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 6, 2020

PRAXIS PRECISION MEDICINES, INC.
(Exact name of registrant as specified in its charter)

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

Praxis Precision Medicines, Inc.
One Broadway, 16th Floor
Cambridge, Massachusetts 02142
(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:

Title of each class	Trade Symbol(s)	Name of each exchange 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 ☒

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 7.01. Regulation FD Disclosure.

On November 6, 2020, Praxis Precision Medicines, Inc. (the "Company") received an email notification from the U.S. Food and Drug Administration that the Company's Investigational New Drug submission for its Phase 2/3 trial of PRAX-114 was placed on clinical hold. A copy of this correspondence is attached hereto and furnished as Exhibit 99.1, and it has been redacted to remove personal identifiable information.

The information in this Item 7.01 of this Form 8-K and Exhibit 99.1 attached hereto shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall any of it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On November 9, 2020, the Company issued a press release titled "Praxis Precision Medicines Provides Regulatory Update on PRAX-114 Program." A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Email Correspondence between the U.S. Food and Drug Administration and Praxis Precision Medicines, Inc., dated November 6, 2020
99.2	Press Release, dated November 9, 2020

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.

PRAXIS PRECISION MEDICINES, INC.

Date: November 9, 2020

By: /s/ Marcio Souza
Marcio Souza
Chief Executive Officer

Exhibit 99.1

From: [redacted]@fda.hhs.gov>
Sent: Friday, November 6, 2020 2:23 PM
To: [redacted]@praxismedicines.com>
Subject: IND 145451

Hello [redacted],

This email is in reference to your IND 145451 dated October 8, 2020 for PRAX-114.

This email serves to inform you that we have reviewed your submission and your study has been placed on a **full clinical hold**.

All Hold and Non-hold comments will be communicated to you in next 30 days via formal correspondence.

Thanks,
[redacted]

[redacted]

Division of Psychiatry
Center for Drug Evaluation & Research
U.S. Food and Drug Administration
[redacted]

Praxis Precision Medicines Provides Regulatory Update On PRAX-114 Program

CAMBRIDGE, Mass., Nov. 9, 2020 (GLOBE NEWSWIRE) – Praxis Precision Medicines, Inc. (NASDAQ: PRAX), a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system disorders characterized by neuronal imbalance, today announced that it has received a response from the U.S. Food and Drug Administration (FDA) on the Investigational New Drug (IND) submission for PRAX-114 for the treatment of major depressive disorder (MDD).

In October 2020, Praxis submitted the IND for PRAX-114 in connection with the initiation of its randomized, placebo-controlled Phase 2/3 clinical trial for PRAX-114 in MDD, as previously discussed with the FDA at a pre-IND meeting earlier this year. At the end of the 30-day IND review period, the FDA notified the Company that the IND has been placed on full clinical hold. The FDA has not provided any reason for the clinical hold. The Company has subsequently been in communication with the FDA, which advised that comments have not been finalized. The Company expects to receive final comments from the FDA within 30 days and intends to work closely with the agency to understand and resolve key issues.

About Praxis

Praxis Precision Medicines is a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system disorders characterized by neuronal imbalance.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the Company's expectations regarding the timing in which it will receive additional communications regarding the clinical hold on its IND submission for PRAX-114 from the FDA. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: ; the timing and outcome of the Company's planned

interactions with regulatory authorities; the timing and anticipated results of our current preclinical studies and future clinical trials, strategy and future operations; the impact of COVID-19 on countries or regions in which we have operations or do business; the delay of any current preclinical studies or future clinical trials or the development of Praxis' drug candidates; the risk that the results of current preclinical studies may not be predictive of future results in connection with future clinical trials; Praxis' ability to successfully demonstrate the safety and efficacy of its drug candidates; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Praxis' final prospectus related to its initial public offering, dated October 20, 2020, as well as discussions of potential risks, uncertainties, and other important factors in Praxis' subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Praxis' views only as of today and should not be relied upon as representing its views as of any subsequent date. Praxis explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Contact:

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