UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from __________ to __________

Commission File Number: 001-39620

PRAXIS PRECISION MEDICINES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-5195942**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
99 High Street, 30th Floor Boston, MA	**02110**
(Address of principal executive offices)	**(Zip Code)**

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

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	**PRAX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 4, 2022, the registrant had 47,118,578, shares of common stock, $0.0001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the success, cost and timing of our product candidate development activities and clinical trials;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- the ability to license additional intellectual property relating to our product candidates from third parties and to comply with our existing license agreements and collaboration agreements;
- the ability and willingness of our third-party research institution collaborators to continue research and development activities relating to our product candidates;
- our ability to commercialize our product candidates, if approved, in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further development and, if approved, commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and, if approved, commercialize our product candidates;
- future agreements with third parties in connection with the commercialization of our product candidates, if approved, and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, and the ongoing conflict in Ukraine on any of the foregoing or other aspects of our business operations, including but not limited to our ongoing and planned preclinical studies and clinical trials.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits hereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report on Form 10-Q, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

PRAXIS PRECISION MEDICINES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(Amounts in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 62,440	$ 138,704
Marketable securities	61,300	137,207
Prepaid expenses and other current assets	8,572	11,498
Total current assets	132,312	287,409
Property and equipment, net	1,077	1,213
Operating lease right-of-use assets	3,097	3,653
Other non-current assets	416	472
Total assets	$ 136,902	$ 292,747
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,122	$ 10,780
Accrued expenses	17,884	26,844
Operating lease liabilities	977	810
Total current liabilities	28,983	38,434
Long-term liabilities:		
Non-current portion of operating lease liabilities	2,756	3,501
Total liabilities	31,739	41,935
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized; 46,864,327 shares issued and outstanding as of September 30, 2022, and 45,300,514 shares issued and outstanding as of December 31, 2021	5	5
Additional paid-in capital	595,165	567,598
Accumulated other comprehensive loss	(536)	(176)
Accumulated deficit	(489,471)	(316,615)
Total stockholders' equity	105,163	250,812
Total liabilities and stockholders' equity	$ 136,902	$ 292,747

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 30,439	$ 33,139	$ 126,711	$ 76,746
General and administrative	13,851	11,634	46,822	31,929
Total operating expenses	44,290	44,773	173,533	108,675
Loss from operations	(44,290)	(44,773)	(173,533)	(108,675)
Other income:				
Other income, net	345	73	677	201
Total other income	345	73	677	201
Loss before income taxes	$ (43,945)	$ (44,700)	$ (172,856)	$ (108,474)
Provision for income taxes	—	(5)	—	(5)
Net loss	$ (43,945)	$ (44,705)	$ (172,856)	$ (108,479)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.96)	$ (1.00)	$ (3.79)	$ (2.61)
Weighted average common shares outstanding, basic and diluted	45,774,376	44,714,941	45,591,888	41,608,017

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(Amounts in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (43,945)	$ (44,705)	$ (172,856)	$ (108,479)
Change in unrealized losses on marketable securities, net of tax	144	25	(360)	(25)
Comprehensive loss	$ (43,801)	$ (44,680)	$ (173,216)	$ (108,504)

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

(Amounts in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	45,300,514	$ 5	$ 567,598	$ (316,615)	$ (176)	$ 250,812
Stock-based compensation expense	—	—	7,886	—	—	7,886
Issuance of common stock from at-the-market public offerings, net of issuance costs	70,410	—	1,368	—	—	1,368
Vesting of restricted stock units	81,130	—	—	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(17,850)	—	(230)	—	—	(230)
Issuance of common stock upon exercise of stock options	72,278	—	333	—	—	333
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	(430)	(430)
Net loss	—	—	—	(68,717)	—	(68,717)
Balance at March 31, 2022	45,506,482	$ 5	$ 576,955	$ (385,332)	$ (606)	$ 191,022
Stock-based compensation expense	—	—	7,611	—	—	7,611
Issuance of common stock under employee stock purchase plan	51,645	—	454	—	—	454
Vesting of restricted stock units	6,361	—	—	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(2,225)	—	(17)	—	—	(17)
Issuance of common stock upon exercise of stock options	13,143	—	67	—	—	67
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	(74)	(74)
Net loss	—	—	—	(60,194)	—	(60,194)
Balance at June 30, 2022	45,575,406	$ 5	$ 585,070	$ (445,526)	$ (680)	$ 138,869
Stock-based compensation expense	—	—	6,730	—	—	6,730
Issuance of common stock from at-the-market public offerings, net of issuance costs of $109	1,105,006	—	2,962	—	—	2,962
Vesting of restricted stock units	5,312	—	—	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(1,638)	—	(6)	—	—	(6)
Issuance of common stock upon exercise of stock options	180,241	—	409	—	—	409
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	144	144
Net loss	—	—	—	(43,945)	—	(43,945)
Balance at September 30, 2022	46,864,327	$ 5	$ 595,165	$ (489,471)	$ (536)	$ 105,163

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (continued)

(Unaudited)

(Amounts in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	38,268,543	$ 4	$ 437,007	$ (149,554)	$ —	$ 287,457
Stock-based compensation expense	—	—	4,666	—	—	4,666
Issuance of common stock upon exercise of stock options	352,506	—	851	—	—	851
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	(86)	(86)
Net loss	—	—	—	(27,373)	—	(27,373)
Balance at March 31, 2021	38,621,049	$ 4	$ 442,524	$ (176,927)	$ (86)	$ 265,515
Stock-based compensation expense	—	—	5,400	—	—	5,400
Issuance of common stock from follow-on public offering, net of offering costs of $229	5,750,000	1	98,412	—	—	98,413
Issuance of common stock upon exercise of stock options	322,113	—	809	—	—	809
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	36	36
Net loss	—	—	—	(36,401)	—	(36,401)
Balance at June 30, 2021	44,693,162	$ 5	$ 547,145	$ (213,328)	$ (50)	$ 333,772
Stock-based compensation expense	—	—	6,521	—	—	6,521
Issuance of common stock upon exercise of stock options	90,909	—	309	—	—	309
Change unrealized loss on marketable securities, net of tax	—	—	—	—	25	25
Net loss	—	—	—	(44,705)	—	(44,705)
Balance at September 30, 2021	44,784,071	$ 5	$ 553,975	$ (258,033)	$ (25)	$ 295,922

