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, 2023

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, a 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 3, 2023, the registrant had 128,550,152, 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
- our expectations with respect to our planned reverse stock split.

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 sections titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, our

Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. 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 sections titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2022, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and elsewhere in this Quarterly Report on Form 10-Q.

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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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 101,085	$ 61,615
Marketable securities	—	38,874
Prepaid expenses and other current assets	2,242	10,351
Total current assets	103,327	110,840
Property and equipment, net	700	971
Operating lease right-of-use assets	2,282	2,901
Other non-current assets	416	416
Total assets	$ 106,725	$ 115,128
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,166	$ 14,672
Accrued expenses	6,979	15,850
Operating lease liabilities	1,095	1,005
Current portion of deferred revenue	1,552	2,818
Total current liabilities	16,792	34,345
Long-term liabilities:		
Non-current portion of operating lease liabilities	1,661	2,495
Non-current portion of deferred revenue	1,516	2,182
Total liabilities	19,969	39,022
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, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized; 128,547,336 shares issued and outstanding as of September 30, 2023, and 49,382,453 shares issued and outstanding as of December 31, 2022	13	5
Additional paid-in capital	713,786	606,918
Accumulated other comprehensive loss	—	(173)
Accumulated deficit	(627,043)	(530,644)
Total stockholders' equity	86,756	76,106
Total liabilities and stockholders' equity	$ 106,725	$ 115,128

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,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 468	$ —	$ 1,932	$ —
Operating expenses:				
Research and development	17,260	30,439	68,378	126,711
General and administrative	8,724	13,851	32,121	46,822
Total operating expenses	25,984	44,290	100,499	173,533
Loss from operations	(25,516)	(44,290)	(98,567)	(173,533)
Other income:				
Other income, net	884	345	2,168	677
Total other income	884	345	2,168	677
Net loss	$ (24,632)	$ (43,945)	$ (96,399)	$ (172,856)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.96)	$ (1.12)	$ (3.79)
Weighted average common shares outstanding, basic and diluted	135,591,429	45,774,376	86,447,174	45,591,888

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,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (24,632)	$ (43,945)	$ (96,399)	$ (172,856)
Change in unrealized losses on marketable securities, net of tax	—	144	173	(360)
Comprehensive loss	$ (24,632)	$ (43,801)	$ (96,226)	$ (173,216)

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, 2022	49,382,453	$ 5	$ 606,918	$ (530,644)	$ (173)	$ 76,106
Stock-based compensation expense	—	—	7,593	—	—	7,593
Issuance of common stock from at-the-market public offerings, net of issuance costs	8,403,809	1	18,095	—	—	18,096
Vesting of restricted stock units	172,798	—	—	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(43,317)	—	(127)	—	—	(127)
Issuance of common stock upon exercise of stock options	44,644	—	101	—	—	101
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	154	154
Net loss	—	—	—	(37,455)	—	(37,455)
Balance at March 31, 2023	57,960,387	$ 6	$ 632,580	$ (568,099)	$ (19)	$ 64,468
Stock-based compensation expense	—	—	5,775	—	—	5,775
Issuance of common stock from follow-on public offering and accompanying pre-funded warrants, net of underwriting discounts, commissions and offering costs of $4,484	64,449,690	6	63,433	—	—	63,439
Issuance of common stock from at-the-market public offerings, net of issuance costs	5,888,128	1	6,031	—	—	6,032
Issuance of common stock under employee stock purchase plan	234,947	—	208	—	—	208
Vesting of restricted stock units	10,813	—	—	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(3,742)	—	(4)	—	—	(4)
Change in unrealized loss on marketable securities, net of tax	—	—	—	—	19	19
Net loss	—	—	—	(34,312)	—	(34,312)
Balance at June 30, 2023	128,540,223	$ 13	$ 708,023	$ (602,411)	$ —	$ 105,625
Stock-based compensation expense	—	—	5,763	—	—	5,763
Vesting of restricted stock units	3,500	—	—	—	—	—
Shares withheld for taxes for vesting of restricted stock units	(1,059)	—	(1)	—	—	(1)
Issuance of common stock upon exercise of stock options	4,672	—	1	—	—	1
Net loss	—	—	—	(24,632)	—	(24,632)
Balance at September 30, 2023	128,547,336	$ 13	$ 713,786	$ (627,043)	$ —	$ 86,756

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, 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 CASH FLOWS

(Unaudited)

