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):
May 20, 2021

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.)**

12230 El Camino Real, Suite 230	
San Diego, California	**92130**
(Address of principal executive offices)	**(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 May 20, 2021, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the quarter ended March 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 May 20, 2021.
104	Cover Page Interactive Data File - The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are 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: May 20, 2021

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

Reneo Pharmaceuticals Reports First Quarter 2021 Financial Results

SAN DIEGO, May 20, 2021 -- Reneo Pharmaceuticals, Inc., 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, 2021 and provided an update on its clinical programs.

Key Operational Highlights

- Initiated the STRIDE study, a global, randomized, double-blind, placebo-controlled Phase 2b clinical trial of REN001 in patients with primary mitochondrial myopathies (PMM)
- Completed an initial public offering (IPO) of the company's common stock for total gross proceeds of approximately $94 million, before deducting underwriting discounts and commissions and offering expenses
- Re-initiated enrollment of two open-label Phase 1b clinical trials in patients with long-chain fatty acid oxidation disorder (LC-FAOD) and in patients with glycogen storage disease type V (McArdle disease)
- Initiated an observational clinical trial in patients with LC-FAOD to better understand changes in disease characteristics over time ("FORWARD" study)
- Appointed Eric Dube, Ph.D. to the Board of Directors and Vineet R. Jindal as Chief Financial Officer

Anticipated Upcoming Milestones

- Enrollment of first patient in the STRIDE study (mid-year 2021)
- Complete enrollment of Phase 1b trials in LC-FAOD and McArdle disease (2H 2021)
- Report results from Phase 1b clinical trials in LC-FAOD and McArdle disease (1H 2022)
- Report results from the FORWARD study (2H 2022)

"Our team's recent efforts have led to the initiation of four clinical trials, key additions to the Board and management team, and the completion of our initial public offering," said Gregory J. Flesher, President and Chief Executive Officer of Reneo. "With a strengthened capital position, we will continue to advance all of our REN001 clinical programs, as well as explore additional opportunities that will help establish Reneo Pharmaceuticals as a leading developer of drugs for rare diseases."

Financial Results for the Three Months Ended March 31, 2021

The company reported a net loss of $7.2 million, or $3.48 per share, for the three months ended March 31, 2021, compared to a net loss of $4.4 million, or $2.20 per share, for the same period in 2020. The company had $91.2 million in cash and cash equivalents as of March 31, 2021, exclusive of the net proceeds of approximately $84.8 million from the IPO.

Research and development (R&D) expenses were $5.5 million for the three months ended March 31, 2021, compared to $3.6 million for the same period in 2020. The increase of $1.9 million was primarily due to an increase of $1.5 million related to clinical trial costs associated with the launch of our STRIDE and FORWARD studies and $0.4 million in employee and personnel related costs due to additional headcount required to support our clinical and CMC programs.

General and administrative (G&A) expenses for the three months ended March 31, 2021 were $1.7 million, compared to $0.9 million for the same period in 2020. This increase of $0.8 million was primarily attributable to an increase of $0.8 million in employee and personnel related expenses.

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 (PPARδ) 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, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except share and par value data)

	MARCH 31, 2021	DECEMBER 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 91,221	$ 53,613
Prepaid expenses and other current assets	2,339	1,412
Total current assets	93,560	55,025
Property and equipment, net	81	69
Other non-current assets	1,680	127
Total assets	$ 95,321	$ 55,221
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 556	$ 908
Accrued expenses	3,374	3,672
Total current liabilities	3,930	4,580
Deferred rent	32	36
Total liabilities	3,962	4,616
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value; 24,302,472 shares authorized at March 31, 2021 and December 31, 2020; 24,302,472 shares issued and outstanding at March 31, 2021 and December 31, 2020, liquidation preference of $49,127 at March 31, 2021 and December 31, 2020	45,652	45,652
Series B convertible preferred stock, $0.0001 par value; 46,881,028 shares authorized at March 31, 2021 and December 31, 2020; 46,881,028 and 23,440,514 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively; liquidation preference of $94,770 and $47,385 as of March 31, 2021 and December 31, 2020, respectively	94,424	47,068
Stockholders' deficit:		
Common stock, $0.0001 par value; 105,000,000 shares authorized at March 31, 2021 and December 31, 2020, 2,148,193 issued and 2,123,733 outstanding at March 31, 2021 and 2,053,070 shares issued and outstanding at December 31, 2020, respectively	—	—
Additional paid-in capital	3,453	2,843
Accumulated deficit	(52,170)	(44,958)
Total stockholders' deficit	(48,717)	(42,115)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 95,321	$ 55,221

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

	THREE MONTHS ENDED MARCH 31,	
	2021	2020
Operating expenses:		
Research and development	$ 5,472	$ 3,578
General and administrative	1,742	924
Total operating expenses	7,214	4,502
Loss from operations	(7,214)	(4,502)
Other income	2	71
Net loss	(7,212)	(4,431)
Unrealized gain on short-term investments	—	6
Comprehensive loss	$ (7,212)	$ (4,425)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.48)	$ (2.20)
Weighted-average shares used in computing net loss per share, basic and diluted	2,070,935	2,015,029

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

	THREE MONTHS ENDED MARCH 31,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (7,212)	$ (4,431)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10	9
Amortization/accretion on short-term investments	—	(15)
Stock-based compensation	471	92
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses and other	(927)	36
Prepaid expenses and other assets	(929)	(137)
Deferred rent	(2)	(1)
Net cash used in operating activities	(8,589)	(4,447)
Cash flows from investing activities		
Purchase of property and equipment	(25)	(1)
Proceeds from maturities of available-for-sale short-term investments	—	5,200
Net cash (used in) provided by investing activities	(25)	5,199
Cash flows from financing activities		
Proceeds from issuance of Series B convertible preferred stock, net of issuance costs	47,258	—
Proceeds from exercise of stock options	187	26
Costs paid in connection with initial public offering	(1,223)	—
Net cash provided by financing activities	46,222	26
Net increase in cash and cash equivalents	37,608	778
Cash and cash equivalents, beginning of period	53,613	17,501
Cash and cash equivalents, end of period	$ 91,221	$ 18,279
Supplemental cash flow information:		
Property and equipment in accounts payable	$ 2	$ —
Unpaid Series B convertible preferred stock issuance costs	$ 19	$ —
Costs incurred in connection with initial public offering included in accrued expenses	$ 361	$ —

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