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Amounts in thousands)

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Cash flows from operating activities:		
Net loss	$ (172,856)	$ (108,479)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	314	89
Stock-based compensation expense	22,227	16,587
Non-cash operating lease expense	556	942
Amortization of premiums and discounts on marketable securities, net	807	1,454
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,326	749
Accounts payable	(658)	4,031
Accrued expenses	(8,431)	5,481
Operating lease liabilities	(578)	(566)
Other	56	15
Net cash used in operating activities	(156,237)	(79,697)
Cash flows from investing activities:		
Purchases of property and equipment	(444)	(519)
Purchases of marketable securities	(83,022)	(164,170)
Maturities of marketable securities	157,761	14,000
Net cash provided by (used in) investing activities	74,295	(150,689)
Cash flows from financing activities:		
Proceeds from follow-on public offering, net of issuance costs	—	98,480
Proceeds from at-the-market offerings, net of issuance costs	4,330	—
Payment of issuance costs for at-the-market offerings and initial public offering	(262)	(575)
Payments of tax withholdings related to vesting of restricted stock units	(253)	—
Proceeds from exercise of options and employee stock purchase plan contributions	1,263	1,968
Net cash provided by financing activities	5,078	99,873
Decrease in cash, cash equivalents and restricted cash	(76,864)	(130,513)
Cash, cash equivalents and restricted cash, beginning of period	139,720	297,208
Cash, cash equivalents and restricted cash, end of period	$ 62,856	$ 166,695
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	62,440	165,679
Restricted cash	416	1,016
Total cash, cash equivalents and restricted cash	$ 62,856	$ 166,695
Supplemental disclosures of non-cash activities:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 4,086
Offering costs included in accrued expenses	$ —	$ 68
Purchases of property and equipment included in accrued expenses	$ —	$ 116

The accompanying notes are an integral part of these condensed consolidated financial statements.

PRAXIS PRECISION MEDICINES, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Nature of the Business

Praxis Precision Medicines, Inc. (“Praxis” or the “Company”) is a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system ("CNS") disorders characterized by neuronal excitation-inhibition imbalance. Normal brain function requires a delicate balance of excitation and inhibition in neuronal circuits, which, when dysregulated, can lead to abnormal function and disease. The Company is applying insights from genetic epilepsies to both rare and more prevalent neurological disorders, using its understanding of shared biological targets and circuits in the brain, to develop patient-guided therapies. The Company applies a deliberate and pragmatic precision approach, leveraging a suite of translational tools including novel transgenic and predictive translational animal models and electrophysiology markers, to enable an efficient path to proof-of-concept in patients. Through this approach, the Company has established a broad CNS portfolio including multiple programs across movement disorders and epilepsy, with four clinical-stage product candidates. For its lead clinical-stage program, the Company expects to announce topline results from the Phase 2b clinical trial in essential tremor in the first quarter of 2023 and expects to initiate a Phase 2 clinical trial for the treatment of Parkinson's disease in the first quarter of 2023. The Company expects the initiation of first-in-patient studies for its lead antisense oligonucleotide epilepsy program in the fourth quarter of 2022 and its lead small molecule epilepsy program in the first quarter of 2023, as well as the launch of an additional clinical epilepsy program this year. In addition, the Company has established a robust pipeline of preclinical stage programs through internal research and in-licensing, including one of the largest portfolios of targeted epilepsy programs in the industry.

Praxis was incorporated in 2015 and commenced operations in 2016. The Company has funded its operations primarily with proceeds from the issuance of redeemable convertible preferred stock and from the sale of common stock through an initial public offering, a follow-on public offering and at-the-market offerings under its shelf registration statement. From inception through September 30, 2022, the Company raised $520.8 million in aggregate cash proceeds from these transactions, net of issuance costs.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Programs currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Liquidity

In accordance with the Financial Accounting Standards Board (“FASB”) Accounting Standards Update (“ASU”) 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these condensed consolidated financial statements are issued.

The Company has incurred recurring losses since its inception, including a net loss of $172.9 million for the nine months ended September 30, 2022. In addition, as of September 30, 2022, the Company had an accumulated deficit of $489.5 million. The Company expects to continue to generate operating losses for the foreseeable future.

The analysis of the Company’s ability to continue as a going concern for the third quarter of 2022 included consideration of the Company’s current cash needs, ongoing research and development plans which are limited to advancing product candidates through, but not beyond their current clinical trial phases, anticipated cost savings resulting from its operational cost reduction plans, including ongoing efforts to eliminate costs not related to the

Company’s strategic focus. Such estimates contain significant judgment as the Company’s ongoing efforts to eliminate costs not related to the Company’s strategic focus contains uncertainties as to whether the Company can attain such benefits. Based on the analysis, the Company concluded that its available cash, cash equivalents and marketable securities as of September 30, 2022 will be sufficient to fund current prioritized operations and capital expenditure requirements into the first quarter of 2024, which is at least 12 months from the filing date of this Quarterly Report on Form 10-Q with the SEC. As a result, the Company concluded that it did not identify conditions or events that raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date these financial statements were issued. The Company’s current operating plan is based on assumptions that may prove to be wrong, and the Company could use its capital resources sooner than it expects, in which case the Company would evaluate further reductions in its expenses or obtaining additional financing sooner than it otherwise would, which additional financing may not be available or may only be available on terms that are not acceptable to the Company.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and ASUs of the FASB.

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2022 are consistent with those discussed in Note 2 to the consolidated financial statements included in the Company's 2021 Annual Report on Form 10-K, other than as noted below.