(Amounts in thousands)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (96,399)	$ (172,856)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	321	314
Stock-based compensation expense	19,131	22,227
Non-cash operating lease expense	619	556
Amortization of premiums and discounts on marketable securities, net	47	807
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	8,109	2,326
Accounts payable	(7,556)	(658)
Accrued expenses	(8,871)	(8,431)
Operating lease liabilities	(744)	(578)
Deferred revenue	(1,932)	—
Other	—	56
Net cash used in operating activities	(87,275)	(156,237)
Cash flows from investing activities:		
Purchases of property and equipment	—	(444)
Purchases of marketable securities	—	(83,022)
Maturities of marketable securities	39,000	157,761
Net cash provided by investing activities	39,000	74,295
Cash flows from financing activities:		
Issuance of common stock from follow-on public offering and accompanying pre-funded warrants, net of underwriting discounts, commissions and offering costs	63,439	—
Proceeds from at-the-market offerings, net of issuance costs	24,128	4,330
Payment of issuance costs for at-the-market offerings	—	(262)
Payments of tax withholdings related to vesting of restricted stock units	(132)	(253)
Proceeds from exercise of stock options and employee stock purchase plan purchases	310	1,263
Net cash provided by financing activities	87,745	5,078
Increase (decrease) in cash, cash equivalents and restricted cash	39,470	(76,864)
Cash, cash equivalents and restricted cash, beginning of period	62,031	139,720
Cash, cash equivalents and restricted cash, end of period	$ 101,501	$ 62,856
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	101,085	62,440
Restricted cash	416	416
Total cash, cash equivalents and restricted cash	$ 101,501	$ 62,856
Supplemental disclosures of non-cash activities:		
Offering costs from follow-on public offering included in accounts payable	$ 184	$ —
Purchases of property and equipment included in accounts payable	$ 50	$ —

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 insights from genetic epilepsies 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 both rare and more prevalent neurological disorders. The Company is applying genetic insights to the discovery and development of therapies for neurological disorders through two proprietary platforms, using its understanding of shared biological targets and circuits in the brain. Each platform has multiple programs currently, with significant potential for additional program and indication expansion:

- ***Cerebrum***™, the Company's small molecule platform, utilizes deep understanding of neuronal excitability and neuronal networks and applies a series of computational and experimental tools to develop orally available precision therapies
- ***Solidus***™, the Company's antisense oligonucleotide, or ASO, platform, is an efficient, targeted precision medicine discovery and development engine anchored on a proprietary, computational methodology

The Company's platforms utilize a deliberate, pragmatic and patient-guided 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 diversified, multimodal CNS portfolio with four clinical-stage product candidates across movement disorders and epilepsy. For the Company's most advanced product candidate under the Cerebrum™ platform, ulixacaltamide (also known as PRAX-944), topline results from the Phase 2b Essential1 clinical trial in essential tremor ("ET"), were announced in the first quarter of 2023. The Company initiated its Phase 3 studies in ET in the fourth quarter of 2023, with enrollment expected to complete in the first half of 2024 and topline results expected in the second half of 2024. The Company initiated its PRAX-562 Phase 2 EMBOLD study in the first quarter of 2023 and expects to announce topline results in the first half of 2024. The Company also announced positive results from its PRAX-628 Phase 1 study in May 2023. In June 2023, the Company initiated a Phase 2 proof of concept study evaluating PRAX-628 in patients with a Photo Paroxysmal Response ("PPR"), with results anticipated in the fourth quarter of 2023. Upon completion of the PPR study, Praxis plans to initiate a Phase 2 study of PRAX-628 in focal epilepsy in the first half of 2024. For the Company's most advanced product candidate under the Solidus™ platform, elsunersen (also known as PRAX-222), the Company completed dosing in the first cohort of its EMBRAVE study and announced preliminary data from the first dose cohort in October 2023.

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 and pre-funded warrants through an initial public offering, follow-on public offerings and at-the-market offerings under its shelf registration statement. From inception through September 30, 2023, the Company raised $613.6 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 $96.4 million for the nine months ended September 30, 2023. In addition, as of September 30, 2023, the Company had an accumulated deficit of $627.0 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash and cash equivalents as of September 30, 2023 of $101.1 million will be sufficient to fund the operating expenditures and capital expenditure requirements necessary to advance its research efforts and clinical trials for at least one year from the date of issuance of these condensed consolidated financial statements. The analysis included consideration of the Company's current financial needs and ongoing research and development plans, which are limited to advancing product candidates through, but not beyond, their current clinical trials. 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 condensed consolidated 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 this case, the Company would evaluate further reductions in its expenses or to obtain additional financing sooner than it otherwise would, which 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, 2023 are consistent with those discussed in Note 2 to the consolidated financial statements included in the Company's 2022 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, 2023, the condensed consolidated statements of operations for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 and the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2023 and 2022 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, 2023, the results of its operations for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine months ended September 30, 2023 and 2022. Financial statement disclosures for the three and nine months ended September 30, 2023 and 2022 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, 2023 are not necessarily indicative of results to be expected for the year ended December 31, 2023, 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 expense, collaboration revenue, 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.

