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 March 31, 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

(State or other jurisdiction of incorporation or organization)

47-5195942 (I.R.S. Employer Identification No.)

99 High Street, 30th Floor Boston, MA (Address of principal executive offices)

02110 (Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

	Trading	Name of each exchange
Title of each class	Symbol(s)	on which registered
Common Stock, par value \$0.0001 per share	PRAX	The Nasdag 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 \boxtimes No \square

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 \boxtimes No \square

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 filerAccelerated filerNon-accelerated filerSmaller reporting company

Emerging growth company \Box

 \mathbf{X}

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 May 5, 2023, the registrant had 62,101,292, 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; and
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 and under the section titled "Risk Factors" in this Quarterly Report on Form 10-Q for the quarter ended March 31, 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 section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022 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)

Assets Image: Control of the section of t		March 31	, 2023	Decem	ber 31, 2022
Cash and cash equivalents \$ 80,839 \$ 61,615 Marketable securities 4,983 38,874 Prepaid expenses and other current assets 8,580 10,351 Total current assets 94,402 110,840 Property and equipment, net 865 971 Operating lease right-of-use assets 2,700 2,901 Other non-current assets 416 416 Total assets \$ 98,383 \$ 115,128 Liabilities \$ 98,383 \$ 115,128 Liabilities \$ 98,383 \$ 115,128 Current liabilities 9,352 15,850 Operating lease liabilities 1,035 1,005 Current liabilities 2,916 34,345 Iong-term liabilities 2,9216 34,345 Long-term liabilities 2,225 2,495 Non-current portion of deferred revenue 1,774 2,182 Total current liabilities 33,915 39,022 Commitments and contingencies (Note 6) 33,915 39,022 Stockholders' equity: — — </td <td>Assets</td> <td></td> <td></td> <td></td> <td></td>	Assets				
Marketable securities 4,983 38,874 Prepaid expenses and other current assets 8,580 10,351 Total current assets 94,402 110,840 Property and equipment, net 865 971 Operating lease right-of-use assets 2,700 2,901 Other non-current assets 416 416 Total assets \$ 98,383 \$ 115,128 Liabilities \$ 98,383 \$ 115,128 Current labilities: \$ 98,383 \$ 115,128 Accounts payable \$ 16,986 \$ 14,672 Account payable \$ 16,986 \$ 14,672 Accound expenses 9,352 15,850 Operating lease liabilities 1,035 1,005 Current labilities 29,916 34,345 Long-term liabilities 29,916 34,345 Long-term labilities 33,915 39,022 Non-current portion of deferred revenue 1,774 2,182 Total current labilities 33,915 39,022 Commitments and contingencies (Note 6) 33,915 39,0	Current assets:				
Prepaid expenses and other current assets 8,580 10,351 Total current assets 94,402 110,840 Property and equipment, net 865 971 Operating lease right-of-use assets 2,700 2,901 Other non-current assets 416 416 Total assets \$ 98,383 \$ 115,128 Liabilities and stockholders' equity \$ 9,352 15,850 Current liabilities: 1,035 1,005 Accrued expenses 9,352 15,850 Operating lease liabilities 1,035 1,005 Current portion of deferred revenue 2,543 2,818 Total current portion of operating lease liabilities 29,916 34,345 Long-term liabilities 2,225 2,495 Non-current portion of deferred revenue 1,774 2,182 Total liabilities 33,915 39,022 Commitments and contingencies (Note 6) 33,915 39,022 Stockholders' equity: - - - Preferred stock, \$0,0001 par value; 15,0,000,000 shares authorized; 57,960,387 shares issued and outstandin	Cash and cash equivalents	\$	80,839	\$	61,615
Total current assets 94,402 110,840 Total current assets 94,402 110,840 Operating lease right-of-use assets 2,700 2,901 Other non-current assets 416 4165 Total assets \$ 98,383 \$ 115,128 Liabilities and stockholders' equity	Marketable securities		4,983		38,874
Property and equipment, net865971Operating lease right-of-use assets2,7002,901Other non-current assets\$ 98,383\$ 115,128Liabilities and stockholders' equity\$ 98,383\$ 115,128Current liabilities:	Prepaid expenses and other current assets		8,580		10,351
Operating lease right-of-use assets 2,700 2,901 Other non-current assets 416 416 Total assets \$ 98,383 \$ 115,128 Liabilities and stockholders' equity \$ 98,383 \$ 115,128 Current liabilities: \$ 9,352 15,850 Accounts payable 9,352 15,850 Operating lease liabilities 1,035 1,005 Current portion of deferred revenue 2,543 2,818 Total current liabilities: 29,916 34,345 Long-term liabilities: 29,916 34,345 Non-current portion of operating lease liabilities 2,225 2,495 Non-current portion of deferred revenue 1,774 2,182 Total liabilities 33,915 39,022 Commitments and contingencies (Note 6) 33,915 39,022 Stockholders' equity. - - Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022 6 5 Additional paid-in capital 632,580 606,918 5	Total current assets		94,402		110,840
Other non-current assets 416 416 Total assets \$ 98,383 \$ 115,128 Liabilities and stockholders' equity - - Current liabilities: - - Accounts payable \$ 16,986 \$ 14,672 Accrued expenses 9,352 15,850 Operating lease liabilities 1,035 1,005 Current portion of deferred revenue 2,543 2,818 Total current liabilities 29,916 34,345 Long-term liabilities 29,916 34,345 Commitements and contingencies (Note 6) 33,915 39,022 Stockholders' equity: - - - Preferred stock, \$0,0001 par value; 10,000,000 shares authorized; 57,960,387 shares issued or outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 2022 6 5 Additional paid-in capital 632,580 606,918 662,580 Accumulated other comprehensive loss (19) (173) 420,916 1(13) Accumulated othericit (568,099) (530,644) 76,1006	Property and equipment, net		865		971
