

REFINITIV

# DELTA REPORT

## 10-Q

PALI - PALISADE BIO, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	4136
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 CHANGES	149
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 DELETIONS	2106
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 ADDITIONS	1881
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended **September 30, March 31, 2023 2024**

**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: **001-33672**

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**PALISADE BIO, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**52-2007292**

(I.R.S. Employer  
Identification No.)

**7750 El Camino Real, Suite 2A**

**Carlsbad, California**

(Address of principal executive offices)

**92009**

(Zip Code)

**(858) 704-4900**

(Registrant's telephone number, including area code)

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

Trading	
Title of each class	Symbol(s)
Common Stock, \$0.01 par value	PALI
	Nasdaq Capital Market

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

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

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

Large accelerated filer ☐

Non-accelerated filer ☒

Emerging growth company ☐

Accelerated filer ☐

Smaller reporting company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 6, 2023 May 8, 2024, there were 9,217,129 937,562 shares of common stock, \$0.01 par value, outstanding.

# Palisade Bio, Inc.

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**PART I**  
**FINANCIAL INFORMATION**

**ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**Palisade Bio, Inc.**  
**Condensed Consolidated Balance Sheets (Unaudited)**  
**(in thousands, except share and per share amounts)**

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 15,312	\$ 12,383	\$ 11,276	\$ 12,432
Prepaid expenses and other current assets	954	2,350	737	896
Total current assets	16,266	14,733	12,013	13,328
Restricted cash	26	26	26	26
Property and equipment, net	10	10	5	10
Right-of-use asset	224	300		
Operating lease right-of-use asset			170	198
Other noncurrent assets	541	694	438	490
Total assets	<u>\$ 17,067</u>	<u>\$ 15,763</u>	<u>\$ 12,652</u>	<u>\$ 14,052</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>				
Current liabilities:				
Accounts payable	\$ 950	\$ 1,759	\$ 459	\$ 698
Accrued liabilities	794	574	1,670	831
Accrued compensation and benefits	529	486	213	778
Current portion of lease liability	117	105		
Debt	259	88		
Current portion of operating lease liability			125	121
Insurance financing debt			—	158

Total current liabilities	2,649	3,012	2,467	2,586
Warrant liability	2	61	2	2
Contingent consideration obligation	212	—	61	61
Lease liability, net of current portion	122	211		
Operating lease liability, net of current portion			58	90
Total liabilities	2,985	3,284	2,588	2,739
Commitments and contingencies (Note 9)				
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Series A Convertible Preferred Stock, \$0.01 par value, 7,000,000 shares authorized; 200,000 issued and outstanding at September 30, 2023 and December 31, 2022	2	2		
Common stock, \$0.01 par value; 280,000,000 shares authorized; 9,210,751 and 2,944,306 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	92	30		
Series A Convertible Preferred Stock, \$0.01 par value, 7,000,000 shares authorized; 200,000 issued and outstanding at March 31, 2024 and December 31, 2023			2	2
Common stock, \$0.01 par value; 280,000,000 shares authorized; 851,302 and 618,056 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively			8	6
Additional paid-in capital	132,523	121,637	135,087	132,811
Accumulated deficit	(118,535)	(109,190)	(125,033)	(121,506)
Total stockholders' equity	14,082	12,479	10,064	11,313
Total liabilities and stockholders' equity	\$ 17,067	\$ 15,763	\$ 12,652	\$ 14,052

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

**Palisade Bio, Inc.**  
**Condensed Consolidated Statements of Operations (Unaudited)**  
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
License revenue	\$ —	\$ —	\$ 250	\$ —	\$ —	\$ 250
Operating expenses:						
Research and development	1,742	1,928	5,160	4,204	2,214	1,241
In-process research and development	362	—	362	—		
General and administrative	1,674	2,075	4,644	7,259	1,459	1,538
Restructuring costs	—	410	—	410		
Total operating expenses	3,778	4,413	10,166	11,873	3,673	2,779
Loss from operations	(3,778)	(4,413)	(9,916)	(11,873)	(3,673)	(2,529)
Other income (expense):						
Other (expense) income:						
Interest expense	(8)	(4)	(11)	(10)	(1)	—
Other income	190	426	598	2,453	147	189
Loss on issuance of warrants	—	—	—	(1,110)		
Total other income, net	182	422	587	1,333	146	189

Net loss	(3,59	(3,9	(9,32	(10,		
	\$ 6)	\$ 91)	\$ 9)	\$ 540)	\$ (3,527)	\$ (2,340)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share*						
					768,137	287,702
Basic and diluted net loss per common share*	(4.1	(18.				
	\$ (0.49)	\$ 0)	\$ (1.55)	\$ 40)	\$ (4.59)	\$ (8.13)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share*						
	7,344	974,	6,031	572,		
	,351	197	,099	684		

(\*) Basic and diluted loss per common share and basic and diluted weighted average share used in computing basic and diluted loss per common share for the three and nine months ended September 30, 2022 March 31, 2023 has been adjusted to reflect the 1-for-50 1-for-15 reverse stock split effected on November 16, 2022 April 5, 2024.

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

**Palisade Bio, Inc.**  
**Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**(in thousands, except share amounts)**  
**(Unaudited)**

For the Three Months Ended September 30, 2023

	Series B Convertible Preferred Stock		Preferred Stock		Common Stock		Additional	Accumulated	Total
							Paid-in	Deficit	Stockholders'
							Capital		Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance, June 30, 2023</b>					6,849,36		130,65		
	—	\$ —	200,000	\$ 2	2	\$ 69	\$ 2	\$ (114,923 )	\$ 15,800
Net loss	—		—	—	—	—	—	(3,596 )	(3,596 )
Stock-based compensation expense and related charges	—	—	—	—	—	—	202	—	202
Issuance of common stock in conjunction with vesting of restricted stock units	—	—	—	—	21,991	—	—	—	—
Issuance of common stock in September 2023 Offering, net of issuance costs of \$345 (Note 6)	—	—	—	—	2,339,39	8	23	1,653	1,676
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	—	—	—	—	—	—	16	(16 )	—
<b>Balance, September 30, 2023</b>	—	\$ —	200,000	\$ 2	1	\$ 92	\$ 3	\$ (118,535 )	\$ 14,082

Three Months Ended March 31, 2024								
	Preferred Stock		Common Stock		Additional	Accumulated	Total	
					Paid-in	d	Stockholders'	
	Shares	Amount	Shares*	Amount*	Capital*	Deficit	Equity	
<b>Balance, December 31, 2023</b>	200,000	\$ 2	618,056	\$ 6	\$ 132,811	\$ (121,506 )	\$ 11,313	
Net loss	—	—	—	—	—	(3,527 )	(3,527 )	
Stock-based compensation expense and related charges	—	—	—	—	118	—	118	

Issuance of common stock for vesting of restricted stock units	—	—	5,186	—	—	—	—
Issuance of common stock in connection with warrant inducement, net of issuance costs of \$2,412 (Note 5)	—	—	228,162	2	2,158	—	2,160
Reverse stock split fractional share settlement	—	—	(102)	—	—	—	—
<b>Balance, March 31, 2024</b>	<u>200,000</u>	<u>\$ 2</u>	<u>851,302</u>	<u>\$ 8</u>	<u>\$ 135,087</u>	<u>\$ (125,033)</u>	<u>\$ 10,064</u>

For the Three Months Ended September 30, 2022									
	Series B Convertible Preferred Stock		Preferred Stock		Common Stock		Additional Paid-in Capital*	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares*	Amount*			
<b>Balance, June 30, 2022</b>							105,39		
	—	\$ —	200,000	\$ 2	437,599	\$ 5	\$ 5	\$ (101,191)	\$ 4,211
Net loss	—	—	—	—	—	—	—	(3,991)	(3,991)
Stock-based compensation expense and related charges	—	—	—	—	—	—	252	—	252
Issuance of Class A Units and Class B Units in August 2022 Public Offering, net of issuance costs of \$2,293 (Note 6)	1,460	—	—	—	987,200	10	11,948	—	11,958
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(1,460)	—	—	—	116,800	1	(1)	—	—
<b>Balance, September 30, 2022</b>					1,541,59		117,59		
	—	\$ —	200,000	\$ 2	9	\$ 16	\$ 4	\$ (105,182)	\$ 12,430

#### Three Months Ended March 31, 2023

	Preferred Stock		Common Stock		Additional	Accumulate	Total
	Shares	Amount	Shares*	Amount*	Paid-in	d	Stockholders'
					Capital*	Deficit	Equity
<b>Balance, December 31, 2022</b>	200,000	\$ 2	196,287	\$ 2	\$ 121,665	\$ (109,190)	\$ 12,479
Net loss	—	—	—	—	—	(2,340)	(2,340)
Stock-based compensation expense and related charges	—	—	—	—	93	—	93
Issuance of common stock in connection with exercise of warrants	—	—	76,188	1	1,348	—	1,349
Issuance of common stock and warrants in January 2023 Offering, net of issuance costs of \$507	—	—	31,789	—	2,166	—	2,166
<b>Balance, March 31, 2023</b>	200,000	\$ 2	304,264	\$ 3	\$ 125,272	\$ (111,530)	\$ 13,747

(\*) Adjusted to reflect the 1-for-50 1-for-15 reverse stock split effected on November 16, 2022 April 5, 2024.

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

## Palisade Bio, Inc.

### Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share amounts)

(Unaudited)

Nine Months Ended September 30, 2023					
Series B Convertible Preferred Stock			Additional	Accumula	Total
			Paid-in	ted	Stockholder
	Preferred Stock	Common Stock	Capital	Deficit	s' Equity (Deficit)

	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance, December 31, 2022</b>					2,944,3		121,63	(109,19		
	—	\$ —	200,000	\$ 2	06	\$ 30	\$ 7	\$ 0)	\$	12,479
Net loss	—	—	—	—	—	—	—	(9,329)		(9,329)
Stock-based compensation expense and related charges	—	—	—	—	—	—	439	—		439
Issuance of common stock in conjunction with vesting of restricted stock units	—	—	—	—	34,653	—	—	—		—
Issuance of common stock upon warrant exercises	—	—	—	—	93	22	1,328	—		1,350
Issuance of common stock and warrants in January 2023										
Offering, net of issuance costs of \$507 (Note 6)	—	—	—	—	476,842	5	2,161	—		2,166
Issuance of common stock and warrants in April 2023 Offering, net of issuance costs of \$854 (Note 6)	—	—	—	—	59	12	5,289	—		5,301
Issuance of common stock in September 2023 Offering, net of issuance costs of \$345 (Note 6)	—	—	—	—	98	23	1,653	—		1,676
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	—	—	—	—	—	—	16	(16)		—
<b>Balance, September 30, 2023</b>					9,210,7		132,52	(118,53		
	—	\$ —	200,000	\$ 2	51	\$ 92	\$ 3	\$ 5)	\$	14,082
<b>Nine Months Ended September 30, 2022</b>										
<b>Series B Convertible Preferred Stock</b>			<b>Total Stockholder's' Equity (Deficit)</b>							
			<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-in Capital*</b>	<b>Accumulated Deficit</b>		
			<b>Shares</b>	<b>Amount</b>	<b>Shares*</b>	<b>Amount*</b>				

<b>Balance, December 31, 2021</b>	—	\$	—	200,000	\$	2	284,780	\$	3	\$ 102,00	\$ (94,642)	\$	7,365
										2			
Net loss	—		—	—		—	—		—	—	(10,540)		(10,540)
Stock-based compensation expense and related charges	—		—	—		—	—		—	946	—		946
Issuance of common stock upon warrant exercises	—		—	—		—	79,886		1	1,273	—		1,274
Issuance of common stock and warrants in May 2022 Registered Direct Offering, net of issuance costs of \$634 (Note 6)	—		—	—		—	72,933		1	1,426	—		1,427
Issuance of Class A Units and Class B Units in August 2022 Public Offering, net of issuance costs of \$2,293 (Note 6)	1,460		—	—		—	987,200		10	11,948			11,958
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	(1,460)		—	—		—	116,800		1	(1)			—
<b>Balance, September 30, 2022</b>							1,541,5			117,59	(105,18		
	—	\$	—	200,000	\$	2	99	\$	16	\$ 4	\$ 2)	\$	12,430

(\*) Adjusted to reflect the 1-for-50 reverse stock split effected on November 16, 2022.

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

**Palisade Bio, Inc.**  
**Condensed Consolidated Statements of Cash Flows (Unaudited)**  
(in thousands)

	Nine Months Ended September 30,	
	2023	2022
Net loss	\$ (9,329)	\$ (10,540)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	4	1
Noncash lease expense	76	140
Loss on issuance of warrants	—	1,110

Fair value of contingent consideration obligation	212	—
Change in fair value of warrant liabilities	(59)	(2,403)
Stock-based compensation and related charges	439	946
Other	(108)	(213)
<b>Changes in operating assets and liabilities:</b>		
Prepaid and other assets and other noncurrent assets	596	744
Accounts payable and accrued liabilities	(184)	706
Accrued compensation	43	(418)
Operating lease liabilities	(77)	(127)
Net cash used in operating activities	(8,387)	(10,054)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(4)	—
Net cash used in investing activities	(4)	—
<b>Cash flows from financing activities:</b>		
Payments on debt	(290)	(524)
Proceeds from issuance of common stock and warrants	9,419	14,401
Proceeds from the exercise of warrants	2,758	—
Payment of equity issuance costs	(567)	(333)
Net cash provided by financing activities	11,320	13,544
Net increase (decrease) in cash, cash equivalents and restricted cash	2,929	3,490
Cash, cash equivalents and restricted cash, beginning of period	12,409	10,521
Cash, cash equivalents and restricted cash, end of period	\$ 15,338	\$ 14,011
<b>Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:</b>		
Cash and cash equivalents	\$ 15,312	\$ 13,985
Restricted cash	26	26
Total cash, cash equivalents and restricted cash	\$ 15,338	\$ 14,011
<b>Supplemental disclosures of cash flow information:</b>		
Interest paid	\$ 10	\$ 10
Right-of-use assets obtained in exchange for lease liabilities	—	355
<b>Supplemental disclosures of non-cash investing and financing activities:</b>		
Equity issuance costs included in accounts payable and accrued liabilities	\$ 50	\$ 683
Non cash impact of exercise price reset on outstanding warrants related to down round provisions	16	—
Issuance of common stock for the cashless exercise of warrants	—	1,274
Fair value of warrants issued to placement agent	384	55

Fair value of warrants issued to underwriter agent	—	459
Issuance of common stock upon conversion of Series B Convertible Preferred Stock	—	58
Insurance financing arrangements included in prepaid and other assets and other noncurrent assets	461	784
Purchase of property and equipment included in accounts payable and accrued liabilities	—	10
	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Net loss	\$ (3,527)	\$ (2,340)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation	1	1
Non-cash operating lease expense	28	25
Recurring fair value measurements of liabilities	—	(43)
Loss on disposal of property and equipment	4	—
Stock-based compensation and related charges	118	93
Changes in operating assets and liabilities:		
Accounts receivable	—	(250)
Prepaid and other current assets and other noncurrent assets	174	278
Accounts payable and accrued liabilities	615	(970)
Accrued compensation and benefits	(565)	(295)
Operating lease liabilities	(28)	(25)
Net cash used in operating activities	(3,180)	(3,526)
<b>Cash flows from financing activities:</b>		
Payments on insurance financing debt	(158)	(88)
Proceeds from issuance of common stock and warrants	—	2,231
Proceeds from the exercise of warrants	2,503	2,710
Payment of warrant inducement issuance costs	(321)	—
Payment of equity issuance costs	—	(413)
Net cash provided by financing activities	2,024	4,440
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,156)	914
Cash, cash equivalents and restricted cash, beginning of year	12,458	12,409
Cash, cash equivalents and restricted cash, end of period	\$ 11,302	\$ 13,323
<b>Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:</b>		
Cash and cash equivalents	\$ 11,276	\$ 13,297
Restricted cash	26	26

Total cash, cash equivalents and restricted cash	\$	11,302	\$	13,323
<b>Supplemental disclosures of cash flow information:</b>				
Interest paid	\$	2	\$	—
<b>Supplemental disclosures of non-cash investing and financing activities:</b>				
Warrant inducement and equity issuance costs included in accounts payable and accrued liabilities	\$	22	\$	12
Fair value of warrants issued to solicitation agent		94		
Fair value of warrants issued to placement agent		—		173
Cash receivable for exercises of warrants included in prepaid and other current assets		—		48
Incremental fair value of modified warrants (Note 5)		1,975		—

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

**PALISADE BIO, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited) (Unaudited)**

## 1. Organization, Business and Financial Condition

### The Merger

On April 27, 2021, Leading Biosciences, Inc. ("LBS") became a wholly owned subsidiary of Seneca Biopharma Inc. ("Seneca") upon consummation of the merger (the "Merger") by and among Seneca, Townsgate Acquisition Sub 1, Inc., a wholly owned subsidiary of Seneca ("Merger Sub"), and LBS, pursuant to which Merger Sub merged with and into LBS, with LBS surviving as a wholly owned subsidiary of Seneca. Immediately following the Merger, Seneca changed its name to "Palisade Bio, Inc."