Common Stock Warrants

The Company accounts for warrants to purchase shares of its common stock in accordance with the guidance in FASB ASC No. 480, *Distinguishing Liabilities from Equity* (ASC 480) and ASC No. 815, *Derivatives and Hedging* (ASC 815). The Company classifies warrants issued for the purchase of shares of its common stock as either equity or liability instruments based on an assessment of the specific terms and conditions of each respective contract. Such assessment includes determining whether the warrants are freestanding financial instruments or embedded in a host instrument, whether the warrants are liabilities within the scope of ASC 480, whether the warrants meet the definition of a derivative in ASC 815 and whether the warrants meet the requirements for equity classification pursuant to the indexation and equity classification criteria in ASC 815. The Company determines the classification for its warrants at the time of issuance and updates its assessment, as necessary. Warrants that meet all of the criteria for equity classification are recorded as a component of additional paid-in capital.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. The calculation of weighted average number of common shares outstanding excludes shares of restricted common stock that are not vested but includes shares of common stock underlying pre-funded warrants. Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, after giving consideration to the dilutive effect of potentially dilutive common shares. For purposes of this calculation, outstanding options to purchase shares of common stock, unvested shares of restricted common stock and potential shares issuable under the 2020 ESPP are considered potentially dilutive common shares. The Company has generated a net loss in all periods presented so the basic and diluted net loss per share are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

Recently Adopted Accounting Pronouncements

On August 5, 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity* (ASU 2020-06). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity’s own equity. ASU 2020-06 eliminates the separation models for convertible debt with cash conversion features and convertible instruments with beneficial conversion features and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity’s own equity. Additionally, ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. The new standard also introduces additional disclosures for convertible instruments. ASU 2020-06 was effective for public companies that are not smaller reporting companies for fiscal years beginning after December 15, 2021. For all other entities, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. ASU 2020-06 is required to be adopted as of the beginning of a fiscal year. ASU 2020-06 may be applied using either a full or modified retrospective method of transition. The Company adopted ASU 2020-06 effective as of January 1. 2023. The adoption of ASU 2020-06 did not have an impact on the Company’s financial statements.

3. Marketable Securities

The Company did not hold any marketable securities as of September 30, 2023. The following is a summary of the Company's investment portfolio as of December 31, 2022 (in thousands):

	As of December 31, 2022			
		Gross Unrealized		Estimated
	Cost	Gains	Losses	Fair Value
Available-for-sale securities:				
Corporate debt securities	$ 35,042	$ —	$ (163)	$ 34,879
Debt securities issued by U.S. government agencies	4,005	—	(10)	3,995
Total securities with a maturity of one year or less	$ 39,047	$ —	$ (173)	$ 38,874
Total available-for-sale securities	$ 39,047	$ —	$ (173)	$ 38,874

As of December 31, 2022, the Company had 7 securities with a total fair market value of $38.9 million in an unrealized loss position. The Company anticipated 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, 2023 and 2022.

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 Company did not hold any financial assets measured at fair value on a recurring basis as of September 30, 2023. The following table presents information about the Company’s financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2022 (in thousands):

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 34,181	$ —	$ —	$ 34,181
Marketable securities:				
Corporate debt securities	—	34,879	—	34,879
Debt securities issued by U.S. government agencies	3,995	—	—	3,995
	$ 38,176	$ 34,879	$ —	$ 73,055

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued external research and development expenses	$ 4,348	$ 10,734
Accrued personnel-related expenses	2,020	2,803
Accrued other expenses	611	2,313
Total accrued expenses	$ 6,979	$ 15,850

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, 2023 and December 31, 2022. This lease qualifies as an operating lease.

7. UCB Option and License Agreement

In December 2022, the Company entered into an Option and License Agreement ("the Collaboration Agreement") with UCB Biopharma SRL ("UCB") for the discovery of small molecule therapeutics as potential treatments of KCNT1-related epilepsies. Under the terms of the Collaboration Agreement, the Company has agreed to perform general biology-related research services as part of a mutually agreed upon research plan in exchange for a $5.0 million upfront payment. In addition, the Company provided UCB an exclusive option to in-license global development and commercialization rights to any resulting KCNT1 small molecule development candidate identified as part of the research plan. If UCB exercises its option to in-license global development and commercialization rights, the Collaboration Agreement stipulates that UCB will assume research, development, manufacturing and commercialization responsibilities and costs. Under the terms of the Collaboration Agreement, the Company will be eligible to receive an option fee and future success-based development and commercialization milestone payments, totaling up to $98.5 million, in addition to tiered royalties on net sales of any resulting products from the Collaboration Agreement.

The Company concluded that UCB is a customer, and as such, the arrangement falls within the scope of Topic 606. At the commencement of the Collaboration Agreement, the Company identified one performance obligation, which was to perform the research services for UCB. The Company determined the transaction price to be $5.0 million, comprised of the upfront payment it received. The option provided to UCB was determined not to be a material right.

