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 3, 2021

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.
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:

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 2.02. Results of Operations and Financial Condition.

On November 3, 2021, Praxis Precision Medicines, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021. A copy of the press release is being furnished as Exhibit 99.1 and a copy of the presentation slides to be used during the Company's conference call on November 3, 2021 to provide a business update is being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K , including Exhibits 99.1 and 99.2 attached hereto, is intended to be furnished and 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 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 filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 3, 2021 (furnished herewith)
99.2	Copy of Praxis Precision Medicines, Inc. presentation slides dated November 3, 2021 (furnished herewith)
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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 3, 2021

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

Praxis Precision Medicines Provides Corporate Update and Reports Third Quarter 2021 Financial Results

Enrollment on track for 1H22 topline results for PRAX-114 Phase 2/3 monotherapy MDD Aria Study and for PRAX-114 Phase 2 dose-ranging MDD Acapella Study

PRAX-114 Phase 2 studies in post-traumatic stress disorder and essential tremor (ET), PRAX-562 Phase 2 study in rare adult cephalgias expected to initiate in 4Q21

Preliminary results for PRAX-944 Phase 2a study for treatment of ET expected in 4Q21

First patient enrolled in PRAX-944 Phase 2b Essential1 Study for treatment of ET; topline results expected in 2H22

Cash and investments of $314.4 million as of September 30, 2021 supports runway into 2Q23

Praxis to host Movement Disorder Day on December 17, 2021

BOSTON, Mass., November 3, 2021 — Praxis Precision Medicines, Inc. (NASDAQ: PRAX), a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system (CNS) disorders characterized by neuronal imbalance, today provided a corporate update and reported financial results for the third quarter ended September 30, 2021.

“The advancements throughout our portfolio in recent months exemplify the potential of an unwavering team and an operational backbone that allows us to efficiently move a diverse set of programs forward in multiple CNS indications,” said Marcio Souza, president and chief executive officer of Praxis. “As we look back on the progress in our first year as a public company and enter a catalyst-rich period with data readouts across each of our three clinical programs, we remain as determined as ever to bring CNS drugs to those in need.”

Recent Business Highlights and Upcoming Milestones:

Psychiatry

- Praxis expects topline results from the ongoing PRAX-114 Phase 2/3, placebo-controlled Aria Study for monotherapy treatment of Major Depressive Disorder (MDD) in the first half of 2022. The Aria Study is intended to serve as one of two trials required by the U.S. Food and Drug Administration (FDA) to demonstrate clinical efficacy to support registration of PRAX-114 for monotherapy treatment of MDD.
- The Company expects topline results from the ongoing PRAX-114 Phase 2, placebo-controlled, dose-ranging Acapella Study in the first half of 2022. The Acapella Study is intended to provide additional understanding of the dose range and to evaluate the safety and efficacy of PRAX-114 at doses of 10, 20, 40 and 60 mg, primarily in adjunctive MDD participants.
- Following the announcement of positive topline results from the PRAX-114 Phase 2a, proof-of-concept trial for treatment of perimenopausal depression, Praxis plans to continue investigation of PRAX-114 for treatment of women with menopausal and mood symptoms in a Phase 2b trial. Plans for the Phase 2b trial will be disclosed in the fourth quarter of 2021.
- Praxis plans to initiate a PRAX-114 Phase 2, placebo-controlled study for treatment of post-traumatic stress disorder (PTSD) in the fourth quarter of 2021. Topline results are expected in the second half of 2022. The trial is designed to evaluate the safety, tolerability and efficacy of a nightly dose of 40 mg of PRAX-114 for 4 weeks in approximately 80 participants with PTSD, using the CAPS-5 total score as the primary endpoint.

Movement Disorders

- The Company has completed dosing in a two-part PRAX-944 Phase 1 study to explore a faster titration regimen. Topline results are expected in the fourth quarter of 2021. The Phase 1 study is designed to evaluate the safety, tolerability and pharmacokinetics (PK) of titrating PRAX-944 up to 120 mg in a 10-day regimen in participants aged 18 to 54 years (Part A) and 55 to 75 years (Part B).

- Praxis is currently in the second of two cohorts of its PRAX-944 Phase 2a trial for treatment of essential tremor (ET), evaluating safety and efficacy in patients titrated up to 120 mg per day. Preliminary open-label safety, tolerability and efficacy data is expected in the fourth quarter of 2021, followed by complete open-label and placebo-controlled, randomized withdrawal results in the first half of 2022.

- Praxis initiated the PRAX-944 Phase 2b Essential1 Study for treatment of ET in the third quarter of 2021 and has started enrolling participants. Topline results are expected in the second half of 2022. Essential1 is a placebo-controlled, dose-ranging clinical trial designed to evaluate the safety, tolerability and efficacy of PRAX-944 at 20, 60 or 120 mg per day.

