, accordingly, does not express an opinion or any other form of assurance about it. This preliminary financial information should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles and reviewed by the Company's auditors.

The information contained in this Current Report on Form 8-K under Item 2.02 is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and will not be incorporated by reference into any filing by the Company under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), unless specifically identified as being incorporated therein by reference.

Item 7.01 Regulation D Disclosure.

On May 3, 2023, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at www.reneopharma.com. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information in this Item 7.01 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information shall not be deemed incorporated by reference into any other filing with the Securities Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 8.01 Other Events.

In April 2023, the Company entered into a non-binding term sheet (the "Term Sheet"), with an investor that holds more than 5% of its common stock and is affiliated with one of its directors, and its affiliated development company for a structured royalty financing of up to $100 million in conditional tranched funding, currently contemplated to include $30.0 million funded in connection with entering into the definitive agreement and the remaining amount in multiple tranches based on the achievement of development and regulatory milestones. If mavodelpar (REN001) is approved in the United States or the European Union, the Company would pay to the investor (1) fixed payments and (2) variable royalty payments based on net sales of mavodelpar, subject to specified caps. Pursuant to the Term Sheet, the Company will also enter into a collaboration agreement with the development company with respect to mavodelpar and establish a joint steering committee. The Term Sheet does not represent a definitive funding agreement and there is no guarantee that the Company will enter into a definitive funding agreement and close the proposed structured financing with the investor. If consummated, the closing is expected to occur in the second quarter of 2023.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the Company's anticipated financial results for the fiscal quarter ended March 31, 2023, the ability of the Company to enter into a definitive agreement with investors and obtain funding on the terms set forth in the Term Sheet, the ability of the Company to satisfy conditions and entering into a collaboration agreement, and the expected timing of the closing. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans," "will," "believes," "anticipates," "expects," "intends," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, that there is no assurance that the Company will enter into a definitive funding agreement with the investor and obtain funding on the terms set forth in the Term Sheet, or at all, and any definitive funding agreement executed pursuant to the Term Sheet would increase the Company's operating complexity, risks and uncertainties associated with the Company's business in general, and the other risks described in the Company's filings with the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation, dated May 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Reneo Pharmaceuticals, Inc.

Date: May 3, 2023

By: /s/ Gregory J. Flesher
Gregory J. Flesher
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1


Reneo
Pharmaceuticals
Nasdaq: RPHM
Corporate Presentation
May 2023

Forward-Looking Statements

This presentation contains "forward-looking" statements that are based on our management's beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our business strategy, objectives and opportunities. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements, including, but not limited to, those related to our dependence on third-party clinical research organizations, manufacturers, suppliers and distributors; our ability to obtain necessary additional capital; our ability to obtain necessary regulatory approvals for our products and, if and when approved, market acceptance of our products; the commercialization plans and expectations for commercializing mavodelpar (REN001) in the United States and rest of world, estimates of the number of patients impacted by PMM or LC-FAOD and who are appropriate for treatment with mavodelpar, the potential benefits of mavodelpar, the financial impact or revenues from any commercialization we undertake, the impact of competitive products and therapies; our ability to attract and retain key employees; the costs of our commercialization plans and development programs; the design, implementation and outcomes of our clinical trials; our ability to manage the growth and complexity of our organization; our ability to maintain, protect and enhance our intellectual property; and our ability to continue to stay in compliance with applicable laws and regulations. You should refer to the section entitled "Risk Factors" set forth in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings we make with the Securities and Exchange Commission (SEC) from time to time for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update any forward-looking statements after the date of this presentation except as may be required by law.

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. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Projections, assumptions and estimates of the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. The trademarks included herein are the property of the owners thereof and are used for reference purposes only.

Mavodelpar is an investigational drug product candidate that is under clinical investigation, and which has not yet been approved for marketing by the U.S. Food and Drug Administration, European Medicines Agency, or any other global regulatory agency. No representation is made as to the safety or effectiveness of this product candidate for the use for which it is being studied.

We use our website (https://www.reneopharma.com) and LinkedIn page (https://www.linkedin.com/company/reneo-pharmaceuticals) as channels of distribution of information about our company, product candidates, planned announcements, attendance at upcoming conferences and other matters. Such information may be deemed material information, and we may use these channels to comply with our disclosure obligations under Regulation Fair Disclosure. Therefore, investors should monitor our website and LinkedIn page in addition to following our SEC filings, press releases, public conference calls and webcasts.