The Company recognizes revenue for its research services performance obligation over time using an input method over the duration of the research services. During the three and nine months ended September 30, 2023, the Company recognized $0.5 million and $1.9 million, respectively, in collaboration revenue related to the Collaboration Agreement in the condensed consolidated statement of operations. As of September 30, 2023, $3.1 million was included in deferred revenue in the condensed consolidated balance sheet, of which $1.6 million was classified as current.

8. Common Stock and Preferred Stock

Common Stock

As of September 30, 2023 and December 31, 2022, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value.

As of September 30, 2023 and December 31, 2022, the Company did not hold any treasury shares.

June 2023 Public Offering

On June 21, 2023, the Company completed a public offering of: (i) an aggregate of 64,449,690 shares of its common stock at a public offering price of $0.95 per share, including the underwriters' full exercise of their option to purchase 9,299,690 additional shares of common stock, and (ii) pre-funded warrants to purchase 7,050,000 shares of common stock at a public offering price of $0.9499 per share of common stock underlying the warrants. The purchase price per share for each pre-funded warrant represents the per share offering price for the common stock, less the $0.0001 per share exercise price for each underlying share. Total net proceeds generated from the offering were approximately $63.4 million, after deducting underwriting discounts, commissions and other offering expenses payable by the Company.

The pre-funded warrants are exercisable at any time on or after the date of issuance at the option of the holder, subject to a beneficial ownership blocker that may limit exercisability. No holder may exercise any portion of the warrants that would cause either the aggregate number of shares of common stock beneficially owned by such holder, together with its affiliates, to exceed 9.99%, or the combined voting power of the securities beneficially owned by such holder, together with its affiliates, to exceed 9.99%. A holder of a pre-funded warrant may increase or decrease this percentage up to 19.99% by providing at least 61 days' prior notice to the Company. The pre-funded warrants do not expire. The pre-funded warrants may be settled through either physical or net share settlement. Following the occurrence of certain fundamental transactions, the holders of the pre-funded warrants have the right to receive upon exercise of the warrants the same amount and kind of securities, cash, or property as they would have been entitled to receive if they had been holders of the common shares issuable under the warrants immediately prior to such transaction. In the event of certain fundamental transactions where the consideration payable to the holders of shares of common stock consists solely of cash and/or marketable securities, the pre-funded warrants will automatically be deemed to be exercised in full pursuant to a cashless exercise effective immediately prior to and contingent upon the consummation of such transaction. As of September 30, 2023, none of the pre-funded warrants had been exercised and remain outstanding.

The Company determined that the pre-funded warrants are freestanding financial instruments because they are both legally detachable and separately exercisable from the common stock sold in the offering. As such, the Company evaluated the pre-funded warrants to determine whether they represent instruments that require liability classification pursuant to the guidance in ASC 480. However, the Company concluded that the pre-funded warrants are not a liability within the scope of ASC 480 due to their characteristics. Further, the Company determined that the pre-funded warrants do not meet the definition of a derivative under ASC 815 because they do not meet the criteria regarding no or little initial net investment. Accordingly, the Company assessed the pre-funded warrants relative to the guidance in ASC No. 815-40, *Contracts in Entity's Own Equity*, to determine the appropriate treatment. The Company concluded that the pre-funded warrants are both indexed to its own stock and meet all other conditions for equity classification. Accordingly, the Company has classified the pre-funded warrants as permanent equity.

Shares Reserved for Future Issuance

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

	September 30, 2023	December 31, 2022
Shares reserved for exercise of outstanding stock options	9,876,256	8,838,028
Shares reserved for exercise of pre-funded warrants	7,050,000	—
Shares reserved for future awards under the 2020 Stock Option and Incentive Plan	2,444,985	1,650,955
Shares reserved for future awards under the 2020 Employee Stock Purchase Plan	932,077	839,922
Shares reserved for vesting of restricted stock units	633,615	743,950
Total shares of authorized common stock reserved for future issuance	20,936,933	12,072,855

Preferred Stock

As of September 30, 2023 and December 31, 2022, the authorized capital stock of the Company included 10,000,000 shares of undesignated preferred stock, $0.0001 par value.

9. 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, 2023 and December 31, 2022 was 9,918,602 shares and 7,449,480 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, 2023 and December 31, 2022 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, 2023 and December 31, 2022 was 1,308,408 shares and 981,306 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, 2022	743,950	$ 23.07
Issued	316,750	2.85
Vested	(187,111)	26.81
Forfeited	(239,974)	11.72
Unvested as of September 30, 2023	633,615	$ 15.91

As of September 30, 2023, total unrecognized compensation cost related to unvested restricted stock units was $7.4 million, which is expected to be recognized over a weighted-average period of 2.04 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, 2022	8,838,028	$ 13.93		
Granted	2,925,941	2.78		
Exercised	(49,316)	2.07		$ 90
Cancelled or Forfeited	(1,838,397)	12.78		
Outstanding as of September 30, 2023	9,876,256	$ 10.90	7.97	$ 222
Exercisable as of September 30, 2023	5,223,043	$ 12.59	7.44	$ 112
Vested and expected to vest as of September 30, 2023	9,876,256	$ 10.90	7.97	$ 222