Unless As used in this Quarterly Report on Form 10-Q, unless the context indicates or otherwise requires, references to the "Company," "Palisade," "Palisade Bio," the "Company," "we," "us," and "our" or "us" similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. In addition, references Any reference to "Seneca" "common shares" or "common stock," refers to the Company's \$0.01 par value common stock. Any reference to "Series A Preferred Stock" refers to the Company's Series A 4.5% Convertible Preferred Stock. Any reference to "Leading

Biosciences, Inc." or "LBS" refer refers to these entities the Company's operations prior to the completion of the Merger. its merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any reference herein that refers to pre-clinical studies also refers to nonclinical studies.

## **Description of Business**

### **Prior Business Focus**

On August 9, 2023, the The Company announced topline data from its U.S. Phase 2 PROFILE study. The data showed that its lead therapeutic candidate at the time, LB1148, did not achieve the primary endpoint in this trial of preventing post-surgical adhesions in patients who underwent bowel resection surgery. Based is a pre-clinical stage biotechnology company focused on the U.S. Phase 2 PROFILE study data, the Company did not believe the safety developing and efficacy results supported further development of LB1148, and accordingly, the Company terminated all further development of LB1148, including its U.S. Phase 3 Return of Bowel Function Study.

### **Change in Strategic Focus**

On September 1, 2023, the Company entered into a research collaboration and license agreement with Giiant Pharma, Inc. ("Giiant") (the "Giiant License Agreement"). The Giiant License Agreement provides the Company with the exclusive worldwide rights to develop, manufacture and commercialize all of Giiant's current and future technologies, including the Company's new lead asset, PALI-2108 (formerly GT-2108), an orally administered, locally-acting, colon-specific phosphodiesterase-4 (PDE4) inhibitor prodrug in development advancing novel therapeutics for patients affected by moderate-to-severely active ulcerative colitis. Pursuant to the terms of the Giiant License Agreement, the Company will pay living with autoimmune, inflammatory, and fibrotic diseases. The Company's lead product candidate, PALI-2108, is being developed as a portion of the joint development costs until the first approval of an investigational new drug approval in the United States ("IND") or clinical trial application in Canada ("CTA"), and will thereafter assume all development, manufacturing, and commercialization costs. Additionally, per the Giiant License Agreement, the Company will pay (i) certain milestone payments (in cash or stock at the Company's election) and (ii) royalty payments. Refer to Note 8, Collaborations and License Agreements, therapeutic for a full discussion of the Giiant License Agreement.

Upon entering into the Giiant License Agreement, the Company's focus became the development and commercialization of PALI-2108 for the treatment of patients living with inflammatory bowel disease (IBD), ("IBD"), including ulcerative colitis and Crohn's disease.

## **Liquidity and Going Concern**

The Company has a limited operating history, and the sales and income potential of the Company's business and market are unproven. The Company has experienced losses and negative cash flows from operations since its inception. As of September 30, 2023 March 31, 2024, the Company had an accumulated deficit of \$118.5 125.0 million and cash and cash equivalents of approximately \$15.3 11.3 million. The Company expects to continue to incur losses into in the foreseeable future. The successful transition to attaining profitable operations achieving profitability is dependent upon achieving a level

of revenues adequate to support the Company's cost structure, costs. There can be no assurances that such profitability will ever be achieved.

Based on the Company's current working capital, anticipated operating expenses, and anticipated net operating losses, there is substantial doubt about the Company's ability to continue as a going concern for a period of one year following the date that these condensed consolidated financial statements are issued. The condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the

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realization of assets and settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Historically, the Company has funded its operations primarily through a combination of debt and equity financings. The Company plans to continue to fund its operations through its cash and cash equivalents on hand, as well as through future equity offerings, debt financings, other third-party funding, and potential licensing or collaboration arrangements. Refer to Note 6, 5, Stockholders' Equity, (Deficit) for discussion of the recent financings undertaken by the Company. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company raises is successful in raising additional capital, it may also be required to modify, delay or abandon some of its plans, which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives. Any of these actions occurrences could materially harm the Company's business, results of operations and future prospects.

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## 2. Summary of Significant Accounting Policies

### ***Basis of Presentation and Consolidation***

In management's opinion, the accompanying interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations and cash flows. The interim results of operations are not necessarily indicative of the results that may occur for the full year. Certain information and note disclosures normally included in the consolidated financial statements

prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the U.S. Securities and Exchange Commission ("SEC"). The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these condensed consolidated financial statements are read in conjunction with the condensed consolidated financial statements and notes included in the Company's financial statements filed on in the Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, which was filed with the SEC on March 22, 2023 March 26, 2024. Certain prior period amounts in the condensed consolidated financial statements and accompanying notes have been reclassified to conform to the current period's presentation.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Leading Biosciences, Inc. LBS and Suzhou Neuralstem Biopharmaceutical Co., Ltd. All the entities are consolidated in the Company's condensed consolidated financial statements and all intercompany activity and transactions, if any, have been eliminated.

### **Reverse Stock Split**

On November 15, 2022 April 5, 2024, the Company effected a 1-for-501-for-15 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each of the Company's shareholders stockholders received one new share of common stock for every 5015 shares such shareholder stockholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all the Company's issued and outstanding shares of common stock equally. The par value and authorized shares of the Company's common stock was were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split also affected the Company's outstanding stock options, stock-based awards, common stock warrants, and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price or conversion price being increased proportionately. Unless otherwise noted, all common stock shares, common stock per share data and shares of common stock underlying convertible preferred stock, stock options stock-based award and common stock warrants included in these condensed consolidated financial statements, including the exercise price or conversion price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

### **Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates, judgments, and assumptions that impact the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the balance sheet, and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's condensed consolidated financial statements relate to clinical trial accruals, accrued research and development expenses and its contingent consideration liabilities, and its derivative financial instruments. obligation. Although these estimates

are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

### **Segment Information**

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, which is the Company's Chief Executive Officer, in making to make decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment, which consists of research and development activities, is the Company's one reportable segment.

### **Cash and Cash Equivalents**

Cash and cash equivalents represent cash available in readily available checking and money market accounts. The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

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### **Restricted Cash**

As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the Company held restricted cash of \$26,000, in a separate restricted bank account as collateral for the Company's corporate credit card program. The Company has classified these deposits as long-term restricted cash on its condensed consolidated balance sheets.

### **Deferred Equity Issuance Costs**

Deferred equity issuance costs consist of the legal, accounting and other direct and incremental costs incurred by the Company related to its equity offerings, if not yet finalized as of the balance sheet date, or shelf registration statement. As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, deferred equity issuance costs of \$75,000 and \$114,000 112,000, respectively, were included in prepaid expenses and other current assets in the condensed consolidated balance sheets. These costs will be netted against additional paid-in capital as a cost of the future equity issuances to which they relate. During the three and nine months ended September 30, 2023 March 31, 2024, the Company netted previously deferred equity issuance costs associated with its shelf registration statement of approximately \$6,000 37,000 against the additional paid-in capital recognized in conjunction with the September 2023 Offering warrant inducement transaction that closed on February 1, 2024 (see Note 6) 5, Stockholders' Equity).

## Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions and in money market accounts, and at times balances may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held nor has the Company experienced any losses in these accounts.

## Fair Value of Financial Instruments

The Company's financial instruments consist principally of cash and cash equivalents, restricted cash, other current receivables, accounts payable, accrued liabilities, insurance financing debt, liability-classified warrants and a contingent consideration obligations. obligation. The carrying amounts of financial instruments such as cash and cash equivalents, restricted cash, other current receivables, accounts payable, and accrued liabilities approximate their related fair values due to the short-term nature of these instruments. The Company invests its excess cash in money market funds which that are classified as level 1 in the fair value hierarchy defined below, due to their short-term maturity, and measured the fair value based on quoted prices in active markets for identical assets. The carrying value of the Company's insurance financing debt as of September 30, 2023 and December 31, 2022 December 31, 2023 approximates its fair value due to the market rate of interest, which is based on level 2 inputs. The Company's derivative financial instruments, consisting of its liability-classified common stock warrants and its contingent consideration obligation are is carried at fair value based on level 3 inputs as defined below. None of the Company's non-financial assets or liabilities are recorded at fair value on a nonrecurring basis.

The Company follows Accounting Standards Codification ("ASC") 820, *Fair Value Measurements and Disclosures*, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability

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in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

- (1) Level 1: observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
- (2) Level 2: inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- (3) Level 3: unobservable inputs for which there is little or no market data, which require the reporting entity to develop own assumptions, which reflect those that a market participant would use.

Further information on the fair value of financial instruments the Company's liability-classified common stock warrants and its contingent consideration obligation can be found in Note 5, 4, Fair Value Measurements.

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### ***Derivative Financial Instruments***

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates its financial instruments, including warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company values its derivatives using the Black-Scholes option pricing model or other acceptable valuation models, including the Monte-Carlo simulation model. Derivative instruments are valued at inception, upon events such as an exercise of the underlying financial instrument, and at subsequent reporting periods. The classification of derivative instruments, including whether such instruments should be recorded as liabilities, is reassessed at the end of each reporting period.

The Company reviews the terms of debt instruments, equity instruments, and other financing arrangements to determine whether there are embedded derivative features, including embedded conversion options that are required to be bifurcated and accounted for separately as a derivative financial instrument. Additionally, in connection with the issuance of financing instruments, the Company may issue freestanding options and warrants.

The Company accounts for its common stock warrants in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). Based upon the provisions of ASC 480 and ASC 815, the Company accounts for common stock warrants as liabilities if the warrant requires net cash settlement or gives the holder the option of net cash settlement, or if it fails the equity classification criteria. The Company accounts for common stock warrants as equity if the contract requires physical settlement or net physical settlement or if the Company has the option of physical settlement or net physical settlement and the warrants meet the requirements to be classified as equity. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date and remeasured at fair value at each balance sheet date with the offsetting adjustments recorded in change in fair value of warrant liability within the condensed consolidated statements of operations. If the terms of a common stock warrant previously classified as a liability are amended and pursuant to such amendment meet the requirements to be classified as equity, the common stock warrants are reclassified to equity at the fair value on the date of the amendment and are not subsequently remeasured. Common stock warrants classified as equity are recorded on a relative fair value basis when they are issued with other equity-classified financial instruments.

### ***Leases***

In accordance with ASC 842, *Leases*, the Company assesses contracts for lease arrangements at inception. Operating right-of-use (“ROU”) assets and **operating lease** liabilities are recognized at the lease commencement date equal to the present value of future lease payments using the implicit, if readily available, or incremental borrowing rate based on the information readily available at the commencement date. ROU assets include any lease payments as of commencement and initial direct costs but exclude any lease incentives. Lease and non-lease components are generally accounted for separately and the Company recognizes operating lease expense straight-line over the term of the lease.

### **Milestone License Revenue**

The Company uses the revenue recognition guidance established by ASC 606, *Revenue From Contracts With Customers* (“ASC 606”). When an agreement falls under the scope of other standards, such as ASC 808, *Collaborative Arrangements*, the Company will apply the recognition, measurement, presentation, and disclosure guidance in ASC 606 to the performance obligations in the agreements if those performance obligations are with a customer. The Company currently does not have any collaborative arrangements with counterparties that are also considered

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customers. For arrangements that include amounts to be paid to the Company upon the achievement of certain development milestones of technology licensed by the Company, the Company recognizes such license revenue using the most likely method. At the end of each reporting period, the Company re-evaluates the probability or achievement of any potential milestones and any related constraints, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue in the period of adjustment. **For the nine months ended September 30, 2023, \$0.3**

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**million of license revenue related to milestones achieved on licensed technology was recognized as revenue. There was no license revenue recognized by the Company in the three months ended September 30, 2023, or the three and nine months ended September 30, 2022.**

### **Contingent Consideration Obligations**

**On September 1, 2023, the Company and Giiant Pharma, Inc. (“Giiant”) entered into a research collaboration and license agreement (the “Giiant License Agreement”)(see Note 7, Collaborations and License Agreements). Pursuant to the Giiant License Agreement, the Company incurred a contingent consideration obligation consisting of milestone payments, which are recognized as a liability measured at fair value, and ongoing royalty payments of five percent a mid-single-digit**

percentage of the adjusted gross proceeds, as defined in the Giiant License Agreement, upon the sales or sublicenses third parties of any products developed from the assets licensed under the Giiant License Agreement (See Note 8). Agreement. Because the contingent consideration associated with the milestone payments may be settled in shares of the Company's common stock solely at the election of the Company, the Company has determined it should be accounted for under ASC 480 and accordingly the Company has recognized it as a liability measured at its estimated fair value at value. At the date end of issuance. At each reporting date, period, the Company re-measures the contingent consideration obligation to its estimated fair value and any resulting change is recognized in In-process research and development expenses in the condensed consolidated statements of operations. The Company has determined that the contingent consideration associated with the royalty payments should be recognized as a liability when they are probable and estimable, in accordance with ASC 450, Contingencies.

### **Research and Development Costs**

Research and development expenses consist primarily of salaries and other personnel related expenses including stock-based compensation costs, and, to the extent applicable, may include pre-clinical costs, clinical trial costs, costs related to acquiring and manufacturing clinical trial materials, and contract services. All research and development costs are expensed as incurred. Pursuant to situations whereby the Company performs any research and development or manufacturing activities under a co-development agreement, the Company records the expense reimbursements from the co-development partner as a reduction to research and development expense once the reimbursement amount is approved for payment by the co-development partner. Expense reimbursements payments made to Giiant pursuant to the terms of the Giiant License Agreement for qualifying development costs are expensed only as the associated research and development costs as incurred, are incurred or other aspects of the drug development or related activities are achieved. In the three and nine months ended September 30, 2023, instances where the expense reimbursements due determined to be recognized exceeds the payments made to Giiant, under the Giiant License Agreement were insignificant.

### **Clinical Trial Expenses**

Expenses related to clinical studies are based on estimates Company recognizes an accrual of the services received and efforts expended pursuant to the Company's contract arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There joint development expenses. In addition, there may be instances in which payments made to the Company's service providers Giiant will temporarily exceed the level of services provided, and result which results in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients, site initiation and the completion of clinical milestones. The Company makes estimates of its accrued expenses as of each balance sheet date in its condensed consolidated financial statements based on facts and circumstances known at that time. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjusts the accrual or prepaid expense balance accordingly. As of September 30, 2023 and December 31, 2022, the Company has accrued \$ joint development expenses. 285,000 and \$184,000, respectively, in clinical trial expenses for which services have been provided but the Company has not yet been invoiced as of the balance sheet date. Clinical trial

expenses are recognized in research and development expenses in the condensed consolidated statements of operations in the period incurred.

### ***In-Process Research and Development Expenses***

In-process research and development ("IPR&D") expenses are recorded when incurred and reflect costs of externally-developed IPR&D projects, including certain transaction costs, acquired directly in a transaction other than a business combination, that do not have an alternative future use. In the three and nine months ended September 30, 2023, the Company recognized the fair value of the contingent consideration milestone payment obligation associated with the

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Giiant License Agreement, including transaction related costs, in In-process research and development expenses in the condensed consolidated statements of operations.

### ***Patent Costs***

Costs related to filing and pursuing patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses in the condensed consolidated statements of operations.

### ***Income Taxes***

The Company follows ASC 740, *Income Taxes*, or ASC Topic 740 ("ASC 740"), in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax assets and liabilities for expected future income tax consequences of events that have been recognized in the Company's condensed consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some of or all the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

### ***Stock-Based Compensation***

The Company's stock-based compensation expense generally includes time-based service-based restricted stock units ("RSUs"), stock options, and market-based performance RSUs ("PSUs"). The Company accounts for forfeitures as they

for each type of award as a reduction of expense. Stock-based compensation expense related to time-based service-based RSUs is based on the market value of the underlying stock on the date of grant and the related expense is recognized ratably over the requisite service period, which is usually the vesting period. The Company estimates the fair value of employee and non-employee stock option grants using the Black-Scholes option pricing model. The determination of the fair value of stock-based payment awards on the date of grant using the Black-Scholes option pricing model is affected by the Company's stock price as well as assumptions, which include the expected term of the award, the expected stock price volatility, risk-free interest rate, and expected dividends over the expected term of the award. Stock-based compensation expense represents the cost of the estimated grant date fair value of employee and non-employee stock option grants recognized ratably over the requisite service period of the awards, which is usually the vesting period. For PSUs with vesting subject to market conditions, the fair value of the award is determined at grant date using the Monte Carlo simulation model, and expense is recognized ratably over the requisite derived service period regardless of whether or not the market condition is satisfied. The Monte Carlo simulation model considers a variety of potential future scenarios under the market condition vesting criteria, including but not limited to share prices for the Company and its peer companies in a selected market index.

The Company does not recognize any share-based compensation expense related to conditional RSUs, stock options, or PSUs that are subject to shareholder stockholder approval. When and if approval is obtained, the Company recognizes share-based compensation expense related to the conditional equity grants ratably to the vesting of shares over the remaining requisite service period.

