

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 10, 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 August 10, 2023, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the second quarter ended June 30, 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.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release Announcing Financial Results, dated August 10, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: August 10, 2023

By: /s/ Gregory J. Flesher

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

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## Reneo Pharmaceuticals Reports Second Quarter 2023 Financial Results

*Topline results of the STRIDE study, the pivotal mavodelpar clinical trial in adult patients with primary mitochondrial myopathies (PMM) due to mitochondrial DNA (mtDNA) defects, anticipated in 4Q23*

IRVINE, Calif., August 10, 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 second quarter ended June 30, 2023 and provided a business update.

"We are looking forward to topline results from our pivotal STRIDE study expected in the fourth quarter this year and continue to be encouraged by the high roll over rate of PMM patients into our open label extension STRIDE AHEAD study, where we have enrolled over 130 patients," said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. "Our recent financing extended our runway, providing the company with what we expect to be sufficient capital to fund operations beyond the potential submission of a new drug application for mavodelpar for the treatment of PMM in the United States anticipated in the first half of 2024."

### Second Quarter and Recent Highlights

- Enrolled over 130 adult patients with PMM due to mtDNA defects into the mavodelpar open-label extension study (STRIDE AHEAD)
- Expanded the inclusion criteria of the STRIDE AHEAD study to allow enrollment of adult patients with PMM due to nuclear DNA (nDNA) defects
- Participated and presented at two major mitochondrial scientific conferences: EUROMIT 2023 Conference (Bologna, Italy) and United Mitochondrial Disease Foundation's Mitochondrial Medicine Symposium (Charlotte, NC)
- Added to the broad-market Russell 2000® and 3000® Indexes
- Raised \$68.3 million in gross proceeds from a public offering and concurrent private placement of common stock

### Financial Results for the Three Months Ended June 30, 2023

We reported a net loss of \$19.5 million, or \$0.65 per share, during the second quarter of 2023, compared to a net loss of \$12.3 million, or \$0.50 per share, for the same period in 2022. We had \$142.7 million in cash, cash equivalents, and short-term investments as of June 30, 2023.

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Research and development (R&D) expenses were \$14.4 million during the second quarter of 2023, compared to \$8.1 million for the same period in 2022. This increase in R&D expenses was primarily due to an increase of \$4.7 million related to clinical and contract manufacturing costs to support the marketing registration for mavodelpar, an increase of \$1.0 million in personnel-related costs due to additional headcount, and an increase of \$0.6 million in medical affairs costs.

General and administrative (G&A) expenses were \$6.6 million during the second quarter of 2023, compared to \$4.3 million for the same period in 2022. This increase in G&A expenses was primarily due to an increase of \$1.2 million in commercial development activities and an increase of \$1.0 million in facility and personnel-related costs due to additional headcount.

In May 2023, we completed a public offering and concurrent private placement in which we sold an aggregate of 8,531,250 shares of common stock at a price of \$8.00 per share totaling approximately \$68.3 million in gross proceeds. After deducting underwriting discounts and commissions and offering expenses, we received total net proceeds of approximately \$63.5 million.

### **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 $\delta$ ). 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](http://reneopharma.com).

### **About Mavodelpar**

Mavodelpar (REN001) is a potent and selective peroxisome proliferator-activated receptor delta (PPAR $\delta$ ) 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](http://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.

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## 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, the potential filing of a new drug application for mavodelpar for the treatment of PMM in the United States, the timing of topline data from the STRIDE study, the sufficiency of the Company’s cash position and the Company’s cash runway. 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.

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**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Balance Sheets**  
(In thousands, except share and par value data)

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 9,081	\$ 19,927
Short-term investments	133,596	81,246
Prepaid expenses and other current assets	3,643	5,180
Total current assets	146,320	106,353
Property and equipment, net	554	453
Right-of-use assets	1,086	1,292
Other non-current assets	79	84
Total assets	\$ 148,039	\$ 108,182
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,828	\$ 1,893
Accrued expenses	11,592	4,827
Operating lease liabilities, current portion	318	404
Total current liabilities	13,738	7,124
Operating lease liabilities, less current portion	897	1,059
Performance award	876	29
Total liabilities	15,511	8,212
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 33,800,788 and 24,699,553 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	3	3
Additional paid-in capital	303,877	236,693
Accumulated deficit	(171,321)	(136,683)
Accumulated other comprehensive loss	(31)	(43)
Total stockholders' equity	132,528	99,970
Total liabilities and stockholders' equity	\$ 148,039	\$ 108,182





**RENEO PHARMACEUTICALS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(In thousands, except share and per share data)  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 14,400	\$ 8,132	\$ 25,389	\$ 17,410
General and administrative	6,639	4,299	11,771	8,036
Total operating expenses	<u>21,039</u>	<u>12,431</u>	<u>37,160</u>	<u>25,446</u>
Loss from operations	(21,039)	(12,431)	(37,160)	(25,446)
Other income	1,508	119	2,522	98
Net loss	<u>(19,531)</u>	<u>(12,312)</u>	<u>(34,638)</u>	<u>(25,348)</u>
Unrealized (loss) gain on short-term investments	(43)	104	12	134
Comprehensive loss	<u>\$ (19,574)</u>	<u>\$ (12,208)</u>	<u>\$ (34,626)</u>	<u>\$ (25,214)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.65)</u>	<u>\$ (0.50)</u>	<u>\$ (1.25)</u>	<u>\$ (1.04)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>30,215,321</u>	<u>24,463,824</u>	<u>27,640,172</u>	<u>24,461,085</u>



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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (34,638)	\$ (25,348)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,364	2,113
Depreciation and amortization	83	41
Amortization/accretion on short-term investments	(2,011)	(22)
Changes in the fair value of performance award	847	(389)
Non-cash lease expense	241	241
Loss on disposal of fixed asset	3	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,542	905
Accounts payable and accrued expenses	6,690	1,726
Operating lease liabilities	(283)	(222)
Net cash used in operating activities	<u>(25,162)</u>	<u>(20,955)</u>
Cash flows from investing activities		
Purchases of property and equipment	(177)	(68)
Purchase of available-for-sale short-term investments	(132,327)	(15,922)
Proceeds from maturities of available-for-sale short-term investments	82,000	30,500
Net cash (used in) provided by investing activities	<u>(50,504)</u>	<u>14,510</u>
Cash flows from financing activities		
Proceeds from public offering of common stock, net of offering costs	58,862	—
Proceeds from private placement of common stock, net of offering costs	4,667	—
Proceeds from issuance of common stock under the at-the-market facility, net of offering costs	1,009	—
Proceeds from issuance of common stock in connection with equity plans	282	49
Net cash provided by financing activities	<u>64,820</u>	<u>49</u>
Net decrease in cash and cash equivalents	<u>(10,846)</u>	<u>(6,396)</u>
Cash and cash equivalents, beginning of period	19,927	124,660
Cash and cash equivalents, end of period	<u>\$ 9,081</u>	<u>\$ 118,264</u>
<b>Noncash operating activities:</b>		
Right-of-use assets obtained in exchange for lease obligations	\$ —	\$ 1,524
<b>Noncash investing and financing activities:</b>		
Property and equipment in accounts payable	\$ 10	\$ —



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