Unaudited Interim Condensed Consolidated Financial Information

The accompanying condensed consolidated balance sheet as of September 30, 2022, the condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021 and the condensed consolidated statements of stockholders’ equity for the three and nine months ended September 30, 2022 and 2021 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the audited annual consolidated financial statements, and in the opinion of management reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company’s financial position as of September 30, 2022, the results of its operations for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021. Financial statement disclosures for the three and nine months ended September 30, 2022 and 2021 are condensed and do not include all disclosures required for an annual set of financial statements in accordance with GAAP.

The results for the three and nine months ended September 30, 2022 are not necessarily indicative of results to be expected for the year ended December 31, 2022, any other interim periods, or any future year or period.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, accrued and prepaid research and development expenses, stock-based compensation expense and the recoverability of the Company’s net deferred tax assets and related valuation allowance. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from those estimates.

Recently Issued Accounting Pronouncements

The Company does not expect any recently issued accounting pronouncements to have a material impact on its financial statements.

3. Marketable Securities

The following is a summary of the Company's investment portfolio as of September 30, 2022 and December 31, 2021 (in thousands):

	As of September 30, 2022			
		Gross Unrealized		Estimated
	Cost	Gains	Losses	Fair Value
Available-for-sale securities:				
Corporate debt securities	$ 44,819	$ —	$ (498)	$ 44,321
Commercial paper	12,996	—	—	12,996
Debt securities issued by U.S. government agencies	4,021	—	(38)	3,983
Total securities with a maturity of one year or less	$ 61,836	$ —	$ (536)	$ 61,300
Total available-for-sale securities	$ 61,836	$ —	$ (536)	$ 61,300

	As of December 31, 2021			
		Gross Unrealized		Estimated
	Cost	Gains	Losses	Fair Value
Available-for-sale securities:				
Corporate debt securities	$ 52,214	$ —	$ (31)	$ 52,183
Commercial paper	34,993	—	—	34,993
Debt securities issued by U.S. government agencies	12,111	—	(8)	12,103
Other debt securities	6,398	1	—	6,399
Total securities with a maturity of one year or less	$ 105,716	$ 1	$ (39)	$ 105,678
Corporate debt securities	31,667	—	(138)	31,529
Total securities with a maturity of one to two years	$ 31,667	$ —	$ (138)	$ 31,529
Total available-for-sale securities	$ 137,383	$ 1	$ (177)	$ 137,207

As of September 30, 2022, the Company had 9 securities with a total fair market value of $48.3 million in an unrealized loss position. As of December 31, 2021, the Company had 14 securities with a total fair market value of $95.8 million in an unrealized loss position. The Company believes that any unrealized losses associated with the decline in value of its securities is temporary and primarily related to the change in market interest rates since purchase, and believes that it is more likely than not that it will be able to hold its debt securities to maturity. Therefore, the Company anticipates a full recovery of the amortized cost basis of its debt securities at maturity and an allowance was not recognized.

Securities are evaluated for impairment at the end of each reporting period. The Company did not record any impairment related to its available-for-sale securities during the three and nine months ended September 30, 2022 and 2021.

4. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset in an orderly transaction between market participants at the measurement date. The Company categorizes financial assets measured at fair value based on a fair value hierarchy. The following fair value hierarchy is used to classify financial assets based on observable inputs and unobservable inputs used to value the financial assets:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical assets;
- Level 2: Quoted prices for similar assets in active markets, quoted prices in markets that are not active, or inputs which are unobservable, either directly or indirectly, for substantially the full term of the asset; or
- Level 3: Prices or valuation techniques that require inputs that are both significant to the valuation of the asset and unobservable.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of September 30, 2022 and December 31, 2021 (in thousands):

	As of September 30, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 58,218	$ —	$ —	$ 58,218
Marketable securities:				
Corporate debt securities	—	44,321	—	44,321
Commercial paper	—	12,996	—	12,996
Debt securities issued by U.S. government agencies	3,983	—	—	3,983
	$ 62,201	$ 57,317	$ —	$ 119,518

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 131,372	$ —	$ —	$ 131,372
Marketable securities:				
Corporate debt securities	—	83,712	—	83,712
Commercial paper	—	34,993	—	34,993
Debt securities issued by U.S. government agencies	12,103	—	—	12,103
Other debt securities	—	6,399	—	6,399
	$ 143,475	$ 125,104	$ —	$ 268,579

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued external research and development expenses	$ 12,978	$ 17,763
Accrued personnel-related expenses	2,648	7,180
Accrued other	2,258	1,901
Total accrued expenses	$ 17,884	$ 26,844

6. Commitments and Contingencies

In May 2021, the Company entered into a sublease agreement for office space located in Boston, Massachusetts that expires on January 31, 2026, with no option to renew or terminate early. The base rent increases by approximately 2% annually. The Company issued a letter of credit to the landlord related to the security deposit, secured by restricted cash, which is reflected within other non-current assets on the accompanying condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021. This lease qualifies as an operating lease.

7. Common Stock and Preferred Stock

Common Stock

As of September 30, 2022 and December 31, 2021, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value.

As of September 30, 2022 and December 31, 2021, the Company did not hold any treasury shares.

Shares Reserved for Future Issuance

The Company has reserved the following shares of common stock for future issuance:

	September 30, 2022	December 31, 2021
Shares reserved for exercise of outstanding stock options	9,159,415	6,468,501
Shares reserved for future awards under the 2020 Stock Option and Incentive Plan	1,364,855	2,667,780
Shares reserved for future awards under the 2020 Employee Stock Purchase Plan	929,661	654,204
Shares reserved for vesting of restricted stock units	789,419	440,079
Total shares of authorized common stock reserved for future issuance	12,243,350	10,230,564

Preferred Stock

As of September 30, 2022 and December 31, 2021, the authorized capital stock of the Company included 10,000,000 shares of undesignated preferred stock, $0.0001 par value.

