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 23, 2022

Reneo Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40315**	**47-2309515**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

18575 Jamboree Road, Suite 275-S, Irvine, California	**92612**
(Address of principal executive offices)	(Zip Code)

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

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 23, 2022, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the fourth quarter and year ended December 31, 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 March 23, 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: March 23, 2022

By:/s/ Gregory J. Flesher
Gregory J. Flesher
Chief Executive Officer

Exhibit 99.1

Reneo Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

Irvine, Calif. March 23, 2022 -- 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, 2021 and provided a business update.

2021 Highlights

- Raised gross proceeds of $94 million in an initial public offering (IPO); cash runway sufficient to fund planned operations into 2024
- Fast Track Designation granted in the U.S. for REN001 in primary mitochondrial myopathy (PMM)
- Initiated enrollment of STRIDE, a global, double-blind, randomized, placebo-controlled Phase 2b clinical trial of REN001 in patients with PMM
- Initiated STRIDE AHEAD, an open-label extension safety trial of REN001 in patients with PMM
- Completed enrollment of open-label Phase 1b clinical trials in patients with McArdle disease and patients with long-chain fatty acid oxidation disorders (LC-FAOD), as well as the FORWARD natural history study in patients with LC-FAOD
- Received a notice of allowance from the U.S. Patent and Trademark Office for a composition of matter patent, which provides exclusivity for REN001 in the U.S. into 2041
- Appointed Ashley Hall, J.D. as Chief Development Officer and Eric Dube, Ph.D., President & CEO of Travere Therapeutics, to the Board of Directors

“2021 was a transformational year for Reneo, highlighted by our debut as a public company and the significant progress we made on our REN001 clinical programs,” said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. “Despite the persistent challenges associated with the global COVID-19 pandemic, we made good progress with enrollment of our pivotal PMM study and completed enrollment of three other clinical studies, including the exploratory Phase 1b trials in McArdle disease and LC-FAOD. Furthermore, we expanded our intellectual property portfolio in the U.S. and strengthened our rare disease capabilities by making key additions to the Executive Team and the Board of Directors. Finally, we ended the year with approximately $147 million in cash and investments which will fund the company through the completion of our pivotal PMM study and into 2024.”

Clinical Update

PMM Program

- Completed analysis of muscle biopsies from the PMM Phase 1b study which showed an increase in the expression of genes involved with the transport and metabolism of nutrients in the mitochondria
- The STRIDE study is currently enrolling patients at 33 trials sites in 13 countries
- Completion of STRIDE enrollment is anticipated by year-end 2022, with data in 2023

LC-FAOD Program

- 21 patients were enrolled in the 12-week open-label LC-FAOD Phase 1b study
- 61 patients were enrolled in the 4-month FORWARD study

- Results of both LC-FAOD studies anticipated in 2Q 2022

McArdle Disease Program

- 17 patients were enrolled in the 12-week open-label McArdle Phase 1b study
- REN001 was generally well tolerated with no drug related serious adverse events observed
- The most common treatment-emergent adverse events were headache, influenza, and increased creatine phosphokinase, the majority reported to be mild in severity
- Baseline 12-minute shuttle walk test (12MSWT) distance was 933 meters
- An increase of 25 meters in the 12MSWT was observed at week 12, with no corresponding change in heart rate, fatigue, or pain
- An increase of 38.5% in fat oxidation as measured by indirect calorimetry was observed at week 12
- Based on the results, Reneo does not intend to pursue a subsequent Phase 2 study in McArdle Disease

Mr. Flesher continued, “We are pleased to see good safety and tolerability of REN001 in McArdle patients, as well as the substantial increase in fatty acid oxidation, a finding that is consistent with our prior clinical experience and encouraging as it relates to the ongoing PMM program. We also saw a modest increase in walk distance, but did not see a corresponding reduction in the common symptoms that McArdle patients experience. Given these findings, we will focus REN001 development on PMM and LC-FAOD, and will continue to explore other diseases that are defined by the impairment of mitochondria to produce cellular energy. We are grateful to the patients, families, and caregivers who made this study in McArdle disease possible,” concluded Mr. Flesher.

Financial Results for Fourth Quarter and Full Year 2021

The company reported a net loss of $10.6 million, or $0.43 per share, during the fourth quarter of 2021, compared to a net loss of $6.3 million, or $3.05 per share, for the same period in 2020. For the full year 2021, Reneo reported a net loss of $39.8 million, or $2.19 per share, compared to a net loss of $19.5 million, or $9.60 per share for the same period in 2020. The company had $147.7 million in cash, cash equivalents and short-term investments as of December 31, 2021.

