

**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 09, 2022

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 9, 2022, Reneo Pharmaceuticals, Inc. (the “Company”) issued a press release reporting the Company’s financial results for the second quarter June 30, 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.

Exhibit No.	Description
99.1	Press Release Announcing Financial Results, dated August 9, 2022.
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: August 9, 2022

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

Reneo Pharmaceuticals Reports Second Quarter 2022 Financial Results

IRVINE, Calif., August 9, 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 June 30, 2022.

“The second quarter was a very productive period for the company, highlighted by advancements in both of our mitochondrial disease programs,” said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. “We recently reported positive results from the REN001 long-chain fatty acid oxidation disorders study, and look forward to meeting with regulators to discuss next steps for this program. In addition, we continued to make good progress with our primary mitochondrial myopathies program, including achievement of two-thirds enrollment in the pivotal STRIDE study, gaining alignment on the planned registration plan in Europe, and announcing plans to begin a third development program in patients with nuclear DNA defects.”

Second Quarter and Recent Highlights

- Published REN001 Phase 1 leg-immobilization study in the Journal of Clinical Trials ([Link](#))
- Reported positive results from REN001 Phase 1b long-chain fatty acid oxidation disorders (LC-FAOD) study
- Announced plans to initiate a third REN001 program in primary mitochondrial myopathies (PMM) patients with nuclear DNA (nDNA) defects
- Appointed Roshawn Blunt to the Board of Directors

Anticipated Milestones

- Presentation of LC-FAOD studies at the International Network for Fatty Acid Oxidation Research and Management (INFORM) Conference, Aug 28-29 (Freiburg, Germany)
- Completion of enrollment in the pivotal STRIDE study, year-end 2022
- Meetings with regulatory agencies to discuss LC-FAOD and nDNA PMM programs, 4Q22/1Q23

Financial Results for the Three Months Ended June 30, 2022

The Company reported a net loss of \$12.3 million, or \$0.50 per share, for the three months ended June 30, 2022, compared to a net loss of \$9.2 million, or \$0.43 per share, for the three months ended June 30, 2021. The Company had approximately \$127 million in cash, cash equivalents and short-term investments as of June 30, 2022.

Research and development expenses for the three months ended June 30, 2022 were \$8.1 million, compared to \$6.3 million for the three months ended June 30, 2021. This increase of \$1.8 million was primarily due to a \$1.1 million increase in personnel-related costs due to the additional headcount required to support our clinical and manufacturing operations. In addition, there was a \$0.4 million increase in clinical trial and manufacturing costs and a \$0.4 million increase in non-clinical activities.

General and administrative expenses for the three months ended June 30, 2022 were \$4.3 million, compared to \$2.9 million during the three months ended June 30, 2021. This increase of \$1.4 million was primarily

attributable to increased costs to operate as a public company, including increases in outside professional services of \$1.1 million and personnel-related expenses of \$0.1 million.

Corporate Access Events

- Baird Global Healthcare Conference, Sep 13-14 (New York)
- Landenburg Thalmann Annual Healthcare Conference, Sep 29 (New York)
- Piper Sandler Annual Healthcare Conference, Nov 29 – Dec 1 (New York)

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 δ). REN001 has been shown to increase transcription of genes involved in mitochondrial function and increase fatty acid oxidation, and may increase production of new mitochondria. For additional information, please see reneopharma.com.

