

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 11, 2023

Reneo Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40315
(Commission File Number)

47-2309515
(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 11, 2023, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the first quarter and year ended March 31, 2023 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 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 Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Announcing Financial Results, dated May 11, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Reneo Pharmaceuticals, Inc.

Date: May 11, 2023

By: /s/ Gregory J. Flesher

Gregory J. Flesher
President and Chief Executive Officer
(Principal Executive Officer)

Reneo Pharmaceuticals Reports First Quarter 2023 Financial Results

- Completed enrollment of the pivotal STRIDE study; topline results anticipated 4Q 2023
- Raised \$68.3 million in gross proceeds from a concurrent public offering and private placement

IRVINE, Calif., May 11, 2023 (GLOBE NEWSWIRE) -- Reneo Pharmaceuticals, Inc. (Nasdaq: RPHM), a clinical-stage pharmaceutical company focused on the development and commercialization of therapies for patients with rare genetic mitochondrial diseases, today reported financial results for the quarter ended March 31, 2023 and provided a business update.

“In the first quarter we achieved a key milestone with the completion of enrollment of the pivotal STRIDE study. We have been encouraged by the patient interest in our mavodelpar program, which led to an over-enrollment in STRIDE and high rate of rollover into the STRIDE AHEAD open-label long-term extension trial,” said Gregory J. Flesher, President and Chief Executive Officer of Reneo Pharmaceuticals. “Subsequent to achieving this milestone, we raised additional capital to strengthen our balance sheet. We expect that this capital will be utilized to support the mavodelpar program through completion and in preparation for commercialization activities, including the potential filing of a new drug application in the first half of 2024.”

First Quarter and Recent Highlights

- Completed enrollment with 213 patients in the pivotal STRIDE study of mavodelpar (REN001) in adult patients with primary mitochondrial myopathies (PMM), exceeding the target enrollment of 200 patients; topline results anticipated in the fourth quarter of 2023
- Enrolled over 100 patients in the STRIDE AHEAD study, the mavodelpar open-label extension (OLE) trial in adult patients with PMM; over 50 patients reaching 6-months in the study
- The STRIDE AHEAD study was amended to allow the enrollment of adult patients with PMM due to nuclear DNA (nDNA) defects; initiate enrollment of nDNA patients in the second quarter of 2023
- Received Fast Track Designation from the United States (US) Food and Drug Administration (FDA) for mavodelpar in a genotype of long-chain fatty acid oxidation disorder (LC-FAOD)
- Presented preclinical poster at Society for Inherited Metabolic Disorders (SIMD) Annual Meeting entitled, PPAR δ Agonist REN001 Improves Mitochondrial Function in Skeletal Muscle: A Potential Treatment for Primary Mitochondrial Myopathies
- Raised \$68.3 million in gross proceeds from a concurrent public offering and private placement in May 2023

Financial Results for the Three Months Ended March 31, 2023

We reported a net loss of \$15.1 million, or \$0.60 per share, during the first quarter of 2023, compared to a net loss of \$13.0 million, or \$0.53 per share, for the same period in 2022. We had \$93.8 million in



cash, cash equivalents, and short-term investments as of March 31, 2023.

Research and development (R&D) expenses were \$11.0 million during the first quarter of 2023, compared to \$9.3 million for the same period in 2022. This increase in R&D expenses was primarily due to an increase of \$1.4 million related to clinical study costs in support of marketing registration of mavodelpar.

General and administrative (G&A) expenses were \$5.1 million during the first quarter of 2023, compared to \$3.7 million for the same period in 2022. This increase in G&A expenses was primarily due to an increase of \$1.1 million in facility and personnel-related costs due to additional headcount.

On May 8, 2023, we completed a public offering in which we sold an aggregate of 7,906,250 shares of common stock, which included the full exercise of the underwriters' option to purchase an additional 1,031,250 shares of common stock, at a price of \$8.00 per share. We received total net proceeds from the offering of approximately \$58.2 million, after deducting underwriting discounts and commissions and offering expenses.

On May 9, 2023, we completed a concurrent private placement in which we sold an aggregate of 625,000 shares of common stock to Abingworth Bioventures 8 L.P., a holder of more than 5% of our common stock, at a price of \$8.00 per share. We received total net proceeds from the private placement of approximately \$4.7 million, after deducting advisor fees and other estimated fees and expenses.

About Reneo Pharmaceuticals

Reneo is a clinical-stage pharmaceutical company focused on the development and commercialization of therapies for patients with rare genetic mitochondrial diseases, which are often associated with the inability of mitochondria to produce adenosine triphosphate (ATP). Our lead product candidate, mavodelpar, is a potent and selective agonist of the peroxisome proliferator-activated receptor delta (PPAR δ). Mavodelpar has been shown to increase transcription of genes involved in mitochondrial function and increase fatty acid oxidation (FAO), and may increase production of new mitochondria. For additional information, please see reneopharma.com.