Total assets\$98,383\$115,128Liabilities and stockholders' equityCurrent liabilities:*16,986\$14,672Accounts payable\$16,986\$14,672Accound expenses9,35215,8500perating lease liabilities1,0351,005Current portion of deferred revenue2,5432,8182,818Total current liabilities29,91634,345Long-term liabilities2,2252,495Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments 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 March 31, 2023 and December 31, 202265Additional paid-in capital632,580606,9135Accourulated other comprehensive loss(19)(173)Accourulated deficit(580,09)(530,644)Total stockholders' equity64,46876,106	Operating lease right-of-use assets		2,700		2,901
LiabilitiesCurrent liabilities:Accounts payable\$ 16,986\$ 14,672Accrued expenses9,35215,850Operating lease liabilities1,0351,005Current portion of deferred revenue2,5432,818Total current liabilities:29,91634,345Long-term liabilities:29,91634,345Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)31,2023 and December 31, 2022-Stockholders' equity:Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; 57,960,387 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Other non-current assets		416		416
Current liabilities: \$ 16,986 \$ 14,672 Accounts payable \$ 16,986 \$ 14,672 Accrued expenses 9,352 15,850 Operating lease liabilities 1,035 1,005 Current portion of deferred revenue 2,543 2,818 Total current liabilities 29,916 34,345 Long-term liabilities: 2,225 2,495 Non-current portion of operating lease liabilities 2,225 2,495 Non-current portion of deferred revenue 1,774 2,182 Total liabilities 33,915 39,022 Commitments and contingencies (Note 6)	Total assets	\$	98,383	\$	115,128
Accounts payable\$16,986\$14,672Accrued expenses9,35215,850Operating lease liabilities1,0351,005Current portion of deferred revenue2,5432,818Total current liabilities29,91634,345Long-term liabilities:29,91634,345Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)	Liabilities and stockholders' equity				
Accrued expenses9,35215,850Operating lease liabilities1,0351,005Current portion of deferred revenue2,5432,818Total current liabilities29,91634,345Long-term liabilities:29,91634,345Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)339,022Stockholders' equity:Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2022Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Current liabilities:				
Operating lease liabilities1,0351,005Current portion of deferred revenue2,5432,818Total current liabilities29,91634,345Long-term liabilities:29,91634,345Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)33,91539,022Stockholders' equity:Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; 57,960,387 shares issued or outstanding as of March 31, 2023 and 29,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)(173)(568,099)(530,644)Total stockholders' equity64,46876,106	Accounts payable	\$	16,986	\$	14,672
Current portion of deferred revenue2,5432,818Total current liabilities29,91634,345Long-term liabilities2,2252,495Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)33,91539,022Stockholders' equity:Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Accrued expenses		9,352		15,850
Total current liabilities29,91634,345Long-term liabilities:Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)31,202339,022Stockholders' equity:Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,9185Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Operating lease liabilities		1,035		1,005
Long-term liabilities: Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments 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 March 31, 2023 and December 31, 2022—Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 20226Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Current portion of deferred revenue		2,543		2,818
Non-current portion of operating lease liabilities2,2252,495Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)339,022Stockholders' equity:Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022——Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 2022——Additional paid-in capital632,580606,9185Accumulated other comprehensive loss(19)(173)(568,099)(530,644)Total stockholders' equity64,46876,106101	Total current liabilities		29,916		34,345
Non-current portion of deferred revenue1,7742,182Total liabilities33,91539,022Commitments and contingencies (Note 6)Stockholders' equity:	Long-term liabilities:				
Total liabilities33,91539,022Commitments 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 March 31, 2023 and December 31, 2022Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Non-current portion of operating lease liabilities		2,225		2,495
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 March 31, 2023 and December 31, 2022Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 2022Additional paid-in capitalAccumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity	Non-current portion of deferred revenue		1,774		2,182
Stockholders' equity:	Total liabilities		33,915		39,022
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2023 and December 31, 2022——Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Commitments and contingencies (Note 6)				
March 31, 2023 and December 31, 2022——Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Stockholders' equity:				
outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 202265Additional paid-in capital632,580606,918Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106			_		_
Accumulated other comprehensive loss(19)(173)Accumulated deficit(568,099)(530,644)Total stockholders' equity64,46876,106	Common stock, \$0.0001 par value; 150,000,000 shares authorized; 57,960,387 shares issued and outstanding as of March 31, 2023, and 49,382,453 shares issued and outstanding as of December 31, 2022		6		5
Accumulated deficit (568,099) (530,644) Total stockholders' equity 64,468 76,106	Additional paid-in capital		632,580		606,918
Total stockholders' equity 64,468 76,106	Accumulated other comprehensive loss		(19)		(173)
	Accumulated deficit	(568,099)		(530,644)
Total liabilities and stockholders' equity \$ 98,383 \$ 115,128	Total stockholders' equity		64,468		76,106
	Total liabilities and stockholders' equity	\$	98,383	\$	115,128