Valuation of Stock Options

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, 2023:

	Three Months Ended September 30,	Nine Months Ended September 30,
	2023	2023
Risk-free interest rate	4.35 %	3.57 %
Expected term (in years)	6.00	6.00
Expected volatility	90.01 %	88.30 %
Expected dividend yield	— %	— %
Weighted average grant-date fair value per share	$ 1.02	$ 2.08

As of September 30, 2023, total unrecognized compensation cost related to unvested stock options was $29.1 million, which is expected to be recognized over a weighted-average period of 1.68 years.

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 2,035	$ 1,999	$ 6,176	$ 8,200
General and administrative	3,728	4,731	12,955	14,027
Total stock-based compensation expense	$ 5,763	$ 6,730	$ 19,131	$ 22,227

10. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Outstanding stock options	9,876,256	9,159,415	9,876,256	9,159,415
Unvested restricted stock units	633,615	789,419	633,615	789,419
Potential shares issuable under the 2020 ESPP	161,713	48,182	161,713	48,182
	10,671,584	9,997,016	10,671,584	9,997,016

Common shares issuable upon exercise of the pre-funded warrants that were sold in connection with the June 2023 underwritten public offering are included in the calculation of weighted average number of common shares outstanding for the three and nine months ended September 30, 2023. Consistent with the guidance in ASC 260-10-45-13, the underlying common shares are issuable for little to no consideration and there are no vesting conditions or contingencies associated with the warrants. Accordingly, the aggregate number of common shares underlying the pre-funded warrants have been considered outstanding for purposes of the calculation of net loss per share from the date of issuance.

11. 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.

12. Restructuring

In June 2022, the Company began a strategic realignment across the Cerebrum™ and Solidus™ platforms, 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 was recognized in research and development expenses and $0.4 million was recognized in general and administrative expenses in the consolidated statement of operations during the nine months ended September 30, 2022. These costs related to employee severance, benefits and related costs. As of December 31, 2022, all costs related to the strategic realignment had been paid.

13. 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 7, 2023. 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” sections of our Annual Report on Form 10-K for the year ended December 31, 2022, our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 and this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, 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 insights from genetic epilepsies 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 both rare and more prevalent neurological disorders. We are applying genetic insights to the discovery and development of therapies for neurological disorders through two proprietary platforms, using our understanding of shared biological targets and circuits in the brain. Each platform currently has multiple programs, with significant potential for additional program and indication expansion:

- ***Cerebrum***™, our small molecule platform, utilizes deep understanding of neuronal excitability and neuronal networks and applies a series of computational and experimental tools to develop orally available precision therapies
- ***Solidus***™, our antisense oligonucleotide, or ASO, platform, is an efficient, targeted precision medicine discovery and development engine anchored on a proprietary, computational methodology

Our platforms utilize a deliberate, pragmatic and patient-guided 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 diversified, multimodal CNS portfolio with four clinical-stage product candidates across movement disorders and epilepsy. For our most advanced product candidate under the Cerebrum™ platform, ulixacaltamide (also known as PRAX-944), topline results from the Phase 2b Essential1 clinical trial in essential tremor, or ET, were announced in the first quarter of 2023. We initiated our Phase 3 studies in ET in the fourth quarter of 2023, with enrollment expected to complete in the first half of 2024 and topline results expected in the second half of 2024. We initiated the PRAX-562 Phase 2 EMBOLD study in the first quarter of 2023 and expect to announce topline results in the first half of 2024. We also announced positive results from our PRAX-628 Phase 1 study in May 2023. In June 2023, we initiated a Phase 2 proof of concept study evaluating PRAX-628 in patients with a Photo Paroxysmal Response, or PPR, with results anticipated in the fourth quarter of 2023. Upon completion of the PPR study, we plan to initiate a Phase 2 study in focal epilepsy in the first half of 2024. For our most advanced product candidate under the Solidus™ platform, elsunersen (also known as PRAX-222), we completed dosing in the first cohort of the EMBRAVE study and announced preliminary data from the first dose cohort in October 2023.

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, contract development and manufacturing organizations 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 $96.4 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $627.0 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, ulixacaltamide, to a late stage clinical trial for the treatment of ET;
- advance our PRAX-562 product candidate in the EMBOLD clinical trial;
- advance our PRAX-222 product candidate in the EMBRAVE clinical trial;
- advance our PRAX-628 product candidate;
- 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.

