

**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): November 08, 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 November 8, 2022, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the third quarter ended September 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 November 8, 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: November 8, 2022

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

Reneo Pharmaceuticals Reports Third Quarter 2022 Financial Results

IRVINE, Calif., November 8, 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 September 30, 2022.

“We continued to advance our REN001 development programs during the third quarter,” said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. “As of today, we have achieved over 80% enrollment in the ongoing pivotal STRIDE study in primary mitochondrial myopathy (PMM) patients with mitochondrial DNA (mtDNA) defects. We remain on track to announce topline data from this study in the fourth quarter of 2023. Moreover, we are pleased that the majority of patients who completed STRIDE are electing to enroll into the long-term STRIDE AHEAD safety study. Furthermore, we announced positive results from the Phase 1b study in long-chain fatty acid oxidation disorders (LC-FAOD) patients with nuclear DNA (nDNA) defects. Finally, we are now in the process of planning both a Phase 2 study in LC-FAOD patients and a study in PMM patients with nDNA defects,” concluded Mr. Flesher.

Third Quarter and Recent Highlights

- Enrolled over 80% of the population in the ongoing pivotal STRIDE study
- Confirmation from U.S. Food and Drug Administration and European Medicines Agency that positive data from the STRIDE and STRIDE AHEAD studies could potentially support registration of REN001 for PMM patients with mtDNA defects
- Announced plans to study REN001 in PMM patients with nDNA defects
- Presentation of Phase 1b study in PMM patients at Mitochondrial Diseases Conference (Rome, Italy)
- Poster presentations of two LC-FAOD studies at the International Network for Fatty Acid Oxidation Research and Management (INFORM) Conference (Freiburg, Germany)
- Announced successful Phase 1b study in LC-FAOD patients with nDNA defects, and plans to move the program forward into Phase 2 development

Anticipated Milestones

- Completion of enrollment in the pivotal STRIDE study in the first quarter of 2023; topline data in the fourth quarter of 2023
- Meetings with regulatory agencies to discuss a Phase 2 study for LC-FAOD patients in the fourth quarter of 2022; update to be provided in the first quarter of 2023
- Update on plans to study REN001 in PMM patients with nDNA defects in the first quarter of 2023

Financial Results for the Three Months Ended September 30, 2022

The Company reported a net loss of \$13.0 million, or \$0.53 per share, for the three months ended September 30, 2022, compared to a net loss of \$12.7 million, or \$0.52 per share, for the three months ended September 30, 2021. The Company had approximately \$116 million in cash, cash equivalents and short-term investments as of September 30, 2022.

Research and development expenses for the three months ended September 30, 2022 were \$9.9 million, compared to \$9.3 million for the three months ended September 30, 2021. This increase of \$0.6 million was primarily due to a \$1.4 million increase in clinical study and manufacturing costs primarily related to the STRIDE study and a \$0.8 million increase in personnel-related costs due to the additional headcount required to support our clinical and manufacturing operations, offset by a \$1.5 million decrease in non-clinical activities.

General and administrative expenses for the three months ended September 30, 2022 were \$3.9 million, compared to \$3.4 million for the three months ended September 30, 2021. This increase of \$0.5 million was primarily attributable to increased costs to operate as a public company, including increases in outside professional services of \$0.8 million offset by a decrease in stock-based compensation of \$0.4 million.

Corporate Access Events

- Jefferies Global Healthcare Conference, Nov 15-17, 2022 (The Waldorf Hilton, London, UK)
- Piper Sandler Healthcare Conference, Nov 29 – Dec 1, 2022 (Lotte New York Palace, New York, NY)
- LifeSci Partners Corporate Access Event, Jan 9-11, 2023 (Beacon Grand Hotel, San Francisco, CA)

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, registration, and commercialization of REN001, results, conduct, progress, plans and timing of Reneo’s clinical studies, completion of enrollment of clinical trials, 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)

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,132	\$ 124,660
Short-term investments	53,948	23,010
Prepaid expenses and other current assets	4,918	6,064
Total current assets	120,998	153,734
Property and equipment, net	241	212
Right-of-use assets	1,186	—
Other non-current assets	79	78
Total assets	\$ 122,504	\$ 154,024
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,189	\$ 2,022
Accrued expenses	6,851	4,180
Operating lease liabilities, current portion	410	—
Total current liabilities	9,450	6,202
Operating lease liabilities, less current portion	943	—
Other long-term liabilities	—	167
Performance award	66	444
Total liabilities	10,459	6,813
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 24,529,646 shares issued and outstanding at September 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	235,151	231,902
Accumulated deficit	(123,083)	(84,728)
Accumulated other comprehensive (loss) income	(26)	34
Total stockholders' equity	112,045	147,211
Total liabilities and stockholders' equity	\$ 122,504	\$ 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 September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 9,938	\$ 9,318	\$ 27,348	\$ 21,069
General and administrative	3,902	3,434	11,938	8,125
Total operating expenses	<u>13,840</u>	<u>12,752</u>	<u>39,286</u>	<u>29,194</u>
Loss from operations	(13,840)	(12,752)	(39,286)	(29,194)
Other income	833	17	931	31
Net loss	<u>(13,007)</u>	<u>(12,735)</u>	<u>(38,355)</u>	<u>(29,163)</u>
Unrealized (loss) gain on short-term investments	(194)	12	(60)	17
Comprehensive loss	<u>\$ (13,201)</u>	<u>\$ (12,723)</u>	<u>\$ (38,415)</u>	<u>\$ (29,146)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.52)</u>	<u>\$ (1.57)</u>	<u>\$ (1.82)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>24,496,313</u>	<u>24,396,798</u>	<u>24,472,974</u>	<u>16,025,813</u>

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (38,355)	\$ (29,163)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,103	2,470
Depreciation and amortization	63	33
Amortization/accretion on short-term investments	(169)	113
Changes in the fair value of performance award	(378)	284
Non-cash lease expense	338	—
Loss on disposal of fixed asset	3	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,146	(3,577)
Accounts payable and accrued expenses	2,838	1,816
Operating lease liabilities	(338)	—
Other current and long-term liabilities	—	62
Net cash used in operating activities	<u>(31,749)</u>	<u>(27,962)</u>
Cash flows from investing activities		
Purchases of property and equipment	(96)	(108)
Purchase of available-for-sale short-term investments	(67,329)	(31,421)
Proceeds from maturities of available-for-sale short-term investments	36,500	—
Net cash used in investing activities	<u>(30,925)</u>	<u>(31,529)</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	—	84,641
Proceeds from issuance of common stock in connection with equity plans	146	407
Net cash provided by financing activities	<u>146</u>	<u>132,287</u>
Net (decrease) increase in cash and cash equivalents	(62,528)	72,796
Cash and cash equivalents, beginning of period	124,660	53,613
Cash and cash equivalents, end of period	<u>\$ 62,132</u>	<u>\$ 126,409</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	\$ —	\$ 56
Vesting of unvested exercised options	\$ —	\$ 19

Contacts:

Joyce Allaire
Managing Director
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com

Danielle Spangler
Investor Relations
Reneo Pharmaceuticals, Inc.
dspangler@reneopharma.com

