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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 10, 2022

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**Reneo Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of incorporation)

001-40315  
(Commission File Number)

47-2309515  
(I.R.S. Employer Identification No.)

**18575 Jamboree Road, Suite 275-S,  
Irvine, California**

(Address of principal executive offices)

**92612**  
(Zip Code)

**(858) 283-0280**

(Registrant's telephone number, including area code)

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 10, 2022, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the first quarter ended March 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 May 10, 2022.</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: May 10, 2022

By: /s/ Gregory J. Flesher

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

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## Reneo Pharmaceuticals Reports First Quarter 2022 Financial Results

IRVINE, Calif., May 10, 2022 (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, 2022.

“During the first quarter of 2022, we continued to make good progress across our REN001 programs,” said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. “The STRIDE study, our ongoing Phase 2b clinical trial in primary mitochondrial myopathies (PMM), is enrolling well with 50% of the target enrollment now complete. In addition, all patients have completed the Phase 1b clinical trial and the FORWARD natural history study in long-chain-fatty acid oxidation disorders (LC-FAOD), and we anticipate sharing the results of both studies in July 2022. Furthermore, we added rare disease drug development and commercialization expertise to our Board of Directors, as well as made changes to the executive leadership team in order to support our planned growth over the coming years,” concluded Mr. Flesher.

### Financial Results for the Three Months Ended March 31, 2022

The Company reported a net loss of \$13.0 million, or \$0.53 per share, for the three months ended March 31, 2022, compared to a net loss of \$7.2 million, or \$3.48 per share, for the three months ended March 31, 2021. The Company had \$138.7 million in cash, cash equivalents and short-term investments as of March 31, 2022.

Research and development expenses for the three months ended March 31, 2022 were \$9.3 million, compared to \$5.5 million for the three months ended March 31, 2021. This increase of \$3.8 million was primarily due to an increase of \$2.2 million related to clinical trial and manufacturing costs associated with the launch of our STRIDE and FORWARD studies as well as our Phase 1b clinical trials of LC-FAOD. In addition, there was a \$0.8 million increase in non-clinical activities and a \$0.8 million increase in personnel-related costs due to the additional headcount required to support our clinical and CMC operations.

General and administrative expenses for the three months ended March 31, 2022 were \$3.7 million, compared to \$1.7 million during the three months ended March 31, 2021. This increase of \$2.0 million was primarily attributable to increased costs to operate as a public company, including increases in outside professional services of \$0.7 million, personnel-related expenses of \$0.6 million, and insurance premiums of \$0.3 million.

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## First Quarter Highlights

- Enrolled the 100<sup>th</sup> patient into the STRIDE study
- Completed all patient visits in the Phase 1b and FORWARD natural history studies in LC-FAOD
- Appointed Paul W. Hoelscher, Executive Vice President, Chief Financial Officer of Horizon Therapeutics plc to the Board of Directors
- Appointed Michael P. Cruse as Chief Operating Officer and Jennifer P. Lam as Principal Financial and Accounting Officer

## Anticipated Milestones

- Results of the Phase 1b clinical trial in LC-FAOD (July 2022)
- Results of the FORWARD natural history study in LC-FAOD (July 2022)
- Completion of enrollment in the STRIDE study (year-end 2022)

## Corporate Access Events

- H.C. Wainwright Global Investment Conference, May 23-26, 2022
- Jefferies Healthcare Conference, June 8-10, 2022

## 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, REN001, is a potent and selective agonist of the peroxisome proliferator-activated receptor delta (PPAR $\delta$ ). REN001 has been shown to increase transcription of genes involved in mitochondrial function and increase fatty acid oxidation, and may increase the production of new mitochondria.

## About REN001

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: primary mitochondrial myopathies (PMM) and long-chain fatty acid oxidation disorders (LC-FAOD). For more information on REN001 clinical trials, please see [clinicaltrials.gov](http://clinicaltrials.gov).