Disclaimer

This presentation contains preliminary financial information as of and for the three months ended March 31, 2023 and is subject to completion. The unaudited, estimated results as of and for the three months ended March 31, 2023 are preliminary and were prepared by the Company's management, based upon estimates, a number of assumptions and currently available information, and are subject to revision based upon, among other things, quarter end closing procedures and/or adjustments, the completion of our interim financial statements and other operational procedures. This preliminary financial information is the responsibility of management and has been prepared in good faith on a consistent basis with prior periods. However, the Company has not completed its financial closing procedures for the three months ended March 31, 2023, and actual results could be materially different from this preliminary financial information, which preliminary information should not be regarded as a representation by the Company or its management as to our actual results as of and for the three months ended March 31, 2023. In addition, the Company's independent registered public accounting firm has not audited, reviewed, compiled, or performed any procedures with respect to this preliminary financial information and does not express an opinion or any other form of assurance with respect to this preliminary financial information. During the course of the preparation of the Company's financial statements and related notes as of and for the three months ended March 31, 2023, the Company may identify items that would require it to make material adjustments to this preliminary financial information. As a result, prospective investors should exercise caution in relying on this information and should not draw any inferences from this information. This preliminary financial information should not be viewed as a substitute for full financial statements prepared in accordance with United States generally accepted accounting principles and audited or reviewed by our auditors.

Investment Highlights

Mavodelpar (REN001)

- Preliminary evidence of efficacy and tolerability from four clinical trials
- Favorable guidance from U.S. and European regulatory agencies

Mitochondrial Diseases

- Rare diseases with high unmet medical need
- Myopathy and reduced life expectancy common

Anticipated Milestones

- Pivotal clinical trial in primary mitochondrial myopathy (PMM) with topline results in 4Q23
- Expansion into two additional mitochondrial disease populations

Financial Overview

- $94 million cash, cash equivalents, and short-term investments as of Mar 31, 2023
- Fundamental investor base

Reneo Pharmaceuticals Pipeline

Reneo is initially developing mavodelpar for patients with rare genetic mitochondrial diseases that typically present with myopathy and have a high unmet medical need

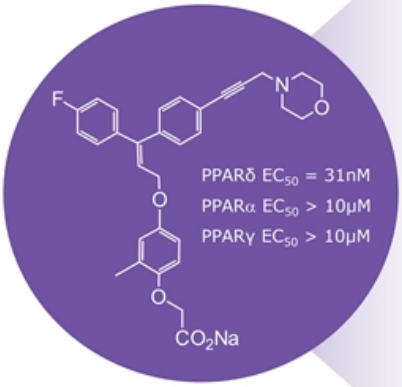
	Preclinical	Phase 1	Phase 2/3	Approved	2023 Anticipated Milestones
PMM primary mitochondrial myopathies	*mitochondrial DNA (mtDNA) mutations/deletions* *nuclear DNA (nDNA) mutations/deletions*				✓ Completed enrollment of pivotal trial in mtDNA PMM (1Q23) • Initiate enrollment of nDNA PMM patients (2Q23) • Topline results of pivotal trial in mtDNA PMM (4Q23)
LC-FAOD long-chain fatty acid oxidation disorders	*nuclear DNA (nDNA) mutations/deletions*				✓ Fast Track designation (LCHAD deficiency) (1Q23) • LC-FAOD clinical strategy update (4Q23)

Mavodelpar Overview

Mavodelpar Overview

Biology

- *Potent and selective agonist of peroxisome proliferator-activated receptor delta (PPARδ)*
- *Regulates generation of cellular energy*
- *Present in multiple tissue types including muscle, brain, kidney, and liver*
- *Activation in response to increased cellular energy needs*