- Praxis plans to initiate a PRAX-114 Phase 2, placebo-controlled, crossover study for daytime treatment of ET to evaluate safety, PK and efficacy of 10 or 20 mg of PRAX-114 in the fourth quarter of 2021. Topline results are expected in the second half of 2022.

- The Company intends to initiate a Phase 2 trial to evaluate the safety, PK and efficacy of PRAX-944 as a non-dopaminergic treatment for the motor symptoms of Parkinson's disease in the first half of 2022.

- Praxis plans to host a Movement Disorder Day in New York City and virtually on Friday, December 17, 2021.

Rare Disease

- Praxis has completed the dosing and safety follow-up period for its single ascending dose (SAD) and multiple ascending dose (MAD) cohorts up to 150 and 120 mg, respectively, in its PRAX-562 Phase 1, healthy volunteer study. A summary of the findings is included below and in the slide deck accompanying our third quarter 2021 corporate update in the Investors + Media section of our website.

    - PRAX-562 was well-tolerated, with no clinically significant safety findings. The most common treatment emergent adverse events (TEAEs) were headache and dizziness. Almost all TEAEs were mild in severity. No drug-related serious adverse events or severe adverse events were observed.

    - The maximum observed concentration was observed between 2 and 3 hours after dosing. There was no impact of food intake on PK. The half-life of PRAX-562 is approximately 4-5 days across the dose range evaluated.

    - Dose-related changes were observed in the exploratory Auditory Steady-State Response (ASSR) electroencephalogram (EEG) translational biomarker. In the 120 mg dose group, a reduction in ASSR of greater than 50% was observed after 14 days QD as compared to baseline.

- Based on the observed signal in the ASSR marker in the Phase 1, healthy volunteer study, Praxis has started dosing patients in the U.S. in a PRAX-562 Phase 1, placebo-controlled, two-cohort EEG study to validate the observed signal. Topline data is expected in the first half of 2022. The study is intended to evaluate ASSR as a biomarker for the PRAX-562 program to further support selection of therapeutic dose levels in Phase 2 studies.

- The Company intends to initiate a PRAX-562 Phase 2 trial in the fourth quarter of 2021 in the U.S. for treatment of patients with rare adult cephalgias, including a cohort of participants with Short-lasting Unilateral Neuralgiform headache attacks with Conjunctival injection and Tearing (SUNCT) and Short-lasting Unilateral Neuralgiform headache with Autonomic symptoms (SUNA), and a cohort of participants with Trigeminal Neuralgia (TN).

- Praxis plans to initiate a PRAX-562 Phase 2 trial for treatment of developmental epileptic encephalopathies (DEEs) in the first half of 2022.

- Praxis has completed the Investigational New Drug (IND) enabling toxicology study for its lead antisense oligonucleotide (ASO) candidate, PRAX-222, and plans to initiate regulatory submissions in order to begin a PRAX-222 Phase 1/2 trial for treatment of SCN2A-DEE in the first half of 2022.

Third Quarter 2021 Financial Results:

As of September 30, 2021, Praxis had $314.4 million in cash, cash equivalents and marketable securities, compared to $296.6 million in cash and cash equivalents as of December 31, 2020. This increase of $17.8 million primarily reflects $98.4 million in net proceeds from the follow-on public offering of shares of our common stock in May 2021, partially offset by cash used in operations of $79.7 million during the nine months ended September 30, 2021. The company's cash, cash equivalents and marketable securities as of September 30, 2021 are expected to fund operations into the second quarter of 2023.

Research and development expenses were $33.1 million for the three months ended September 30, 2021, compared to $12.8 million for the three months ended September 30, 2020. The increase in R&D expenses of approximately $20.4 million was primarily attributable to $10.9 million in increased expenses related to our clinical-stage programs, $5.2 million in increased personnel-related costs due to increased headcount and $2.9 million in increased expenses related to our discovery-stage programs.

General and administrative expenses were $11.6 million for the three months ended September 30, 2021, compared to $3.4 million for the three months ended September 30, 2020. The increase in general and administrative expenses of $8.2 million was primarily attributable to $4.7 million in increased personnel-related costs due to increased headcount, $1.8 million in increased professional fees and a $1.7 million increase in other general and administrative expenses.

Praxis reported net loss of $44.7 million for the three months ended September 30, 2021, including $6.5 million of stock-based compensation expense, compared to a net loss of $16.2 million for the three months ended September 30, 2020, including $1.0 million of stock-based compensation expense.

As of September 30, 2021, Praxis had 44.8 million shares of common stock outstanding.

