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 11, 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.)**

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

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

12230 El Camino Real, Suite 230, San Diego, California 92130
(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 11, 2021, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the quarter ended June 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 August 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: August 11, 2021

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

Exhibit 99.1

Reneo Pharmaceuticals Reports Second Quarter 2021 Financial Results

First patient dosed in STRIDE study of REN001 in primary mitochondrial myopathies

Irvine, August 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 June 30, 2021 and provided an update on its clinical programs.

"The second quarter of 2021 was highly productive for the Reneo team as we launched the international STRIDE study, completed enrollment of the McArdle disease study, and made substantial progress in our long-chain fatty acid oxidation disorders studies," said Gregory J. Flesher, President and Chief Executive Officer of Reneo Pharmaceuticals. "In addition, we completed our initial public offering, and now have sufficient capital to fund operations through all of our planned near-term clinical milestones."

Key Operational Highlights

- Dosed the first patient in the STRIDE study, a global, randomized, double-blind, placebo-controlled Phase 2b clinical trial of REN001 in patients with primary mitochondrial myopathies (PMM)
- Completed enrollment of study REN001-103, an open-label Phase 1b clinical trial in patients with glycogen storage disease type V (McArdle disease)
- Dosed 20 patients to date in study REN001-102, an open-label Phase 1b clinical trial in patients with long-chain fatty acid oxidation disorder (LC-FAOD)
- Enrolled 18 patients to date in the FORWARD study, an observational clinical trial in patients with LC-FAOD
- The company was added to the Russell 2000® and Russell 3000® Indices

Financial Results for the Three Months Ended June 30, 2021

The company reported a net loss of $9.2 million, or $0.43 per share, for the three months ended June 30, 2021, compared to a net loss of $3.7 million, or $1.82 per share, for the same period in 2020. The company had $167.3 million in cash, cash equivalents and short-term investments as of June 30, 2021.

Research and development expenses for the three months ended June 30, 2021 were $6.3 million, compared to $2.8 million for the three months ended June 30, 2020. This increase of $3.5 million in research and development expenses was primarily due to an increase of $2.3 million related to clinical trial 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 and $0.4 million in employee and personnel related costs due to additional headcount required to support our clinical and CMC programs, offset by a $0.7 million decrease in expense related to completion of preclinical studies. The net increase was further offset by a reduction in credits to research and development expenses related to tax rebates paid in cash by the United Kingdom government, as the Company did not receive a credit in the three months ended June 30, 2021 but received a $1.5 million tax rebate in the three months ended June 30, 2020.

General and administrative expenses for the three months ended June 30, 2021, were $2.9 million, compared to $0.9 million during the three months ended June 30, 2020. This increase of $2.0 million was primarily attributable to an increase of $1.0 million in employee and personnel related expenses, an increase of $0.4 million of directors and officers insurance premiums following our IPO, an increase of $0.4 million of compensation charge related to a stock-based performance award, and a net increase of $0.2 million of various other expense items.

Anticipated Upcoming Milestones

- Results from the Phase 1b clinical trial in McArdle disease (1Q 2022)
- Results from the Phase 1b clinical trial in LC-FAOD (1H 2022)
- Results from the FORWARD study (2H 2022)

Corporate Access Events

- Citi's 16th Annual BioPharma Conference, September 8-10, 2021
- H.C. Wainwright 23rd Annual Global Investment Conference, September 13-15, 2021
- Baird Global Healthcare Conference, September 14-15, 2021
- SVB Leerink Neuromuscular, Rare Diseases & Genetic Medicines Event, September 22-23, 2021
- Cantor Global Healthcare Conference, September 27-30, 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 (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, the regulatory approval path for REN001 and uses of capital. 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)

	JUNE 30, 2021	DECEMBER 31, 2020
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 140,368	$ 53,613
Short-term investments	26,963	—
Prepaid expenses and other current assets	3,810	1,412
Total current assets	171,141	55,025
Property and equipment, net	85	69
Other non-current assets	78	127
Total assets	$ 171,304	$ 55,221
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 434	$ 908
Accrued expenses	2,902	3,672
Total current liabilities	3,336	4,580
Deferred rent	54	36
Performance Award	363	—
Total liabilities	3,753	4,616
Commitments and contingencies		
Series A convertible preferred stock, $0.0001 par value; zero and 24,302,472 shares authorized at June 30, 2021 and December 31, 2020, respectively; zero and 24,302,472 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively; liquidation preference of $0 and $49,127 at June 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 June 30, 2021 and December 31, 2020, respectively; zero and 23,440,514 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively; liquidation preference of $0 and $47,385 as of June 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 June 30, 2021 and December 31, 2020, respectively; zero shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 and 105,000,000 shares authorized at June 30, 2021 and December 31, 2020, respectively; 24,305,822 and 24,288,699 shares issued and outstanding at June 30, 2021, respectively and 2,053,070 shares issued and outstanding at December 31, 2020	3	—
Additional paid-in capital	228,929	2,843
Accumulated deficit	(61,386)	(44,958)
Accumulated other comprehensive income	5	—
Total stockholders' equity (deficit)	167,551	(42,115)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 171,304	$ 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 JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 6,279	$ 2,817	$ 11,751	$ 6,395
General and administrative	2,949	882	4,691	1,807
Total operating expenses	9,228	3,699	16,442	8,202
Loss from operations	(9,228)	(3,699)	(16,442)	(8,202)
Other income	12	12	14	84
Net loss	(9,216)	(3,687)	(16,428)	(8,118)
Unrealized gain (loss) on short-term investments	5	(6)	5	1
Comprehensive loss	$ (9,211)	$ (3,693)	$ (16,423)	$ (8,117)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (1.82)	$ (1.40)	$ (4.02)
Weighted-average shares used in computing net loss per share, basic and diluted	21,364,369	2,022,174	11,770,948	2,018,602

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

	SIX MONTHS ENDED JUNE 30,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (16,428)	$ (8,118)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20	18
Amortization/accretion on short-term investments	33	(16)
Changes in the fair value of Performance Award	363	—
Stock-based compensation	1,325	180
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses and other	(1,164)	934
Prepaid expenses and other assets	(2,457)	(380)
Deferred rent	18	(2)
Net cash used in operating activities	(18,290)	(7,384)
Cash flows from investing activities		
Purchases of property and equipment	(31)	(1)
Purchase of available-for-sale short-term investments	(26,989)	—
Proceeds from maturities of available-for-sale short-term investments	—	6,200
Net cash (used in) provided by investing activities	(27,020)	6,199
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 exercise of stock options	187	26
Net cash provided by financing activities	132,065	26
Net increase (decrease) in cash and cash equivalents	86,755	(1,159)
Cash and cash equivalents, beginning of period	53,613	17,501
Cash and cash equivalents, end of period	$ 140,368	$ 16,342
Supplemental cash flow information:		
Property and equipment in accounts payable	$ 10	$ —
Costs incurred in connection with initial public offering included in accrued expenses	$ 30	$ —

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