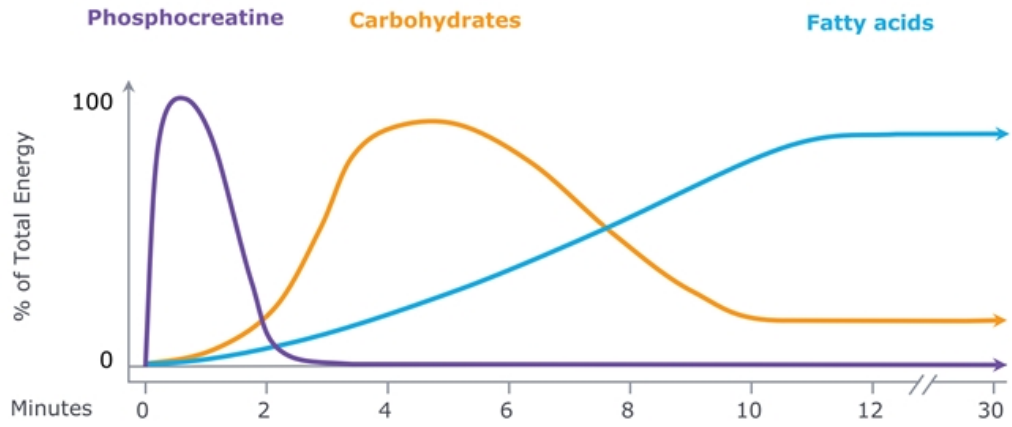


1. Increases transcription of genes central to mitochondrial function

2. Drives production of new mitochondria

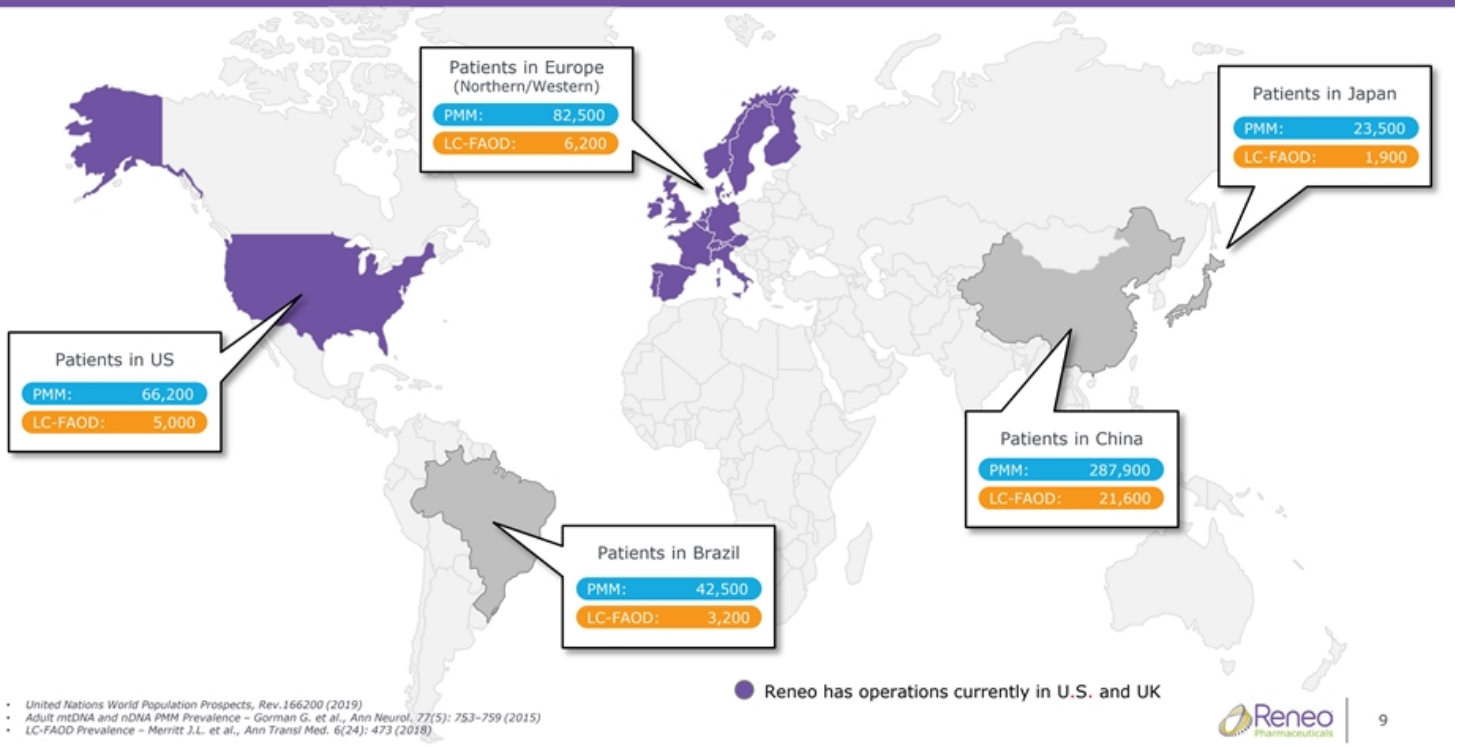
3. Increases oxidation of fatty acids and cellular energy production

Nutrient Utilization by Mitochondria



- Fatty acid oxidation becomes the predominant nutrient source for generation of cellular energy by the mitochondria during periods of increased energy demand
- Patients with PMM and LC-FAOD experience myopathy, weakness, fatigue, or deterioration of muscle due to impaired mitochondrial energy production

Prevalence in Key Rare Disease Markets

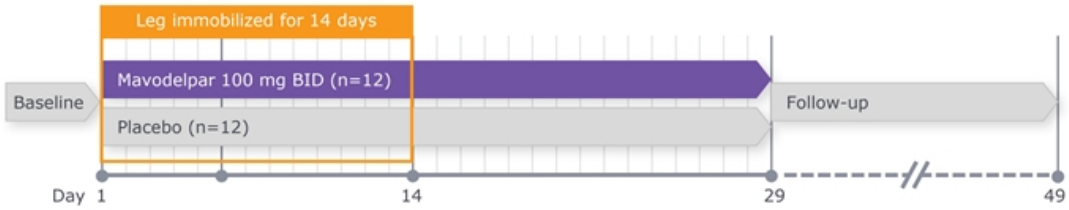


- *United Nations World Population Prospects, Rev.166200 (2019)*
- *Adult mtDNA and nDNA PMM Prevalence – Gorman G. et al., Ann Neurol. 77(5): 753–759 (2015)*
- *LC-FAOD Prevalence – Merritt J.L. et al., Ann Transl Med. 6(24): 473 (2018)*