8. Stock-Based Compensation

2020 Stock Option and Incentive Plan

The total number of shares of common stock authorized for issuance under the 2020 Stock Option and Incentive Plan (the "2020 Plan") as of September 30, 2022 and December 31, 2021 was 7,449,480 shares and 5,184,455 shares, respectively.

2017 Stock Incentive Plan

The total number of shares of common stock authorized for issuance under the 2017 Stock Incentive Plan (the "2017 Plan") as of September 30, 2022 and December 31, 2021 was 5,937,763 shares. Any authorization to issue new options under the 2017 Plan was cancelled upon the effectiveness of the 2020 Plan and no further awards will be granted under the 2017 Plan.

2020 Employee Stock Purchase Plan

The total number of shares of common stock authorized for issuance under the 2020 Employee Stock Purchase Plan (the "2020 ESPP") as of September 30, 2022 and December 31, 2021 was 981,306 shares and 654,204 shares, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity:

	Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2021	440,079	$ 41.86
Issued	652,328	15.00
Vested	(92,803)	48.11
Forfeited	(210,185)	22.76
Unvested as of September 30, 2022	789,419	$ 23.42

As of September 30, 2022, total unrecognized compensation cost related to unvested restricted stock units was $14.6 million, which is expected to be recognized over a weighted-average period of 2.88 years.

Stock Options

The following table summarizes the Company's stock option activity:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(In years)	(In thousands)
Outstanding as of December 31, 2021	6,468,501	$ 16.92		
Granted	3,932,802	9.29		
Exercised	(265,662)	3.04		$ 850
Cancelled or Forfeited	(976,226)	17.99		
Outstanding as of September 30, 2022	9,159,415	$ 13.94	8.49	$ 327
Exercisable as of September 30, 2022	2,993,364	$ 14.69	7.55	$ 71
Vested and expected to vest as of September 30, 2022	8,956,409	$ 13.91	8.56	$ 318

The aggregate intrinsic value of stock options outstanding, exercisable, and vested and expected to vest is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock at September 30, 2022. The aggregate intrinsic value of stock options exercised is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock on the date of exercise for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock on the exercise date.

Stock Option Valuation

The weighted-average assumptions that the Company used in the Black-Scholes option pricing model to determine the grant-date fair value of stock options granted to employees and non-employees on the date of grant were as follows for the three and nine months ended September 30, 2022:

	Three Months Ended September 30,	Nine Months Ended September 30,
	2022	2022
Risk-free interest rate	2.76 %	2.50 %
Expected term (in years)	6.00	6.07
Expected volatility	88.08 %	89.22 %
Expected dividend yield	— %	— %
Weighted average grant-date fair value per share	$ 2.16	$ 6.70

As of September 30, 2022, total unrecognized compensation cost related to unvested stock options was $53.0 million, which is expected to be recognized over a weighted-average period of 2.38 years.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 1,999	$ 2,787	$ 8,200	$ 7,136
General and administrative	4,731	3,734	14,027	9,451
Total stock-based compensation expense	$ 6,730	$ 6,521	$ 22,227	$ 16,587

9. Net Loss per Share

The following potential shares of common stock, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Outstanding stock options	9,159,415	6,414,070	9,159,415	6,414,070
Unvested restricted stock units	789,419	383,196	789,419	383,196
Potential shares issuable under the 2020 ESPP	48,182	—	48,182	—
	9,997,016	6,797,266	9,997,016	6,797,266

10. Related Party Transactions

On September 11, 2019, the Company entered into a Cooperation and License Agreement (the “License Agreement”) with RogCon Inc. (“RogCon”). Under the License Agreement, RogCon granted to the Company an exclusive, worldwide license under RogCon’s intellectual property to research, develop and commercialize products for the treatment of all forms of epilepsy and/or neurodevelopmental disorders in each case caused by any mutation of the SCN2A gene. Pursuant to the terms of the License Agreement, the Company will conduct, at its own cost and expense, the research and development activities assigned to it under the associated research plan. In addition, the Company is responsible for reimbursing RogCon for any costs associated with research and development activities RogCon performs at the request of the Company. One of the founders of RogCon became the Company’s General Counsel in June 2020. The Company continues to reimburse RogCon for its out-of-pocket costs incurred for activities performed under the License Agreement. Expenses incurred during all periods presented were not material. As of September 30, 2022, the Company had accrued expenses of $0.3 million due to RogCon under the License Agreement.

11. Restructuring

In June 2022, the Company began a strategic realignment to focus resources on its Movement Disorders and Epilepsy franchises, which resulted in a reduction of the Company’s workforce.

The Company incurred $1.0 million of costs related to the realignment, of which $0.6 million has been recognized in research and development expenses and $0.4 million has been recognized in general and administrative expenses in the condensed consolidated statement of operations during the nine months ended September 30, 2022. These costs relate to employee severance, benefits and related costs. The Company does not expect to incur any additional significant costs related to the strategic realignment.

As of September 30, 2022, all of the $1.0 million costs were paid.

12. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the condensed consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. The Company has concluded that no subsequent events have occurred that require disclosure.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (the "SEC") on February 28, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of our Quarterly Report on Form 10-Q for the six months ended June 30, 2022, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company translating genetic insights into the development of therapies for central nervous system, or CNS, disorders characterized by neuronal excitation-inhibition imbalance. Normal brain function requires a delicate balance of excitation and inhibition in neuronal circuits, which, when dysregulated, can lead to abnormal function and disease. We are applying insights from genetic epilepsies to both rare and more prevalent neurological disorders, using our understanding of shared biological targets and circuits in the brain, to develop patient-guided therapies. We apply a deliberate and pragmatic precision approach, leveraging a suite of translational tools including novel transgenic and predictive translational animal models and electrophysiology markers, to enable an efficient path to proof-of-concept in patients. Through this approach, we have established a broad CNS portfolio with multiple programs across movement disorders and epilepsy, with four clinical-stage product candidates. For our lead clinical-stage program, we expect to announce topline results from the Phase 2b clinical trial in essential tremor, or ET, in the first quarter of 2023 and expect to initiate a Phase 2 clinical trial for the treatment of Parkinson's disease, or PD, in the first quarter of 2023. We expect the initiation of first-in-patient studies for our lead antisense oligonucleotide, or ASO, epilepsy program in the fourth quarter of 2022 and our lead small molecule epilepsy program in the first quarter of 2023, as well as the launch of an additional clinical epilepsy program this year. In addition, we have established a robust pipeline of preclinical-stage programs through internal research and in-licensing, including one of the largest portfolios of targeted epilepsy programs in the industry.

