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): April 28, 2022

PRAXIS PRECISION MEDICINES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-39620 (Commission File Number) 47-5195942 (I.R.S. Employer Identification No.)

Praxis Precision Medicines, Inc. 99 High Street, 30th Floor Boston, Massachusetts 02110 (Address of principal executive offices, including zip code)

(617) 300-8460 (Registrant's telephone number, including area code)

Not Applicable

(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:

	Trade	Name of each exchange
Title of each class	<u>Symbol(s)</u>	on which registered
Common Stock, \$0.0001 par value per share	PRAX	The Nasdaq Global Select Market

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 \Box

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. \Box

Item 8.01. Other Events.

On April 28, 2022, Praxis Precision Medicines, Inc. (the "Company") received an email communication from the U.S. Food and Drug Administration (the "FDA") that the Company's Investigational New Drug application for the study of PRAX-222, an antisense oligonucleotide for the treatment of patients with SCN2A gain-of-function mutations, was placed on clinical hold. The clinical hold letter detailing the reasons for the hold is expected to be received from the FDA within 30 days of April 28, 2022.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the timing of receipt of additional details for the clinical hold of the PRAX-222 study from the FDA. The forward-looking statements included in this Current Report on Form 8-K are subject to a number of risks, uncertainties and assumptions, including, without limitation, the expected timing of review by governmental authorities. These statements are based only on facts currently known by the Company and speak only as of the date of this Current Report on Form 8-K. As a result, you are cautioned not to rely on these forward-looking statements and the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

SIGNATURE

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.

Date: April 29, 2022

By: /s/ Marcio Souza

> Marcio Souza Chief Executive Officer

PRAXIS PRECISION MEDICINES, INC.