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

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

	Three Mor Marc	 inded
	 2023	2022
Collaboration revenue	\$ 683	\$
Operating expenses:		
Research and development	25,504	52,652
General and administrative	 13,270	 16,197
Total operating expenses	38,774	68,849
Loss from operations	(38,091)	(68,849)
Other income:		
Other income, net	 636	 132
Total other income	636	132
Net loss	\$ (37,455)	\$ (68,717)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.71)	\$ (1.51)
Weighted average common shares outstanding, basic and diluted	 53,102,907	45,455,179

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

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

(Amounts in thousands)

		Months Aarch 31	
	2023		2022
Net loss	\$ (37,4	55) \$	(68,717)
Change in unrealized losses on marketable securities, net of tax	:	54	(430)
Comprehensive loss	\$ (37,5	01) \$	(69,147)

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

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(Unaudited)

(Amounts in thousands, except share data)

				Additional Paid-In	А	ccumulated		ccumulated Other mprehensive	Total Stockholders'			
	Shares		Amount		Capital		Deficit		Loss		Equity	
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	

Commo	on Stoc	n Stock Additional Paid-In				ccumulated		Accumulated Other Omprehensive	St	Total ockholders'
Shares	A	Amount		Capital		Deficit		Loss	00	Equity
45,300,514	\$	5	\$	567,598	\$	(316,615)	\$	(176)	\$	250,812
—		_		7,886		_		_		7,886
70,410		_		1,368		_		_		1,368
81,130		_		_		_		_		_
(17,850)		_		(230)		_		_		(230)
72,278		_		333		_		_		333
—		—		_		—		(430)		(430)
_		_		—		(68,717)		_		(68,717)
45,506,482	\$	5	\$	576,955	\$	(385,332)	\$	(606)	\$	191,022
	Shares 45,300,514 	Shares // 45,300,514 \$	45,300,514 \$ 5 70,410 81,130 (17,850) 72,278	Shares Amount 45,300,514 \$ 5 \$ 70,410 - - 81,130 - - (17,850) - 72,278	Shares Amount Paid-In Capital 45,300,514 \$ 5 \$ 567,598 7,886 70,410 1,368 81,130 (17,850) (230) 72,278 333	Shares Amount Paid-In Capital A 45,300,514 \$ 5 \$ 567,598 \$ - - - 7,886 \$ \$ 70,410 - 1,368 \$ \$ \$ 11,130 - - - \$ \$ 12,278 - 333 \$ \$ \$ - - - - \$ \$	Shares Amount Paid-In Capital Accumulated Deficit 45,300,514 \$ 5 \$67,598 \$(316,615) - - 7,886 - 70,410 - 1,368 - 81,130 - - - (17,850) - (230) - 72,278 - 333 - - - - - - - - (68,717)	Common Stock Additional Paid-In Capital Accumulated Deficit Constraint Deficit Constraint Deficit 45,300,514 \$ 5 \$ 567,598 \$ (316,615) \$ 7,886 70,410 1,368 81,130 (17,850) (230)	Common Stock Additional Paid-in Capiton Accumulated Deficit Other Comprehensive Loss 45,300,514 \$ 5 567,598 \$ (316,615) \$ (176) 7,886 70,410 1,368 81,130 (230) 72,278 333 (430) (68,717)	Common Stock Additional Paid-In Capital Accumulated Deficit Other Comprehensive Loss Stup State 45,300,514 \$ 5 \$ 567,598 \$ (316,615) \$ (176) \$ 7,886