Within Movement Disorders, our lead clinical candidate, PRAX-944, is being developed for the treatment of ET and PD. We expect to report topline results from the Phase 2b placebo-controlled Essential1 Study for daytime treatment of ET in the first quarter of 2023. Following topline results, we intend to meet with the U.S. Food and Drug Administration, or the FDA, for an end-of-Phase 2 meeting in the first half of 2023 and initiate our Phase 3 development program in ET in mid-2023. We plan to initiate a Phase 2, placebo-controlled trial to evaluate the efficacy, safety, and tolerability of PRAX-944 as a non-dopaminergic treatment for the motor symptoms of PD in the first quarter of 2023, and expect to report topline results in the second half of 2023.

Within Epilepsy, we plan to initiate the first dose cohort of the EMBRAVE study for PRAX-222, an ASO designed to decrease the expression levels of the protein encoded by the gene SCN2A in pediatric patients with early-seizure-onset SCN2A Developmental and Epileptic Encephalopathy, or DEE, in the fourth quarter of 2022. Following collection of the safety and efficacy data from the first cohort of patients in the EMBRAVE study, the data will be evaluated and submitted to the FDA to seek authorization for dose escalation. Topline results from the initial dose cohort are expected in 2023. We plan to initiate a Phase 2, placebo-controlled study with PRAX-562 in the first quarter of 2023 for the treatment of rare pediatric DEEs, with initial cohorts in SCN2A and SCN8A DEEs, and expect to report topline results in 2023. In October 2022, we received additional detail from the FDA regarding the clinical hold for our Investigational New Drug application for PRAX-562 for the treatment of pediatric patients with SCN2A and SCN8A DEEs. Based on the feedback from the FDA, we expect that no new preclinical or clinical studies will be required to clear the clinical hold. In addition, we expect to initiate a Phase 1 study with PRAX-628 in the fourth quarter of 2022 and subsequently initiate a Phase 2 study in focal epilepsy in 2023.

Our disclosed preclinical pipeline also consists of discovery programs in development for KCNT1 related epilepsy, three ASOs targeting SCN2A in patients with loss-of-function mutations, PCDH19 and SYNGAP1, respectively, and two additional discovery programs for undisclosed targets in movement disorders and epilepsy. We plan to advance ASO candidate PRAX-080 for PCDH19 into preclinical development in 2023.

Following the completion of the PRAX-114 Phase 2 Acapella Study for the treatment of Major Depressive Disorder in the third quarter of 2022, we do not currently plan to pursue further development of PRAX-114 for psychiatric disorders. The PRAX-114 Phase 2 Acapella study (N=110) was 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. Topline data indicated a linear dose response trend on the primary endpoint of change from baseline in the 17-item Hamilton Depression Rating Scale total score at Day 15, but were not statistically significant. In multiple secondary endpoints evaluating 40 mg of PRAX-114 relative to placebo, nominal statistical significance was achieved at Day 4, but not maintained at subsequent timepoints.

We were incorporated in 2015 and commenced operations in 2016. Since inception, we have devoted substantially all of our resources to developing our preclinical and clinical product candidates, building our intellectual property, or IP, portfolio, business planning, raising capital and providing general and administrative support for these operations. We employ a “virtual” research and development model, relying heavily upon external consultants, collaborators and contract research organizations, or CROs, to conduct our preclinical and clinical activities. Since inception, we have financed our operations primarily with proceeds from the sale and issuance of equity securities.

We are a development stage company and we have not generated any revenue from product sales, and do not expect to do so for several years, if at all. All of our product candidates are still in preclinical and clinical development. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates, if approved. We have incurred recurring operating losses since inception, including a net loss of $172.9 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $489.5 million. We expect to incur significant expenses and operating losses for the foreseeable future as we expand our research and development activities. In addition, our losses from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will be maintained or increased in connection with our ongoing activities, as we:

- advance our lead product candidate, PRAX-944, to a late stage clinical trial;
- advance our PRAX-562 product candidate in the Phase 2 clinical trial;
- advance our PRAX-222 product candidate in the EMBRAVE clinical trial;
- advance our PRAX-628 product candidate in the Phase 1 clinical trial;
- advance our preclinical candidates to clinical trials;
- further invest in our pipeline;
- further invest in our manufacturing capabilities;
- seek regulatory approval for our product candidates;
- maintain, expand, protect and defend our IP portfolio;
- acquire or in-license technology;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval; and
- when needed, increase our headcount to support our development efforts and any future commercialization efforts.

In addition, as we progress toward potential marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $123.7 million. We believe that our cash, cash equivalents and marketable securities as of September 30, 2022 will enable us to fund our operating expenses and capital expenditures into the first quarter of 2024. We have based this analysis on our current cash needs, ongoing research and development plans which are limited to advancing product candidates through, but not beyond their current clinical trial phases, anticipated cost savings resulting from our operational cost reduction plans, including ongoing efforts to eliminate costs not related to our strategic focus. Such estimates contain significant judgement as our ongoing efforts to eliminate costs not related to our strategic focus contains uncertainties as to whether we can attain such benefits. Our current operating plan is based on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect, in which case we would evaluate further reductions in our expenses or obtaining additional financing sooner than we otherwise would, which additional financing may not be available or may only be available on terms that are not acceptable to us. See "—Liquidity and Capital Resources."

Restructuring

In June 2022, we began a strategic realignment to focus resources on our Movement Disorders and Epilepsy franchises, which resulted in a reduction of our workforce.