#### **Basic and Diluted Net Loss Per Common Share**

Basic net loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, plus potentially dilutive common shares, consisting of stock-based awards and equivalents, and common stock warrants. For purposes of this calculation, stock-based awards and common stock warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The Company's Series A Convertible Preferred Stock and certain of the Company's outstanding warrants contain non-forfeitable rights to dividends with the common stockholders, and therefore are considered to be participating securities. The Series A Convertible Preferred Stock and the warrants do not have a contractual obligation to fund the losses of the Company; therefore, the application of the two-class method is not required when the Company is in a net loss position but is required if the Company is in a net income position. When in a net income position, diluted earnings per share is computed using the more dilutive of the two-class method or the if-converted and treasury stock methods.

As the Company was in a net loss position for all periods presented, basic and diluted net loss per common share for the three and nine months ended September 30, 2023 and September 30, 2022 were calculated under the if-converted and treasury stock methods. For the three and nine months ended September 30, 2023 and September 30, 2022, basic and diluted net loss per common share were the same as all common stock equivalents were anti-dilutive for both periods.

The following table presents the calculation of weighted average shares used to calculate basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2023	2022	2023	2022
Basic and diluted net loss per common share:				
Net loss	\$ (3,596)	\$ (3,991)	\$ (9,329)	\$ (10,540)
Adjustment to record the impact of exercise price reset on outstanding warrants related to down round provisions	(16)	—	(16)	—
Net loss attributable to common shares - basic and diluted	\$ (3,612)	\$ (3,991)	\$ (9,345)	\$ (10,540)
Weighted average shares used in calculating basic and diluted net loss per common share	7,344,351	974,197	6,031,099	572,684
Basic and diluted net loss per common share	\$ (0.49)	\$ (4.10)	\$ (1.55)	\$ (18.40)

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effects would be anti-dilutive:

	September 30,	
	2023	2022
Stock options	543,188	51,650
Restricted stock units	342,970	—
Warrants for common stock	4,080,908	2,458,470
Series A Convertible Preferred Stock	129	129
<b>Total</b>	<b>4,967,195</b>	<b>2,510,249</b>

## Comprehensive Loss

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the same as its reported net loss for all periods presented.

### Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The ASU introduced a new credit loss methodology, the Current Expected Credit Losses ("CECL") methodology, which requires earlier recognition of credit losses, while also providing additional transparency about credit risk. The CECL methodology utilizes a lifetime "expected credit loss" measurement objective for the recognition of credit losses for loans, held-to maturity debt securities, trade receivables and other receivables measured at amortized cost at the time the financial asset is originated or acquired. After the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. In November 2019, the FASB issued an amendment making this ASU effective for fiscal years beginning after December 15, 2022 for smaller reporting companies. The Company adopted this standard as of January 1, 2023 and determined it did not have a material impact on its condensed consolidated financial statements and related disclosures for the three and nine months ended September 30, 2023.

### 3. Balance Sheet Details

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid insurance	\$ 562	\$ 581
Other receivables	135	1,438
Prepaid subscriptions and fees	160	157
Prepaid software licenses	17	54
Deferred equity issuance costs	75	114
Prepaid other	5	6
	<u>\$ 954</u>	<u>\$ 2,350</u>

Other receivables as of December 31, 2022 includes a \$1.4 million receivable for the cash exercise price of common stock purchase warrants that had been exercised but the cash had not yet been received by the Company as of the December 31, 2022 balance sheet date. The entire amount of this other receivable was received in January 2023.

Other noncurrent assets consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid insurance, less current portion	\$ 529	\$ 682
Other noncurrent assets	12	12
	<u>\$ 541</u>	<u>\$ 694</u>

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued accounts payable	\$ 357	\$ 69
Accrued clinical trial costs	285	184
Accrued director stipends	106	141
Accrued severance and benefits (Note 9)	—	180
Accrued other	46	—
	<u>\$ 794</u>	<u>\$ 574</u>

#### 4. Common Stock Warrants

The Company's outstanding common stock warrants that are classified as equity warrants are included as a component of stockholder's equity (deficit) at the date of grant at the relative fair value at that grant date. Common stock warrants accounted for as liabilities in accordance with the authoritative accounting guidance are included in non-current liabilities. The Company had common stock warrants outstanding of 4,080,908 and 1,055,672 at September 30, 2023 and December 31, 2022, respectively. Of the Company's common stock warrants exercisable at September 30, 2023, (i) 205,201 common stock warrants have an exercise price of \$0.84, (ii) 1,012,631 common stock warrants have an exercise price of \$2.375, (iii) 2,272,723 common stock warrants have an exercise price of \$2.64, (iv) 136,363 common stock warrants have an exercise price of \$3.30, (v) 63,158 common stock warrants have an exercise price of \$2.9668, (vi) 140,364 common stock warrants have an exercise price of \$1.05, and (vii) the remaining 250,468 common stock warrants have a weighted-average exercise price of \$104.24. Only the 205,201 common stock warrants outstanding that have an exercise price of \$0.84 are subject to down round price reset provisions.

#### Liability-Classified Warrants

The Company accounts for certain of its warrants as liability-classified in accordance with ASC 480 and ASC 815.

#### Senior Secured Promissory Note Warrants

In connection with the transactions contemplated by the Merger, on December 16, 2020, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an investor (the "Investor") pursuant to which, among other things, the Company agreed to issue warrants to purchase shares of the Company's common stock ("Senior Secured Promissory Note Warrants"). The Senior Secured Promissory Note Warrants expire five years from the date of registration of the warrants, or August 10, 2026. As of September 30, 2023, the Senior Secured Promissory Note Warrants outstanding were exercisable for 17,177 shares of the Company's common stock at an exercise price of \$194.00 per common stock warrant.

#### *May 2021 Warrants*

On May 20, 2021, pursuant to the terms of the Securities Purchase Agreement, the Company issued to the Investor warrants to purchase shares of common stock (the "May 2021 Warrants"). All of the outstanding May 2021 Warrants were exercised by the investor in the fourth quarter of 2021 and the first quarter of 2022 in exchange for 26,186 shares and 79,886 shares of the Company's common stock, respectively. As of September 30, 2023, there are no May 2021 Warrants outstanding.

#### *July 2021 Warrants*

On July 21, 2021, the Company and the Investor entered into an agreement to waive certain provisions of the previous Security Purchase Agreement (the "July 2021 Waiver Agreement"). As consideration for the July 2021 Waiver Agreement, the Company issued the Investor additional warrants to purchase shares of the Company's common stock (the "July 2021 Warrants"). The July 2021 Warrants expire five years from the date of registration of the warrants, or August 19, 2026. As of September 30, 2023, the July 2021 Warrants outstanding were exercisable for 22,000 shares of the Company's common stock at an exercise price of \$181.50 per common stock warrant.

#### *January 2022 Warrants*

On January 31, 2022, the Company and the Investor entered into an agreement to irrevocably waive any adjustment to the exercise price of the Senior Secured Promissory Note Warrants and the May 2021 Warrants held by the Investor from and after January 31, 2022 for the Company's issuances of equity or equity-linked securities at a price below the exercise price of the warrants (the "January 2022 Waiver Agreement"). The waiver of any adjustments to the exercise price of the Senior Secured Promissory Note Warrants and the May 2021 Warrants was considered a modification to those warrants. The modification was determined to have no impact on the valuation of the warrants.

As consideration for the foregoing, pursuant to the January 2022 Waiver Agreement, the Company issued the Investor additional warrants to purchase shares of the Company's common stock (the "January 2022 Warrants"). The initial fair value of the January 2022 Warrants was determined to be \$1.1 million and is included in loss on issuance of warrants in the consolidated statements of operations for the nine months ended September 30, 2022.

The January 2022 Warrants expire five and a half years from the date of issuance, or July 31, 2027. As of September 30, 2023, the January 2022 Warrants outstanding were exercisable for 45,000 shares of the Company's common stock at an

exercise price of \$55.00 per common stock warrant.

### ***Equity-Classified Warrants***

The Company accounts for the majority of its warrants as equity-classified in accordance with ASC 480 and ASC 815. Equity-classified warrants are recorded in equity based on their relative fair value on the date of issuance.

The exercise price of certain of the Company's outstanding equity-classified warrants can be adjusted in the event of issuances of the Company's common stock at a price lower than the exercise price of those warrants then in effect (the "Down Round Feature"). During the three and nine months ended September 30, 2023, the Down Round Feature was triggered on 205,201 of the Company's outstanding equity-classified warrants due to the September 7, 2023 announcement of an agreement to issue common stock of the Company (see September 2023 Offering at Note 6). As a result of the triggering of the Down Round Feature, the exercise price of any outstanding warrants including the Down Round Feature was adjusted down to \$0.84, which represents the price per share of the equity being offered in the September 7, 2023 announcement.

The Company calculated the value of the effect of Down Round Feature measured as the difference between the fair of the warrants impacted, using a Monte Carlo valuation model, immediately before and immediately after the Down

Round Feature was triggered using the original exercise price and the new exercise price. The difference in fair value of the effect of the Down Round Feature of \$16,000 and was recognized as a deduction from the loss available to common shareholders for the three and nine months ended September 30, 2023. The exercise price of any outstanding warrants subject to down round price reset provisions will continue to be adjusted in the event the Company issues additional shares of common stock below the current exercise price, in accordance with the terms of the warrants. Only 205,201 common stock warrants outstanding as of September 30, 2023 are subject to down round price reset provisions.

### ***January 2023 Registered Direct Offering and Private Placement Warrants***

In connection with the January 2023 Offering (see Note 6, Stockholders' Equity (Deficit)), on January 4, 2023 the Company issued (i) 37,000 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of \$2.3749 per warrant, with such warrants having an exercise price of \$0.0001 per warrant and a perpetual term (ii) 538,789 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of \$2.3749 per warrant, with such warrants having an exercise price of \$0.0001 per warrant and a perpetual term; (iii) 1,052,631 warrants to purchase shares of the Company's common stock at an exercise price of \$2.375 per share and a term of five years, and (iv) 63,158 warrants to purchase shares of the Company's common stock to the offering placement agent at an exercise price of \$2.9688 per share and a term of five years. All of the warrants issued in the January 2023 Offering were determined to be equity-classified. As of September 30, 2023, all of the pre-funded warrants issued with the January 2023 Offering have been exercised for shares of the Company's common stock.

### April 2023 Registered Direct Offering and Private Placement Warrants

In connection with the April 2023 Offering (see Note 6, Stockholders' Equity (Deficit)), on April 3, 2023 the Company issued (i) 1,061,164 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of \$2.6399, with such warrants having an exercise price of \$0.0001 per share and a perpetual term, (ii) 2,272,723 warrants to purchase shares of the Company's common stock at an exercise price of \$2.64 per share and a term of five years from the date of issuance, and (iii) 136,363 warrants to purchase shares of the Company's common stock to the offering placement agent at an exercise price of \$3.30 per share and a term of five years. All of the warrants issued in the April 2023 Offering were determined to be equity-classified. As of September 30, 2023, all of the pre-funded warrants issued with the April 2023 Offering have been exercised for shares of the Company's common stock.

### September 2023 Offering

In connection with the September 2023 Offering (see Note 6, Stockholders' Equity (Deficit)), on September 11, 2023 the Company issued 140,364 warrants to purchase shares of the Company's common stock to the offering placement agent at an exercise price of \$1.05 per share and a term of five years and are immediately exercisable from issuance (the "September 2023 Placement Agent Warrants"). The fair value of the September 2023 Placement Agent Warrants was recognized by the Company as an equity issuance cost which reduced the additional paid-in capital recognized from the September 2023 Offering.

The following table summarizes warrant activity during the nine months ended September 30, 2023:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2022	1,055,672	\$ 26.48	3.32
Granted	5,302,192	1.75	4.64
Exercised	(2,203,993)	0.61	0.73
Forfeited, expired or cancelled	(72,963)	2.56	—
Warrants outstanding, September 30, 2023	4,080,908	8.67	4.38

## 5. Fair Value Measurements

### Contingent Consideration Obligations

Pursuant to the Giiant License Agreement entered into on September 1, 2023, the Company incurred a contingent consideration obligation related to future milestone payments. The Company has an obligation to make contingent consideration payments to Giiant upon the achievement of development milestones (as set forth in the Giiant License Agreement), in either cash or shares of the Company's common stock, at the Company's election. Because the contingent consideration may be settled in shares of the Company's common stock, the Company has determined it should be accounted for under ASC 480, *Distinguishing Liabilities from Equity*, and accordingly has recognized it as a liability measured at its estimated fair value at the date of issuance.

At each reporting date, the Company re-measures the contingent consideration obligation **offers** to its estimated fair value and any resulting change is recognized **employees an opportunity to participate** in In-process research and development in the condensed consolidated statements of operations. The fair value of the contingent consideration obligation is determined using a probability-based model which estimates the likelihood of success in achieving each of the defined milestones which is then discounted to present value using the Company's borrowing rate. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting.

As of September 1, 2023, the date the contingent consideration obligation was incurred, the fair value of the liability was determined to be approximately \$212,000. There was no change in the fair value of the contingent consideration obligation in the three and nine months ended September 30, 2023. As of September 30, 2023, the fair value of the contingent consideration obligation of approximately \$212,000 was recognized as a noncurrent liability in the condensed consolidated balance sheet.

### ***Liability-Classified Warrants***

The Company has issued warrants that are accounted for as liabilities based upon the guidance of ASC 815. Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the trading market price of the Company's common stock. Because liability-classified financial instruments are initially and subsequently carried at fair value, the Company's financial results will reflect the volatility in these estimate and assumption changes. Changes in fair value are recognized as a component of other income in the condensed consolidated statement of operations.

As of September 30, 2023, the fair value of the Senior Secured Promissory Note Warrants outstanding was determined using a Black-Scholes option pricing model valuation model to be insignificant due to the low market price of the Company's stock at the date of valuation relative to the exercise price of the Senior Secured Promissory Note Warrants outstanding.

As of September 30, 2023, the fair value of each of the July 2021 Warrants outstanding and the January 2022 Warrants outstanding was determined using a Monte Carlo simulation model to be insignificant due to the low market price of the

Company's stock at the date of valuation relative to the exercise price of each of the July 2021 Warrants outstanding and January 2022 Warrants outstanding.

The following table summarizes the activity of the Company's Level 3 warrant liabilities during the three and nine months ended September 30, 2023 and 2022 (in thousands):

Warrant Liabilities	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2023	2022	2023	2022
Fair value at beginning of period	\$ 2	\$ 469	\$ 61	\$ 2,651
Initial fair value at the original issuance date	—	—	—	1,110
Change in fair value during the period	—	(385)	(59)	(2,403)
Fair value of liability classified warrants exercised	—	—	—	(1,274)
Fair value at end of period	<u>\$ 2</u>	<u>\$ 84</u>	<u>\$ 2</u>	<u>\$ 84</u>

The change in fair value of warrant liabilities during the three and nine months ended September 30, 2023 and 2022 is included in Other income (expense) in the condensed consolidated statements of operations.

## 6. Stockholders' Equity (Deficit)

### Classes of Stock

#### Common Stock

As of September 30, 2023, the Company was authorized to issue 280,000,000 shares of \$0.01 par value common stock. Each share of common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

On November 15, 2022, the Company effected the Reverse Stock Split. Accordingly, each of the Company's shareholders received one new share of the Company's common stock for every 50 shares of the Company's common stock such its shareholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all of the Company's issued and outstanding shares of the Company's common stock equally. The Reverse Stock Split also affected the Company's outstanding stock options, warrants and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately to the Reverse Stock Split ratio. No fractional shares were issued as a result of the Reverse Stock Split with any fractional shares that would have otherwise resulted from the Reverse Stock Split paid in cash, at an amount equal to the resulting fractional interest in one share of the Company's common stock to which the shareholder would otherwise be entitled, multiplied by the closing trading price of the Company's common stock on November 15, 2022. The amount of cash paid for fractional shares was insignificant.

As a result of the Reverse Stock Split, the number of issued and outstanding shares of the Company's common stock was adjusted from 77,080,169 shares to approximately 1,541,508 shares. Each share of the Company's common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

#### ***Preferred Stock***

As of September 30, 2023, the Company was authorized to issue 7,000,000 shares of \$0.01 par value preferred stock of which 1,000,000 shares have been designated as Series A 4.5% Convertible Preferred Stock ("Series A Convertible Preferred Stock") and 200,000 of which are issued and outstanding. As of September 30, 2023, the Company's Series A Convertible Preferred Stock issued in the amount of 200,000 preferred stock shares is convertible into 129 shares of common stock.

#### ***January 2023 Registered Direct Offering and Private Placement***

On January 4, 2023, the Company closed on an agreement with certain institutional and accredited investors pursuant to which it agreed to sell and issue, in a registered direct offering (the "January 2023 Registered Offering"), an aggregate of (i) 476,842 shares of the Company's common stock, par value \$0.01 per share, at a purchase price per share of \$2.375, and (ii) 37,000 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of \$2.3749, with such warrants having an exercise price of \$0.0001 per share and a perpetual term. Additionally, in a concurrent private placement, the Company also agreed to sell and issue to such purchasers, an aggregate of (i) 538,789 pre-funded warrants to purchase shares of the Company's common stock at a purchase price of \$2.3749, with such warrants having an exercise price of \$0.0001 per share and a perpetual term; and (ii) 1,052,631 warrants to purchase shares of the Company's common stock at an exercise price of \$2.375 per share and a term of five years from the date of issuance (the "January 2023 Private Placement") (collectively, the January 2023 Registered Offering and

the January 2023 Private Placement are referred to as the "January 2023 Offering"). All the warrants are immediately exercisable from their date of issuance.