Research and development (R&D) expenses were $7.1 million during the fourth quarter of 2021, compared to $5.1 million for the same period in 2020. For the full year 2021, R&D expenses were $28.2 million, compared to $15.9 million for the same period in 2020. The increase in R&D expense for 2021 was primarily due to an increase of $5.7 million related to clinical and manufacturing activities for REN001, $3.0 million in personnel related costs due to support growth in its development activities, and $2.0 million in milestone costs under the vTv Therapeutics License Agreement, offset by a $1.5 million tax rebate received in 2020 from the U.K. government for qualifying research expense incurred in the U.K.

General and administrative (G&A) expenses were $3.5 million during the fourth quarter of 2021, compared to $1.1 million for the same period in 2020. For the full year 2021, G&A expenses were $11.6 million, compared to $3.6 million for the same period in 2020. The increase in G&A expenses for 2021 was primarily as a result of its IPO in April 2021 and increased operating activities necessary to operate as a public company, which consisted of increases in personnel-related expenses of $5.1 million, insurance premiums of $1.1 million, and outside professional services of $1.3 million.

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 (PPARδ). 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 (PPARδ) 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.

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 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 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 par value and share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 124,660	$ 53,613
Short-term investments	23,010	—
Prepaid expenses and other current assets	6,064	1,412
Total current assets	153,734	55,025
Property and equipment, net	212	69
Other non-current assets	78	127
Total assets	$ 154,024	$ 55,221
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,022	$ 908
Accrued expenses	4,180	3,672
Total current liabilities	6,202	4,580
Deferred rent	167	36
Performance award	444	—
Total liabilities	6,813	4,616
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value; zero and 24,302,472 shares authorized and outstanding at December 31, 2021 and 2020, respectively; liquidation preference of $0 and $49,127 at December 31, 2021 and 2020, respectively	—	45,652
Series B convertible preferred stock, $0.0001 par value; zero and 46,881,028 shares authorized at December 31, 2021 and 2020, respectively; zero and 23,440,514 shares issued and outstanding at December 31, 2021 and 2020, respectively; liquidation preference of $0 and $47,385 as of December 31, 2021 and 2020, respectively	—	47,068
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 and 105,000,000 shares authorized at December 31, 2021 and 2020, respectively; 24,457,838 and 24,455,390 shares issued and outstanding at December 31, 2021, respectively; and 2,053,070 shares issued and outstanding at December 31, 2020	3	—
Additional paid-in capital	231,902	2,843
Accumulated deficit	(84,728)	(44,958)
Accumulated other comprehensive income	34	—
Total stockholders' equity (deficit)	147,211	(42,115)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 154,024	$ 55,221

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,	
	2021	2020	2021	2020
	(unaudited)			
Operating expenses:				
Research and development	$ 7,100	$ 5,118	$ 28,169	$ 15,944
General and administrative	3,524	1,133	11,649	3,608
Total operating expenses	10,624	6,251	39,818	19,552
Loss from operations	(10,624)	(6,251)	(39,818)	(19,552)
Other income (loss)	17	(2)	48	87
Net loss	(10,607)	(6,253)	(39,770)	(19,465)
Unrealized gain (loss) on short-term investments	17	(3)	34	(3)
Comprehensive loss	$ (10,590)	$ (6,256)	$ (39,736)	$ (19,468)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (3.05)	$ (2.19)	$ (9.60)
Weighted-average shares used in computing net loss per share, basic and diluted	24,427,455	2,049,550	18,143,487	2,028,198

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

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (39,770)	$ (19,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	50	37
Amortization/accretion on short-term investments	202	(17)
Changes in the fair value of performance award	444	—
Loss on disposal of property, plant & equipment	—	2
Stock-based compensation	3,891	393
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses and other	1,780	1,486
Prepaid expenses and other assets	(4,711)	(967)
Deferred rent	131	(5)
Net cash used in operating activities	(37,983)	(18,536)
Cash flows from investing activities		
Purchases of property and equipment	(198)	(24)
Purchase of available-for-sale short-term investments	(31,406)	—
Proceeds from maturities of available-for-sale short-term investments	8,228	7,400
Net cash (used in) provided by investing activities	(23,376)	7,376
Cash flows from financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	47,238	47,185
Proceeds from initial public offering, net of offering costs	84,612	—
Proceeds from issuance of common stock pursuant to equity award plans	556	87
Net cash provided by financing activities	132,406	47,272
Effect of exchange rates on cash and cash equivalents		—
Net increase in cash and cash equivalents	71,047	36,112
Cash and cash equivalents, beginning of period	53,613	17,501
Cash and cash equivalents, end of period	$ 124,660	$ 53,613
Supplemental cash flow information:		
Vesting of unvested exercised options	$ 4	$ —
Unpaid Series B convertible preferred stock issuance costs	$ —	$ 117
Costs incurred in connection with initial public offering included in accrued expenses	$ —	$ 33
Property and equipment in accounts payable	$ —	$ 5

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