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(Amounts in thousands)

	Three Months Ended March 31,				
	2023		2022		
Cash flows from operating activities:					
Net loss	\$ (37,455)	\$	(68,717)		
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation expense	106		93		
Stock-based compensation expense	7,593		7,886		
Non-cash operating lease expense	201		180		
Amortization of premiums and discounts on marketable securities, net	45		375		
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets	1,771		(1,061)		
Accounts payable	2,314		2,489		
Accrued expenses	(6,498)		4,616		
Operating lease liabilities	(240)		(26)		
Deferred revenue	(683)		—		
Other	 		56		
Net cash used in operating activities	(32,846)		(54,109)		
Cash flows from investing activities:					
Purchases of property and equipment	—		(289)		
Purchases of marketable securities	—		(83,022)		
Maturities of marketable securities	34,000		74,761		
Net cash provided by (used in) investing activities	34,000		(8,550)		
Cash flows from financing activities:					
Proceeds from at-the-market offerings, net of issuance costs	18,096		1,368		
Payment of issuance costs for at-the-market offerings	—		(262)		
Payments of tax withholdings related to vesting of restricted stock units	(127)		(230)		
Proceeds from exercise of stock options	101		333		
Net cash provided by financing activities	18,070		1,209		
Increase (decrease) in cash, cash equivalents and restricted cash	19,224		(61,450)		
Cash, cash equivalents and restricted cash, beginning of period	62,031		139,720		
Cash, cash equivalents and restricted cash, end of period	\$ 81,255	\$	78,270		
Reconciliation of cash, cash equivalents and restricted cash:					
Cash and cash equivalents	80,839		77,854		
Restricted cash	416		416		
Total cash, cash equivalents and restricted cash	\$ 81,255	\$	78,270		

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

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 excitationinhibition 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. An end-of-Phase 2 meeting is scheduled with the U.S. Food and Drug Administration in June 2023 and the Company intends to initiate a Phase 3 study in ET in the second half of 2023. The Company initiated its PRAX-562 Phase 2 EMBOLD study in the first quarter of 2023 and expects to announce topline results in the fourth quarter of 2023. The Company also announced positive results from its PRAX-628 Phase 1 study in May 2023 and expects to initiate a Phase 2 study in focal epilepsy in the fourth quarter of 2023. For the Company's most advanced product candidate under the Solidus™ platform, PRAX-222, it expects to announce topline results from the first dose cohort of its EMBRAVE study in the second half of 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 through an initial public offering, a follow-on public offering and at-the-market offerings under its shelf registration statement. From inception through March 31, 2023, the Company raised \$544.1 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 the condensed consolidated financial statements are issued.

The Company has incurred recurring losses since its inception, including a net loss of \$37.5 million for the three months ended March 31, 2023. In addition, as of March 31, 2023, the Company had an accumulated deficit of \$568.1 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash, cash equivalents and marketable securities as of March 31, 2023 may not be sufficient to fund operations for at least the next twelve months from the date of issuance of these condensed consolidated financial statements which raises substantial doubt about the Company's ability to continue as a going concern, and the Company will need to obtain additional funding. The Company expects to finance its operations through potential public or private equity financings, debt financings, collaboration agreements or other capital sources. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

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 months ended March 31, 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 March 31, 2023, the condensed consolidated statements of operations for the three months ended March 31, 2023 and 2022, the condensed consolidated statements of comprehensive loss for the three months ended March 31, 2023 and 2022, the condensed consolidated statements of cash flows for the three months ended March 31, 2023 and 2022 and the condensed consolidated statements of stockholders' equity for the three months ended March 31, 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 March 31, 2023, the results of its operations for the three months ended March 31, 2023 and 2022 and 2022 and its cash flows for the three months ended March 31, 2023 and 2022 and 2022 and its cash flows for the three months ended March 31, 2023 and 2022 and 2022 and its cash flows for the three months ended March 31, 2023 and 2022 and 2022 and its cash flows for the three months ended March 31, 2023 and 2022 and 2022 and its cash flows for the three months ended March 31, 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 months ended March 31, 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.