Pursuant to a placement agency agreement dated as of December 30, 2022, the Company engaged Ladenburg Thalmann & Co. Inc. (the "January 2023 Placement Agent"), to act as the exclusive placement agent in connection with the January 2023 Registered Offering and concurrent private placement transaction. The Company issued warrants to the January 2023 Placement Agent to purchase an aggregate of 63,158 shares of the Company's common stock (the "January 2023 Placement Agent Warrants"). The January 2023 Placement Agent Warrants have an exercise price of \$2.9688 per share and a term of five years. The January 2023 Placement Agent Warrants are immediately exercisable from issuance. The fair value of the January 2023 Placement Agent Warrants was recognized by the Company as an equity issuance cost which reduced the additional paid-in capital recognized from the January 2023 Offering.

Gross cash proceeds from the January 2023 Offering were approximately \$2.5 million and net cash proceeds were approximately \$2.2 million after deducting equity issuance costs of approximately \$0.3 million, which excludes the grant date fair value of the January 2023 Placement Agent Warrants of approximately \$0.2 million.

### **April 2023 Registered Direct Offering and Private Placement**

On April 3, 2023, the Company entered into securities purchase agreements with certain institutional and accredited investors pursuant to which the Company agreed to sell and issue, in a registered direct offering (the "April 2023 Registered Offering"), an aggregate of 756,317 shares of the Company's common stock, at a purchase price per share of \$2.64. Additionally, in a concurrent private placement, the Company also agreed to sell and issue to such purchasers, an aggregate of (i) 455,242 unregistered shares of the Company's common stock, at a purchase price per share of \$2.64, (ii) 1,061,164 prefunded warrants to purchase shares of the Company's common stock at a purchase price of \$2.6399 per prefunded warrant, with such warrants having an exercise price of \$0.0001 per share and a perpetual term; and (iii) 2,272,723 common stock warrants to purchase shares of the Company's common stock at an exercise price of \$2.64 per share and a term of five years from the date of issuance (the "April 2023 Private Placement") (collectively, April 2023 Registered Offering and April 2023 Private Placement are referred to as the "April 2023 Offering"). All of the warrants issued in the Private Offering are immediately exercisable from their date of issuance.

Pursuant to a placement agency agreement dated as of April 3, 2023, the Company engaged Ladenburg Thalmann & Co. Inc. (the "April 2023 Placement Agent"), to act as the exclusive placement agent in connection with the April 2023 Offering. The Company issued warrants to the April 2023 Placement Agent to purchase an aggregate of 136,363 shares of the Company's common stock (the "April 2023 Offering Placement Agent Warrants"). The April 2023 Offering Placement Agent Warrants have an exercise price of \$3.30 per share and a term of five years and are immediately exercisable from issuance. The fair value of the April 2023 Offering Placement Agent Warrants was recognized by the Company as an equity issuance cost which reduced the additional paid-in capital recognized from the April 2023 Offering.

Gross cash proceeds from the April 2023 Offering were approximately \$6.0 million and net cash proceeds were approximately \$5.3 million after deducting cash equity issuance costs of approximately \$0.7 million, which excludes the grant date fair value of the April 2023 Placement Agent Warrants of approximately \$0.2 million.

### **September 2023 Equity Offering**

On September 7, 2023, the Company entered into securities purchase agreements with certain institutional investors, pursuant to which the Company agreed to sell and issue an aggregate of 2,339,398 shares of the Company's common stock, par value \$0.01 per share, at a purchase price per share of \$0.84 (the "September 2023 Offering"). The shares of the Company's common stock offered in the September 2023 Offering were pursuant to an effective shelf registration statement on Form S-3 filed with the SEC. The September 2023 Offering closed on September 11, 2023.

Gross cash proceeds from the September 2023 Offering were approximately \$2.0 million and net cash proceeds were approximately \$1.7 million after deducting cash equity issuance costs of approximately \$0.3 million, which excludes the grant date fair value of the September 2023 Placement Agent Warrants of approximately \$0.1 million. The fair value of the September 2023 Offering Placement Agent Warrants was recognized by the Company as an equity issuance cost.

## **7. Equity Incentive Plans**

In 2013, LBS adopted the 2013 Employee, Director, and Consultant Equity Incentive Plan, (as amended and restated, the "2013 Plan"). Upon the closing of the Merger, each outstanding, unexercised and unexpired LBS option under the 2013 Plan, whether vested or unvested, was assumed by the Company and converted into an option to purchase common stock of the Company and became exercisable by the holder of such option in accordance with its terms. In connection with the closing of the Merger, no further awards will be made under the 2013 Plan.

In April 2021, in connection with the closing of the Merger, the Company's shareholders approved the Palisade Bio, Inc. 2021 Equity Incentive Plan (the "2021 EIP Plan"). In June 2023, the Company's shareholders approved amendments to the 2021 EIP Plan to increase (i) the number of shares of common stock issuable under the plan by 708,072 shares and (ii) the annual evergreen share increase amount from 4% to 7.5% of the outstanding shares of common stock on January 1 of each year. As of September 30, 2023, there were 73,462 shares of the Company's common stock authorized and available for issuance as equity-based awards under the 2021 EIP Plan.

Also in April 2021, the Company's shareholder approved the Palisade Bio, Inc. 2021 Employee Stock Purchase Plan (the "2021 ESPP" "ESPP"). In June 2023, the Company's shareholders approved amendments to the 2021 ESPP to increase (i) the number of shares of common stock authorized under the plan by 109,944 shares and (ii) the annual evergreen share increase amount from 1% to 2.5% of the outstanding shares of common stock on January 1 of each year.

All employees are eligible to participate in the ESPP while employed by the Company. The ESPP permits eligible employees to purchase common stock through payroll deductions, which may not exceed \$25,000 or 10,000 666 shares of the Company's shares of common stock each offering period, as defined in the ESPP, at a price equal to 85% of the fair value of the Company's common stock at the beginning or end of the offering period, whichever is lower. The ESPP is intended to qualify under Section 423 of the Internal Revenue Code. The first offering period under the plan commenced on July 1, 2023 and will end on November 20, 2023. As of September 30, 2023, there were 144,547 shares of the Company's common stock authorized and available under the ESPP and there have been no shares issued under the ESPP.

The Company estimates the fair value of ESPP grants awards on their grant date the first day of the offering period using the Black-Scholes option pricing model. The estimated fair value of ESPP grants awards is amortized on a straight-line basis over the requisite service period of the grants award. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of ESPP grants. ESPP compensation expense awards.

### **Basic and Diluted Net Loss Per Common Share**

Basic net loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of shares of common stock outstanding during the period, plus any potentially dilutive common shares, consisting of stock-based awards and equivalents, and common stock warrants. For purposes of this calculation, stock-based awards and equivalents and common stock warrants are considered to be potential common shares and are only included in the calculation of diluted net loss per common share when their effect is dilutive.

The Company's Series A Convertible Preferred Stock and certain of the Company's outstanding common stock warrants contain non-forfeitable rights to dividends with the common stockholders, and therefore are considered to be participating securities. The Series A Convertible Preferred Stock and the common stock warrants do not have a contractual obligation to fund the losses of the Company; therefore, the application of the two-class method is not required when the Company is in a net loss position but is required if the Company is in a net income position. When in a net income position, diluted net earnings per common share is computed using the more dilutive of the two-class method or the if-converted and treasury stock methods.

As the Company was in a net loss position for all periods presented, basic and diluted net loss per common share for the three and nine months ended September 30, 2023 was approximately \$ March 31, 2024 and March 31, 2023 were calculated under the if-converted and treasury stock methods. For both the three months ended March 31, 2024 and March 31, 2023, basic and diluted net loss per common share were the same as all common stock equivalents were anti-dilutive for both periods.

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The following table presents the calculation of weighted average shares used to calculate basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2024	2023
Basic and diluted net loss per common share:		
Net loss available to common stockholders - basic and diluted	\$ (3,527)	\$ (2,340)
Weighted average shares used in calculating basic and diluted net loss per common share	768,137	287,702
Basic and diluted net loss per common share	<u>\$ (4.59)</u>	<u>\$ (8.13)</u>

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effects would be anti-dilutive:

In November 2021,

	March 31,	
	2024	2023
Stock options	41,937	4,180

Restricted stock units	20,833	2,802
Warrants for common stock	285,891	107,115
Series A Convertible Preferred Stock	8	8
<b>Total</b>	<b>348,669</b>	<b>114,105</b>

### Comprehensive Loss

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss was the Company's compensation committee same as its reported net loss for all periods presented.

### Recently Issued or Adopted Accounting Pronouncements

No new accounting pronouncements issued or adopted during the three months ended March 31, 2024 that had or are expected to have a material impact on the Company's condensed consolidated financial statements or disclosures.

### 3. Balance Sheet Details

Prepaid expenses and other current assets consisted of the Company's board following (in thousands):

	March 31, 2024	December 31, 2023
Prepaid insurance	\$ 294	\$ 428
Other receivables	153	148
Prepaid subscriptions and fees	173	138
Prepaid software licenses	36	64
Deferred equity issuance costs	75	112
Prepaid other	6	6
	<b>\$ 737</b>	<b>\$ 896</b>

Other noncurrent assets consisted of directors (the "Board") adopted the Palisade Bio, Inc. 2021 Inducement Award Plan (the "2021 Inducement Plan"). The 2021 Inducement Plan was adopted in order following (in thousands):

	March 31, 2024	December 31, 2023
Prepaid insurance, less current portion	\$ 426	\$ 478
Other noncurrent assets	12	12
	<b>\$ 438</b>	<b>\$ 490</b>

Accrued liabilities consisted of the following (in thousands):

	March 31, 2024	December 31, 2023
Accrued accounts payable	\$ 89	\$ 166
Accrued clinical trial expenses	10	20
Accrued director stipends	35	106
Accrued severance and benefits (Note 8)	35	131
Accrued joint development expenses (Note 7)	1,180	98
Current portion of contingent consideration obligation (Note 4)	143	143
Accrued other	178	167
	<u>\$ 1,670</u>	<u>\$ 831</u>

#### 4. Fair Value Measurements

##### **Contingent Consideration Obligation**

Pursuant to grant equity-based awards to individuals not previously employed by the Giant License Agreement, the Company as incurred a contingent consideration obligation related to future milestone payments. The Company has an inducement obligation to join the Company. On August 7, 2023, the Company's compensation committee make contingent consideration payments to Giant, in either cash or shares of the Board approved an increase Company's common stock solely at the Company's election, upon the achievement of development milestones (as set forth in the Giant License Agreement). Because the contingent consideration may be settled in shares of the Company's common stock, authorized the Company has determined it should be accounted for under ASC 480, and available for issuance accordingly has recognized it as a liability measured at its estimated fair value.

At the end of each reporting period, the Company re-measures the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the condensed consolidated statements of operations. The fair value of the contingent consideration obligation is determined using a probability-based model that estimates the likelihood of success in achieving each of the defined milestones that is then discounted to present value using the Company's incremental borrowing rate. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The significant assumptions used in the calculation of the fair value as of March 31, 2024 included a discount rate of

1,000,000 16.0 shares. % and management's updated projections of the likelihood of success in achieving each of the defined milestones based on empirical, published industry data.

As of September 30, 2023 both March 31, 2024 and December 31, 2023, the fair value of the contingent consideration liability was determined to be approximately \$204,000. Accordingly, there were was 916,640 no change in the fair value of the contingent consideration obligation for the three months ended March 31, 2024. As of both March 31, 2024 and December 31, 2023, \$143,000 of the contingent consideration obligation was recognized in accrued liabilities in the condensed consolidated balance sheet as it is expected to be settled within one-year of the balance sheet date. The remaining amount of the contingent consideration liability of \$61,000 was recognized as a noncurrent liability in the condensed consolidated balance sheet as of both March 31, 2024 and December 31, 2023.

Liability-Classified Warrants

The Company has issued warrants that are accounted for as liabilities based upon the guidance of with ASC 480 and ASC 815. Estimating fair values of liability-classified financial instruments requires the development of estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. Changes in fair value of the liability-classified warrants, if any, are recognized as a component of other income in the condensed consolidated statement of operations.

As of March 31, 2024, the fair value of the Company's liability-classified warrants outstanding was determined using a Black-Scholes option pricing model valuation model to be insignificant due to the low market price of the Company's stock at the date of valuation relative to the exercise price of the underlying warrants outstanding.

The following table summarizes the activity of the Company's Level 3 warrant liabilities during the three months ended March 31, 2024 and 2023 (in thousands):

Warrant Liabilities	Three Months Ended March 31,	
	2024	2023
Fair value at beginning of year	\$ 2	\$ 61
Change in fair value during the period	—	(43)
Fair value at end of period	\$ 2	\$ 18

5. Stockholders' Equity

Classes of Stock

### **Common Stock**

As of March 31, 2024, the Company was authorized to issue 280,000,000 shares of \$0.01 par value common stock. Each share of common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

On April 5, 2024, the Company effected the Reverse Stock Split. Accordingly, each of the Company's stockholders received one share of the Company's common stock for every 15 shares of the Company's common stock authorized that such stockholder held immediately prior to the effective time of the Reverse Stock Split. The Reverse Stock Split affected all of the Company's issued and available outstanding shares of the Company's common stock equally. The Reverse Stock Split also affected the Company's outstanding stock-based awards, warrants and other exercisable or convertible securities and resulted in the shares underlying such instruments being reduced and the exercise price or conversion price being increased proportionately by the Reverse Stock Split ratio. No fractional shares were issued as a result of the Reverse Stock Split with any fractional shares that would have otherwise resulted from the Reverse Stock Split paid in cash, at an amount equal to the resulting fractional interest in one share of the Company's common stock that the stockholder would otherwise be entitled, multiplied by the closing trading price of the Company's common stock on April 5, 2024. The amount of cash paid for issuance as equity-based awards under fractional shares was immaterial to the 2021 Inducement Plan. Company's financial statements.

As a result of the Reverse Stock Options Split, the number of issued and outstanding shares of the Company's common stock was adjusted from 12,771,015 shares to 851,302 shares. Each share of the Company's common stock entitles the holder thereof to one vote on each matter submitted to a vote at a meeting of stockholders.

### **Preferred Stock**

As of March 31, 2024, the Company was authorized to issue 7,000,000 shares of \$0.01 par value preferred stock of which 1,000,000 shares have been designated as Series A 4.5% Convertible Preferred Stock ("Series A Convertible Preferred Stock") and 200,000 of which are issued and outstanding. As of March 31, 2024, all of the Company's 200,000 shares of Series A Convertible Preferred Stock outstanding are convertible into an aggregate of 8 shares of the Company's common stock.

### **Recent Equity Offerings**

On September 11, 2023, the Company completed a registered direct offering of common stock pursuant to an effective shelf registration statement on Form S-3 (the "September 2023 Offering"). Gross cash proceeds from the September 2023 Offering were \$2.0 million and net cash proceeds were \$1.7 million after deducting cash equity issuance costs of approximately \$0.3 million.

On April 3, 2023, the Company completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the "April 2023 Offering"). Gross cash proceeds from the April 2023 Offering were \$6.0 million and net cash proceeds were \$5.3 million after deducting cash equity issuance costs of approximately \$0.7 million.

On January 4, 2023, the Company completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the "January 2023 Offering"). Gross cash proceeds from the January 2023 Offering were \$2.5 million and net cash proceeds were approximately \$2.2 million after deducting cash equity issuance costs of approximately \$0.3 million.

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### **Common Stock Warrants and Warrant Exercises**

On January 30, 2024, the Company entered into warrant inducement agreements (the "Warrant Inducement Agreements") with certain accredited and institutional holders (collectively, the "Warrant Holders") of certain of the Company's remaining outstanding common stock warrants issued on May 10, 2022 (the "May 2022 Warrants"), January 4, 2023 (the "January 2023 Warrants"), and April 5, 2023 (the "April 2023 Warrants"), as well as certain outstanding Series 2 warrants issued on August 16, 2022 (the "Series 2 Warrants") (collectively, the "Existing Warrants"). Pursuant to the Warrant Inducement Agreements, the exercise price of each of Existing Warrants exercised was reduced to \$10.97 per share. Each of the Warrant Holders that exercised its Existing Warrants pursuant to the Warrant Inducement Agreements, received one replacement warrant to purchase a share of the Company's common stock (the "Replacement Warrants") for each Existing Warrant exercised (in its entirety, the "February 2024 Warrant Inducement").

The Company believes that stock options align the interests of its employees and directors with the interests of its stockholders. Stock option awards Replacement Warrants are generally granted with exercisable immediately, have an exercise price equal per share of \$10.97, and expire five years from the date of issuance, which was February 1, 2024. The Replacement Warrants are subject to adjustment in the market event of stock splits, dividends, subsequent rights offerings, pro rata distributions, and certain fundamental transactions, as more fully described in the Replacement Warrants. The Replacement Warrants contain standard anti-dilution provisions but do not contain any price protection provisions with respect to future securities offerings of the Company.