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, 2023, we had cash and cash equivalents of $101.1 million. We believe that our cash and cash equivalents as of September 30, 2023 will enable us to fund our operating expenses and capital expenditures into the first quarter of 2025. We have based this analysis on our current financial needs and ongoing research and development plans, which are limited to advancing product candidates through, but not beyond, their current clinical trials. We have based our assessment on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

We have not generated any revenue from the sale of products since inception and do not expect to generate any revenue from the sale of products for several years, if at all. As discussed in Note 7 to our condensed consolidated financial statements, we entered into an Option and License Agreement, or the Collaboration Agreement, with UCB Biopharma SRL, or UCB, in December 2022. We recognized $0.5 million and $1.9 million of collaboration revenue from the Collaboration Agreement during the three and nine months ended September 30, 2023, respectively.

Operating Expenses

Research and Development Expenses

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 IP 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, such as information technology, 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 condensed 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 platforms and product candidates upon commencement. Due to the number of ongoing studies and our ability to use resources across platforms, indirect or shared operating costs incurred for our research and development platforms, such as personnel, facility costs and certain consulting costs, are not recorded or maintained on a platform-specific basis.

The following table reflects our research and development expenses, including direct expenses summarized by platform 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,	
	2023	2022	2023	2022
Cerebrum™	$ 5,832	$ 16,293	$ 23,857	$ 76,720
Solidus™	2,806	3,655	16,330	13,883
Personnel-related (including stock-based compensation)	6,840	8,714	21,744	30,590
Other indirect research and development expenses	1,782	1,777	6,447	5,518
Total research and development expenses	$ 17,260	$ 30,439	$ 68,378	$ 126,711

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 our product candidates.

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, such as information technology. 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 platform 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. There was no income tax provision recognized for the three and nine months ended September 30, 2023 and 2022.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

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

	Three Months Ended September 30,		Change
	2023	2022	
Collaboration revenue	$ 468	$ —	$ 468
Operating expenses:			
Research and development	17,260	30,439	(13,179)
General and administrative	8,724	13,851	(5,127)
Total operating expenses	25,984	44,290	(18,306)
Loss from operations	(25,516)	(44,290)	18,774
Other income:			
Other income, net	884	345	539
Total other income	884	345	539
Net loss	$ (24,632)	$ (43,945)	$ 19,313

Collaboration Revenue

The $0.5 million increase in collaboration revenue is associated with the revenue recorded as research services are provided and costs are incurred under the Collaboration Agreement with UCB that was executed in December 2022.

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, 2023	Three Months Ended September 30, 2022	Change
Cerebrum™	$ 5,832	$ 16,293	$ (10,461)
Solidus™	2,806	3,655	(849)
Personnel-related (including stock-based compensation)	6,840	8,714	(1,874)
Other indirect research and development expenses	1,782	1,777	5
Total research and development expenses	$ 17,260	$ 30,439	$ (13,179)

The $13.2 million decrease in research and development expenses was primarily attributable to the following:

- $10.5 million decrease in expense related to our Cerebrum™ platform, driven primarily by:
  - $4.2 million decrease in spend for our ulixacaltamide program, primarily due to prior year Phase 1 spending and decreased activity related to our Essential1 study, partially offset by costs related to Essential3 study start up activities;
  - $2.9 million decrease in clinical-related spend for our PRAX-114 program due to our strategic realignment in the second quarter of 2022;
  - $1.4 million decrease in spend for our PRAX-562 program, primarily related to prior year manufacturing spend and Phase 1 trial spend, partially offset by current quarter costs related to the EMBOLD Phase 2 clinical trial;
  - $1.4 million decrease in activities for our earlier stage assets; and
  - $0.6 million decrease in clinical-related spend for our PRAX-628 Phase 1 clinical trial.
- $0.8 million decrease in expense related to our Solidus™ platform, primarily related to prior year PRAX-222 toxicology spend and clinical study spend, partially offset by current quarter spend for our EMBRAVE Phase 2 clinical trial; and
- $1.9 million decrease in personnel-related costs due to decreased headcount.

General and Administrative Expense

The $5.1 million decrease in general and administrative expenses was primarily attributable to the following:

- $2.5 million decrease in personnel costs due to decreased headcount;
- $1.9 million decrease in consulting expenses and professional fees, and
- $0.7 million decrease in other general and administrative expenses.

Other Income

Other income for the three months ended September 30, 2023 was comprised of interest income on our cash and cash equivalents. Other income for the three months ended September 30, 2022 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, 2023 and 2022

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Change
Collaboration revenue	$ 1,932	$ —	$ 1,932
Operating expenses:			
Research and development	68,378	126,711	(58,333)
General and administrative	32,121	46,822	(14,701)
Total operating expenses	100,499	173,533	(73,034)
Loss from operations	(98,567)	(173,533)	74,966
Other income:			
Other income, net	2,168	677	1,491
Total other income	2,168	677	1,491
Net loss	$ (96,399)	$ (172,856)	$ 76,457

Collaboration Revenue

The $1.9 million increase in collaboration revenue is associated with the revenue recorded as research services are provided and costs are incurred under the Collaboration Agreement with UCB that was executed in December 2022.