Recently Issued Accounting Pronouncements

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

3. Marketable Securities

The following is a summary of the Company's investment portfolio as of March 31, 2023 and December 31, 2022 (in thousands):

		As of March 31, 2023									
			Gross Unrealized					Estimated			
		Cost	Gai	ins	Losses			Fair Value			
Available-for-sale securities:											
Corporate debt securities	\$	5,002	\$	_	\$	(19)	\$	4,983			
Total securities with a maturity of one year or less	\$	5,002	\$	—	\$	(19)	\$	4,983			
Total available-for-sale securities	\$	5,002	\$	_	\$	(19)	\$	4,983			
			As of	Decen	nber 3	1, 2022					
			Gross Unrealized					Estimated			
		Cost				Losses		Fair Value			
Available-for-sale securities:											

	COSL			LUSSES		 all value
Available-for-sale securities:						
Corporate debt securities	\$ 35,042	\$	_	\$ (2	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	\$	_	\$ (2	173)	\$ 38,874
Total available-for-sale securities	\$ 39,047	\$	_	\$ (2	173)	\$ 38,874

As of March 31, 2023, the Company had 1 security with a total fair market value of \$5.0 million in an unrealized loss position. The Company believes that any unrealized losses associated with the decline in value of its securities is temporary and primarily related to the change in market interest rates since purchase, and believes that it is more likely than not that it will be able to hold its debt securities to maturity. Therefore, the Company anticipates a full recovery of the amortized cost basis of its debt securities at maturity and an allowance was not recognized.

Securities are evaluated for impairment at the end of each reporting period. The Company did not record any impairment related to its available-for-sale securities during the three months ended March 31, 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 following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of March 31, 2023 and December 31, 2022 (in thousands):

	As of March 31, 2023									
	 Level 1 Level 2			Level 3		Total				
Assets:										
Cash equivalents:										
Money market funds	\$ 62,976	\$	_	\$	_	\$	62,976			
Marketable securities:										
Corporate debt securities			4,983		—		4,983			
	\$ 62,976	\$	4,983	\$	_	\$	67,959			
				_						

As of December 31, 2022										
Level 1 Level 2		Level 2		Level 3		Total				
\$	34,181	\$	_	\$	_	\$	34,181			
	_		34,879		_		34,879			
	3,995		_		_		3,995			
\$	38,176	\$	34,879	\$	_	\$	73,055			
		\$ 34,181 	\$ 34,181 \$ 	Level 1 Level 2 \$ 34,181 \$ — — 34,879 3,995 —	Level 1 Level 2 \$ 34,181 \$ \$ 34,879 3,995	Level 1 Level 2 Level 3 \$ 34,181 \$ \$ - 34,879 3,995	Level 1 Level 2 Level 3 \$ 34,181 \$ - \$ - 34,879 - \$ 3,995 - -			

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 20)23	December	31, 2022
Accrued external research and development expenses	\$ 6	,355	\$	10,734
Accrued personnel-related expenses	1	,748		2,803
Accrued other expenses	1	,249		2,313
Total accrued expenses	\$ 9	,352	\$	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 March 31, 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 Agreement, 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 months ended March 31, 2023, the Company recognized \$0.7 million in collaboration revenue related to the Collaboration Agreement in the condensed consolidated statement of operations. As of March 31, 2023, \$4.3 million was included in deferred revenue in the condensed consolidated balance sheet, of which \$2.5 million was classified as current.

8. Common Stock and Preferred Stock

Common Stock

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

Shares Reserved for Future Issuance

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

	March 31, 2023	December 31, 2022
Shares reserved for exercise of outstanding stock options	10,691,062	8,838,028
Shares reserved for future awards under the 2020 Stock Option and Incentive Plan	2,113,892	1,650,955
Shares reserved for future awards under the 2020 Employee Stock Purchase Plan	1,167,024	839,922
Shares reserved for vesting of restricted stock units	754,756	743,950
Total shares of authorized common stock reserved for future issuance	14,726,734	12,072,855

Preferred Stock

As of March 31, 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 March 31, 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 March 31, 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 March 31, 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	301,550	2.95
Vested	(172,798)	27.89
Forfeited	(117,946)	 14.27
Unvested as of March 31, 2023	754,756	\$ 15.40