About Praxis
Praxis Precision Medicines is a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system disorders (CNS) characterized by neuronal imbalance. Praxis is applying insights from genetic epilepsies to broader neurological and psychiatric disorders, using our understanding of shared biological targets and circuits in the brain. Praxis has established a broad portfolio, including multiple disclosed programs across CNS disorders including depression, epilepsy, movement disorders and pain syndromes, with three clinical-stage product candidates. For more information, please visit https://praxismedicines.com/ and follow us on LinkedIn and Twitter.

Forward-Looking Statements
This press release may contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including express or implied statements regarding Praxis' future expectations, plans and prospects, including, without limitation, statements regarding expectations, plans and timing for clinical data, the sufficiency of our cash, cash equivalents and marketable securities, the anticipated timing of our clinical trials and regulatory filings, and the development of our product candidates, including the design of our clinical trials and the treatment potential of our product candidates as well as other statements containing the words "anticipate," "believe," "continue," "could," "endeavor," "estimate," "expect," "anticipate," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "will" or "would" and similar expressions that constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995.

The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical trials

and in the availability and timing of data from ongoing clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; the expected timing of submissions for regulatory approval or review by governmental authorities; regulatory approvals to conduct trials or to market products; whether Praxis' cash resources will be sufficient to fund Praxis' foreseeable and unforeseeable operating expenses and capital expenditure requirements; risks, uncertainties and assumptions regarding the impact of the continuing COVID-19 pandemic on Praxis' business, operations, strategy, goals and anticipated timelines, Praxis' ongoing and planned preclinical activities, Praxis' ability to initiate, enroll, conduct or complete ongoing and planned clinical trials, Praxis' timelines for regulatory submissions and Praxis' financial position; and other risks concerning Praxis' programs and operations are described in additional detail in its Annual Report on Form 10-K for the year ended December 31, 2020, its Quarterly Reports on Form 10-Q and other subsequent filings made with the Securities and Exchange Commission from time to time. Although Praxis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Praxis. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this press release speaks only as of the date on which it is made. Praxis undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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PRAXIS PRECISION MEDICINES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(Amounts in thousands)

(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 165,679	$ 296,608
Marketable securities	148,691	—
Prepaid expenses and other current assets	4,969	5,718
Property and equipment, net	625	82
Operating lease right-of-use assets	4,028	754
Other non-current assets	416	15
Total assets	$ 324,408	$ 303,177
Liabilities and stockholders' equity		
Accounts payable	$ 7,544	$ 4,088
Accrued expenses	16,529	10,869
Operating lease liabilities	4,413	763
Common stock	5	4
Additional paid-in capital	553,975	437,007
Accumulated other comprehensive loss	(25)	—
Accumulated deficit	(258,033)	(149,554)
Total liabilities and stockholders' equity	$ 324,408	$ 303,177

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 33,139	$ 12,786	$ 76,746	$ 28,704
General and administrative	11,634	3,431	31,929	7,552
Total operating expenses	44,773	16,217	108,675	36,256
Loss from operations	(44,773)	(16,217)	(108,675)	(36,256)
Other income:				
Other income, net	73	1	201	134
Total other income	73	1	201	134
Loss before benefit from income taxes	(44,700)	(16,216)	(108,474)	(36,122)
Benefit from (provision for) income taxes	(5)	—	(5)	8
Net loss	$ (44,705)	$ (16,216)	$ (108,479)	$ (36,114)
Accretion and cumulative dividends on redeemable convertible preferred stock	—	(3,943)	—	(8,046)
Gain on repurchase of redeemable convertible preferred stock	—	—	—	493
Net loss attributable to common stockholders	$ (44,705)	$ (20,159)	$ (108,479)	$ (43,667)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.00)	$ (12.10)	$ (2.61)	$ (26.53)
Weighted average common shares outstanding, basic and diluted	44,714,941	1,665,902	41,608,017	1,645,982


PRAXIS
3Q 2021
CORPORATE UPDATE
November 2021
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Forward-looking statements

This presentation may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, including but not limited to express or implied statements regarding the current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development plans, our preclinical and clinical results and other future conditions. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. Any forward-looking statements in this presentation 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 presentation, including, without limitation, risks relating to: (i) the success and timing of our ongoing clinical trials, (ii) the success and timing of our product development activities and initiating clinical trials, (iii) the success and timing of our collaboration partners' ongoing and planned clinical trials, (iv) our ability to obtain and maintain regulatory approval of any of our product candidates, (v) our plans to research, discover and develop additional product candidates, (vi) our ability to enter into collaborations for the development of new product candidates, (vii) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, (viii) our ability to meet any specific milestones set forth herein, and (ix) uncertainties and assumptions regarding the impact of the COVID-19 pandemic on our business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements.