● Reneo has operations currently in U.S. and UK

Leg Immobilization Study: Overview

Randomized, blinded, placebo-controlled clinical trial in healthy adult volunteers during and after leg immobilization



Primary Objective

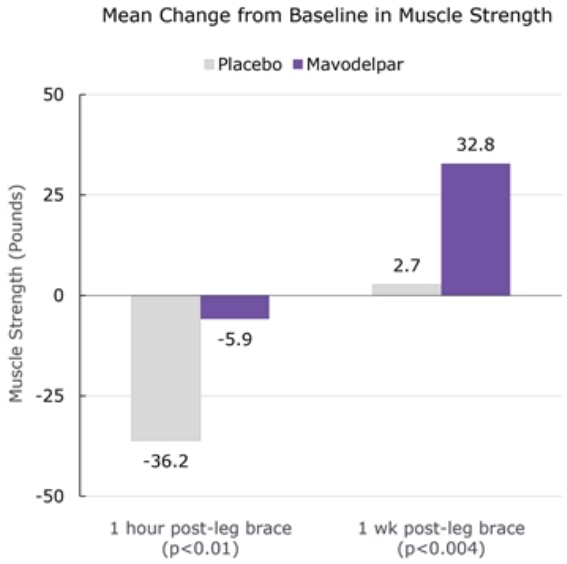
- Evaluate safety and tolerability of 28 days of mavodelpar in healthy volunteers

Secondary Objectives

- Changes in muscle strength and size
- Changes in expression of PPARδ regulated genes involved in mitochondrial function and biogenesis

- *Davies M. et al., J Clin Trials. 12:495 (2022)*

Leg Immobilization Study: Changes in Muscle Strength

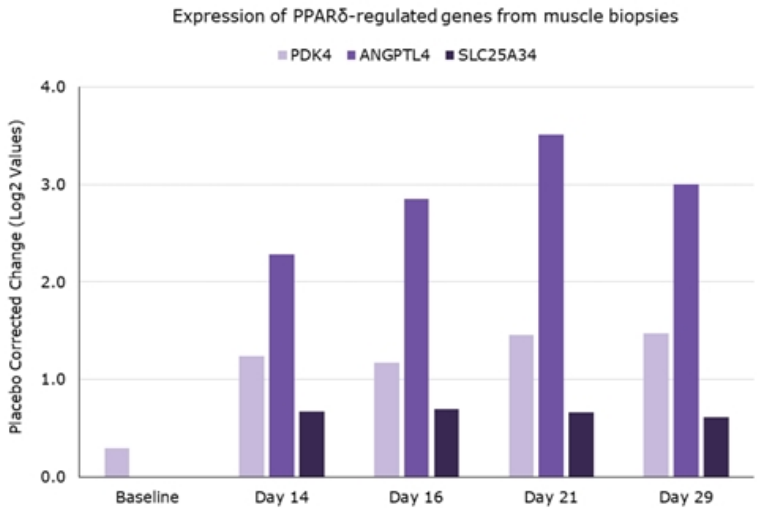


(p-value from a mixed model with baseline value as covariate)

- No serious adverse events (SAEs) related to mavodelpar treatment
- Treatment-emergent adverse events (TEAEs) were similar between subjects treated with mavodelpar or placebo
- Subjects treated with mavodelpar had substantially more leg strength compared to placebo subjects
  - *Greater preservation of muscle strength following immobilization*
  - *Greater increase in muscle strength one week after immobilization*

- *Davies M. et al., J Clin Trials. 12:495 (2022)*

Leg Immobilization Study: Changes in Gene Expression



- Subjects treated with mavodelpar showed increases in expression of PPARδ-regulated genes of interest
  - *Pyruvate dehydrogenase lipoamide kinase isozyme 4 (**PDK4**) encodes for a protein that plays a key role in regulation of glucose and fatty acid metabolism*
  - *Angiopoietin-like 4 (**ANGPTL4**) encodes for a protein that is directly involved in regulating lipid metabolism*
  - *Solute carrier family 25 member 34 (**SLC25A34**) encodes for a protein that is known to transport molecules across the mitochondrial membrane*

- *Davies M. et al., J Clin Trials. 12:495 (2022)*

Primary Mitochondrial Myopathies (PMM)

Characteristics

- PMMs are rare disorders caused by mutations within mitochondrial DNA (mtDNA) or nuclear DNA (nDNA)
- Mutations hamper the ability of mitochondria to generate energy
- Most pronounced in tissues with high energy demand (muscle, brain, and heart)

Symptoms

- Debilitating fatigue
- Myopathy
- Exercise intolerance
- Muscle pain
- Severe lack of endurance
- Reduced life expectancy