The Warrant Holders collectively exercised an aggregate of 228,162 Existing Warrants consisting of: (i) 4,865 May 2022 Warrants, (ii) 4,267 Series 2 Warrants, (iii) 67,511 January 2023 Warrants, and (iv) 151,519 April 2023 Warrants. As a result of the exercises of the Existing Warrants, the Company issued an aggregate of 228,162 shares of its common stock. The February 2024 Warrant Inducement closed on February 1, 2024 with the Company receiving net cash proceeds of approximately \$2.2 million consisting of gross cash proceeds of \$2.5 million, less cash equity issuance costs of approximately \$0.3 million.

The February 2024 Warrant Inducement, which resulted in the lowering of the exercise price of Company's stock at the date the grants are awarded, a term as determined by the Company's Board but generally not to exceed ten-years, Existing

Warrants and generally vest in equal proportions each quarter over three years. The Company's equity incentive plans allow for the issuance of both incentive stock options and non-statutory stock options.

the Replacement Warrants, is considered a modification of the Existing Warrants under the guidance of ASC 815-40. The fair value modification is consistent with the Equity Issuance classification under that guidance as the reason for the modification was to induce the holders of options granted the Existing Warrants to cash exercise their Existing Warrants, resulting in the nine months ended September 30, 2023 and September 30, 2022 is estimated as imminent exercise of the grant date Existing Warrants, which raised equity capital and generated gross cash proceeds for the Company of approximately \$2.5 million. As pursuant to the guidance of ASC 480 and ASC 815 the Existing Warrants and Replacement Warrants were classified as equity instruments before and after the modification, and as the modification is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$2.0 million as an equity issuance cost netted against the additional paid-in capital recognized from the associated warrant exercises. The amount of the equity issuance cost recognized for the warrant modification was determined using the Black-Scholes option pricing model using as the assumptions incremental fair value of the modified Existing Warrants and additional Replacement Warrants issued as compared to the fair value of the original Existing Warrants immediately prior to their modification.

The solicitation agent fees associated with the February 2024 Warrant Inducement consisted of: (i) a cash fee equal to 7.75% of the gross proceeds received by the Company, (ii) a common stock purchase warrant to purchase such number of shares of common stock equal to 6% of the aggregate number shares issued pursuant to the exercise of the Existing Warrants, with an exercise price of \$10.97 per share, and a term of five years from issuance (the "Solicitation Agent Warrants"), and (iii) \$35,000 of out-of-pocket expenses. The fair value of the Solicitation Agent Warrants was recognized by the Company as an equity issuance cost, which reduced the additional paid-in capital recognized from the issuance of common stock in connection with the exercise of the Existing Warrants.

Total equity issuance costs recognized in the following table: February 2024 Warrant Inducement of \$2.4 million include cash equity issuance costs of \$0.3 million, non-cash warrant modification costs of approximately \$2.0 million, and non-cash issuance costs associated with the Solicitation Agent Warrants of \$0.1 million.

	Nine Months Ended September 30,	
	2023	2022
Weighted-average exercise price per share	\$ 1.64	\$ 40.32
Weighted-average expected term (years)	5.64	5.81
Weighted-average risk-free interest rate	3.98 %	2.30 %
Weighted-average expected dividend yield	—	—
Weighted-average volatility	68.75 %	73.66 %

Risk-free interest rate. The Company bases the risk-free interest rate assumption on observed interest rates appropriate accounts for the expected term majority of its warrants as equity-classified in accordance with ASC 480 and

ASC 815. The Company's outstanding common stock warrants that are classified as equity warrants are included as a component of stockholders' equity based on their relative fair value on their date of issuance. Common stock warrants accounted for as liabilities in accordance with the authoritative accounting guidance are included in noncurrent liabilities. The Company had exercisable common stock warrants outstanding of 285,891 and 272,211 at March 31, 2024 and December 31, 2023, respectively. Of the Company's common stock warrants exercisable at March 31, 2024, 251,262 common stock warrants have an exercise price of \$10.97 and the remaining 34,646 common stock warrants have a weighted average exercise price of \$812.54. Of the outstanding common stock warrants, only 9,414 are subject

to price reset provisions in the event future sales of the stock option grants.

Expected dividend yield. The Company bases Company's securities are sold at a price per share less than the expected dividend yield assumption on the fact that it has never paid cash dividends and has no present intention to pay cash dividends.

Expected volatility. Due to the Company's limited operating history and lack exercise price of company-specific historical or implied volatility, the expected volatility assumption is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the biotechnology industry.

Expected term. The expected term represents the period of time that options are expected to be outstanding. As the Company does not have sufficient historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its vesting period. such warrants.

The following table summarizes warrant activity during the three months ended March 31, 2024:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2023	272,211	\$ 144.78	4.12
Granted	241,848	10.97	4.84
Exercised	(228,162)	10.97	—
Forfeited, expired or cancelled	(6)	27,000.00	—

Warrants outstanding, March 31, 2024	285,891	107.85	4.66
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## 6. Equity Incentive Plans

### Equity Incentive Plans

The Company's stock-based compensation generally includes RSUs, PSUs, and stock option activity options.

There were no RSUs, stock options or other equity-based awards issued under any of the Company's equity incentive plans in the three months ended March 31, 2024. During the three months ended March 31, 2023, the Company granted 2,967 RSUs at a weighted-average fair market value of \$48.79 per RSU, and related information under 2,040 stock options at a weighted average grant date fair market value of \$22.65 per stock option.

### Employee Stock Purchase Plan

Compensation expense associated with the 2013 Plan, the 2021 EIP Plan and the 2021 Inducement Plan ESPP for the nine three months ended September 30, 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	43,658	\$ 311.74	6.08	\$ —
Granted	510,160	1.64	9.72	—
Exercised	—	—	—	—
Forfeited, expired or cancelled	(10,630)	238.00	—	—
Outstanding at September 30, 2023	543,188	21.91	9.56	—
Vested and expected to vest at September 30, 2023	543,188	21.91	9.56	—
Exercisable at September 30, 2023	64,155	165.86	8.51	—

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2023 was \$0.93 per share. The fair value of the options vested during the nine months ended September 30, 2023 March 31, 2024 was approximately \$241,000 5,000.

On February 6, 2023, the Company granted to certain members of management a total of There was 81,500 no stock options that were conditional subject to shareholder approval (the "Conditional Stock Options"), which such approval was received at the Company's annual shareholder meeting held on June 8, 2023. Accordingly, the Company began to recognize share-based compensation expense related to the Conditional Stock Options during the three and nine months ended September 30, 2023 ratably to the vesting of the awards.

### Restricted Stock Units

During the nine months ended September 30, 2023, the Company granted under the 2021 EIP Plan and 2021 Inducement Plan time-based restricted stock units ("RSUs") to employees. The RSUs generally vest proportionally each quarter over a term of one or three years.

The following table summarizes RSU activity and related information under the 2021 EIP Plan and the 2021 Inducement Plan for the nine months ended September 30, 2023:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share	Weighted Average Remaining Contractual Life (Years)
Non-vested at December 31, 2022	—	\$ —	—
Granted	380,102	1.58	—
Vested	(34,653)	2.48	—
Forfeited	(2,479)	3.15	—
Non-vested at September 30, 2023	342,970	1.49	2.12

The fair value of the RSUs vested during the nine months ended September 30, 2023 was approximately \$55,000.

On February 6, 2023, the Company granted to certain members of management a total of 59,500 RSUs that were conditional subject to shareholder approval (the "Conditional RSUs"), which such approval was received at the Company's annual shareholder meeting held on June 8, 2023. Accordingly, the Company began to recognize share-based compensation expense related to the Conditional RSUs during the three and nine months ended September 30, 2023 ratably to the vesting of the awards.

### Performance Based Stock Units

On February 6, 2023, the Company granted to certain members of management a total of 68,700 market-based performance restricted stock units ("PSUs") which vest (a) 50% when the volume weighted average price of the Company's common stock over 20 consecutive trading days is \$3.20 or greater ("vesting Tranche 1"), and (b) 50% when such volume weighted average price of the Company's common stock over 20 consecutive trading days is \$4.25 or greater ("vesting Tranche 2"). The PSUs were conditional subject to shareholder approval, which such approval was received at the Company's annual shareholder meeting held on June 8, 2023. The fair value of each of the market-based vesting tranches of the PSUs was determined using a Monte Carlo simulation model which considered a variety of potential share prices for the Company's common stock. The weighted-average grant date fair value per share of vesting Tranche 1 and vesting Tranche 2 of the PSUs was \$1.50 per award share and \$1.47 per award share, respectively, and was determined using the

following key assumptions: (i) a risk-free interest rate of 3.74%, (ii) expected stock price volatility of 76.6%, (iii) a cost of equity of 27.99%, and (iv) an expected contractual life of 9.66 years. As shareholder approval of the PSUs was received, the Company is recognizing the share-based compensation expense associated with the PSUs ratably over ESPP in the derived service period of 1.75 years for Tranche 1 and 2.48 years for vesting Tranche 2, regardless of whether or not the market condition for vesting is satisfied. None of the PSUs vested during the nine three months ended September 30, 2023 and all of the PSUs granted during the nine months ended September 30, 2023 remain outstanding as of September 30, 2023 March 31, 2023.

### Share-Based Compensation Expense

The allocation of stock-based compensation for all stock awards is as follows (in thousands):

	Three Months Ended September		Nine Months Ended September	
	30,		30,	
	2023	2022	2023	2022
Research and development expense	\$ 70	\$ 63	\$ 186	\$ 174
General and administrative expense	122	189	243	772
Total	\$ 192	\$ 252	\$ 429	\$ 946

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	Three Months Ended March 31,	
	2024	2023
Research and development expense	\$ 47	\$ 49
General and administrative expense	66	44
Total	\$ 113	\$ 93

As of September 30, 2023 March 31, 2024, the unrecognized compensation cost related to outstanding options was \$0.70.4 million, which is expected to be recognized over a weighted-average period of approximately 1.891.75 years and the unrecognized compensation cost related to outstanding time-based and performance-based RSUs was \$0.40.3 million, which is expected to be recognized over a weighted average period of approximately 2.122.04 years.

## 8.7. Collaborations and License Agreements

### Research Collaboration and License Agreement with Giiant

On September 1, 2023 (the “Effective Date”), the Company entered into the Giiant License Agreement whereby the Company **has** received an exclusive, worldwide license (with the right to sublicense in multiple tiers) to develop, manufacture, and commercialize substantially all of the assets of Giiant, including: (i) the PALI-2108 (**formerly GT-2108**) compound, and (ii) the PALI-1908 (**formerly GT-1908**) compound and the associated intellectual property around each of the foregoing (the “Giiant Licensed Assets”). The Giiant License Agreement has a perpetual term.

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Pursuant to the Giiant License Agreement, the Company and Giiant have established a joint development committee (“JDC”), consisting of one Giiant appointee and two Company appointees. The JDC **will be is** responsible for: (i) overseeing the day-to-day development of the Giiant Licensed Assets through Proof of Concept (as defined below), and (ii) **the** creation and implementation of the development plan and development budget for **such development the Giiant Licensed Assets** (the “Giiant Development Plan”) and any amendments or updates thereto.

Prior to receiving regulatory approval to commence a Phase 1 clinical trial (as such term is defined in the Giiant License Agreement) (the “Proof of Concept”), each of the Company and Giiant shall be solely responsible for all costs and expenses incurred by such party for the joint development of the Giiant Licensed Assets, except as set forth in the Giiant Development Plan. Prior to reaching the Proof of Concept, the Company will reimburse **or advance** Giiant up to an amount in the low seven-digit range for costs and expenses incurred by them, subject to increase upon unanimous consent of all members of the JDC, and provided that the costs and expenses are included in the Giiant Development Plan budget and are approved by the JDC. Upon reaching the Proof of Concept, the Company will be solely responsible for all costs and expenses incurred for the development, manufacturing, regulatory and commercialization of the Giiant Licensed Assets. **For the three months ended March 31, 2024, the Company has recognized expenses related to the joint development plan with Giiant in the amount of approximately \$1.6 million, which are included in research and development expenses in the condensed consolidated statements of operations. At March 31, 2024 and December 31, 2023, the Company has accrued joint development expenses of approximately \$1.2 million and approximately \$0.1 million, respectively, in Accrued liabilities in the condensed consolidated balance sheets.**

As consideration for the **Giiant** Licensed Assets, the Company will (i) make **certain** payments between the mid six-digit range and low seven-digit range upon the achievement of **the** development milestones (as set forth in the Giiant License Agreement), in either cash or shares of the Company’s common stock, at the Company’s election (“Giiant Milestone Payments”), and (ii) pay ongoing royalty payments of **five percent a mid-single-digit percentage** of the adjusted gross proceeds, as defined in the Giiant License Agreement, upon the sales or sublicenses of any products developed from the Giiant Licensed Assets to third parties (“Giiant Royalty Payments”) (collectively, the Giiant Milestone Payments and the Giiant Royalty Payments are referred to as the “Giiant License Payments”). The Giiant License Payments are subject to a

maximum payment cap in the very low eight-digit range, which will be increased or decreased on a dollar-for-dollar basis based on a formula related to the aggregate of development costs incurred by the parties ("Payment Cap").

In The Company has made no Giiant License Payments since the event that Giiant desires to sell or assign any rights to receive commencement of the Giiant License Payments, it will be required to notify Company of such offer or proposal ("Offer Notice"). The Company will then have a right of first refusal for thirty days from the receipt of such Offer Notice, to acquire the rights and obligations contained in such Offer Notice on the same terms. Agreement.

The Company may unilaterally terminate the Giiant License Agreement for: (i) convenience, ("Company Convenience Termination"), (ii) the failure to achieve Proof of Concept within eighteen months of September 1, 2023, subject to extension upon the occurrence of certain event, ("Proof of Concept Termination"), or (iii) a material breach by Giiant, that is not cured within ninety (90) days of written notice ("Giiant Material Breach Termination").

In the event of a Company Convenience Termination, the Giiant License Agreement will be terminated and Giiant will retain unencumbered ownership of the Giiant Licensed Assets and no further License Payments will be required of Company.

In the event of a Proof of Concept Termination or Giiant Material Breach Termination, the Company may elect to terminate the Giiant License Agreement. In such instance, the Company will remain obligated to continue making the Giiant License Payments, if any, if and when they become due. notice.

Giiant may unilaterally terminate the Giiant License Agreement only for a material breach by Company that is not cured within ninety days of written notice ("Company Material Breach Termination") provided however that upon the Payment Cap being achieved, that right will terminate and the Giiant License Agreement will become perpetual. In the event of a Company Material Breach Termination, the Giiant License Agreement, including the License will be

terminated and Giiant will retain unencumbered ownership of the Giiant Licensed Assets, including any improvements made up until such termination and the Company will be under no further obligations.

### ***Co-Development and Distribution Agreement with Newsoara***

LBS has entered into a co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the "Newsoara Co-Development Agreement"). Pursuant to the Newsoara Co-Development Agreement (and subsequent assignment agreement), LBS granted or licensed Newsoara an exclusive right under certain patents to develop, use, sell, offer to sell, import, and otherwise commercialize licensed products (the "Newsoara Licensed Products") for any and all indications in the People's Republic of China, including the regions of Hong Kong and Macao, but excluding Taiwan (the "Territory"). The Newsoara Licensed Products only include the drug asset referred to as LB1148. The right includes the right to grant sublicenses to third parties, subject to LBS' written consent, provided that both parties agreed that Newsoara would be permitted to use a certain partner for development purposes. The Newsoara Co-Development Agreement obligates Newsoara to initially use LBS as the exclusive supplier for all of Newsoara's requirements for Newsoara Licensed Products in the Territory. During the term of the Newsoara Co-Development Agreement, Newsoara may request to manufacture the Newsoara Licensed Products in the Territory, subject

to satisfying certain conditions to LBS' reasonable satisfaction. LBS is obligated to approve Newsoara manufacturing rights without undue refusal or delay. Where the Company performs any research and development or manufacturing activities under the Newsoara Co-Development Agreement, the Company records the expense reimbursement from Newsoara as a reduction to research and development expense.

In consideration of the rights granted to Newsoara under the Newsoara Co-Development Agreement, Newsoara paid LBS a one-time upfront fee of \$1.0 million. In addition, Newsoara is obligated to make (i) payments of up to \$6.75 million in the aggregate upon achievement of certain regulatory and commercial milestones, (ii) payments in the low six-digit range per licensed product upon achievement of a development regulatory milestone, and (iii) tiered royalty payments ranging from the mid-single-digit to low-double-digit percentage range on annual net sales of Licensed Products, subject to adjustment to the royalty percentage in certain events, including a change of control, the expiration of certain patents rights, and royalties paid by Newsoara third parties. To date, Newsoara has met all of its payment obligations under the Newsoara Co-Development Agreement.

During the nine three months ended September 30, 2023 March 31, 2023, the Company recognized license revenue of \$0.3 million earned upon Newsoara's achievement of a development milestone under the Newsoara Co-Development Agreement during the first quarter of 2023. During the three months ended September 30, 2023 and March 31, 2024, the three and nine months ended September 30, 2022, there were Company recognized no milestone payments earned license revenue from Newsoara under the Newsoara Co-Development Agreement.