For further information regarding the risks, uncertainties and other factors that may cause differences between our expectations and actual results, you should review the "Risk Factors" section of our Annual Report on Form 10-K filed for the period ended December 31, 2020, our Quarterly Reports on Form 10-Q and other subsequent filings with the Securities and Exchange Commission.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

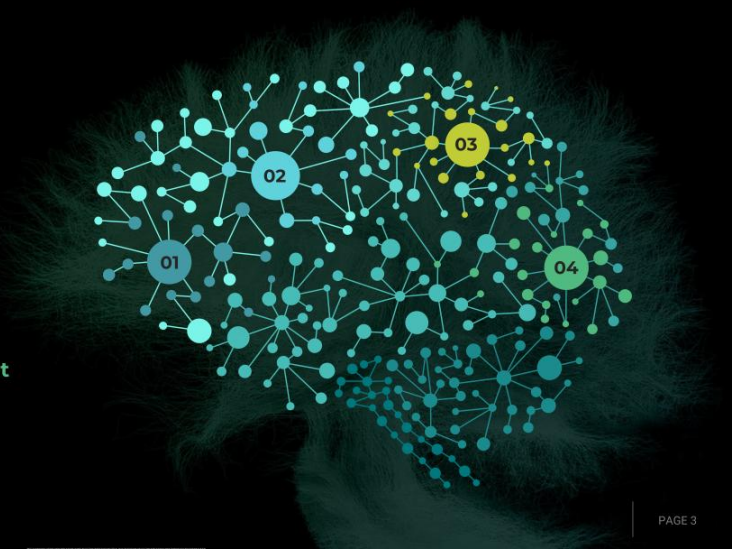
Leveraging genetics to efficiently translate insights into therapies repeatedly

01 **Targets identified through genetics**

02 **Translational tools to inform development**

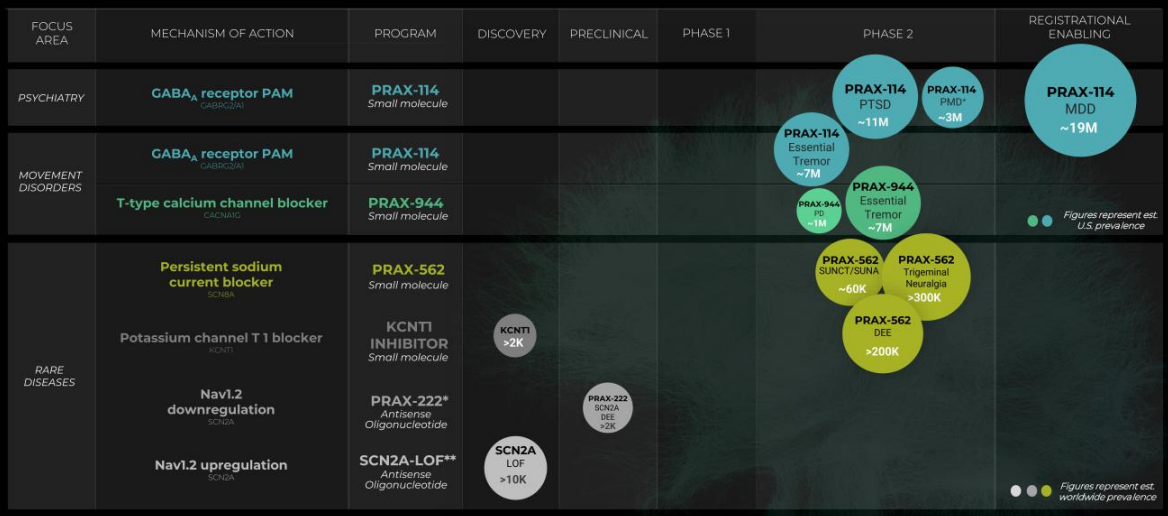
03 **Efficient, rigorous clinical development paths to PoC**