Prevalence*

- All adult PMM (23:100,000)
  - Symptomatic mtDNA (9.6:100,000)
  - Symptomatic nDNA (2.9:100,000)

Current Treatments

- No approved therapies
- Over-the-counter vitamins and supplements commonly used

** Adult mtDNA and nDNA PMM Prevalence – Gorman G. et al., Ann Neurol. 77(5): 753–759 (2015)*

PMM Phase 1b Trial: Overview

Open-label clinical trial in adult PMM subjects with mtDNA defects and myopathy

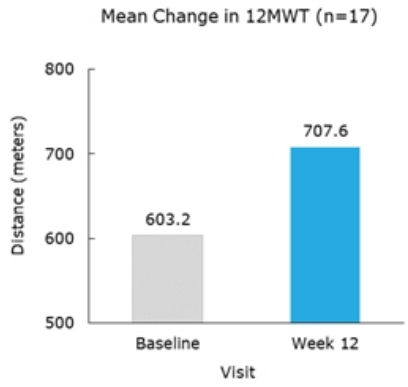
Primary Objective

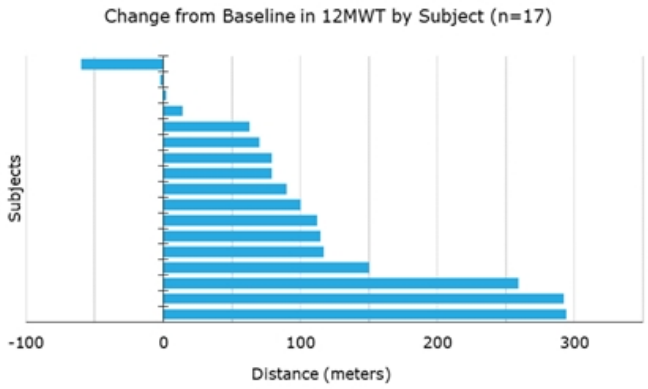
- Evaluate safety and tolerability of 12 weeks of treatment with mavodelpar in PMM patients

Secondary Objectives

- Evaluate safety and tolerability of 48 weeks treatment with mavodelpar in PMM patients
- Explore changes in clinical outcome such as exercise tests, oxygen consumption, and symptoms

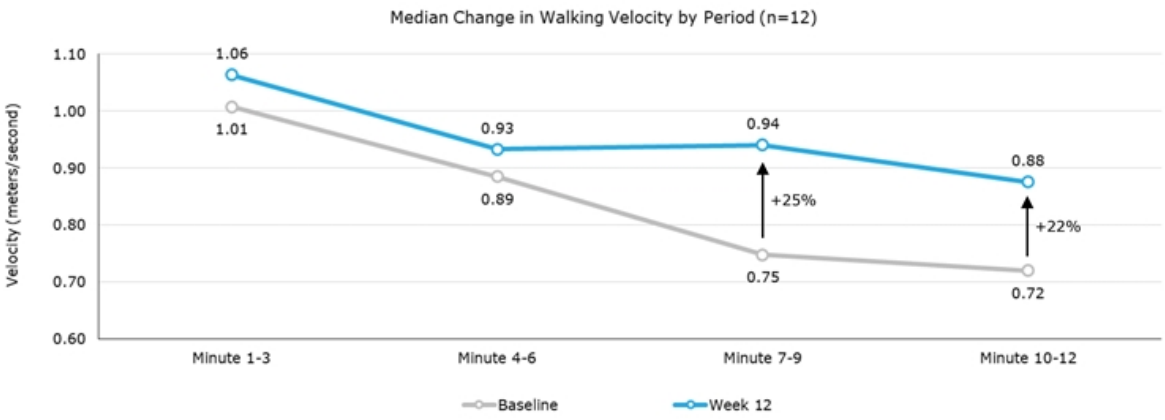
PMM Phase 1b Trial: Changes in 12-Minute Walk Test (12MWT)





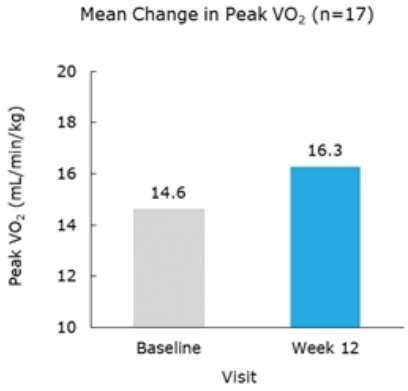
- Mean increase over baseline in 12MWT distance of 104.4 meters, 95% CI [53.1, 155.6]
- 13 of 17 (76%) patients had greater than a 50-meter increase 12MWT distance

