

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): March 27, 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 March 27, 2023, Reneo Pharmaceuticals, Inc. (the “Company”) issued a press release reporting the Company’s financial results for the fourth quarter and year ended December 31, 2022 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 March 27, 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: March 27, 2023

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

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## Reneo Pharmaceuticals Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

**IRVINE, Calif., March 27, 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 and year ended December 31, 2022 and provided a business update.

### 2022 and Recent Highlights

- Achieved the target enrollment of 200 patients in the pivotal STRIDE study of mavodelpar (REN001) in adult patients with primary mitochondrial myopathies (PMM); topline results anticipated in the fourth quarter of 2023
- Enrolled 85% of eligible STRIDE study patients in the STRIDE AHEAD study, the mavodelpar long-term safety clinical trial in adult patients with PMM
- Received confirmation from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) that positive data from the STRIDE and STRIDE AHEAD studies could potentially support registration of mavodelpar for adult patients with PMM due to mitochondrial DNA (mtDNA) defects
- Disclosed plans to study mavodelpar in adult patients with PMM due to nuclear DNA (nDNA) defects in the STRIDE AHEAD study
- Positive results from Phase 1b study in adult patients with long-chain fatty acid oxidation disorder (LC-FAOD) and plans to move the program forward into Phase 2 development
- Appointed Michael P. Cruse to the role of Chief Operating Officer and Jennifer P. Lam to the role of Principal Financial and Accounting Officer
- Appointed Paul W. Hoelscher and Roshawn Blunt to the Board of Directors

"We made significant progress with our mavodelpar development programs and expanded both our leadership team and Board of Directors in 2022," said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. "We recently achieved target enrollment of the STRIDE study and anticipate announcing topline results of this pivotal clinical trial in the fourth quarter of 2023. In addition, we anticipate dosing our first adult patient with PMM due to nDNA defects in the coming months, and expect to finalize our plans for the LC-FAOD Phase 2 program later this year. Finally, as we move closer towards the potential commercialization of mavodelpar, we have strengthened our financial, commercial, and operational expertise by making key changes to the leadership team and Board of Directors," concluded Mr. Flesher.

## Financial Results for Fourth Quarter and Full Year 2022

We reported a net loss of \$13.6 million, or \$0.56 per share, during the fourth quarter of 2022, compared to a net loss of \$10.6 million, or \$0.43 per share, for the same period in 2021. For the full year 2022, we reported a net loss of \$52.0 million, or \$2.12 per share, compared to a net loss of \$39.8 million, or \$2.19 per share, for the full year 2021. We had \$101.2 million in cash, cash equivalents, and short-term investments as of December 31, 2022.

Research and development (R&D) expenses were \$10.4 million during the fourth quarter of 2022, compared to \$7.1 million for the same period in 2021. For the full year 2022, R&D expenses were \$37.7 million, compared to \$28.2 million for the full year 2021. The increase in R&D expense for 2022 was primarily due to an increase of \$6.4 million related to clinical and manufacturing costs primarily related to our STRIDE and STRIDE AHEAD studies and an increase of \$2.8 million in personnel related costs due to the additional headcount required to support our clinical and manufacturing operations.

General and administrative (G&A) expenses were \$4.2 million during the fourth quarter of 2022, compared to \$3.5 million for the same period in 2021. For the full year 2022, G&A expenses were \$16.1 million, compared to \$11.6 million for the full year 2021. This increase in G&A expenses for 2022 was primarily due to an increase of \$2.9 million in outside professional services and an increase of \$1.2 million in facility and personnel related costs due to additional headcount.

## 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.

### **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, announcement of topline data from the STRIDE study and dosing of our first adult patient with PMM due to nDNA defects. 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)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 19,927	\$ 124,660
Short-term investments	81,246	23,010
Prepaid expenses and other current assets	5,180	6,064
Total current assets	106,353	153,734
Property and equipment, net	453	212
Right-of-use assets	1,292	—
Other non-current assets	84	78
Total assets	\$ 108,182	\$ 154,024
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,893	\$ 2,022
Accrued expenses	4,827	4,180
Operating lease liabilities, current portion	404	—
Total current liabilities	7,124	6,202
Operating lease liabilities, less current portion	1,059	—
Other long-term liabilities	—	167
Performance award	29	444
Total liabilities	8,212	6,813
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at December 31, 2022 and December 31, 2021; 24,699,553 shares issued and outstanding at December 31, 2022; and 24,457,838 and 24,455,390 shares issued and outstanding at December 31, 2021, respectively	3	3
Additional paid-in capital	236,693	231,902
Accumulated deficit	(136,683)	(84,728)
Accumulated other comprehensive (loss) income	(43)	34
Total stockholders' equity	99,970	147,211
Total liabilities and stockholders' equity	\$ 108,182	\$ 154,024

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:	<b>(Unaudited)</b>			
Research and development	\$ 10,357	\$ 7,100	\$ 37,705	\$ 28,169
General and administrative	4,205	3,524	16,143	11,649
Total operating expenses	<u>14,562</u>	<u>10,624</u>	<u>53,848</u>	<u>39,818</u>
Loss from operations	(14,562)	(10,624)	(53,848)	(39,818)
Other income	962	17	1,893	48
Net loss	<u>(13,600)</u>	<u>(10,607)</u>	<u>(51,955)</u>	<u>(39,770)</u>
Unrealized (loss) gain on short-term investments	(17)	17	(77)	34
Comprehensive loss	<u>\$ (13,617)</u>	<u>\$ (10,590)</u>	<u>\$ (52,032)</u>	<u>\$ (39,736)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.43)</u>	<u>\$ (2.12)</u>	<u>\$ (2.19)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>24,484,302</u>	<u>24,427,455</u>	<u>24,496,425</u>	<u>18,143,487</u>



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

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (51,955)	\$ (39,770)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,320	3,891
Depreciation and amortization	88	50
Amortization/accretion on short-term investments	(817)	202
Changes in the fair value of performance award	(415)	444
Non-cash lease expense	441	—
Loss on disposal of fixed asset	17	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	878	(4,711)
Accounts payable and accrued expenses	518	1,780
Operating lease liabilities	(437)	—
Other current and long-term liabilities	—	131
Net cash used in operating activities	<u>(47,362)</u>	<u>(37,983)</u>
Cash flows from investing activities		
Purchases of property and equipment	(346)	(198)
Purchase of available-for-sale short-term investments	(101,596)	(31,406)
Proceeds from maturities of available-for-sale short-term investments	44,100	8,228
Net cash used in investing activities	<u>(57,842)</u>	<u>(23,376)</u>
Cash flows from financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	47,238
Proceeds from initial public offering, net of offering costs	—	84,612
Proceeds from at-the-market facility, net of offering costs	193	—
Proceeds from issuance of common stock in connection with equity plans	278	556
Net cash provided by financing activities	<u>471</u>	<u>132,406</u>
Net (decrease) increase in cash and cash equivalents	(104,733)	71,047
Cash and cash equivalents, beginning of year	124,660	53,613
Cash and cash equivalents, end of year	<u>\$ 19,927</u>	<u>\$ 124,660</u>
<b>Noncash operating activities:</b>		
Right-of-use assets obtained in exchange for lease obligations	\$ 1,733	\$ —
<b>Noncash investing and financing activities:</b>		
Vesting of unvested exercised options	\$ —	\$ 4

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