The Newsoara Co-Development Agreement will expire upon the later of the expiration date of the last valid claim of any licensed patent covering the Newsoara Licensed Products in the Territory. In addition, the Newsoara Co-Development Agreement can be terminated (i) by either party for the other party's material breach that remains uncured for a specified time period after written notice or for events related to the other party's insolvency, (ii) by LBS if Newsoara challenges or attempts to interfere with any licensed patent rights and, (iii) by Newsoara for any reason upon specified prior written notice.

### ***License Agreements with the Regents of the University of California***

The Company has entered into three license agreements, as amended, with the Regents of the University of California ("Regents") for exclusive commercial rights to certain patents, technology and know-how. Concurrent with the Company's decision to terminate the development of LB1148, on October 20, 2023 the Company terminated two of its license agreements with Regents. As of March 31, 2024, the only license agreement remaining with Regents is that entered into with LBS in August 2015, as amended in December 2019 and September 2022 (the "2015 UC License"). The licensed

assets are related to 2015 UC License was retained for the Company's products and assays under development. The Regents are entitled to certain development and sales milestones.

In conjunction with sole purpose of maintaining the Newsoara Co-Development Agreement under which the Company may receive future milestone or royalty payments through the term of the license. Accordingly, pursuant to the 2015 UC License, the Company is obligated to pay a percentage of non-royalty licensing revenue it receives from Newsoara under the Newsoara Co-Development Agreement to Regents a portion of the sublicense revenue ranging from 30 percent to 35 percent of one-third of the upfront payment and milestone payments received from Newsoara. As of September 30, 2023 During the three months ended March 31, 2024, the Company recognized no sublicense fees or license maintenance fees due to Regents in research and December 31, 2022, sublicensing payables of approximately \$46,000 and \$13,000, respectively, were included in current liabilities development expenses in the condensed consolidated balance sheets. statements of operations. During the three months ended March 31, 2023, there were approximately \$29,000 in sublicense fees and no license maintenance fees due to Regents recognized in research and development expenses in the condensed consolidated statements of operations.

The 2015 UC License will expire upon the expiration date of the longest-lived patent right licensed under the 2015 UC License. The Regents may terminate the 2015 UC License if: (i) a material breach by us is not cured within 60 days, (ii) the Company files a claim asserting the Regents licensed patent rights are invalid or unenforceable, or (iii) the Company files for bankruptcy. The Company also has the right to terminate the 2015 UC License at any time upon at least 90 days' written notice.

### **Contingent Value Right**

Immediately prior to the closing of the Merger, Seneca issued each share of its common stock held by Seneca stockholders of record, one contingent value right ("CVR"). The CVR entitled the holder (the "CVR Holder") to receive, pro rata with the other CVR Holders, 80% of the net proceeds, if any and subject to certain minimum distribution limitations ("CVR Payment Amount"), received from the sale or licensing of the intellectual property owned, licensed or controlled by Seneca immediately prior to the closing of the Merger (the "Legacy Technology"); provided however that the CVR Holders are only entitled to receive such CVR Payment Amount if the sale or licensing of such Legacy Technology occurred on or before October 27, 2022 ("Legacy Monetization"). Pursuant to the terms of the CVR agreement ("CVR Agreement"), CVR Holders are only entitled to receive CVR Payment Amounts received within 48-months following the closing of the Merger. The CVR Agreement also provides that no distributions will be made to the CVR Holders in the event such distribution is less than \$0.3 million.

## 23 NSI-189 – Exclusive License and Subsequent Exercise of Purchase Option

Prior to the Merger, Seneca exclusively licensed certain patents and technologies, including a sublicense covering a synthetic intermediate, of the Company's NSI-189 assets ("189 License"), along with a purchase option through December 16, 2023 ("Purchase Option"). On October 22, 2021, Alto Neuroscience ("Alto") agreed to terms of an early exercise of the Purchase Option under the 189 License and entered into an asset transfer agreement ("ATA"). Alto is a U.S. based public, clinical-stage biopharmaceutical company with a mission to redefine psychiatry by leveraging neurobiology to develop personalized and highly effective treatment options.

Pursuant to the terms of the CVR Agreement, no distribution was required to be made to the CVR Holders as the CVR Payment Amount after deducting costs and expenses required to maintain the 189 License was less than \$0.3 million. In accordance with the terms of the CVR Agreement, the net proceeds from the sale of the NSI-189 assets, less any applicable transaction costs and expenses, were deposited into the CVR escrow to be used to pay costs and expenses associated with the monetization of the Company's other Legacy Technologies.

In addition, Alto will be required to pay the Company up to an aggregate of \$4.5 million upon the achievement of certain development and regulatory approval milestones for NSI-189 (or a product containing or otherwise derived from NSI-189), which is now known as ALTO-100. If Alto sells or grants to a third party a license to the patents and other rights specific to ALTO-100 prior to the achievement of a specified clinical development milestone, Alto will be required to pay to the Company a low-double digit percentage of any consideration received by Alto from such license or sale, provided that the maximum aggregate consideration Alto will be required to pay to the Company under the ATA, including the upfront payment and all potential milestones and transaction-related payments, will not exceed \$5.0 million.

Alto has successfully completed a Phase 2a clinical trial of ALTO-100 and is currently enrolling a Phase 2b clinical trial from which topline data is expected in the second half of 2024. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, a milestone payment of \$1.5 million will be due from Alto under the ATA. If this occurs within 48-months of the closing of the Merger, the CVR Holders will be entitled to a CVR Payment Amount, with the remaining 20% of the net proceeds deposited into the CVR escrow. If the milestone is met after 48-months of the closing of the Merger, all the net proceeds will be paid to the Company. There can be no assurance that CVR holders will receive CVR Payment Amounts from the sale of the NSI-189 assets.

### NSI-532.IGF-1

On October 27, 2022, the Company entered an agreement to license NSI-532.IGF-1 to the Regents of the University of Michigan ("University of Michigan") for maintaining NSI-532.IGF-1 cell lines, continued development, maintaining patent protection, and seeking licensees. The Company received no upfront fees for the license. NSI-532.IGF-1 is a pre-clinical cell therapy being investigated as a potential therapy for prevention and treatment of Alzheimer's disease. The University of Michigan shall bear 100% of the costs for patent filing, prosecution, maintenance, and enforcement of the patent rights. The Company will receive 50% of net revenues received by the University of Michigan from the licensing of patent rights through the last-to-expire patent in patent rights, unless otherwise earlier terminated, less all reasonable and actual out-of-

pocket costs incurred in the litigation of patent rights. There can be no assurance that NSI-532.IGF-1 will ever be successfully monetized or that CVR holders will receive CVR Payment Amounts from the sale of the NSI-532.IGF-1 assets.

## 9.8. Commitments and Contingencies

### Corporate Office Lease

On May 12, 2022, the Company entered into a new, non-cancelable facility operating lease (the "Corporate Office Lease") of office space for its corporate headquarters replacing its existing corporate headquarters lease that expired on July 31, 2022. The Corporate Office Lease is for 2,747 square feet of an office building in Carlsbad, California. The initial contractual term is for 39-months commencing on June 1, 2022 and expiring on August 31, 2025. The Company has the option to renew the Corporate Office Lease for an additional 36-month period at the prevailing market rent upon completion of the initial lease term. The Company has determined it is not reasonably certain likely that it will exercise this renewal option.

Commencing on June 1, 2022, the Company is subject to contractual monthly lease payments of \$10,850, plus certain utilities, for the first 12 months with 3 percent escalations at the first, second and third lease commencement anniversaries. The Corporate Office Lease is subject to conditional abatement of fifty percent (50%) of such base rent during the second, third and fourth full calendar months of the initial lease term, as set forth in the lease agreement, as well as a \$28,000 tenant improvement allowance.

The Corporate Office Lease is also subject to additional variable charges for common area maintenance, insurance, taxes and other operating costs. This additional variable rent expense is not estimable at lease inception. Therefore, it is excluded from the Company's straight-line expense calculation at lease inception and is expensed as incurred.

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As of September 30, 2023 March 31, 2024, the Company recognized an operating right-of-use asset related to the Corporate Office Lease in the amount of \$224,000 170,000 and a current and noncurrent operating lease liability related to the Corporate Office Lease of \$117,000 125,000 and \$122,000 58,000, respectively. As of September 30, 2023 March 31, 2024, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately \$263,000 196,000, including imputed interest of \$24,000 13,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 1.9 1.4 years.

Maturities of the Company's operating lease liabilities as of September 30, 2023 March 31, 2024 are as follows:

Year ending December 31,		
2023 (remaining)	\$ 34	
2024	136	
2024 (remaining)		\$ 137
2025	93	59
Total operating lease payments	263	196
Less: imputed interest	(24)	(13)
Total operating lease obligations	\$ 239	\$ 183

The Company recognized operating lease expense associated with its Corporate Office Lease and its predecessor corporate headquarters lease of approximately \$32,000 and \$97,000 in both the three and nine months ended September 30, 2023 March 31, 2024 and \$49,000 and \$157,000 in the three and nine months ended September 30, 2022 March 31, 2023, respectively.

### Insurance Financing Arrangements

Consistent with past practice, in June 2023, the Company entered into an agreement to finance certain an insurance policies which policy that renewed in May 2023. The financing arrangement entered into in June 2023 has a stated annual interest rate of 7.92% and is payable over a 9-month period with the first payment commencing June 30, 2023. The insurance financing arrangement is secured by the associated insurance policy. As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the aggregate remaining balance under the Company's insurance financing arrangements in place at each time was \$0.3 zero million and \$0.1 0.2 million, respectively.

### Restructuring Costs

In order to better utilize the Company's resources on the implementation of its refocused clinical programs business plans and corporate strategy, on September 9, 2022 the Company committed to a cost-reduction plan. This cost-reduction plan on September 9, 2022 (the "2022 Cost-Reduction Plan") and a reduction-in-workforce on October 27, 2023 (the "2023 RIF"). The 2022 Cost-Reduction Plan consisted primarily of a reduction of approximately 20% reduction in the Company's employee workforce to better align the Company's resources with its proposed business plan. The 2023 RIF consisted of a 25% reduction in the Company's employee workforce, specifically research and development employees that were no longer deemed critical for the Company's development of PALI-2108.

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As of December 31, 2022, the Company recognized accrued liabilities on its condensed consolidated balance sheets in the amount of approximately \$180,000 related to severance and benefits owed pursuant to employment agreements and the execution of severance and release agreements associated with the restructuring, all of which was paid in cash in the nine months ended September 30, 2023. The Company recognized no restructuring expense expenses related to either the

2022 Cost-Reduction Plan or the 2023 RIF for the three months ended March 31, 2024 and March 31, 2023. Total expenses related to the cost-reduction plan 2022 Cost-Reduction Plan and the 2023 RIF through March 31, 2023 were approximately \$0.4 million and \$0.2 million, respectively. The Company does not expect to incur any other significant costs associated with either the 2022 Cost-Reduction Plan or the 2023 RIF.

The following table summarizes the change in the Company's accrued restructuring liabilities under both the 2022 Cost-Reduction Plan and the 2023 RIF, which consisted solely of employee compensation and benefits and is classified within Accrued liabilities in the condensed consolidated balance sheets as of the three and nine months ended September 30, 2023 and the three and nine months ended September 30, 2022 and had each period shown (in thousands): no further liabilities recognized related to severance and benefits owed as September 30, 2023.

	Three Months Ended March 31,	
	2024	2023
Balance as of the beginning of year	\$ 131	\$ 180
Cash paid	(96)	(175)
Balance as of the end of period	\$ 35	\$ 5

Legal Proceedings

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company through September 30, 2023 March 31, 2024, which will have, individually or in aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

Indemnification

In accordance with the Company's certificate of incorporation, as amended, amended and restated memorandum bylaws, and articles of association, indemnification agreements, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

## 10. Related Party Transactions 9. Subsequent Events

### Director stipends

Unpaid cash stipends owed to the Company's directors for their annual board service are recorded on the Company's condensed consolidated balance sheets within accrued liabilities. These liabilities were \$105,625 and \$141,250 as of September 30, 2023, and December 31, 2022, respectively.

### Separation agreement with former Chief Executive Officer May 2024 Offering

On October 11, 2022 May 1, 2024, the Company entered into a separation securities purchase agreement with its former Chief Executive Officer whereby an institutional investor, pursuant to which the parties Company agreed to sell and issue, in a mutual release private placement, (i) 85,100 shares of claims. Subsequent the Company's common stock at a purchase price per share of \$6.5015, and (ii) 530,142 prefunded warrants to paying purchase shares of the Company's common stock at a purchase price of \$6.5014 per prefunded warrant, with such prefunded warrants being immediately exercisable, having an exercise price of \$0.0001 per share, and a perpetual term, and (iii) common stock warrants to purchase 922,863 shares of the Company's common stock at an exercise price of \$6.314 per share and a term of seven years from the date of issuance (the "May 2024 Warrants") (collectively, the "May 2024 Offering").

The Company issued warrants to the placement agent in the May 2024 Offering to purchase an aggregate 36,914 shares of the Company's common stock (the "May 2024 Placement Agent Warrants"). The May 2024 Placement Agent Warrants have substantially the same terms as the May 2024 Warrants, except that the exercise price of each of the May 2024 Placement Agent Warrants is \$10.727 per share and the term is five years from issuance.

The May 2024 Offering closed on May 6, 2024 for net cash proceeds to the Company of approximately \$3.6 million, consisting of gross cash proceeds of \$22,000 4.0 pursuant to the terms of the separation agreement, the Company determined that it is not probable that any additional compensation would be due to the former Chief Executive Officer and therefore, the Company has not recognized any accrual related to compensation or benefits owed pursuant to the separation agreement as of September 30, 2023.

## 11. Subsequent Events

In order to better utilize the Company's resources on the implementation of its refocused business plans and corporate strategy, on October 27, 2023, the Company committed to a reduction in workforce. This consisted of a 25% reduction in workforce that were no longer deemed critical for the Company's development of PALI-2108.

Associated with the reduction in workforce, the Company will recognize million less cash equity issuance costs of approximately \$0.20.4 million in the fourth quarter of 2023 consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements. million.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements in this Quarterly Report on Form 10-Q that are not strictly historical are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. You can identify these forward-looking statements because they involve the Company's our expectations, intentions, beliefs, plans, projections, anticipations, or other characterizations of future events or circumstances. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that may cause actual results to differ materially from those in the forward-looking statements as a result of any number of factors. Some of these factors are more fully discussed in the section of this Quarterly Report entitled "Risk Factors" and elsewhere herein. The Company does We do not undertake to update any of these forward-looking statements or announce the results of any revisions to these forward-looking statements except as required by law.

The Company recommends We recommend investors read this entire Quarterly Report on Form 10-Q, including the "Risk Factors" section, the condensed consolidated financial statements, and related notes thereto. As used in this Quarterly Report on Form 10-Q, unless the context indicates or otherwise requires, "Palisade," "Palisade Bio," "the Company," "the Company," "we," "us," and "our" or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. In addition, references to "Seneca" and "Seneca Biopharma, Inc." are to the Registrant prior to the completion of the Merger, as described below. Any reference to "common shares" or "common stock," refers to the Company's our \$0.01 par value common stock. Any reference to "Series A Preferred Stock" refers to the Company's our Series A 4.5% Convertible Preferred Stock. Any reference to "Leading Biosciences, Inc." or "LBS" refers to the Company's our operations prior to the completion of the Merger, as described below. The information contained herein is current as of the date of this Quarterly Report (September 30, 2023), unless another date is specified. our merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any technology that the Company we currently owns own or may acquire the rights to in the future is referred to by the Company us as either a "product candidate" or "product candidates". Additionally, any reference herein that refers to pre-clinical studies also refers to nonclinical studies.

### The Merger

On April 27, 2021, Leading Biosciences, Inc. ("LBS") became a wholly owned subsidiary of Seneca Biopharma Inc. ("Seneca") upon consummation of the merger (the "Merger") by and among Seneca, Townsgate Acquisition Sub 1, Inc., a wholly owned subsidiary of Seneca ("Merger Sub"), and LBS, pursuant to which Merger Sub merged with and into LBS, with LBS surviving as a wholly owned subsidiary of Seneca. Immediately following the Merger, Seneca changed its name to "Palisade Bio, Inc."

### **Prior Business Focus**

On August 9, 2023, the Company announced topline data from its U.S. Phase 2 PROFILE study. The data showed that its lead therapeutic candidate at the time, LB1148, did not achieve the primary endpoint in this trial of preventing post-surgical adhesions in patients who underwent bowel resection surgery. Based on the U.S. Phase 2 PROFILE study data, the Company did not believe the safety and efficacy results supported further development of LB1148, and accordingly, the Company terminated all further development of LB1148, including its U.S. Phase 3 Return of Bowel Function Study.

### **Change in Strategic Focus**

On September 1, 2023, the Company entered into a research collaboration and license agreement with Giiant Pharma, Inc. ("Giiant") (the "Giiant License Agreement"). The Giiant License Agreement provides the Company with the exclusive worldwide rights to develop, manufacture and commercialize all of Giiant's current and future technologies, including the Company's new lead asset, PALI-2108 (formerly GT-2108), an orally administered, locally-restricted, colon-specific phosphodiesterase-4 (PDE4) inhibitor prodrug in development for patients affected by moderate-to-severely active ulcerative colitis.

Upon entering into the Giiant License Agreement, the Company's focus became the development and commercialization of PALI-2108 for the treatment of inflammatory bowel disease ("IBD").