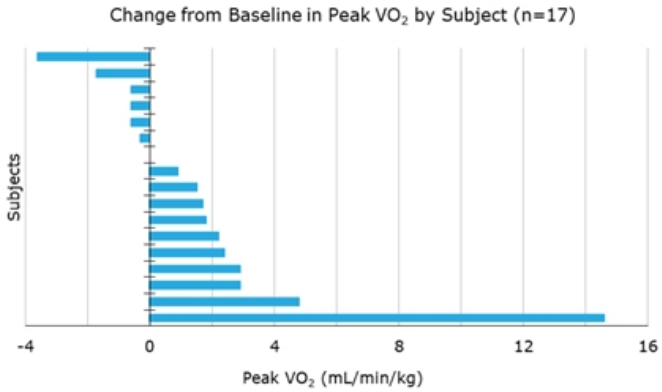
PMM Phase 1b Trial: Changes in Walking Velocity



- Walking velocity of PMM patients decreased at each 3-minute period during the 12MWT
- Following 12 weeks of treatment with mavodelpar, walking velocity increased compared to baseline
- The greatest increase in walking velocity occurred during the second half of the 12MWT

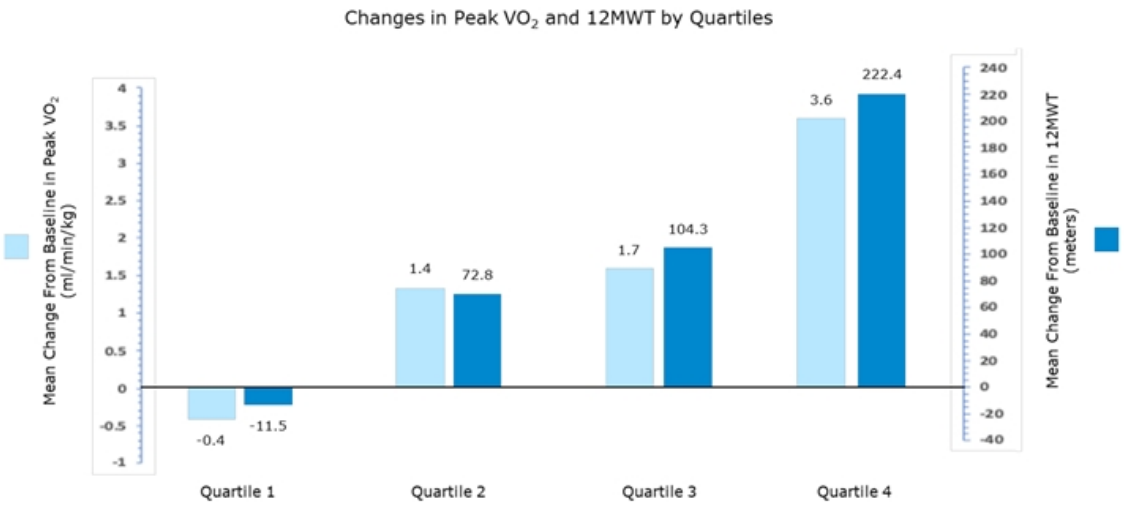
PMM Phase 1b Trial: Changes in Peak Oxygen Consumption (VO_2)





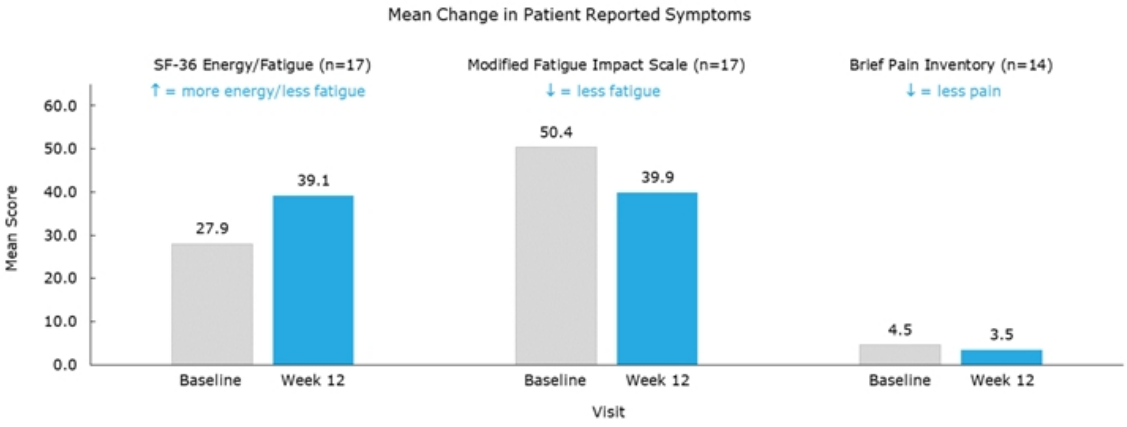
- Mean increase over baseline in peak VO_2 of 1.7 mL/min/kg, 95% CI [-0.3, 3.7]
- 10 patients (59%) had an increase in peak VO_2 of 0.9 mL/min/kg or greater