## About PMM

PMM are a group of disorders caused by genetic mutations within the mitochondrial DNA or nuclear DNA that affect the activity of enzymes or other proteins in the mitochondria. In PMM 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 or exercise intolerance, movement

disorder, deafness, blindness, and droopy eyelids among others. The prognosis for these disorders ranges in severity from progressive weakness to death.

### **About STRIDE**

STRIDE is a global, randomized, double-blind, placebo-controlled Phase 2b clinical trial designed to assess the efficacy and safety of 100 mg REN001 administered orally once daily to patients with PMM. Approximately 200 adult PMM patients with alterations in mitochondrial DNA and a history of myopathy are expected to be enrolled into STRIDE. The primary efficacy endpoint of the trial is the change from baseline in the distance walked during a 12-minute walk test (12MWT) after 24 weeks of treatment. Secondary efficacy endpoints include safety, and patient reported outcomes, including changes from baseline in the Modified Fatigue Impact Scale (MFIS); Patient Global Impression of Change scale (PGIC); and other patient-reported outcomes.

### **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 results, conduct, progress and timing of Reneo's clinical trials, presentation of data from clinical trials, the regulatory approval path for REN001, intellectual property protection matters, the strength of Reneo's balance sheet and the adequacy of cash on hand. 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)

	As of March 31, 2022 (Unaudited)	As of December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 121,094	\$ 124,660
Short-term investments	17,568	23,010
Prepaid expenses and other current assets	4,053	6,064
Total current assets	142,715	153,734
Property and equipment, net	237	212
Right-of-use assets	1,382	—
Other non-current assets	78	78
Total assets	\$ 144,412	\$ 154,024
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,566	\$ 2,022
Accrued expenses	5,887	4,180
Operating lease liabilities, current portion	457	—
Total current liabilities	7,910	6,202
Operating lease liabilities, less current portion	1,127	—
Other long-term liabilities	—	167
Performance award	57	444
Total liabilities	9,094	6,813
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 24,458,550 shares issued and outstanding at March 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	233,015	231,902
Accumulated deficit	(97,764)	(84,728)
Accumulated other comprehensive income	64	34
Total stockholders' equity	135,318	147,211
Total liabilities and stockholders' equity	\$ 144,412	\$ 154,024

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

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Operating expenses:		
Research and development	\$ 9,278	\$ 5,472
General and administrative	3,737	1,742
Total operating expenses	13,015	7,214
Loss from operations	(13,015)	(7,214)
Other (loss) income	(21)	2
Net loss	(13,036)	(7,212)
Unrealized gain on short-term investments	30	—
Comprehensive loss	\$ (13,006)	\$ (7,212)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.53)	\$ (3.48)
Weighted-average shares used in computing net loss per share, basic and diluted	24,458,290	2,070,935



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

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (13,036)	\$ (7,212)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,107	471
Depreciation and amortization	19	10
Amortization/accretion on short-term investments	1	—
Changes in the fair value of performance award	(387)	—
Non-cash lease expense	143	—
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,251	(927)
Prepaid expenses and other assets	2,011	(929)
Operating lease liabilities	(108)	—
Other current and long-term liabilities	—	(2)
Net cash used in operating activities	<u>(8,999)</u>	<u>(8,589)</u>
Cash flows from investing activities		
Purchases of property and equipment	(44)	(25)
Purchase of available-for-sale short-term investments	(16,029)	—
Proceeds from maturities of available-for-sale short-term investments	21,500	—
Net cash provided by (used in) investing activities	<u>5,427</u>	<u>(25)</u>
Cash flows from financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	47,258
Proceeds from issuance of common stock pursuant to equity award plans	6	187
Costs paid in connection with initial public offering	—	(1,223)
Net cash provided by financing activities	<u>6</u>	<u>46,222</u>
Net (decrease) increase in cash and cash equivalents	(3,566)	37,608
Cash and cash equivalents, beginning of period	124,660	53,613
Cash and cash equivalents, end of period	<u>\$ 121,094</u>	<u>\$ 91,221</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	\$ —	\$ 2
Unpaid Series B convertible preferred stock issuance costs	\$ —	\$ 19
Accrued deferred initial public offering costs	\$ —	\$ 361

**Contacts:**

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