
**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 11, 2021

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
(I.R.S. Employer
Identification No.)

18575 Jamboree Road, Suite 275-S,
Irvine, CA
(Address of principal executive offices)

92612
(Zip Code)

Registrant's telephone number, including area code: (858) 283-0280

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 11, 2021, Reneo Pharmaceuticals, Inc. (the “Company”) issued a press release reporting the Company’s financial results for the quarter ended September 30, 2021 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 11, 2021.
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 12, 2021

By: /s/ Gregory J. Flesher

Gregory J. Flesher

Chief Executive Officer

Reneo Pharmaceuticals Reports Third Quarter 2021 Financial Results

Irvine, Calif. November 11, 2021 -- 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, 2021 and provided an update on its clinical programs.

“We continued to make good progress across multiple fronts during the third quarter of 2021,” said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. “We initiated the global PMM Phase 2b study, completed enrollment of the LC-FAOD Phase 1b study, and anticipate completion of enrollment of the LC-FAOD natural history study by year-end 2021. In addition, we expanded our leadership team by making several key hires, including the appointment of Ashley Hall, J.D., as Chief Development Officer. Finally, we strengthened our REN001 patent portfolio with the recent notice of allowance for a key composition of matter patent in the United States,” concluded Mr. Flesher.

Key Operational Highlights

- Initiated enrollment of STRIDE, a global, double-blind, randomized, placebo-controlled Phase 2b trial of REN001 in patients with PMM
- Completed enrollment in REN001-102, an open-label Phase 1b clinical trial in patients with LC-FAOD
- Appointed Ashley Hall as Chief Development Officer to lead nonclinical and clinical operations, global regulatory affairs, pharmaceutical development, and program management
- Received a notice of allowance from the United States Patent and Trademark Office (USPTO) for a composition of matter patent application covering the REN001 drug substance. The patent application is expected to issue as a patent in 2022 and to provide patent protection for REN001 in the United States into 2041.

Financial Results for the Three Months Ended September 30, 2021

The company reported a net loss of \$12.7 million, or \$0.52 per share, for the three months ended September 30, 2021, compared to a net loss of \$5.1 million, or \$2.48 per share, for the same period in 2020. The company had \$157.7 million in cash, cash equivalents and short-term investments as of September 30, 2021.

Research and development expenses for the three months ended September 30, 2021 were \$9.3 million, compared to \$4.4 million for the three months ended September 30, 2020. This increase of \$4.9 million was primarily due to an increase of \$2.1 million related to clinical trial and manufacturing costs associated with the launch of our STRIDE and FORWARD studies as well as the restart of our Phase 1b clinical trials of LC-FAOD and McArdle disease, a \$2.0 million increase in licensing costs and a \$0.7 million increase in employee and personnel related costs due to additional headcount required to support our clinical and CMC programs.

General and administrative expenses for the three months ended September 30, 2021 were \$3.4 million, compared to \$0.7 million during the three months ended September 30, 2020. This increase of \$2.7 million was primarily attributable to an increase of \$1.8 million in employee and personnel related expenses, consisting of \$1.0 million of stock-based compensation and \$0.8 million of employee compensation as a result of increased headcount, an increase of \$0.4 million of directors and officers' insurance premiums following our initial public offering and an increase of \$0.6 million for outside professional services.

Anticipated Upcoming Milestones

- Results of the Phase 1b clinical trial of REN001 in McArdle disease (1Q 2022)
- Results of the Phase 1b clinical trial of REN001 in LC-FAOD (2Q 2022)
- Results of the FORWARD natural history study in LC-FAOD (2Q 2022)

Upcoming Corporate Access Events

- Credit Suisse 30th Annual Healthcare Conference, November 8 - 11, 2021
- Jefferies 12th Annual London Healthcare Conference, November 16 – 19, 2021
- Piper Sandler 33rd Annual Healthcare Conference, November 30 – December 2, 2021

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). Reneo is developing REN001 to modulate genes critical to metabolism and generation of ATP, which is the primary source of energy for cellular processes. 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.

About REN001

REN001 is a potent and selective peroxisome proliferator-activated receptor delta (PPAR δ) agonist currently in clinical development for three rare genetic mitochondrial diseases that typically present with myopathy and have high unmet medical needs: primary mitochondrial myopathies (PMM), long-chain fatty acid oxidation disorders (LC-FAOD), and glycogen storage disorder type V (McArdle disease). For more information on REN001 clinical trials, please see clinicaltrials.gov.