PMM Phase 1b Trial: Changes in Peak VO_2 and 12MWT by Quartile



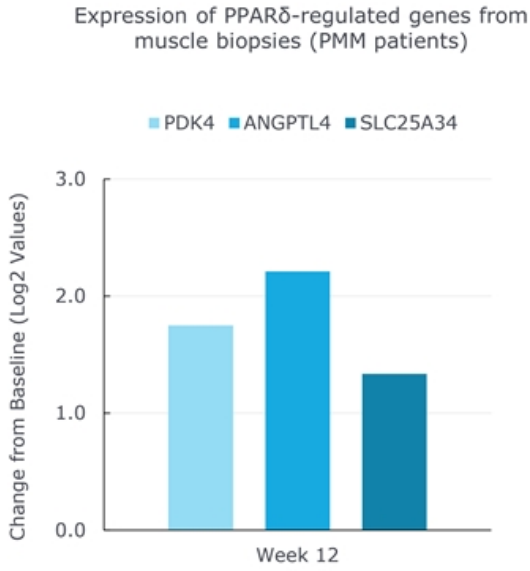
- Mean change over baseline in peak VO_2 parallels mean change over baseline in 12MWT

PMM Phase 1b Trial: Changes in Symptoms



- Mean change in SF-36 energy/fatigue score of 11.2, 95% CI [1.2, 21.2]
- Mean change in Modified Fatigue Impact Scale of -10.5, 95% CI [-16.3, -4.6]
- Mean change in Brief Pain Inventory of -1.0, 95% CI [-0.2, -1.9]

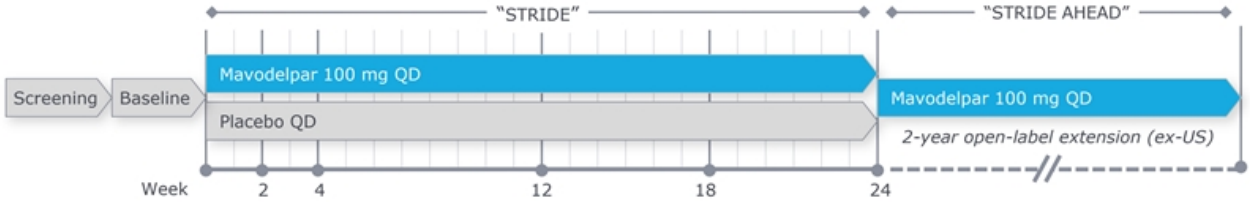
PMM Phase 1b Trial: Changes in Gene Transcription



- Muscle biopsies were performed at baseline and after 12 weeks of treatment with mavodelpar
- Differential gene expression was performed on biopsies from seven (7) subjects that had sufficient sample quantity and quality for analysis at baseline and week 12
- A statistically significant increase over baseline was observed in the expression of **PDK4**, **ANGPTL4**, and **SLC25A34**
  - *Gene expression data is consistent with the findings from the leg immobilization study*

Pivotal PMM Phase 2b Trial and Open-Label Extension Study

RDBPC clinical trial in adult PMM patients with mtDNA defects and myopathy, plus 2-year open-label extension study



STRIDE Primary Objective

- Change from baseline to week 24 in distance walked during 12MWT

STRIDE Secondary/Exploratory Objectives

- Changes from baseline in PROMIS® Short Form Fatigue 13a, Modified Fatigue Impact Scale (MFIS), Patient Global Impression of Change (PGIC), Patient Global Impression of Severity (PGIS), 30 Second Sit-To-Stand (30STS) Test, Brief Pain Inventory (BPI), 36-Item Health Survey (SF-36), Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP), and Pedometer Step Counts

STRIDE and STRIDE AHEAD Status

- STRIDE – Completed enrollment in March 2023 (N=213); topline results anticipated 4Q23
- STRIDE AHEAD – Over 100 patients enrolled to date (50 beyond 6 months); adding nDNA PMM patients 2Q23

PMM Phase 1b and 2b Studies: Baseline Characteristics

PMM Study	PMM Phase 1b	PMM Phase 2b* (STRIDE Study)
Subjects	N=17	N=213
Sex (%)		
Male	29.4%	29.1%
Female	70.6%	70.9%
Age (years)		
Mean	55.2	46.6
Median	55	48
SD	7.5	12.8
Body Mass Index (kg/mg^2)		
Mean	24.3	24.5
Median	24.5	23.7
SD	4.0	5.7
12-Minute Walk Test (meters)		
Mean	603.2	653.8
Median	525	662
SD	250.1	160.4
Modified Fatigue Impact Scale (score)		
Mean	50.4	43.9
Median	48	46
SD	18.6	17.9

** Preliminary data, subject to change*

Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD)