As of March 31, 2023, total unrecognized compensation cost related to unvested restricted stock units was \$10.5 million, which is expected to be recognized over a weighted-average period of 2.50 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		ggregate insic Value
			(In years)	(In t	housands)
Outstanding as of December 31, 2022	8,838,028	\$ 13.93			
Granted	2,629,255	2.97			
Exercised	(44,644)	2.27		\$	83
Cancelled or Forfeited	(731,577)	10.28			
Outstanding as of March 31, 2023	10,691,062	\$ 11.53	8.23	\$	23
Exercisable as of March 31, 2023	4,517,923	\$ 13.74	7.33	\$	23
Vested and expected to vest as of March 31, 2023	10,488,056	\$ 11.47	8.46	\$	23

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 months ended March 31, 2023:

		onths Ended rch 31,	
	2023		
Risk-free interest rate		3.51 %	
Expected term (in years)		6.00	
Expected volatility		88.22 %	
Expected dividend yield		— %	
Weighted average grant-date fair value per share	\$	2.22	

As of March 31, 2023, total unrecognized compensation cost related to unvested stock options was \$40.8 million, which is expected to be recognized over a weighted-average period of 2.05 years.

Stock-Based Compensation

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

		Three Months Ended March 31,			
	20	23	2022		
Research and development	\$	2,223 \$	3,214		
General and administrative		5,370	4,672		
Total stock-based compensation expense	\$	7,593 \$	7,886		

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 March 3	
	2023	2022
Outstanding stock options	10,691,062	7,862,576
Unvested restricted stock units	754,756	840,277
Potential shares issuable under the 2020 ESPP	179,768	30,341
	11,625,586	8,733,194

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. 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" section of our Annual Report on Form 10-K for the year ended December 31, 2022 and set forth in the "Risk Factors" section of Form 10-Q for the three months ended March 31, 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. An end-of-Phase 2 meeting is scheduled with the U.S. Food and Drug Administration, or FDA, in June 2023 and we intend to initiate a Phase 3 study in ET in the second half of 2023. We initiated the PRAX-562 Phase 2 EMBOLD study in the first quarter of 2023 and expect to announce topline results in the fourth quarter of 2023. We also announced positive results from our PRAX-628 Phase 1 study in May 2023 and expect to initiate a Phase 2 study in focal epilepsy in the fourth quarter of 2023. For our most advanced product candidate under the Solidus[™] platform, PRAX-222, we expect to announce topline results from the first dose cohort of our EMBRAVE study in the second half of 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 \$37.5 million for the three months



ended March 31, 2023. As of March 31, 2023, we had an accumulated deficit of \$568.1 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 March 31, 2023, we had cash, cash equivalents and marketable securities of \$85.8 million, which we expect will enable us to fund our operating expenses and capital expenditures into the second quarter of 2024. We have based this analysis on our current cash needs, ongoing research and development plans which are limited to advancing product candidates through, but not beyond their current clinical trial phases and continued operational efficiency. Since our cash, cash equivalents and marketable securities as of March 31, 2023 may not be sufficient to fund our operations for at least the next twelve months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there is substantial doubt about our ability to continue as a going concern. Our future viability is dependent on our ability to raise additional capital to finance our operations. We expect to finance our operations through potential public or private equity financings, debt financings, collaboration agreements or other capital sources. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all. 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. During the three months ended March 31, 2023, we recognized \$0.7 million of collaboration revenue from the Collaboration Agreement.

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 March 31,			
	2023		2022	
Cerebrum™	\$ 11,135	\$	33,955	
Solidus™	3,602		6,042	
Personnel-related (including stock-based compensation)	8,126		11,141	
Other indirect research and development expenses	2,641		1,514	
Total research and development expenses	\$ 25,504	\$	52,652	

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 months ended March 31, 2023 and 2022.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

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

	Three Months Ended March 31,			Change		
		2023		2022		
Collaboration revenue	\$	683	\$	_	\$	683
Operating expenses:						
Research and development		25,504		52,652		(27,148)
General and administrative		13,270		16,197		(2,927)
Total operating expenses		38,774		68,849		(30,075)
Loss from operations		(38,091)		(68,849)		30,758
Other income:						
Other income, net		636		132		504
Total other income		636		132		504
Net loss	\$	(37,455)	\$	(68,717)	\$	31,262

