

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 14, 2023

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  
(IRS Employer  
Identification No.)

18575 Jamboree Road, Suite 275-S  
Irvine, California  
(Address of Principal Executive Offices)

92612  
(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 8.01 Other Events.**

On March 14, 2023, Reneo Pharmaceuticals, Inc. (the “Company”) announced the achievement of the target enrollment of its STRIDE study. The STRIDE study is a global, randomized, double-blind, placebo-controlled pivotal Phase 2b trial of mavodelpar in adult patients with primary mitochondrial myopathies (“PMM”) due to mitochondrial DNA (“mtDNA”) defects. The STRIDE study is designed to assess the efficacy and safety of 100 mg mavodelpar administered orally, once daily for 24 weeks. The primary efficacy endpoint is the change from baseline in the distance walked during the 12-minute walk test at week 24. Topline data from the STRIDE study are expected in the fourth quarter of 2023.

STRIDE AHEAD is a 24-month, open-label, long-term safety trial outside of the United States in patients with PMM. The STRIDE AHEAD study was recently amended to allow enrollment of patients with PMM due to both mtDNA and nuclear DNA defects.

The Company intends to submit the data from STRIDE, together with the long-term safety data from STRIDE AHEAD, to the U.S. Food and Drug Administration and the European Medicines Agency in planned marketing applications in 2024.

### **Forward-Looking Statements**

Statements contained in this Current Report on Form 8-K 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 completion of enrollment of clinical trials, announcement of topline data from the STRIDE study, and the submission of marketing 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 the Company’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 the Company’s business in general, and the other risks described in the Company’s filings with the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company 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.

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**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 14, 2023

By: /s/ Gregory J. Flesher  
Gregory J. Flesher  
President and Chief Executive Officer  
(Principal Executive Officer)

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