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 17, 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 8.01. Other Events.

On November 17, 2020, Praxis Precision Medicines, Inc. issued a press release titled “Praxis Precision Medicines Provides Update On PRAX-114 IND Submission For The Treatment Of Major Depressive Disorder.” A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 17, 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 17, 2020

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

Exhibit 99.1

Praxis Precision Medicines Provides Update On PRAX-114 IND Submission For The Treatment Of Major Depressive Disorder

- Praxis expects to initiate Phase 2/3 clinical trial for PRAX-114 in MDD in 1H21-

CAMBRIDGE, Mass., Nov. 17, 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 comments from the U.S. Food and Drug Administration (FDA) on the full clinical hold of its Investigational New Drug (IND) submission for PRAX-114 for the treatment of major depressive disorder (MDD).

The IND for PRAX-114 was placed on clinical hold by the FDA pending the resolution of certain non-clinical pharmacology and toxicology matters. In its comment letter, the FDA proposed that the Company conduct further toxicological investigation of the effect of PRAX-114 and its metabolites on fertility, reproduction, and embryofetal development to support the planned trial. The Company believes that the results of its ongoing standard fertility and reproductive studies, expected to be completed in the first quarter of 2021, together with the available toxicology package will satisfy the FDA request. The FDA also requested updates to the Investigator's Brochure and to the requirements for contraception in the protocol.

The Company now expects to initiate the randomized, placebo-controlled Phase 2/3 clinical trial for PRAX-114 in MDD in the first half of 2021. The Company is in dialogue with the FDA and intends to explore potential options to accelerate the initiation of the Phase 2/3 clinical trial.

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. Praxis is applying insights into the genetic mutations that drive excitation-inhibition imbalance in diseases to select biological targets for severe pediatric epilepsies and more broadly for prevalent psychiatric diseases and neurologic disorders. Praxis has established a broad portfolio, including five disclosed programs across multiple central nervous system disorders including, depression, epilepsy, movement disorders and pain syndromes, with three clinical-stage product candidates.

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, including resolution of the current PRAX-114 clinical hold; 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.

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