We incurred $1.0 million of costs related to the realignment, of which $0.6 million has been recognized in research and development expenses and $0.4 million has been recognized in general and administrative expenses in the condensed consolidated statement of operations during the nine months ended September 30, 2022. These costs relate to employee severance, benefits and related costs. We do not expect to incur any additional significant costs related to the strategic realignment.

As of September 30, 2022, all of the $1.0 million costs were paid.

COVID-19 Business Update

In light of the ongoing COVID-19 pandemic, we continue to experience some disruptions and increased risk in our operations and those third parties upon whom we rely. These include disruptions and risks related to the conduct of our clinical trials and preclinical studies as policies at various clinical sites and federal, state, local and foreign laws, rules and regulations continue to evolve, including quarantines, travel restrictions and redirection of healthcare resources toward pandemic response efforts. The COVID-19 pandemic has impacted the enrollment of some of our ongoing clinical trials, including slower patient enrollment and treatment in some of our clinical studies, the impact of which has varied by clinical study and program, but none of which have significantly impacted our overall clinical trial timelines. While we have experienced limited financial impacts to date, given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic such as increased inflation, our business, financial condition and results of operations could be materially adversely affected. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

Financial Operations Overview

Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Research and Development Expense

The nature of our business and primary focus of our activities generate a significant amount of research and development costs. Research and development expenses represent costs incurred by us for the following:

- costs to develop our portfolio;
- discovery efforts leading to development candidates;
- clinical development costs for our product candidates; and
- costs to develop our manufacturing technology and infrastructure.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites and CROs, that conduct our preclinical and clinical studies and in-licensing arrangements;
- costs incurred to maintain compliance with regulatory requirements;
- costs incurred with third-party contract development and manufacturing organizations to acquire, develop and manufacture materials for preclinical and clinical studies; and
- depreciation, amortization and other direct and allocated expenses, including rent and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated balance sheets as prepaid expenses or accrued expenses. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized, even when there is no alternative future use for the research and development. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

As a company operating in a virtual environment, a significant portion of our research and development costs have been external costs. We track direct external research and development expenses to specific franchises and product candidates upon commencement. Due to the number of ongoing studies and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development franchises, such as personnel, facility costs and certain consulting costs, are not recorded or maintained on a franchise-specific basis.

The following table reflects our research and development expenses, including direct expenses summarized by major franchise and other exploratory CNS indications and indirect or shared operating costs recognized as research and development expenses during each period presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Movement disorders	$ 9,262	$ 6,735	$ 26,777	$ 12,107
Epilepsy	7,630	4,942	32,579	15,707
Psychiatry	2,642	9,188	28,394	19,029
Other exploratory CNS indications	414	1,475	2,853	2,957
Personnel-related (including stock-based compensation)	8,714	8,334	30,590	21,584
Other indirect research and development expenses	1,777	2,465	5,518	5,362
Total research and development expenses	$ 30,439	$ 33,139	$ 126,711	$ 76,746

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will be maintained or increase in the foreseeable future as we advance our product candidates through the development phase, and as we continue to discover and develop additional product candidates, build manufacturing capabilities and expand into additional therapeutic areas.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research and development personnel;
- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to successfully complete clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, our product candidates;
- our successful enrollment in and completion of clinical trials;
- the costs associated with the development of any additional product candidates we identify in-house or acquire through collaborations;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression of our product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trade secret and other IP protection and regulatory exclusivity for our product candidates, if approved;
- our receipt of marketing approvals from applicable regulatory authorities;
- our ability to commercialize products, if approved, whether alone or in collaboration with others; and
- the continued acceptable safety profiles of the product candidates following approval.

A change in any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect, or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time to complete our clinical development activities. We may never obtain regulatory approval for any of our product candidates. Drug commercialization will take several years and require significant development costs.

General and Administrative Expense

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits and stock-based compensation, for personnel in our executive, finance, legal, commercial and administrative functions. General and administrative expenses also include legal fees relating to corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; commercial-related costs to support market assessments and scenario planning; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for office rent and other operating costs. Costs to secure and defend our IP are expensed as incurred and are classified as general and administrative expenses. These costs relate to the operation of the business and are unrelated to the research and development function or any individual franchise or product candidate.

We anticipate that our general and administrative expenses may increase in the future as we increase our headcount, when needed, to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also expect to incur additional IP-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income

Other Income, Net

Other income, net consists of interest income from our cash, cash equivalents and marketable securities and amortization of investment premiums and discounts.

Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or for our earned research and development tax credits due to our uncertainty of realizing a benefit from those items. Income taxes are determined at the applicable tax rates adjusted for non-deductible expenses, research and development tax credits and other permanent differences. Our income tax provision may be significantly affected by changes to our estimates. The income tax provision for the three and nine months ended September 30, 2022 and 2021 was not material.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our consolidated statements of operations for each period presented (in thousands):

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Change
Operating expenses:			
Research and development	$ 30,439	$ 33,139	$ (2,700)
General and administrative	13,851	11,634	2,217
Total operating expenses	44,290	44,773	(483)
Loss from operations	(44,290)	(44,773)	483
Other income:			
Other income, net	345	73	272
Total other income	345	73	272
Loss before income taxes	$ (43,945)	$ (44,700)	$ 755
Provision for income taxes	—	(5)	5
Net loss	$ (43,945)	$ (44,705)	$ 760

Research and Development Expense

The following table summarizes our research and development expenses for each period presented, along with the changes in those items (in thousands):

	Three Months Ended September 30,		Change
	2022	2021	
Movement disorders	$ 9,262	$ 6,735	$ 2,527
Epilepsy	7,630	4,942	2,688
Psychiatry	2,642	9,188	(6,546)
Other exploratory CNS indications	414	1,475	(1,061)
Personnel-related (including stock-based compensation)	8,714	8,334	380
Other indirect research and development expenses	1,777	2,465	(688)
Total research and development expenses	$ 30,439	$ 33,139	$ (2,700)

The $2.7 million decrease in research and development expenses was primarily attributable to the following:

- $6.5 million decrease in expense related to our psychiatry franchise, driven primarily by a decrease in clinical-related spend for our PRAX-114 Phase 2/3 Aria clinical trial for which we announced topline results in the second quarter of 2022;
- $2.7 million increase in expense related to our epilepsy franchise, driven primarily by an increase in preclinical activities for PRAX-628 and our earlier stage assets and an increase in clinical-related spend to support the initiation of the PRAX-222 EMBRAVE clinical trial; and
- $2.5 million increase in expense related to our movement disorders franchise, driven primarily by an increase in clinical-related spend for our PRAX-944 Phase 2b Essential1 clinical trial and our Phase 1 healthy volunteers trial.