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, 2023	Nine Months Ended September 30, 2022	Change
Cerebrum™	$ 23,857	$ 76,720	$ (52,863)
Solidus™	16,330	13,883	2,447
Personnel-related (including stock-based compensation)	21,744	30,590	(8,846)
Other indirect research and development expenses	6,447	5,518	929
Total research and development expenses	$ 68,378	$ 126,711	$ (58,333)

The $58.3 million decrease in research and development expenses was primarily attributable to the following:

- $52.9 million decrease in expense related to our Cerebrum™ platform, driven primarily by:
  - $29.0 million decrease in clinical-related spend for our PRAX-114 program due to our strategic realignment in the second quarter of 2022;
  - $11.6 million decrease in spend for our PRAX-562 program primarily related to prior year manufacturing spend and Phase 1 trial spending, partially offset by costs for our EMBOLD Phase 2 clinical trial in 2023;
  - $9.1 million decrease in spend for our ulixacaltamide program, primarily due to prior year Phase 2a and Phase 1 trial spend, prior year manufacturing costs and decreased spend in the current year related to our Essential1 trial, partially offset by startup costs related to our Essential3 study;
  - $5.4 million decrease in activities for our earlier stage assets due to prioritization of our clinical-stage programs; and
  - $2.2 million increase in clinical-related spend for our PRAX-628 program driven by our Phase 1 clinical trial and our Phase 2 PPR clinical trial.
- $8.8 million decrease in personnel-related costs due to decreased headcount;

- $2.4 million increase in expense related to our Solidus™ platform, primarily driven by costs associated with the initiation of the PRAX-222 EMBRAVE study in 2023 and associated milestone payment earned by Ionis Pharmaceuticals, Inc., or Ionis, partially offset by manufacturing expenses incurred in the prior year and a $2.0 million license fee earned by Ionis in 2022; and

- $0.9 million increase in indirect expenses, none of which were individually significant.

General and Administrative Expense

The $14.7 million decrease in general and administrative expenses was primarily attributable to the following:

- $6.8 million decrease in professional fees and consulting expenses;

- $5.6 million decrease in personnel-related costs due to decreased headcount; and

- $2.3 million decrease in other general and administrative expenses.

Other Income

Other income for the nine months ended September 30, 2023 and 2022 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, follow-on public offerings and at-the-market offerings under our shelf registration statement. From inception through September 30, 2023, we have raised $613.6 million in aggregate cash proceeds from such transactions, net of issuance costs. As of September 30, 2023, we had cash and cash equivalents of $101.1 million.

In November 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 acted as sales agent. We terminated the Sales Agreement in June 2023. During the nine months ended September 30, 2023, we issued and sold 14,291,937 shares under the sales agreement for aggregate net proceeds of $24.1 million. We issued and sold a total of 18,279,207 shares under the Sales Agreement for aggregate net proceeds of $40.7 million after deducting commissions and offering expenses payable by us.

On June 21, 2023, we completed a public offering of: (i) an aggregate of 64,449,690 shares of common stock at a public offering price of $0.95 per share, including the underwriters' full exercise of their option to purchase 9,299,690 additional shares of common stock, and (ii) pre-funded warrants to purchase 7,050,000 shares of common stock at a public offering price of $0.9499 per share. The purchase prices per share for each pre-funded warrant represents the per share offering price for the common stock, less the $0.0001 per share exercise price for each underlying share. Total net proceeds generated from the offering were approximately $63.4 million, after deducting underwriting discounts, commissions and other offering expenses payable by us.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (87,275)	$ (156,237)
Investing activities	39,000	74,295
Financing activities	87,745	5,078
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 39,470	$ (76,864)

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, 2023, net cash used in operating activities of $87.3 million was primarily due to our $96.4 million net loss and $11.0 million in changes in operating assets and liabilities primarily related to decreases in accrued expenses and accounts payable, partially offset by $20.1 million of non-cash charges primarily related to stock-based compensation.

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.

Investing Activities

During the nine months ended September 30, 2023, net cash provided by investing activities of $39.0 million was primarily related to maturities of marketable securities.

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.

Financing Activities

During the nine months ended September 30, 2023, net cash provided by financing activities of $87.7 million consisted primarily of net proceeds from at-the-market offerings and our June 2023 follow-on public offering.

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.

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 Cerebrum™ and Solidus™ platforms;
- 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.

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 and cash equivalents as of September 30, 2023 will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2025. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

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 platforms 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; 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 7, 2023, other than as disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

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 cash, cash equivalents and marketable securities we may hold at any time may be in the form of money market funds or marketable debt securities 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 at any given time, an immediate change in market interest rates of 100 basis points would not have a material impact 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, 2023. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, 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.