Collaboration Revenue

The \$0.7 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 March 31,			Change
	 2023		2022	
Cerebrum™	\$ 11,135	\$	33,955	\$ (22,820)
Solidus™	3,602		6,042	(2,440)
Personnel-related (including stock-based compensation)	8,126		11,141	(3,015)
Other indirect research and development expenses	2,641		1,514	1,127
Total research and development expenses	\$ 25,504	\$	52,652	\$ (27,148)

The \$27.1 million decrease in research and development expenses was primarily attributable to the following:

- \$22.8 million decrease in expense related to our Cerebrum™ platform, driven primarily by:
 - a \$14.6 million decrease in clinical-related spend for our PRAX-114 program due to our strategic realignment in the second quarter of 2022;
 - a \$6.7 million decrease in spend for our PRAX-562 program, primarily related to the prior year completion of our Phase 1 clinical trial and prior year manufacturing campaign purchases, partially offset by startup costs related to the EMBOLD Phase 2 clinical trial in the first quarter of 2023;
 - a \$2.3 million decrease in activities for our earlier stage assets;
 - a \$1.3 million decrease in spend for our ulixacaltamide program, primarily due to the completion of a manufacturing campaign in the prior year; and
 - an \$2.0 million increase in clinical-related spend for our PRAX-628 Phase 1 clinical trial.
- \$2.4 million decrease in expense related to our Solidus[™] platform, driven primarily by the payment of a \$2.0 million license fee to lonis Pharmaceuticals, Inc. in January of 2022 upon exercise of our exclusive option to obtain the rights and license to further develop and commercialize PRAX-222;
- \$3.0 million decrease in personnel-related costs due to decreased headcount; and
- \$1.1 million increase in indirect expenses, none of which were individually significant.

General and Administrative Expense

The \$2.9 million decrease in general and administrative expenses was primarily attributable to the following:

- \$1.2 million decrease in consulting expenses; and
- \$1.7 million decrease in other general and administrative expenses, including decreased personnel costs.

Other Income

Other income for the three months ended March 31, 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, a follow-on public offering and at-the-market offerings under our shelf registration statement. From inception through March 31, 2023, we have raised \$544.1 million in aggregate cash proceeds from such transactions, net of issuance costs. As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$85.8 million.

On November 3, 2021, we entered into an Open Market Sale Agreement, or the Sales Agreement, with Jefferies LLC, or Jefferies, to provide for the offering, issuance and sale of up to an aggregate amount of \$125.0 million of common stock from time to time in at-the-market offerings for which Jefferies acts as sales agent. During the three months ended March 31, 2023, we issued and sold 8,403,809 shares under the Sales Agreement for aggregate net proceeds of \$18.1 million after deducting commissions and offering expenses payable by us. As of March 31, 2023, we have issued and sold a total of 12,391,079 shares under the Sales Agreement for aggregate net proceeds of \$34.7 million after deducting commissions and offering expenses payable by us.

Cash Flows

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

	-	Three Months Ended March 31,			
		2023		2022	
Net cash (used in) provided by:					
Operating activities	\$	(32,846)	\$	(54,109)	
Investing activities		34,000		(8,550)	
Financing activities		18,070		1,209	
Net increase (decrease) in cash, cash equivalents and restricted cash	\$	19,224	\$	(61,450)	

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 three months ended March 31, 2023, net cash used in operating activities of \$32.8 million was primarily due to our \$37.5 million net loss and \$3.3 million in changes in operating assets and liabilities primarily related to a decrease in accrued expenses, partially offset by \$7.9 million of non-cash charges primarily related to stock-based compensation.

During the three months ended March 31, 2022, net cash used in operating activities of \$54.1 million was primarily due to our \$68.7 million net loss, partially offset by \$8.5 million of non-cash charges primarily related to stock-based compensation, and \$6.1 million in changes in operating assets and liabilities primarily related to increases in accounts payable and accrued expenses.

Investing Activities

During the three months ended March 31, 2023, net cash provided by investing activities of \$34.0 million was related to maturities of marketable securities.

During the three months ended March 31, 2022, net cash used in investing activities of \$8.6 million was primarily related to the purchase of marketable securities, partially offset by the maturity of marketable securities.

Financing Activities



During the three months ended March 31, 2023, net cash provided by financing activities of \$18.1 million consisted of net proceeds from at-the-market offerings.

During the three months ended March 31, 2022, net cash provided by financing activities of \$1.2 million consisted of net proceeds from at-the-market offerings of \$1.4 million and proceeds 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.