04 **Patient-guided development strategies**



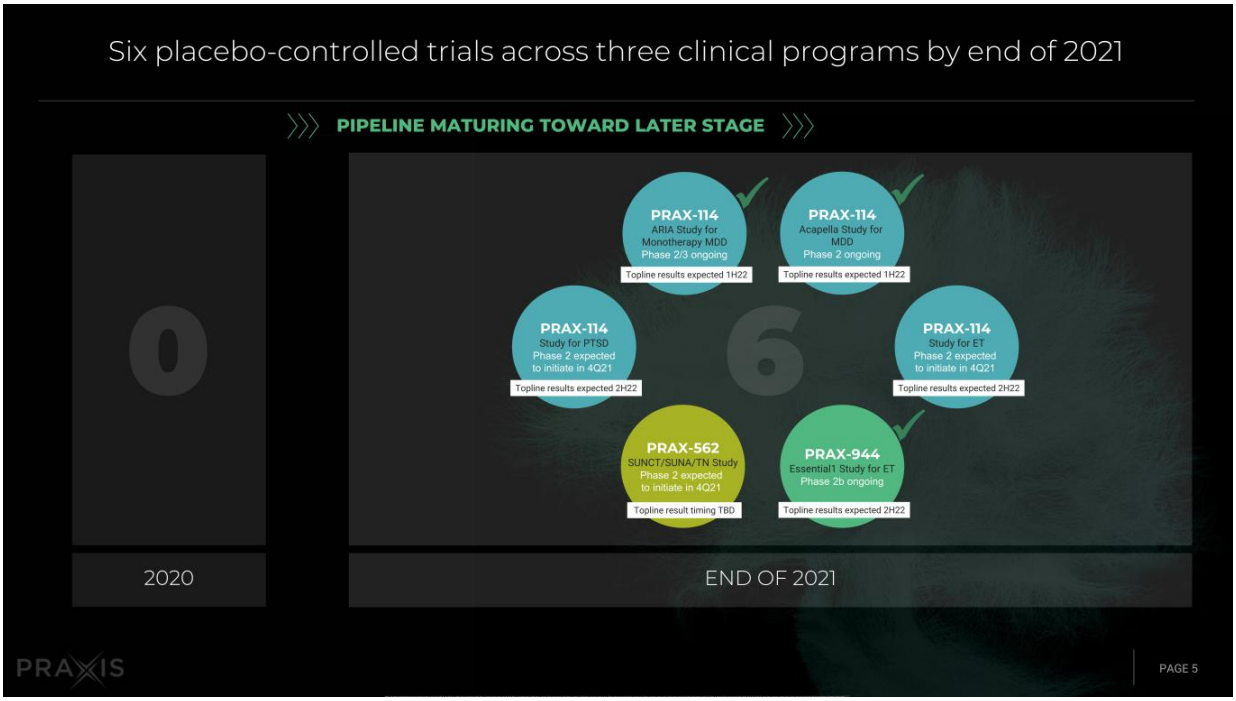
PRAXIS

Broad portfolio of highly differentiated programs across multiple CNS disorders



* PRAX-222 is a collaboration with Ionis Pharmaceuticals, and RogCon Inc; Ionis is eligible to receive double-digit royalties on net product sales worldwide.
** SCN2A-LOF is a collaboration with The Florey Institute; collaboration includes 2 additional ASOs with undisclosed targets
⁺ Phase 2b trial in women with menopausal & mood symptoms
PRAX-114 Phase 2 trials for ET and PTSD, PRAX-944 Phase 2 trial for PD and PRAX-562 trials for SUNCT/SUNA/TN and for DEEs have not initiated
Prevalence based on internal estimates