About PMM

PMM are a group of disorders that affect roughly 1 in 5,000 people worldwide. PMM are caused by genetic mutations in the mitochondrial or nuclear DNA that reduce the ability of mitochondria to produce energy from nutrient sources. This energy deficit particularly affects tissues and organs 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 after 24 weeks of treatment. Secondary efficacy endpoints include 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, the regulatory approval path for REN001 and patent issuance and protection matters. 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	SEPTEMBER 30, 2021 (unaudited)	DECEMBER 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 126,409	\$ 53,613
Short-term investments	31,325	—
Prepaid expenses and other current assets	4,931	1,412
Total current assets	162,665	55,025
Property and equipment, net	200	69
Other non-current assets	78	127
Total assets	<u>\$ 162,943</u>	<u>\$ 55,221</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,271	\$ 908
Accrued expenses	5,082	3,672
Total current liabilities	6,353	4,580
Deferred rent	98	36
Performance Award	284	—
Total liabilities	6,735	4,616
Commitments and contingencies		
Series A convertible preferred stock, \$0.0001 par value; zero and 24,302,472 shares authorized at September 30, 2021 and December 31, 2020, respectively; zero and 24,302,472 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively; liquidation preference of \$0 and \$49,127 at September 30, 2021 and December 31, 2020, respectively	—	45,652
Series B convertible preferred stock, \$0.0001 par value; zero and 46,881,028 shares authorized at September 30, 2021 and December 31, 2020, respectively; zero and 23,440,514 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively; liquidation preference of \$0 and \$47,385 as of September 30, 2021 and December 31, 2020, respectively	—	47,068
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value, 10,000,000 and zero shares authorized at September 30, 2021 and December 31, 2020, respectively; zero shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value; 200,000,000 and 105,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 24,417,558 and 24,407,722 shares issued and outstanding at September 30, 2021, respectively and 2,053,070 shares issued and outstanding at December 31, 2020	3	—
Additional paid-in capital	230,309	2,843
Accumulated deficit	(74,121)	(44,958)
Accumulated other comprehensive income	17	—
Total stockholders' equity (deficit)	156,208	(42,115)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 162,943</u>	<u>\$ 55,221</u>

RENEO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share data)

	<u>THREE MONTHS ENDED SEPTEMBER 30,</u>		<u>NINE MONTHS ENDED SEPTEMBER 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Operating expenses:				
Research and development	\$ 9,318	\$ 4,431	\$ 21,069	\$ 10,826
General and administrative	3,434	668	8,125	2,475
Total operating expenses	<u>12,752</u>	<u>5,099</u>	<u>29,194</u>	<u>13,301</u>
Loss from operations	(12,752)	(5,099)	(29,194)	(13,301)
Other income	17	5	31	89
Net loss	(12,735)	(5,094)	(29,163)	(13,212)
Unrealized gain (loss) on short-term investments	12	(4)	17	—
Comprehensive loss	<u>\$ (12,723)</u>	<u>\$ (5,098)</u>	<u>\$ (29,146)</u>	<u>\$ (13,212)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (2.48)</u>	<u>\$ (1.82)</u>	<u>\$ (6.54)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>24,396,798</u>	<u>2,052,838</u>	<u>16,025,813</u>	<u>2,021,031</u>

RENEO PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2021	2020
Cash flows from operating activities		
Net loss	\$ (29,163)	\$ (13,212)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	33	27
Amortization/accretion on short-term investments	113	(17)
Changes in the fair value of performance award	284	—
Stock-based compensation	2,470	264
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses and other	1,816	20
Prepaid expenses and other assets	(3,577)	(203)
Deferred rent	62	(4)
Net cash used in operating activities	<u>(27,962)</u>	<u>(13,125)</u>
Cash flows from investing activities		
Purchases of property and equipment	(108)	(8)
Purchase of available-for-sale short-term investments	(31,421)	—
Proceeds from maturities of available-for-sale short-term investments	—	7,400
Net cash (used in) provided by investing activities	<u>(31,529)</u>	<u>7,392</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 exercise of stock options	407	77
Net cash provided by financing activities	<u>132,287</u>	<u>77</u>
Net increase (decrease) in cash and cash equivalents	72,796	(5,656)
Cash and cash equivalents, beginning of period	53,613	17,501
Cash and cash equivalents, end of period	<u>\$ 126,409</u>	<u>\$ 11,845</u>
Supplemental cash flow information:		
Vesting of unvested exercised options	\$ 19	\$ —
Property and equipment in accounts payable	\$ 56	\$ —

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