About Mavodelpar

Mavodelpar (REN001) is a potent and selective peroxisome proliferator-activated receptor delta (PPAR δ) agonist currently in clinical development for two rare genetic mitochondrial diseases that typically present with myopathy and have high unmet medical needs: PMM and LC-FAOD. For additional information, please see clinicaltrials.gov.

About PMM

PMM are a group of rare, genetic metabolic disorders caused by mutations or deletions in the mtDNA or nDNA. These genetic alterations hamper the ability of mitochondria to generate energy from nutrient sources, resulting in energy deficits that are most pronounced in tissues with high energy demand such as muscle, brain, and heart. The symptoms of PMM include muscle weakness, exercise intolerance, movement disorder, deafness, blindness, and droopy eyelids among others. The prognosis for these disorders ranges in severity from progressive weakness to death.



Forward-Looking Statements

Statements contained in this press release 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 potential development, registration and commercialization of mavodelpar, results, conduct, progress, plans and timing of Reneo’s clinical trials, timing for the filing of a new drug application and for the first patient enrolled in the STRIDE AHEAD study, announcement of topline data from the STRIDE study and the use of the proceeds from our recent public offering and private placement. 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 Reneo’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, risks and uncertainties associated with Reneo’s business in general, and the other risks described in Reneo’s filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Reneo 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.



RENEO PHARMACEUTICALS, INC.

Consolidated Balance Sheets

(In thousands, except share and par value data)

	March 31, 2023 <u>(Unaudited)</u>	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,395	\$ 19,927
Short-term investments	63,392	81,246
Prepaid expenses and other current assets	3,231	5,180
Total current assets	<u>97,018</u>	<u>106,353</u>
Property and equipment, net	581	453
Right-of-use assets	1,188	1,292
Other non-current assets	81	84
Total assets	<u>\$ 98,868</u>	<u>\$ 108,182</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,802	\$ 1,893
Accrued expenses	8,316	4,827
Operating lease liabilities, current portion	363	404
Total current liabilities	<u>10,481</u>	<u>7,124</u>
Operating lease liabilities, less current portion	979	1,059
Performance award	324	29
Total liabilities	<u>11,784</u>	<u>8,212</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 25,107,430 and 24,699,553 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	3	3
Additional paid-in capital	238,859	236,693
Accumulated deficit	(151,790)	(136,683)
Accumulated other comprehensive income (loss)	12	(43)
Total stockholders' equity	<u>87,084</u>	<u>99,970</u>
Total liabilities and stockholders' equity	<u>\$ 98,868</u>	<u>\$ 108,182</u>



RENEO PHARMACEUTICALS, INC.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 10,991	\$ 9,278
General and administrative	5,132	3,737
Total operating expenses	16,123	13,015
Loss from operations	(16,123)	(13,015)
Other income (loss)	1,016	(21)
Net loss	(15,107)	(13,036)
Unrealized gain on short-term investments	55	30
Comprehensive loss	\$ (15,052)	\$ (13,006)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.60)	\$ (0.53)
Weighted-average shares used in computing net loss per share, basic and diluted	25,036,410	24,458,290



RENEO PHARMACEUTICALS, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (15,107)	\$ (13,036)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,157	1,107
Depreciation and amortization	41	19
Amortization/accretion on short-term investments	(770)	1
Changes in the fair value of performance award	295	(387)
Non-cash lease expense	120	143
Loss on disposal of fixed asset	3	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,952	2,011
Accounts payable and accrued expenses	3,398	1,251
Operating lease liabilities	(137)	(108)
Net cash used in operating activities	<u>(9,048)</u>	<u>(8,999)</u>
Cash flows from investing activities		
Purchases of property and equipment	(172)	(44)
Purchase of available-for-sale short-term investments	(28,321)	(16,029)
Proceeds from maturities of available-for-sale short-term investments	47,000	21,500
Net cash provided by investing activities	<u>18,507</u>	<u>5,427</u>
Cash flows from financing activities		
Proceeds from at-the-market facility, net of offering costs	1,009	6
Net cash provided by financing activities	<u>1,009</u>	<u>6</u>
Net increase (decrease) in cash and cash equivalents	10,468	(3,566)
Cash and cash equivalents, beginning of period	19,927	124,660
Cash and cash equivalents, end of period	<u>\$ 30,395</u>	<u>\$ 121,094</u>
Noncash operating activities:		
Right-of-use assets obtained in exchange for lease obligations	\$ —	\$ 1,524



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