As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$85.8 million. We are unable to estimate the exact amount of our working capital requirements, but based on our current operating plan, we believe that our cash, cash equivalents and marketable securities as of March 31, 2023 will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2024. We have incurred recurring losses since our inception, including a net loss of \$37.5 million for the three months ended March 31, 2023. In addition, as of March 31, 2023, we had an accumulated deficit of \$568.1 million. We expect to continue to generate operating losses for the foreseeable future. We have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year of the issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Since we expect that our cash, cash equivalents and marketable securities as of March 31, 2023 may not be sufficient to fund operations for at least the next twelve months from the date of issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there is substantial doubt about our ability to continue as a going concern. Our future viability is dependent on our ability to raise additional capital to finance our operations. We expect to finance our operations through potential public or private equity financings, debt financings, collaboration agreements or other capital sources. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all. 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.

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.

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures.

Management's Evaluation of Our Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. Based on the evaluation of our disclosure controls and procedures as of March 31, 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.

Risks Related to Research and Development and the Biopharmaceutical Industry

Risks Related to Preclinical and Clinical Development

Preclinical and clinical drug development involves a lengthy, complex and expensive process, with an uncertain outcome. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, pivotal clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signs of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Certain of our product candidates failed to meet the primary endpoint in later stage clinical trials and we may in the future have product candidates that fail to show the desired safety and efficacy results in later stage clinical trials despite having progressed through preclinical studies and initial clinical trials. There can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of our product candidates. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with the Good Laboratory Practice requirements and other applicable regulations of the U.S. Food and Drug Administration, or the FDA;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials; delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- · delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;



- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- · delays caused by operational issues at clinical sites;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols; failure to perform in accordance with the FDA's or any other regulatory authority's Good Clinical Practice requirements, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence
 of adverse events in trials of the same class of agents conducted by other companies;
- · changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- · selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipated;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators
 requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract development and manufacturing organization, or CDMO, and delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. Before commencing a clinical trial, the FDA or comparable foreign regulatory authorities could raise questions about or concerns with our proposed clinical protocol. For example, the FDA has previously issued clinical holds on certain of our product candidates, and we could not commence the respective clinical trial until such questions or concerns were resolved.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, we may need to amend clinical trial protocols that could require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Some of our trials are, have been, and may in the future be open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials. Additionally, the trial design differences and placebo effects that may be possible in clinical research for the indications we are studying may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials or to interpret the clinical out rang of our trials. In addition, we plan to conduct clinical trials of certain of our product candidates, including ulixacaltamide, utilizing novel primary endpoints for which the FDA and other regulatory authorities in connection with the design and implementation of our clinical studies, utilizing novel trial endpoints may increase the risk that the FDA and other regulatory authorities in connection with the design and implementation of our clinical studies, utilizing novel trial endpoints may increase the risk that the FDA and other regulatory authorities in connection with condities will consider the results from such trials, even if successful, insufficient to establish the safety or efficacy of our product candidates, which could requ

Further, conducting clinical trials in foreign countries, such as the European Union, for our product candidates presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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

Recent Sales of Unregistered Equity Securities

We did not make any sales of unregistered securities during the three months ended March 31, 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 March 31, 2023.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Exhibit Number	Description
<u>3.1</u>	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).
<u>3.2</u>	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).
<u>10.1</u>	Separation Letter Agreement, dated as of March 21, 2023, by and between Praxis Precision Medicines, Inc. and Nicole Sweeny (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-39620) filed on March 21, 2023).
<u>31.1*</u>	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the</u> <u>Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2*</u>	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.
<u>32.1**</u>	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 herewi	th.

** 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:	May 11, 2023	By:	/s/ Marcio Souza
			Marcio Souza
			Chief Executive Officer and Director (Principal Executive Officer)
Date:	May 11, 2023	By:	/s/ Timothy Kelly
			Timothy Kelly
			Chief Financial Officer (Principal Financial Officer)

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: May 11, 2023

By:

/s/ MARCIO SOUZA

Marcio Souza Chief Executive Officer (Principal Executive Officer)

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: May 11, 2023

By:

/s/ TIMOTHY KELLY

Timothy Kelly Chief Financial Officer (Principal Financial Officer)

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 March 31, 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: May 11, 2023

By:

/s/ MARCIO SOUZA

Marcio Souza Chief Executive Officer (Principal Executive Officer)

Date: May 11, 2023

By:

/s/ TIMOTHY KELLY

Timothy Kelly Chief Financial Officer (Principal Financial Officer)