General and Administrative Expense

The $2.2 million increase in general and administrative expenses was primarily due to an increase in personnel-related costs due to increased headcount.

Other Income

Other income for the three months ended September 30, 2022 and 2021 was comprised of interest income on our cash, cash equivalents and marketable securities and investment premium and discount amortization.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our consolidated statements of operations for each period presented (in thousands):

	Nine Months Ended September 30,		Change
	2022	2021	
Operating expenses:			
Research and development	$ 126,711	$ 76,746	$ 49,965
General and administrative	46,822	31,929	14,893
Total operating expenses	173,533	108,675	64,858
Loss from operations	(173,533)	(108,675)	(64,858)
Other income:			
Other income, net	677	201	476
Total other income	677	201	476
Loss before income taxes	$ (172,856)	$ (108,474)	$ (64,382)
Provision for income taxes	—	(5)	5
Net loss	$ (172,856)	$ (108,479)	$ (64,377)

Research and Development Expense

The following table summarizes our research and development expenses for each period presented, along with the changes in those items (in thousands):

	Nine Months Ended September 30,		
	2022	2021	Change
Movement disorders	$ 26,777	$ 12,107	$ 14,670
Epilepsy	32,579	15,707	16,872
Psychiatry	28,394	19,029	9,365
Other exploratory CNS indications	2,853	2,957	(104)
Personnel-related (including stock-based compensation)	30,590	21,584	9,006
Other indirect research and development expenses	5,518	5,362	156
Total research and development expenses	$ 126,711	$ 76,746	$ 49,965

The $50.0 million increase in research and development expenses was primarily attributable to the following:

- $16.9 million increase in expense related to our epilepsy franchise, driven primarily by an increase in preclinical activities for PRAX-628 and our earlier stage assets, an increase in clinical-related spend for our PRAX-562 Phase 1 trials in healthy volunteers, an increase in clinical-related spend to support the initiation of the PRAX-222 EMBRAVE clinical trial, and the payment of a $2.0 million license fee to Ionis Pharmaceuticals, Inc. in January of 2022 upon exercise of our exclusive option to obtain the rights and license to further develop and commercialize PRAX-222;
- $14.7 million increase in expense related to our movement disorders franchise, driven primarily by an increase in clinical-related spend for our PRAX-944 Phase 2b Essential1 clinical trial, an increase in clinical-related spend for our PRAX-114 Phase 2 clinical trial evaluating PRAX-114 for the treatment of ET, and an increase in clinical-related spend for our PRAX-944 Phase 1 healthy volunteer trials;
- $9.4 million increase in expense related to our psychiatry franchise, driven primarily by an increase in clinical-related spend for our PRAX-114 Phase 2 Acapella clinical trial which was initiated in the second quarter of 2021 and our Phase 2 placebo-controlled study evaluating PRAX-114 for the treatment of post-traumatic stress disorder which was initiated in the fourth quarter of 2021; and
- $9.0 million increase in personnel-related costs due to increased headcount.

General and Administrative Expense

The $14.9 million increase in general and administrative expenses was primarily attributable to the following:

- $10.9 million increase in personnel-related costs due to increased headcount; and
- $3.4 million increase in professional fees, including a $1.6 million increase in legal fees due to increased corporate activity and patent-related work.

Other Income

Other income for the nine months ended September 30, 2022 and 2021, was comprised of interest income on our cash, cash equivalents and marketable securities and investment premium and discount amortization.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant losses in each period. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all.

To date, we have financed our operations primarily with proceeds from the issuance of redeemable convertible preferred stock and from the sale of common stock through an initial public offering, a follow-on public offering and at-the-market offerings under our shelf registration statement. From inception through September 30, 2022, we have raised $520.8 million in aggregate cash proceeds from such transactions, net of issuance costs. As of September 30, 2022, we had cash, cash equivalents and marketable securities of $123.7 million.

On November 3, 2021, we entered into an Open Market Sale Agreement, or the sales agreement, with Jefferies LLC, or Jefferies, to provide for the offering, issuance and sale of up to an aggregate amount of $125.0 million of common stock from time to time in at-the-market offerings for which Jefferies acts as sales agent. During the three months ended September 30, 2022, we issued and sold 1,105,006 shares under the sales agreement for aggregate net proceeds of $3.0 million after deducting commissions and offering expenses payable by us. During the nine months ended September 30, 2022, we issued and sold 1,175,416 shares under the sales agreement for aggregate net proceeds of $4.3 million after deducting commissions and offering expenses payable by us. We have issued and sold a total of 1,567,413 shares under the sales agreement for aggregate net proceeds of $11.4 million after deducting commissions and offering expenses payable by us.

Historical Cash Flows

The following table provides information regarding our cash flows for each period presented (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (156,237)	$ (79,697)
Investing activities	74,295	(150,689)
Financing activities	5,078	99,873
Net decrease in cash, cash equivalents and restricted cash	$ (76,864)	$ (130,513)

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we have invested in developing our portfolio, drug discovery efforts and related infrastructure. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in operating assets and liabilities, which are primarily the result of increased expenses and timing of vendor payments.

During the nine months ended September 30, 2022, net cash used in operating activities of $156.2 million was primarily due to our $172.9 million net loss and $7.3 million in changes in operating assets and liabilities primarily related to a decrease in accrued expenses, partially offset by $23.9 million of non-cash charges primarily related to stock-based compensation.