PRAXIS


Six placebo-controlled trials across three clinical programs by end of 2021
PIPELINE MATURING TOWARD LATER STAGE
0
2020
6
PRAX-114
ARIA Study for Monotherapy MDD
Phase 2/3 ongoing
Topline results expected 1H22
PRAX-114
Acapella Study for MDD
Phase 2 ongoing
Topline results expected 1H22
PRAX-114
Study for PTSD
Phase 2 expected to initiate in 4Q21
Topline results expected 2H22
PRAX-114
Study for ET
Phase 2 expected to initiate in 4Q21
Topline results expected 2H22
PRAX-562
SUNCT/SUNA/TN Study
Phase 2 expected to initiate in 4Q21
Topline result timing TBD
PRAX-944
Essential1 Study for ET
Phase 2b ongoing
Topline results expected 2H22
END OF 2021
PRAXIS
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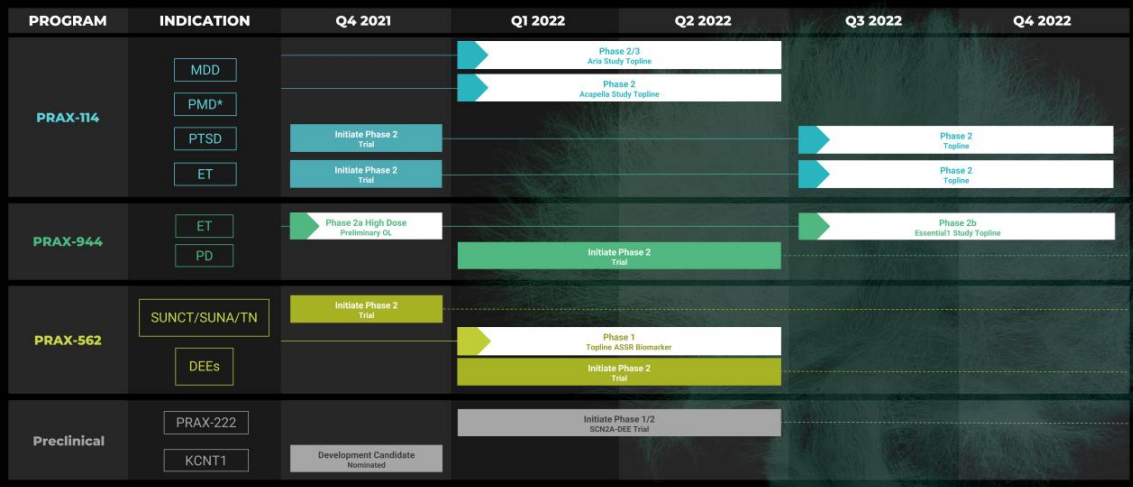
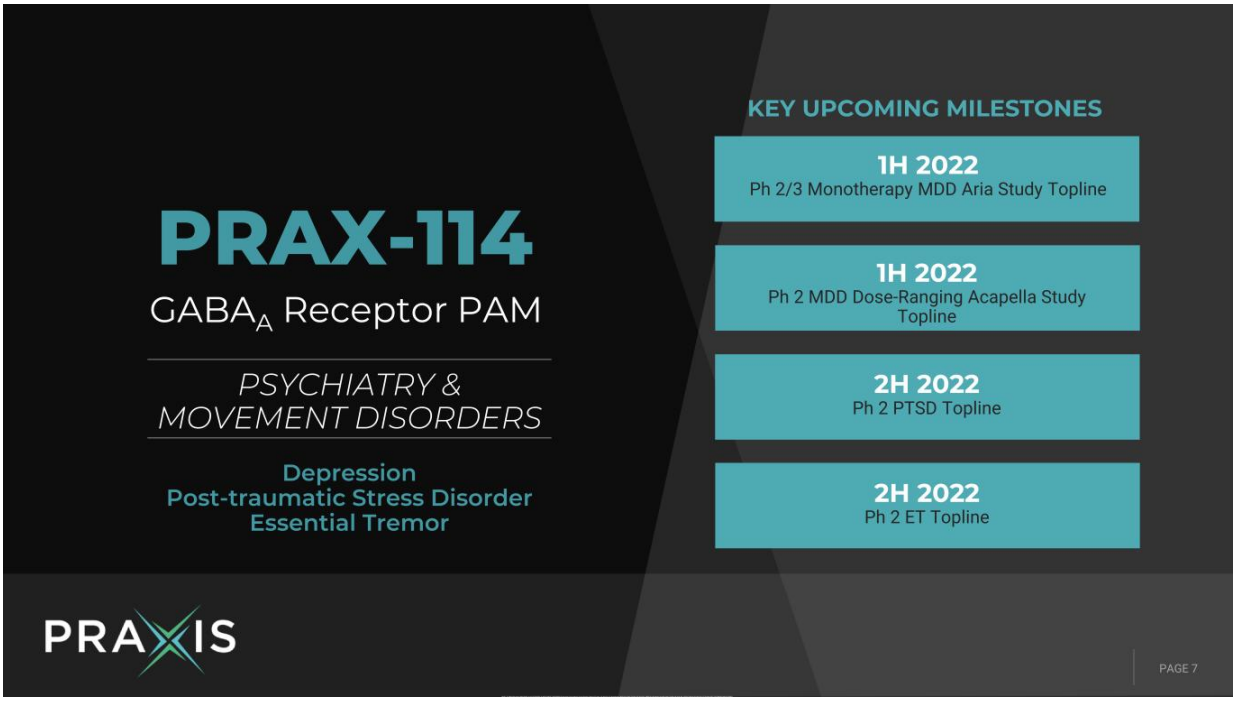
Substantial potential for value creation across the portfolio

MULTIPLE POTENTIAL VALUE-CREATING MILESTONES
EXPECTED WITHIN THE NEXT 12+ MONTHS



* Plans for upcoming PRAX-114 Phase 2b study in women with menopausal and mood symptoms to be disclosed by end of 2021


PRAX-114
GABA$_A$ Receptor PAM
PSYCHIATRY & MOVEMENT DISORDERS
Depression
Post-traumatic Stress Disorder
Essential Tremor
KEY UPCOMING MILESTONES
1H 2022
Ph 2/3 Monotherapy MDD Aria Study Topline
1H 2022
Ph 2 MDD Dose-Ranging Acapella Study Topline
2H 2022
Ph 2 PTSD Topline
2H 2022
Ph 2 ET Topline
PRAXIS
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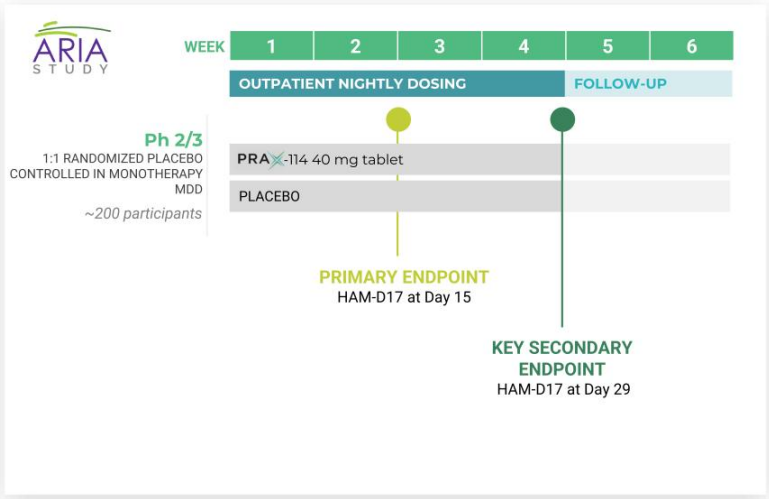
PRAX-114 monotherapy MDD Phase 2/3 Aria Study topline data expected 1H 2022