As a result of the Company's business plan materially changing, the risk factors contained in Part II Item 1A. Risk Factors in this Quarterly Report on Form 10-Q should be read and reviewed within the context of the Company's new development plan, specifically the development and commercialization of PALI-2108.

The Company's Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is provided, in addition to the accompanying condensed consolidated financial statements and notes, to assist you in understanding the Company's **our** results of operations, financial condition and cash flows. The MD&A is organized as follows:

- *Executive Overview* — Discussion of the Company's **our** business and overall analysis of financial and other items affecting the **our** Company in order to provide context for the remainder of MD&A.
- *Results of Operations* — Analysis of the Company's **our** financial results comparing the three **and nine** months ended **September 30, 2023** **March 31, 2024** and **2022**. **2023**.

- *Liquidity and Capital Resources* — An analysis of cash flows and discussion of the Company's financial condition and future liquidity needs.

## Executive Overview

Palisade is We are a biopharmaceutical pre-clinical stage biotechnology company focused on developing and advancing novel targeted therapeutics for serious chronic gastrointestinal patients living with autoimmune, inflammatory, and fibrotic diseases. The Company's strategic focus is the pre-clinical and clinical development of its Our lead product candidate, PALI-2108, which is at an early stage of development, being developed as a therapeutic for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Crohn's disease ("CD").

### PALI-2108

PALI-2108 PALI-2108, our lead product candidate, is a precision orally administered, locally-restricted, prodrug PDE4 inhibitor that operates through a sophisticated mechanism within colon tissues, targeting the key enzyme phosphodiesterase-4 ("PDE4"). This enzyme is pivotal in cAMP hydrolysis, and by inhibiting PDE4, intracellular cAMP levels are elevated. This elevation leads to the downregulation of inflammatory cytokines and a reduction in the expression of cell adhesion molecules. By modulating these processes, PALI-2108 effectively prevents the local infiltration and activation of inflammatory cells in the colon tissues, offering a targeted approach for UC treatment. With a glucuronic-derived sugar moiety, PALI-2108 remains minimally absorbed until activated by the colonic bacterium enzyme  $\beta$ -glucuronidase. This prodrug exhibits colon preference, as demonstrated in DSS-induced UC mouse models and oxazolone colitis-induced mice, showcasing its localized bioactivation and colon-specific phosphodiesterase-4 (PDE4) inhibitor prodrug distribution.

Our target engagement study seems to indicate comparable binding to cAMP-specific PDE4 in early-stage development the colon. PALI-2108's dose-dependent efficacy, lack of systemic toxicity demonstrated in tolerated dose studies, and promising results in pre-clinical models position it as a novel and targeted therapy for patients affected by moderate-to-severely active ulcerative colitis. The Company also believes moderate-to-severe UC.

We have produced investigational drug batches of PALI-2108 that PALI-2108 may be an effective treatment for Crohn's disease. PALI-2108 is currently undergoing investigational are compliant with Good Manufacturing Practice ("GMP"). We have completed rodent and initiated non-rodent, non-pivotal investigation new drug approval in the United States application ("IND") and clinical trial application in Canada -enabling or a Canadian Clinical Trial Application ("CTA") enabling -enabling pre-clinical studies including nonclinical safety of PALI-2108 and toxicology, chemistry, manufacturing and controls and completing the validation of pharmacokinetic/pharmacodynamics assays. The Company believes it will are

currently initiating pivotal IND/CTA-enabling pre-clinical studies, which we expect to be able to complete nonclinical IND/CTA enabling activities completed by the end of the third quarter of 2024. We plan to submit an IND/CTA in the third quarter of 2024 and plans to submit its initial IND/CTA prior to initiate clinical trials of PALI-2108 in the fourth quarter of 2024. By the end of 2024, 2024, we plan to submit an IND/CTA and initiate a Phase 1a single ascending dose ("SAD") and multiple ascending dose ("MAD") clinical study including food effects in normal healthy volunteers evaluating the safety, tolerability, and pharmacokinetics as well as evaluate a MAD cohort of UC patients with elevated PDE4-associated biomarkers for pharmacodynamic effects. Topline data from the Phase 1a SAD/MAD trial is expected late in the first half of 2025. Following the completion of the Phase 1a SAD/MAD trial, we plan to initiate a Phase 1b/2 POC trial in UC patients in the second half of 2025.

### **Our Precision Medicine Approach**

**Market** We are developing a biomarker-based patient selection approach which, if developed, will aid clinicians in identifying patients who may respond to therapy with a locally acting PDE4 inhibitor such as PALI-2108. We are working with our team of precision medicine focused bioinformatics developers to identify biomarkers and develop optimal algorithms to aid in patient selection, which we believe may enrich the responder population and improve the rate of clinical response previously demonstrated with PDE4 inhibitors. This involves the use of clinical and multiomics data from a large patient population which will be used to identify PDE4-related biomarkers that are associated with disease, correlate with severity, correlate with clinical biomarkers, and are modified with local PDE4 inhibitor therapy in the colon. We have curated clinical study data, including longitudinal biomarker and clinical outcome data, to develop a deep understanding of the potential for patient response to PDE4 therapy, and we are in discussions with potential partners to access additional large scale IBD databanks with clinical, patient-reported, and molecular data that will be used to support and further validate the approach. Additionally, we have initiated the development of corresponding biomarker assays for these PDE4-related biomarkers that will be used in clinical studies with the aim to develop FDA-approved tests for selecting potential responders to PALI-2108.

**The Company believes that if developed and approved for marketing, Recent Developments in the pre-clinical studies of PALI-2108 could be an effective treatment for IBD. The Company's initial indications for PALI-2108 are:**

- Ulcerative colitis.** A condition involving inflammation On January 29, 2024, we disclosed the presentation of results demonstrating local bioactivation of PALI-2108 and sores (ulcers) along the lining of the large intestine (colon) colon-specific distribution and rectum.limited systemic exposure in pre-clinical models. PALI-2108 had similar target engagement to other PDE4 inhibitors, dose-dependent efficacy in a UC model, and no systemic toxicity in pre-clinical studies. The results also demonstrated localized bioactivation, an expanded therapeutic window, and potent PDE4 inhibitory activity in pre-clinical studies.
- On April 16, 2024, we announced the successful completion of a critical analysis evaluating the ex-vivo bioactivation of PALI-2108. PALI-2108 exhibited efficient ex-vivo conversion into its active PDE4 inhibitor form in stool samples from both normal healthy volunteers and patients with UC. The assessment of samples using LC-MS analysis showed PALI-2108 was converted into its active PDE4 inhibitor form at a mean rate of 90.1% with conversion steadily increasing over time. As an orally administered, locally acting colon-specific PDE4 inhibitor prodrug, this milestone represents a significant step forward in understanding the pharmacological profile and potential therapeutic utility of PALI-2108 for patients affected by UC.

Crohn's On April 23, 2024, we disclosed the initiation of a strategic collaboration with Strand Life Sciences, a bioinformatics specialist. This collaboration aims to advance our precision medicine initiatives tailored specifically for UC therapeutics. The collaboration with Strand provides us access to advanced bioinformatics tools vital for understanding complex disease pathways and predicting responses to PDE4 inhibitors. Leveraging data from over ten UC clinical studies, we have curated a pipeline of 1600 UC patient samples, including transcriptomics and clinical outcomes. This curated dataset, enables us to identify biomarkers for selecting UC patient responders, utilizing machine learning to develop the precision medicine approach that may enable selection of UC patient responders to PALI-2108.

. A condition characterized by 22

- On May 1, 2024, we announced the successful completion of our analysis to determine the effects of bioactivated PALI-2108 on TNF- $\alpha$  production in a whole blood assay. This study included WB samples from 14 clinically healthy adults. Findings from the study demonstrated that PALI-2108 exhibited efficacy in inhibiting TNF- $\alpha$  production induced by lipopolysaccharide ("LPS") in this ex-vivo peripheral whole blood assay. Pre-treatment of human whole blood samples with bioactivated PALI-2108 resulted in a significant reduction in LPS-induced TNF- $\alpha$  production compared to non-pretreated samples. Specifically, our proprietary PDE4 inhibitor, shown to be released by the inflammation local bioconversion of the lining of the digestive tract, which often can involve the deeper layers of the digestive tract. Crohn's disease most commonly affects the small intestine. However, it can also affect the large intestine and uncommonly, the upper gastrointestinal tract.

Both ulcerative colitis and Crohn's disease are usually characterized by diarrhea, rectal bleeding, abdominal pain, fatigue and weight loss. For some people, IBD is only a mild illness. For others, it's a debilitating condition that can lead to life-threatening complications. Based on statistics from the Centers for Disease Control and the United European Gastroenterology, it is estimated that globally, there are approximately 3.6 million individuals suffering from IBD, resulting in a combined global market opportunity of \$20 billion by 2031 (Source: Global Data).

### ***Giant License Agreement***

On September 1, 2023, the Company entered into the Giant License Agreement. Under the terms of the Giant License Agreement, the Company obtained the rights to develop, manufacture, and commercialize all compounds from Giant, existing now and PALI-2108 prodrug in the future, and any product containing or delivering any licensed compound, in any formulation or dosage, demonstrated a mean half-maximal inhibitory concentration ( $IC_{50}$ ) for all human and non-human therapeutic uses TNF- $\alpha$  inhibition of 0.022  $\mu$ M, compared to 0.41  $\mu$ M for any and all indications worldwide, including those technologies that are the basis of PALI-2108. Pursuant to the terms of the Giant License Agreement, pre-clinical development PALI-2108 will be jointly undertaken by the Company and representatives of Giant and the Company will pay or reimburse a portion of the joint development costs. Upon the first approval of either an IND or CTA, the apremilast, showcasing its potent anti-inflammatory activity.

Company will assume all development, manufacturing, regulatory and commercialization costs. Additionally, per the terms of the Giant License Agreement, the Company will pay (i) certain milestone payments (in cash or stock at the Company's election) and (ii) royalty payments.

### Recent Financings

In January 2023, the Company February 2024, we completed a registered direct offering and concurrent private placement warrant inducement transaction for net cash proceeds of approximately \$2.2 million consisting of gross cash proceeds of \$2.5 million, less cash equity issuance costs of approximately \$0.3 million.

In April 2023, the Company May 2024, we completed a registered direct offering and concurrent private placement for net cash proceeds of approximately \$5.3 million \$3.6 million consisting of gross cash proceeds of \$6.0 million \$4.0 million, less cash equity issuance costs of approximately \$0.7 million \$0.4 million.

In September 2023, the Company completed an equity offering and for net cash proceeds of approximately \$1.7 million consisting of gross cash proceeds of \$2.0 million, less cash equity issuance costs of approximately \$0.3 million.

The Company intends We intend to use the net proceeds from these the recent financings for working capital and general corporate purposes, including the development of PALI-2108 for PALI-2108. With the treatment additional net cash proceeds of IBD. Based upon \$3.6 million received subsequent to the Company's end of the first quarter of 2024 from the May 2024 private placement, combined with our cash and cash equivalents balance of \$15.3 million \$11.3 million as of September 30, 2023 March 31, 2024, the Company believes it has we believe we have sufficient cash to fund its our currently planned operations into through the first quarter of 2025.

## RESULTS OF OPERATIONS

### License Revenue

The Company We generated no revenues from the sale of its proposed therapies our product candidates for any of the periods presented. In For the nine three months ended September 30, 2023 March 31, 2023, the Company we recognized licensing license revenue of approximately \$0.3 million from the co-development and distribution agreement with Newsoara, a joint venture established with Biolead Medical Technology Limited, as amended, (the "Co-Development" "Newsoara Co-Development Agreement"). During For the three months ended September 30, 2023 and the three and nine months ended September 30, 2022 March 31, 2024, there was we recognized no licensing revenue recognized by the Company. license revenue.

### Research and Development Expenses

Research and development expenses have historically consisted primarily of costs incurred for the clinical development of the Company's our product candidate LB1148, which LB1148. On August 9, 2023, based on August 9, 2023 the Company

announced did not achieve results of the primary endpoint efficacy and therefore, safety data of the Company will no longer be pursuing its development. U.S. Phase 2 PROFILE study, we terminated the development of LB1148. The research and development costs included:

- salaries and employee-related costs, including stock-based compensation;
- laboratory and vendor expenses related to the execution of pre-clinical and clinical trials;
- expenses under agreements with third-party contract research organizations, investigative clinical trial sites to conduct research and development activities on the Company's behalf, and consultants;
- costs related to develop and manufacture pre-clinical study and clinical trial material; and
- regulatory expenses.

While the decision has been made by the Company to no longer pursue the clinical development of LB1148, the Company continued. We do not expect to incur any significant costs in 2024 or beyond related to its development in the third quarter of 2023 and expects to continue to incur expenses through the end of the year primarily associated with the closing down of the associated clinical trials albeit at a lower amount than in previous periods. Although of LB1148. Accordingly, the nature of the Company's research and development expenses is expected to shift from clinical activities to those pre-clinical activities associated with the development of PALI-2108, the Company expects its overall net research and development expenses to remain consistent with prior periods. PALI-2108.

The Company's direct research and development expenses are tracked by product candidate and consist primarily of external costs, such as fees paid under third-party license agreements and to outside consultants, Contract Research Organizations ("CROs"), clinical site, contract manufacturing organizations ("CMOs") and research laboratories in

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connection with its pre-clinical development, process development, manufacturing, clinical development, and

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regulatory activities. The Company does not allocate employee costs and costs associated with its discovery efforts, laboratory supplies and facilities, including other indirect costs, to specific product candidates because these costs are deployed across multiple programs and, as such, are not separately classified. The Company primarily uses internal resources. As needed, we manage third parties that are engaged to conduct its (i) research as well as for managing its activities, (ii) pre-clinical, clinical and translational science development activities, and (iii) process development, and clinical development activities. Pursuant to situations whereby the Company performs development. When we perform any

research and development or manufacturing activities under a co-development agreement, the Company records we record the expense reimbursement from the co-development partner as a reduction to research and development expense once the reimbursement amount is approved for payment by the co-development partner. Pursuant to agreements whereby the Company performs where we perform research and development activities under a joint development plan, such as the Company's our research and collaboration with Giiant expense reimbursements made to Giiant pursuant to the terms of the Giiant License Agreement for Pharma, Inc. ("Giiant"), qualifying development costs are expensed as research and development costs as incurred.

### ***In-Process Research On September 1, 2023, we entered into a research collaboration and Development Expenses***

In-process research license agreement for substantially all of Giiant's current and development ("IPR&D") expenses are recorded when incurred and reflect costs of externally-developed IPR&D projects, including certain transaction costs, acquired directly in a transaction other than a business combination, that do not have an alternative future use. proposed products (the "Giiant License Agreement").

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salary and employee-related costs and benefits, professional fees for legal, intellectual property, investor and public relations, accounting and audit services, insurance costs, director's director and committee fees, and stipends, and general corporate expenses.

### ***Going Concern***

The Company believes it has We believe we have sufficient cash to fund its our currently planned operations into through the first quarter of 2025. Notwithstanding, the Company's our management has evaluated all conditions and events, considered in the aggregate, that raise substantial doubt about the Company's our ability to continue as a going concern within one year after the date that the these financial statements are issued, including: (i) the probability that significant changes to the Company's our anticipated level of operations, due to factors that are within or outside of the Company's our control, would cause the Company's our available cash as of the date of this filing to not be sufficient to fund its our anticipated level of operations for the next 12 months, and (ii) the uncertainties of the cost and timing of the Company's our efforts to in-license or acquire a new additional product candidate. candidates. In the opinion of management, these factors, among others, raise substantial doubt about the our ability of the Company to continue as a going concern as of the filing date of this Quarterly Report on Form 10-Q and for one year from the issuance of the condensed consolidated financial statements.

### ***Reverse Stock Split***

On November 15, 2022 April 5, 2024, the Company we effected a 1-for-50 1-for-15 reverse stock split of its our issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each of the Company's shareholders our stockholders received one new share of our common stock for every 50 15 shares such shareholder stockholder held immediately prior to the effective time of the Reverse Stock Split. Unless otherwise noted, all

common stock shares, common stock per share data and shares of common stock underlying convertible preferred stock, stock options stock-based awards and common stock warrants included in these condensed consolidated financial statements, including the exercise or conversion price of such equity instruments, as applicable, have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

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## Results of Operations

### Comparison of the three months ended September 30, 2023 March 31, 2024 and 2022 2023

The following table summarizes the Company's our results of operations for the three months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

	Three Months Ended		Change	
	September 30,			
	2023	2022	\$	%
Operating expenses				
Research and development	\$ 1,742	\$ 1,928	\$ (186)	(10)%
In-process research and development	362	—	362	n/a
General and administrative	1,674	2,075	(401)	(19)%
Restructuring costs	—	410	(410)	n/a
Total operating expenses	3,778	4,413	(635)	(14)%
Loss from operations	(3,778)	(4,413)	635	(14)%
Other income (expense):				
Interest expense	(8)	(4)	(4)	100%
Other income	190	426	(236)	(55)%
Total other income, net	182	422	(240)	(57)%
Net loss	\$ (3,596)	\$ (3,991)	\$ 395	(10)%

### Research and Development Expenses

The \$0.2 million, or 10%, decrease in research and development expenses from \$1.9 million for the three months ended September 30, 2022 to \$1.7 million for the three months ended September 30, 2023 is attributable to the Company concluding its U.S. Phase 2 PROFILE study of LB1148 in early third quarter of 2023 and its completion of enrollment in its dose-optimization study of LB1148 in the second quarter of 2023. The Company has subsequently concluded it will no longer pursue the development of LB1148 and has begun to close down its PROFILE study. Comparatively, in the third quarter of 2022, the Company was actively enrolling its U.S. Phase 2 PROFILE study and incurring expenses while initiating its U.S. Phase 3 INTEGRITY study for the accelerated return of bowel function following GI surgery. Accordingly, drug-manufacturing related expenses decreased by approximately \$0.5 million, investigator site fees decreased by approximately \$0.2 million, and clinical trial consultants and contract labor decreased by approximately \$0.1 million in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. Also contributing to the year-over-year decrease was lower research and development salaries and benefits of approximately \$0.1 million in the three months ended September 30, 2023 compared to the three months ended September 30, 2022, primarily due to a decrease in research and development employee headcount.