About REN001

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 disorders caused by genetic mutations within the mitochondrial DNA or nDNA 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 LC-FAOD

LC-FAOD are a group of rare genetic metabolic disorders caused by mutations or deletions in the nDNA. These genetic alterations prevent the body from breaking down long-chain fatty acids during metabolism. The most severe cases of LC-FAOD are diagnosed within the first few days or weeks of life. Young patients often present with a severe energy deficit that results in lethargy, liver dysfunction, hypoglycemia, encephalopathy, and high risk for sudden death. Older patients usually present with muscle weakness, exercise intolerance, muscle aches, or rhabdomyolysis which can damage the heart and kidneys and cause permanent disability or even 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 and commercialization

of REN001, results, conduct, progress, plans and timing of Reneo's clinical studies, including the planned registration plan in Europe, presentation of data from clinical trials, meetings with regulatory agencies and the regulatory approval path for REN001. 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)

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 118,264	\$ 124,660
Short-term investments	8,588	23,010
Prepaid expenses and other current assets	5,159	6,064
Total current assets	132,011	153,734
Property and equipment, net	236	212
Right-of-use assets	1,283	—
Other non-current assets	78	78
Total assets	\$ 133,608	\$ 154,024
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,560	\$ 2,022
Accrued expenses	6,367	4,180
Operating lease liabilities, current portion	408	—
Total current liabilities	8,335	6,202
Operating lease liabilities, less current portion	1,061	—
Other long-term liabilities	—	167
Performance award	55	444
Total liabilities	9,451	6,813
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 24,479,646 shares issued and outstanding at June 30, 2022; and 24,457,838 and 24,455,390 shares issued and outstanding at December 31, 2021, respectively	3	3
Additional paid-in capital	234,062	231,902
Accumulated deficit	(110,076)	(84,728)
Accumulated other comprehensive income	168	34
Total stockholders' equity	124,157	147,211
Total liabilities and stockholders' equity	\$ 133,608	\$ 154,024

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 8,132	\$ 6,279	\$ 17,410	\$ 11,751
General and administrative	4,299	2,949	8,036	4,691
Total operating expenses	<u>12,431</u>	<u>9,228</u>	<u>25,446</u>	<u>16,442</u>
Loss from operations	(12,431)	(9,228)	(25,446)	(16,442)
Other income	119	12	98	14
Net loss	<u>(12,312)</u>	<u>(9,216)</u>	<u>(25,348)</u>	<u>(16,428)</u>
Unrealized gain on short-term investments	104	5	134	5
Comprehensive loss	<u>\$ (12,208)</u>	<u>\$ (9,211)</u>	<u>\$ (25,214)</u>	<u>\$ (16,423)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.43)</u>	<u>\$ (1.04)</u>	<u>\$ (1.40)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>24,463,824</u>	<u>21,364,369</u>	<u>24,461,085</u>	<u>11,770,948</u>

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (25,348)	\$ (16,428)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,113	1,325
Depreciation and amortization	41	20
Amortization/accretion on short-term investments	(22)	33
Changes in the fair value of performance award	(389)	363
Non-cash lease expense	241	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	905	(2,457)
Accounts payable and accrued expenses	1,726	(1,164)
Operating lease liabilities	(222)	—
Other current and long-term liabilities	—	18
Net cash used in operating activities	<u>(20,955)</u>	<u>(18,290)</u>
Cash flows from investing activities		
Purchases of property and equipment	(68)	(31)
Purchase of available-for-sale short-term investments	(15,922)	(26,989)
Proceeds from maturities of available-for-sale short-term investments	30,500	—
Net cash provided by (used in) investing activities	<u>14,510</u>	<u>(27,020)</u>
Cash flows from financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	—	47,239
Proceeds from initial public offering, net of offering costs	—	84,639
Proceeds from issuance of common stock in connection with equity plans	49	187
Net cash provided by financing activities	<u>49</u>	<u>132,065</u>
Net (decrease) increase in cash and cash equivalents	(6,396)	86,755
Cash and cash equivalents, beginning of period	124,660	53,613
Cash and cash equivalents, end of period	<u>\$ 118,264</u>	<u>\$ 140,368</u>
Noncash operating activities:		
Right-of-use assets obtained in exchange for lease obligations	\$ 1,524	\$ —
Noncash investing and financing activities:		
Property and equipment in accounts payable	\$ —	\$ 10
Accrued deferred initial public offering costs	\$ —	\$ 30

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