PHASE 2/3

First of two registrational trials for monotherapy MDD

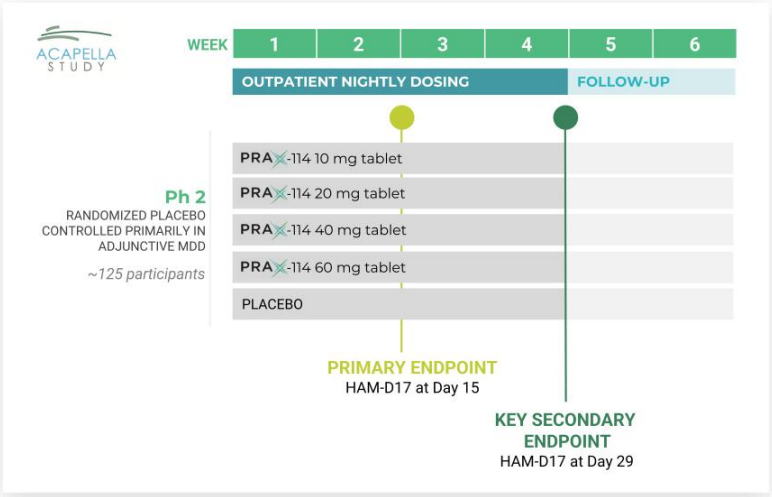
KEY INCLUSION CRITERIA

Ages 18-65
HAM-D17 ≥ 23
At least one prior episode of MDD

KEY EXCLUSION CRITERIA

Treatment-resistant depression
Current antidepressant treatment

PRAX-114 MDD Phase 2 Acapella Study topline data expected 1H 2022



PHASE 2

Dose-ranging study to evaluate safety and efficacy of PRAX-114 at doses of 10, 20, 40 and 60 mg

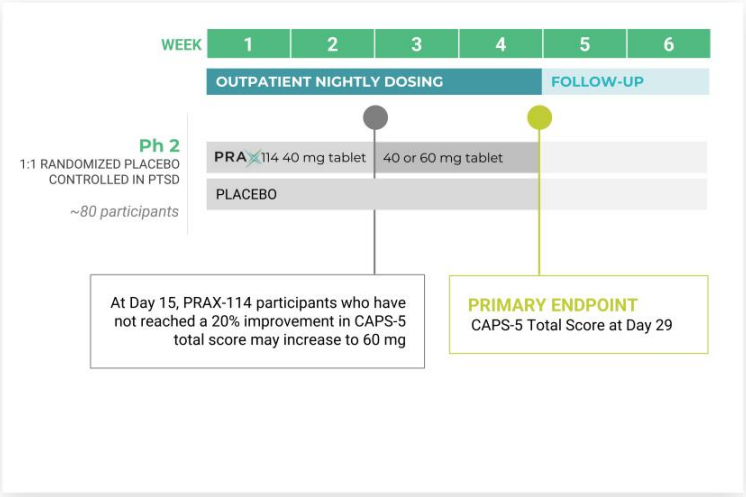
KEY INCLUSION CRITERIA

Ages 18-65
HAM-D17 ≥ 23
At least one prior episode of MDD
Inadequate response to treatment in current episode of at least 12 weeks

KEY EXCLUSION CRITERIA

Treatment-resistant depression

PRAX-114 PTSD Phase 2 study expected to initiate in 4Q21



TOPLINE DATA EXPECTED 2H22

To evaluate safety, tolerability and efficacy of PRAX-114 for treatment of adults with PTSD

KEY INCLUSION CRITERIA

Ages 18-65
CAPS-5 ≥ 30
PTSD diagnosis with duration of >6 months

PRAX-114 ET Phase 2 study expected to initiate in 4Q21

STUDY DESIGN

Randomized, double-blind, placebo-controlled, cross-over study

~15 participants

TOPLINE DATA EXPECTED 2H22

To evaluate safety, tolerability, PK and efficacy of daytime dosing of PRAX-114 for treatment of adults with ET

Participants will receive a single daily dose in each period followed by a washout between periods of at least 3 days