Characteristics

- LC-FAOD are rare disorders caused by mutations within nuclear DNA (nDNA)
- Inherited genetic errors of metabolism resulting in the inability to use dietary long-chain fatty acids as energy sources
- Mutations in genes that code for enzymes that perform long-chain fatty acid oxidation

Symptoms

- Young children – lethargy, liver dysfunction, hypoglycemia, high risk for sudden death, cardiomyopathy
- Older patients – limited endurance, muscle aches, rhabdomyolysis

Prevalence*

- VLCAD deficiency (1:120,000 to 1:42,500)
- LCHAD deficiency (1:150,000 to 1:110,000)

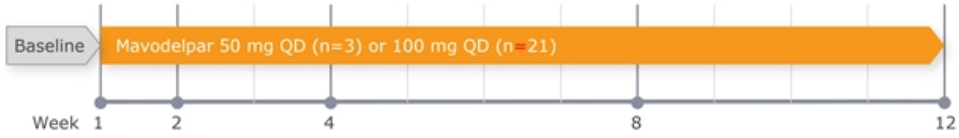
Current Treatments

- DOLJOVI®, a fatty acid supplement similar to medium chain triglyceride oil (MCT)
- Therapy includes a fat-restricted diet, supplementing with short or medium chain fatty acids

** LC-FAOD Prevalence – Merritt J.L. et al., Ann Transl Med. 6(24): 473 (2018)*

LC-FAOD Phase 1b Study: Overview

Open-label clinical trial in adult LC-FAOD subjects with mutations in LCHAD, CPTs, VLCAD, and TFP genes



Primary Objective

- Evaluate safety and tolerability of 12 weeks of treatment with mavodelpar in LC-FAOD patients

Secondary Objectives

- Explore changes in clinical outcome such as exercise tests and symptoms after 12 weeks of treatment with mavodelpar

Program Status

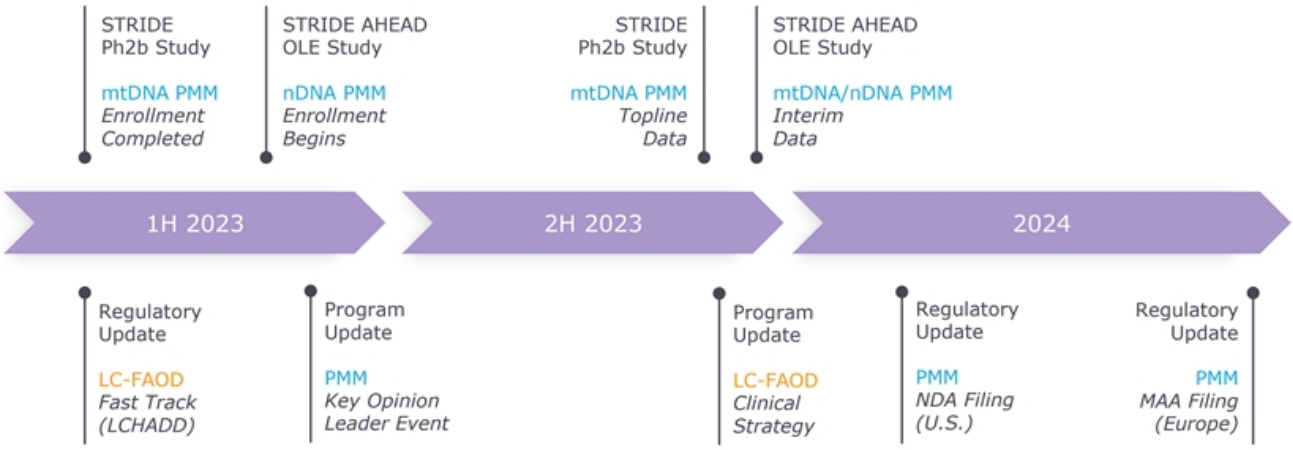
- U.S. FDA Fast Track designation received (LCHAD deficiency)

LC-FAOD Phase 1b Study: 12MWT, SF-36 Energy/Fatigue, and MFIS

Preclinical	12MWT [meters]			SF-36 Energy/Fatigue			MFIS Total		
Gene Defect	n	Baseline	Change	n	Baseline	Change	n	Baseline	Change
LCHAD	5	547.7 (133.4)	73.7 (18.0)	5	44.3 (10.4)	19.5 (11.7)	5	32.8 (6.5)	-9.8 (4.2)
CPT2	6	949.6 (119.1)	51.9 (49.4)	6	57.7 (3.2)	0.8 (4.9)	6	23.5 (6.7)	1.0 3.3)
VLCAD	5	864.3 (65.1)	-36.7 (42.1)	5	57.3 (9.3)	-17.8 (7.8)	5	17.8 (6.8)	15.6 (8.5)

- Mean increase over baseline in 12MWT distance over 50 meters in LCHAD and CPT2 defects
- Initiated regulatory discussion to guide further development; LC-FAOD clinical strategy update 4Q23

Mavodelpar Roadmap



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