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 13, 2023

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)**	**(IRS 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

(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 13, 2023, Reneo Pharmaceuticals, Inc. (the "Company") issued a press release reporting the Company's financial results for the third quarter ended September 30, 2023 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 13, 2023.
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 13, 2023

By: /s/ Gregory J. Flesher

Gregory J. Flesher
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 99.1

Reneo Pharmaceuticals Reports Third Quarter 2023 Financial Results

Topline data results from the pivotal STRIDE study are expected in December 2023

IRVINE, Calif., November 13, 2023 (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 third quarter ended September 30, 2023 and provided a business update.

“We are looking forward to sharing topline results of our pivotal STRIDE study in December,” said Gregory J. Flesher, President and CEO of Reneo Pharmaceuticals. “In addition, we continue to be encouraged by the high participation rate in our STRIDE AHEAD open-label extension study, and are happy to announce enrollment of our first patient with PMM due to nuclear DNA defect in this ongoing trial. This is a very exciting time for the Reneo team and we want to thank our clinicians, patients, and stakeholders for supporting the mavodelpar development program.”

Third Quarter and Recent Highlights

- Completed last patient last visit in the pivotal STRIDE study in adult patients with primary mitochondrial myopathies (PMM) due to mitochondrial DNA (mtDNA) defects; topline results expected in December 2023
- Enrolled 88% of eligible STRIDE study patients in the STRIDE AHEAD open-label extension study; 65 patients treated beyond 52-weeks
- Dosed the first patient with PMM due to a nuclear DNA (nDNA) defect in the STRIDE AHEAD open-label extension study
- Presented multiple posters at scientific conferences highlighting additional mavodelpar data
- Received Notice of Allowance from the U.S. Patent and Trademark Office for patent application No. 18/101,527 entitled “Use of PPAR-Delta Agonists in the Treatment of Disease,” with anticipated expiration in 2041
- Repurchased 576,443 shares of our common stock for an aggregate purchase price of approximately $4.4 million directly from vTv Therapeutics, LLC in a private, non-underwritten transaction on October 30, 2023; all repurchased shares were retired

Financial Results for the Three Months Ended September 30, 2023

We reported a net loss of $19.2 million, or $0.57 per share, during the third quarter of 2023, compared to a net loss of $13.0 million, or $0.53 per share, for the same period in 2022. We had $125.6 million in

cash, cash equivalents, and short-term investments as of September 30, 2023.

Research and development (R&D) expenses were $13.6 million during the third quarter of 2023, compared to $9.9 million for the same period in 2022. This increase in R&D expenses was primarily due to an increase of $2.2 million related to clinical development and contract manufacturing costs to support the marketing registration for mavodelpar, an increase of $1.0 million in medical affairs costs, and an increase of $0.9 million in personnel-related costs due to additional headcount, offset by a decrease of $0.5 million of other R&D activities.

General and administrative (G&A) expenses were $7.3 million during the third quarter of 2023, compared to $3.9 million for the same period in 2022. This increase in G&A expenses was primarily due to an increase of $2.1 million in commercial development activities and an increase of $1.2 million in facility and personnel-related costs due to additional headcount.

About STRIDE

The STRIDE study is a global, randomized, double-blind, placebo-controlled pivotal Phase 2b trial of mavodelpar in adult patients with PMM due to mtDNA defects. The study is designed to investigate the efficacy and safety of 100 mg mavodelpar administered once-daily over a 24-week period. The primary efficacy endpoint of the trial is the change from baseline in the distance walked during the 12-minute walk test (12MWT) at week 24. Secondary and exploratory endpoints include changes from baseline in PROMIS® Short Form Fatigue 13a, Modified Fatigue Impact Scale (MFIS), Patient Global Impression of Change (PGIC), Patient Global Impression of Severity (PGIS), 30 Second Sit-To-Stand (30STS) Test, Brief Pain Inventory (BPI), 36-Item Health Survey (SF-36), Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP), and Pedometer Step Count.