KEY INCLUSION CRITERIA

Ages 18 or older
Diagnosis of moderate to severe ET
TETRAS UL score ≥10

PRAX-944

T-Type calcium channel inhibitor

MOVEMENT DISORDERS

Essential Tremor
Parkinson's Disease

KEY UPCOMING MILESTONES

Q4 2021
Ph2a ET High Dose Cohort Preliminary OL

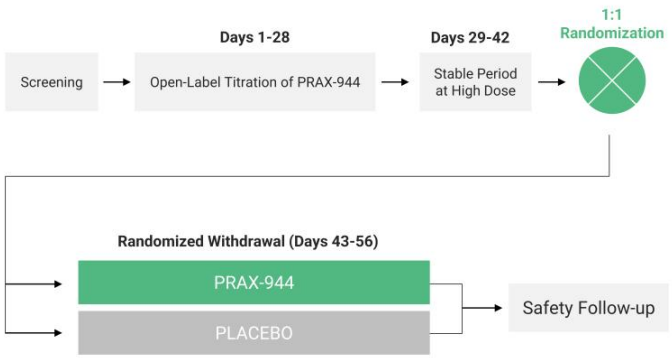
1H 2022
Initiate Ph2 PD Trial

2H 2022
Ph2b Essential1 Study Topline

PRAXIS

PRAX-944 Phase 2a high dose cohort preliminary results expected in 4Q 2021

PART B: Open-Label Titration & Randomized Withdrawal Study
Up to 120 mg



To evaluate safety, tolerability and efficacy of PRAX-944 in patients treated up to 120 mg per day

4Q21

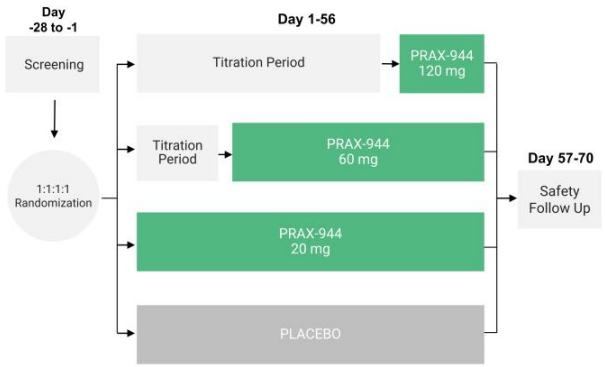
Preliminary open-label safety, tolerability and efficacy results

1H22

Complete open-label and placebo-controlled randomized withdrawal results

Enrollment has initiated for PRAX-944 ET Phase 2b Essential1 Study

Randomized, double-blind, placebo-controlled study in ~112 participants



TOPLINE DATA EXPECTED 2H22

Dose-ranging study to evaluate safety, tolerability and efficacy of PRAX-944 for treatment of adults with ET

KEY INCLUSION CRITERIA

Ages 18 or older

Diagnosis of ET for at least 3 years

TETRAS UL score ≥10

PRAX-562

Persistent Sodium Channel Blocker

RARE DISEASES

Adult Cephalgias
Pediatric Epilepsies (DEEs)

KEY UPCOMING MILESTONES

Q4 2021
Initiate Ph 2 Adult Cephalgias Trial

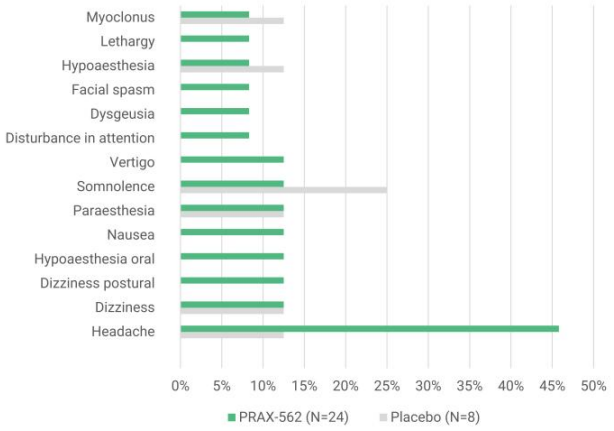
1H 2022
Topline Ph 1 ASSR Biomarker

1H 2022
Initiate Ph 2 DEE Trial

PRAXIS

PRAX-562 well tolerated in Phase 1 healthy volunteer study

Percentage of treatment emergent adverse events (TEAEs) reported in ≥5% of PRAX-562 participants*



No clinically significant safety findings

All TEAEs mild to moderate in severity

No drug-related SAEs or severe AEs

PRAXIS

* TEAEs related to blood sample collection excluded

PRAX-562 development strategy in rare cephalgias and pediatric epilepsies

OBJECTIVE

Identify PoC and safety in SUNCT/SUNA & Trigeminal Neuralgia while continuing efforts to expand to rare pediatric epilepsies