During the nine months ended September 30, 2021, net cash used in operating activities of $79.7 million was primarily due to our $108.5 million net loss, partially offset by $19.1 million of non-cash charges primarily related to stock-based compensation and $9.7 million in changes in operating assets and liabilities primarily related to an increase in accrued expenses and accounts payable.

Investing Activities

During the nine months ended September 30, 2022, net cash provided by investing activities of $74.3 million was primarily related to maturities of marketable securities, partially offset by purchases of marketable securities.

During the nine months ended September 30, 2021, net cash used in investing activities of $150.7 million was primarily related to the purchase of marketable securities, partially offset by the maturities of marketable securities.

Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities of $5.1 million consisted of net proceeds from at-the-market offerings of $4.3 million and proceeds from purchases of common stock under our employee stock purchase plan and from the exercise of stock options, partially offset by the payment of issuance costs for our at-the-market offerings and the payment of taxes related to the vesting of restricted stock units.

During the nine months ended September 30, 2021, net cash provided by financing activities of $99.9 million consisted of net proceeds from our follow-on public offering of $98.5 million and net proceeds from the exercise of stock options, partially offset by the payment of issuance costs for our initial public offering.

Plan of Operation and Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- advance the clinical development of our clinical-stage product candidates within our movement disorders and epilepsy franchises;
- advance the development of any additional product candidates;
- conduct research and continue preclinical development of potential product candidates;
- make strategic investments in manufacturing capabilities;
- maintain our IP portfolio and opportunistically acquire complementary IP;
- seek to obtain regulatory approvals for our product candidates;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- when needed, add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operations as a public company; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

In June 2022, following the Aria Study topline results, we announced a strategic realignment to focus resources on our Movement Disorders and Epilepsy franchises, which resulted in a reduction of our workforce and future operating expenses and extended our cash runway**.**

We are unable to estimate the exact amount of our working capital requirements, but based on our current operating plan, we believe that our cash, cash equivalents and marketable securities as of September 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2024. We have based this analysis on our current cash needs, ongoing research and development plans which are limited to advancing product candidates through, but not beyond their current clinical trial phases, anticipated cost savings resulting from our operational cost reduction plans, including ongoing efforts to eliminate costs not related to our strategic focus. Such estimates contain significant judgement as our ongoing efforts to eliminate costs not related to our strategic focus contains uncertainties as to whether we can attain such benefits. Our current operating plan is based on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect, in which case we would evaluate further reductions in our expenses or obtaining additional financing sooner than we otherwise would, which additional financing may not be available or may only be available on terms that are not acceptable to us.

Because of the numerous risks and uncertainties associated with product development and potential collaborations with third parties for the development of our product candidates, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of preclinical studies and clinical trials for our franchises and product candidates;
- the number and characteristics of product candidates and technologies that we develop or may in-license;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our IP rights and defending any IP-related claims;
- the continuation of our existing licensing arrangements and entry into new collaborations and licensing arrangements;
- the costs we incur in maintaining business operations;
- the costs associated with being a public company;
- the revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval;
- the effect of competing technological and market developments;
- the impact of any business interruptions to our operations or to those of our manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or similar public health crisis; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates, although we currently have no commitments or agreements to complete any such acquisitions or investments in businesses.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. Market volatility could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially result in dilution to the holders of our common stock.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no changes to our critical accounting policies from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates” included in our Annual Report on Form 10-K filed with the SEC on February 28, 2022.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, such standards will not have a material impact on our condensed consolidated financial statements or do not otherwise apply to our current operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash, cash equivalents and marketable securities are or may be in the form of money market funds or marketable debt securities and are or may be invested in U.S. Treasury and U.S. government agency obligations. However, because of the short-term nature and low risk profile of the instruments in our portfolio, an immediate change in market interest rates of 100 basis points would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

Item 4. Controls and Procedures.

Management’s Evaluation of Our Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

As of the date of this Quarterly Report on Form 10-Q, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

There have been no material changes from the risk factors previously disclosed in the section entitled "Risk Factors" of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 filed with the SEC on August 8, 2022.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Equity Securities

We did not make any sales of unregistered securities during the three months ended September 30, 2022.

Use of Proceeds from Public Offering of Common Stock

In October 2020, we completed the initial public offering of our common stock, or IPO, pursuant to which we issued and sold 11,500,000 shares of our common stock at a price to the public of $19.00 per share. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-249074), which was declared effective by the Securities and Exchange Commission on October 15, 2020.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not make any repurchases of shares of common stock during the three months ended September 30, 2022.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Praxis Precision Medicines, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39620) filed on October 20, 2020).
3.2	Amended and Restated Bylaws of Praxis Precision Medicines, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39620) filed on January 7, 2022).
10.1	Transition Agreement dated July 26, 2022, by and between Praxis Precision Medicines, Inc. and Bernard Ravina (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39620) filed on July 26, 2022.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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 thereunto duly authorized.

			PRAXIS PRECISION MEDICINES, INC.
Date:	November 9, 2022	By:	/s/ Marcio Souza
			Marcio Souza
			Chief Executive Officer and Director (Principal Executive Officer)
Date:	November 9, 2022	By:	/s/ Timothy Kelly
			Timothy Kelly
			Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marcio Souza, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Praxis Precision Medicines, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:	November 9, 2022	By:	/s/ MARCIO SOUZA
			Marcio Souza Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy Kelly, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Praxis Precision Medicines, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2022

By: /s/ TIMOTHY KELLY
Timothy Kelly
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Praxis Precision Medicines, Inc. (the "Company") for the quarter ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date:	November 9, 2022	By:	/s/ MARCIO SOUZA
			Marcio Souza Chief Executive Officer (Principal Executive Officer)
Date:	November 9, 2022	By:	/s/ TIMOTHY KELLY
			Timothy Kelly Chief Financial Officer (Principal Financial Officer)