The risk factors set forth below update, and should be read in conjunction with, the risk factors previously disclosed in the section entitled "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 7, 2023 and in the sections entitled "Risk Factors" of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023 and June 30, 2023 filed with the SEC on May 11, 2023 and August 9, 2023, respectively.

Risks Related to Preclinical and Clinical Development

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously reported. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. Others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, preliminary or topline data that we report differ from later, final or actual results, or if others, including the FDA and comparable foreign regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Risks Related to our Reverse Stock Split

The reverse stock split may not increase the market price per share of our common stock meaningfully or at all, and any such increase may not be sustained or may be insufficient to generate increased investor interest, maintain liquidity for our stockholders, or maintain our market capitalization.

On November 6, 2023, our stockholders approved amendments to our Amended and Restated Certificate of Incorporation to effect a reverse stock split to all of the outstanding shares of our common stock at a ratio ranging from any whole number between 1-for-5 and 1-for-25, or the reverse stock split, subject to our board of directors’ authority to elect, without further action on the part of our stockholders, whether to effect the reverse stock split and, if so, to determine the reverse stock split ratio from among the approved range. While we anticipate that the reverse stock split will result in an increase in the market price per share of our common stock, we cannot be assured that such increase will occur or, if it does, that such increase will result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including our business and financial performance, general market conditions and our prospects for future success.

Even assuming an increase in the market price per share of our common stock occurs as a result of the reverse stock split, there is no guarantee that such increase will enhance the level of investment in our common stock by institutional investors or increase analyst and broker interest in our company. In addition, it is possible that the reverse stock split may adversely affect our stockholders' liquidity by reducing the number of shares outstanding after the reverse stock split, particularly if the price of our common stock does not increase as a result of the reverse stock split, or if it does not increase in proportion to the reduction in the number of shares of our common stock outstanding immediately before the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for our common stock, thus reducing our stockholders' liquidity.

Furthermore, should the per share market price of our common stock fail to increase in proportion to the reverse stock split ratio, or should the overall value of our common stock decline, after the reverse stock split, then the value of the shares of our common stock held by our stockholders will also decrease. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of our common stock will remain the same after the reverse stock split is effected.

Any of the foregoing would have an adverse effect on our common stock and could adversely affect our business.

The reverse stock split may not result in more normalized trading in our common stock or decrease the market volatility of our common stock and could result in increased trading costs for our stockholders.

Reverse stock splits can be viewed negatively by the market and it is difficult to predict how the market will respond to a reverse stock split of our common stock. Due to the smaller number of shares of our common stock that will be outstanding after the reverse stock split, trading in our common stock may decrease and, due to the decrease in trading volume, smaller trades in our common stock could result in increased volatility as compared to the trading volume and volatility of our common stock prior to the reverse stock split.

The reverse stock split will also increase the number of stockholders who own "odd lots" of less than 100 shares of our common stock. A purchase or sale of less than 100 shares (an "odd lot" transaction) may result in incrementally higher trading costs through certain brokers, particularly "full service" brokers. Therefore, those stockholders who own fewer than 100 shares of our common stock following the reverse stock split may be required to pay higher transaction costs if they sell their shares of our common stock.

The authorized shares of common stock that will become available as a result of the reverse stock split may not be sufficient to fulfill our current and anticipated corporate purposes.

Because the reverse stock split will decrease the number of outstanding shares of our common stock by a ratio in the range of 1-for-5 to 1-for-25 but would not effect a decrease to the number of shares of common stock that we are authorized to issue, the reverse stock split will result in a relative increase in the number of unissued shares of our common stock. Such relative increase in the number of unissued shares of our common stock may not be sufficient to fulfill our current and anticipated corporate purposes, including financing activities, public or private offerings of common stock, issuance of options and other equity awards pursuant to our incentive plans, and strategic business development transactions. If the increase in the number of unissued shares of our common stock generated by the reverse stock split proves insufficient to fulfill our corporate purposes, we may need to delay corporate activities and incur additional expenses in order to obtain stockholder approval to increase our authorized shares of common stock, or we may have to abandon such activities entirely. Accordingly, we may be prevented from acting promptly, or at all, to fulfill our corporate purposes, which could adversely affect our business and prospects.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

Recent Sales of Unregistered Equity Securities

We did not make any sales of unregistered securities during the three months ended September 30, 2023.

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, 2023.

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).
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 7, 2023	By:	/s/ Marcio Souza
			Marcio Souza
			Chief Executive Officer and Director (Principal Executive Officer)
Date:	November 7, 2023	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 7, 2023	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 7, 2023	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, 2023 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 7, 2023	By:	/s/ MARCIO SOUZA
			Marcio Souza Chief Executive Officer (Principal Executive Officer)
Date:	November 7, 2023	By:	/s/ TIMOTHY KELLY
			Timothy Kelly Chief Financial Officer (Principal Financial Officer)