About STRIDE AHEAD

The STRIDE AHEAD study is an open-label extension (OLE) trial being conducted outside of the United States in patients with PMM due to mtDNA defects who participated in the STRIDE study or the mavodelpar Phase 1b study. The study is designed to evaluate the long-term safety and tolerability of 100 mg mavodelpar administered once-daily over a 24-month period. STRIDE AHEAD was amended to allow enrollment of treatment naïve patients with PMM due to nDNA defects.

About PMM

PMM are a group of rare, genetic metabolic disorders caused by mutations or deletions in the mtDNA or nDNA. 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, 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 Mavodelpar

Mavodelpar (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: PMM and long-chain fatty acid oxidation disorder. For additional information, please see clinicaltrials.gov.

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, mavodelpar (REN001), is a potent and selective agonist of the peroxisome proliferator-activated receptor delta (PPARδ). Mavodelpar has been shown to increase transcription of genes involved in mitochondrial function, increase fatty acid oxidation, and may increase production of new mitochondria. For additional information, please see reneopharma.com.

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 mavodelpar, the timing of topline results from the STRIDE study and the anticipated expiration for patent applications. 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, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 11,737	$ 19,927
Short-term investments	113,877	81,246
Prepaid expenses and other current assets	3,158	5,180
Total current assets	128,772	106,353
Property and equipment, net	529	453
Right-of-use assets	1,006	1,292
Other non-current assets	81	84
Total assets	$ 130,388	$ 108,182
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,473	$ 1,893
Accrued expenses	10,765	4,827
Operating lease liabilities, current portion	325	404
Total current liabilities	13,563	7,124
Operating lease liabilities, less current portion	812	1,059
Performance award	1,069	29
Total liabilities	15,444	8,212
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 33,872,166 and 24,699,553 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	3	3
Additional paid-in capital	305,479	236,693
Accumulated deficit	(190,517)	(136,683)
Accumulated other comprehensive loss	(21)	(43)
Total stockholders' equity	114,944	99,970
Total liabilities and stockholders' equity	$ 130,388	$ 108,182

RENEO PHARMACEUTICALS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,622	$ 9,938	$ 39,009	$ 27,348
General and administrative	7,266	3,902	19,038	11,938
Total operating expenses	20,888	13,840	58,047	39,286
Loss from operations	(20,888)	(13,840)	(58,047)	(39,286)
Other income	1,692	833	4,213	931
Net loss	(19,196)	(13,007)	(53,834)	(38,355)
Unrealized gain (loss) on short-term investments	10	(194)	22	(60)
Comprehensive loss	$ (19,186)	$ (13,201)	$ (53,812)	$ (38,415)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.53)	$ (1.81)	$ (1.57)
Weighted-average shares used in computing net loss per share, basic and diluted	33,807,945	24,496,313	29,718,689	24,472,974

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (53,834)	$ (38,355)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,793	3,103
Depreciation and amortization	126	63
Amortization/accretion on short-term investments	(3,551)	(169)
Changes in the fair value of performance award	1,040	(378)
Non-cash lease expense	354	338
Loss on disposal of fixed asset	5	3
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,025	1,146
Accounts payable and accrued expenses	6,507	2,838
Operating lease liabilities	(394)	(338)
Net cash used in operating activities	(43,929)	(31,749)
Cash flows from investing activities		
Purchases of property and equipment	(196)	(96)
Purchase of available-for-sale short-term investments	(190,058)	(67,329)
Proceeds from maturities of available-for-sale short-term investments	161,000	36,500
Net cash used in by investing activities	(29,254)	(30,925)
Cash flows from financing activities		
Proceeds from public offering of common stock, net of offering costs	58,862	—
Proceeds from private placement of common stock, net of offering costs	4,667	—
Proceeds from issuance of common stock under the at-the-market facility, net of offering costs	1,009	—
Proceeds from issuance of common stock in connection with equity plans	455	146
Net cash provided by financing activities	64,993	146
Net decrease in cash and cash equivalents	(8,190)	(62,528)
Cash and cash equivalents, beginning of period	19,927	124,660
Cash and cash equivalents, end of period	$ 11,737	$ 62,132
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	$ 11	$ —

Contacts:

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

Matthew Purcell
Media Inquiries
Russo Partners, LLC
matthew.purcell@russopartnersllc.com