Partially offsetting these decreases in the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was (i) an increase of approximately \$0.4 million in translational research costs, (ii) an increase of approximately \$0.2 million in clinical trial vendor costs, primarily attributable to the data management activities and statistical analysis associated with closing down of the U.S. Phase 2 PROFILE study, U.S. Phase 1 dose-optimization study, and the U.S. Phase 3 INTEGRITY study, and (iii) an increase in recruiting costs of \$0.1 million associated with the Company's efforts to identify and hire additional key research and development employees, specifically the Company's new Chief Medical Officer hired on September 5, 2023.

#### *In-process research and development*

In connection with the Giant License Agreement entered into by the Company, in the three months ended September 30, 2023 the Company recognized In-process research and development expenses in the amount of \$0.4 million, which consisted of the fair value of the contingent consideration milestone payment obligation in the amount of \$0.2 million and transaction related costs in the amount of \$0.2 million. There were no such expenses recognized in the three months ended September 30, 2022.

#### *General and Administrative Expenses*

General and administrative expenses decreased by approximately \$0.4 million, or 19%, from \$2.1 million for the three months ended September 30, 2022 to \$1.7 million for the three months ended September 30, 2023, primarily as a result of cost-saving opportunities implemented by the Company in the third and fourth quarters of 2022, including those associated with the cost-reduction plan announced on September 9, 2022. Compared to the three months ended September 30, 2022, general and administrative employee compensation costs in the three months ended September 30, 2023 decreased by

approximately \$0.4 million primarily due to a \$0.3 million decrease in salaries and benefits and a \$0.1 million decrease in stock-based compensation expense.

### *Restructuring Expenses*

The Company recognized restructuring costs of \$0.4 million for the three months ended September 30, 2022, consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements with employees terminated under a cost-reduction plan announced on September 9, 2022. There were no restructuring costs or related liabilities recognized for the three months ended September 30, 2023.

### *Other income (expense)*

Other income, net, for the three months ended September 30, 2023 includes dividend income of approximately \$0.2 million from the Company's short-term investments of excess cash in money market funds with maturities of three months or less.

Other income, net, for the three months ended September 30, 2022 consists primarily of a \$0.4 million non-cash gain associated with the revaluation of liability-classified warrants in the period.

### **Comparison of the nine months ended September 30, 2023 and 2022**

The following table summarizes the Company's results of operations for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended							
	September 30,		Change		Three Months Ended March 31,		Change	
	2023	2022	\$	%	2024	2023	\$	%
License revenue	\$ 250	\$ —	\$ 250	n/a	\$ —	\$ 250	\$ (250)	n/a
Operating expenses								
Research and development	5,160	4,204	956	23 %	2,214	1,241	973	78 %
In-process research and development	362	—	362	n/a				
General and administrative	4,644	7,259	(2,615)	(36)%	1,459	1,538	(79)	(5)%
Restructuring costs	—	410	(410)	n/a				
Total operating expenses	10,166	11,873	(1,707)	(14)%	3,673	2,779	894	32 %
Loss from operations	(9,916)	3)	57	6)%	(3,673)	(2,529)	(1,144)	45 %

Other income (expense):								
Other (expense) income:								
Interest expense			1					
	(11)	(10)	(1)	0%	(1)	—	(1)	n/a
Other income			(1,8	(7				
	598	2,453	55)	6)%	147	189	(42)	(22)%
Loss on issuance of warrants			1,1	n/				
	—	(1,110)	10	a				
Total other income, net			(74	(5				
	587	1,333	6)	6)%	146	189	(43)	(23)%
Net loss		(10,54	1,2	(1				
	\$ (9,329)	\$ 0)	\$ 11	1)%	\$ (3,527)	\$ (2,340)	\$ (1,187)	51%

#### License revenue

During the nine three months ended September 30, 2023 March 31, 2023, the Company we recognized license revenue of \$0.3 million earned upon the achievement of a milestone under the Newsoara Co-Development Agreement. During the nine three months ended September 30, 2022 March 31, 2024, the Company we recognized no license revenue.

#### Research and Development Expenses

The \$1.0 million, or 23% 78%, increase in research and development expenses from \$4.2 million \$1.2 million for the nine three months ended September 30, 2022 March 31, 2023 to \$5.2 million \$2.2 million for the nine three months ended September 30, 2023 March 31, 2024 is attributable to the Company's increased clinical trial activity approximately \$1.6 million of expenses recognized that were directly related to both the Phase 2 PROFILE study joint development of our new lead asset, PALI-2108, partially offset by a decrease in costs directly related to our development of LB1148, which we ceased in August of 2023, and the Company's dose-optimization study, lower employee-related costs.

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which initiated and completed enrollment in the second quarter As a result of 2023. Although the Company has decided our decision to no longer pursue the clinical development of LB1148, and is in the process of closing down the related clinical trial studies, increased direct clinical trial-related costs, attributable to these studies in including clinical trial vendor fees, investigator site fees, and clinical trial consultant and contractor fees, decreased by approximately \$0.3 million for the first nine three months of 2023 ended March 31, 2024, compared to the same period of 2022 resulted in higher three months ended March 31, 2023. Similarly, drug manufacturing costs, regulatory activity costs and translational research and development expenses. Clinical trial-related costs decreased approximately \$0.1 million for the nine three months ended September 30, 2023 increased approximately \$1.5 million March 31, 2024, compared to the nine three months ended September 30, 2022 primarily due to (i) a \$1.0 million increase in translational research March 31, 2023. Employee-related costs (ii) a \$0.3 million increase in clinical trial vendor costs, and (iii) a decreased by approximately \$0.2 million increase in

investigator site fees. In addition, research and development employee compensation-related costs increased in for the nine three months ended September 30, 2023 March 31, 2024, compared to the nine three months ended September 30, 2022 by approximately \$0.3 million, primarily due to increased year-over-year headcount, and recruiting costs increased \$0.2 million compared to the same period last year March 31, 2023 as a result of the Company's efforts to identify and hire additional key a 25% reduction in our employee workforce, specifically research and development employees specifically the Company's Chief Medical Officer hired on September 5, 2023. Partially offsetting these increases in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 was a decrease in drug manufacturing-related costs of \$0.7 million and a decrease in regulatory activities of \$0.3 million.

#### *In-process research and development*

In connection with the Giant License Agreement entered into by the Company, in the nine months ended September 30, 2022 the Company recognized In-process research and development expenses in the amount of \$0.4 million, which consisted of the fair value of the contingent consideration milestone payment obligation in the amount of \$0.2 million and transaction related costs in the amount of \$0.2 million. There that were no such expenses recognized longer deemed critical for our development of PALI-2108, in the nine months ended September 30, 2022. October 2023.

#### *General and Administrative Expenses*

General and administrative expenses decreased remained virtually flat at approximately \$1.5 million for both the three months ended March 31, 2024 and March 31, 2023. For the three months ended March 31, 2024, shareholder services costs attributable to our March 2024 special meeting of shareholders held to approve the Reverse Stock Split, and ongoing consultant and contract labor increased by approximately \$2.6 million, or 36%, from \$7.3 million for the nine months ended September 30, 2022 to \$4.6 million for the nine months ended September 30, 2023, primarily as a result of cost-saving opportunities implemented by the Company in the third and fourth quarters of 2022, including those associated with the cost-reduction plan announced on September 9, 2022. Compared to the nine months ended September 30, 2022, general and administrative employee compensation costs in the nine months ended September 30, 2023 decreased by approximately \$1.4 million \$0.1 million each compared to the nine three months ended September 30, 2022 primarily due to a \$0.9 million decrease March 31, 2023. Offsetting these increases were lower net professional fees, lower insurance costs, and lower board of director and committee fees in salaries and benefits and a \$0.5 million decrease in stock-based compensation expense. Other decreases in general and administrative expenses during the nine three months ended September 30, 2023 March 31, 2024, compared to the same period of last year include (i) a \$0.4 million decrease in professional fees, investor relations fees, and shareholder services costs, (ii) a \$0.3 million decrease in consultants and contract labor costs, (iii) a \$0.2 million decrease in employee recruiting costs, (iv) a \$0.1 million decrease in insurance costs, and (v) a \$0.2 million decrease in general operating costs.

#### *Restructuring Expenses*

The Company recognized restructuring costs of \$0.4 million for the nine three months ended September 30, 2022, consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and

release agreements with employees terminated under a cost-reduction plan announced on September 9, 2022. There were no restructuring costs or related liabilities recognized for the nine months ended September 30, 2023 March 31, 2023.

#### Other (expense) income (expense)

Other income, net, for the nine three months ended September 30, 2023 March 31, 2024 includes primarily dividend income of approximately \$0.5 million \$147,000 from our investments of excess cash in money market funds with maturities of three months or less in the Company's short-term period.

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Other income, net, for the three months ended March 31, 2023 includes dividend income of approximately \$147,000 from our investments of excess cash in money market funds with maturities of three months or less and a non-cash gain of approximately \$0.1 million \$43,000 associated with the revaluation of liability-classified warrants in the period.

Other income, net, for the nine months ended September 30, 2022 includes a \$2.4 million non-cash gain associated with the revaluation of liability-classified warrants in the period, which was partially offset by a \$1.1 million non-cash loss on the issuance of warrants. On January 31, 2022, the Company issued 45,000 warrants to certain investors as consideration for the waiver of certain rights pursuant to the underlying warrant agreements (the "January 2022 Warrants"). As a result of this issuance, the Company recognized a \$1.1 million non-cash loss upon the issuance of the January 2022 Warrants, which represents the fair value of the warrants on the date of issuance.

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## Liquidity and Capital Resources

### Financial Condition

Since the Company's our inception, it has we have financed its our operations through the sales of its our securities, issuance of long-term debt, the exercise of investor common stock warrants, and to a lesser degree, grants and research contracts as well as the licensing of its our intellectual property to third parties. Refer to the paragraph under the heading "Going Concern" in the Results of Operations section above for management's assessment of the Company's our ability to continue as a going concern.

### Sources of Liquidity

Management expects the Company We expect to incur substantial operating losses for the foreseeable future. The Company We will need to raise additional capital through a combination of equity offerings, debt financings, collaborations, and other similar arrangements. The Company's Our ability to raise additional capital may be adversely impacted by by: (i) general political or economic conditions, (ii) inflation, (iii) rising interest rates, (iv) ongoing supply chain disruptions, (v) the ongoing global conflicts, including those in the Ukraine and Middle East, (vi) limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry, (vii) or a resurgence of COVID-19, COVID-19 variants, or another pandemic. In the event the Company is we are unable to access additional capital, it we may need to curtail or greatly reduce its our operations, which could have a materially adverse impact on its our business, financial condition, and results of operations.

### **Recent Equity Offerings**

On January 4, 2023 May 6, 2024, we completed a private placement of common stock, prefunded warrants to purchase common stock and warrants to purchase common stock (the "May 2024 Offering"). Gross cash proceeds from the Company closed May 2024 Offering were \$4.0 million and net cash proceeds were approximately \$3.6 million after deducting cash equity issuance costs of approximately \$0.4 million.

On September 11, 2023, we completed a registered direct offering of common stock pursuant to an effective shelf registration statement on Form S-3 (the "September 2023 Offering"). Gross cash proceeds from the September 2023 Offering were \$2.0 million and net cash proceeds were \$1.7 million after deducting cash equity issuance costs of approximately \$0.3 million.

On April 3, 2023, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the "April 2023 Offering"). Gross cash proceeds from the April 2023 Offering were \$6.0 million and net cash proceeds were \$5.3 million after deducting cash equity issuance costs of approximately \$0.7 million.

On January 4, 2023, we completed a registered direct offering and concurrent private placement of common stock and warrants to purchase common stock (the "January 2023 Offering"). Gross cash proceeds from the January 2023 Offering were \$2.5 million and net cash proceeds were approximately \$2.2 million after deducting cash equity issuance costs of approximately \$0.3 million.

### **Warrant Exercises**

On April 3, 2023 January 30, 2024, we entered into warrant inducement agreements (the "Warrant Inducement Agreements") with certain accredited and institutional holders (collectively, the Company completed a registered direct offering "Warrant Holders") of certain of our remaining outstanding common stock purchase warrants issued pursuant to: (i) common stock warrants issued on May 10, 2022, (ii) the January 2023 Offering, and concurrent private placement (the "April 2023 Offering"). Gross cash proceeds from (iii) the April 2023 Offering, were \$6.0 million as well as certain outstanding Series 2 warrants issued on August 16, 2022 (collectively, the "Existing Warrants"). Pursuant to the Warrant Inducement Agreements, the exercise price of each Existing Warrant was reduced to \$10.97 per share. Each of the Warrant Holders that exercised their Existing Warrants pursuant to the Warrant Inducement Agreements received one

replacement warrant for each Existing Warrant exercised with each such replacement warrant having a term of five years from issuance and an exercise price per share of \$10.97 (in its entirety, the "February 2024 Warrant Inducement"). The Warrant Holders collectively exercised an aggregate of 228,162 Existing Warrants. As a result of the exercises of the Existing Warrants, we issued an aggregate of 228,162 shares of our common stock. The February 2024 Warrant

Inducement closed on February 1, 2024 with us receiving net cash proceeds were \$5.3 million after deducting cash equity issuance costs of approximately \$0.7 million.

On September 11, 2023, the Company completed a registered direct offering pursuant to an effective shelf registration statement on Form S-3 filed with the SEC (the "September 2023 Offering"). Gross \$2.2 million consisting of gross cash proceeds from the September 2023 Offering were \$2.0 million and net cash proceeds were \$1.7 million after deducting of \$2.5 million, less cash equity issuance costs of approximately \$0.3 million.

Refer to Note 6, *Shareholders' Equity (Deficit)* for further details.

Warrant Exercises

During the nine three months ended September 30, 2023 March 31, 2023, the Company we received gross cash proceeds of approximately \$2.8 million \$2.7 million from common stock warrant exercises, approximately \$1.4 million of which related to common stock warrant exercises on December 30, 2022 for which the related cash was not received by the Company us until January 2023.

Cash Flows

As of September 30, 2023 March 31, 2024, the Company we had \$15.3 million \$11.3 million in cash, cash equivalents and restricted cash. The following table shows a summary of the Company's our cash flows for the nine three months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands):

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Net cash used in operating activities	\$ (8,387)	\$ (10,054)	\$ (3,180)	\$ (3,526)
Net cash used in investing activities	(4)	—		
Net cash provided by financing activities	11,320	13,544	2,024	4,440

Net Cash Used in Operating Activities

Cash used in operating activities was \$8.4 million approximately \$3.2 million for the nine three months ended September 30, 2023 March 31, 2024, which reflects a \$9.3 million an approximately \$3.5 million net loss adjusted for \$0.4 million (i) approximately \$0.2 million of net cash inflows related to changes in operating assets and liabilities

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and (ii) certain non-cash items impacting the net loss, consisting primarily of a \$0.4 million an approximately \$0.1 million non-cash expense recognized for stock-based compensation and related charges, and a non-cash expense of \$0.2 million related to the recognition of the fair value of the contingent consideration obligation incurred pursuant to the Giant Licensing Agreement transaction. charges. The net cash inflow from operating assets and liabilities was driven by a cash inflow outflow of approximately \$0.6 million from the payment of employee cash bonuses in the period that was more than offset by a cash inflow of approximately \$0.8 million from: (i) a decrease in prepaids and other current assets and others other noncurrent assets, which was primarily attributable to the amortization of the current and non-current portions of the Company's prepaid insurance policies, and (ii) an increase in accounts payable and accrued liabilities, which was primarily due to an increase in accrued joint development expenses associated with the Giant License Agreement and the timing of accounts payable payments that were partially offset by a \$0.2 million accrued severance payments and lower accrued director stipends.

Cash used in operating activities of approximately \$3.5 million for the three months ended March 31, 2023 reflects an approximately \$2.3 million net loss for the period adjusted for (i) approximately \$1.3 million of net cash outflows related to changes in operating assets and liabilities and (ii) certain non-cash items impacting the net loss, consisting primarily of an approximately \$0.1 million non-cash expense recognized for stock-based compensation and related charges. The net cash outflow from operating assets and liabilities was primarily due the recording of an approximately \$0.3 million accounts receivable for license revenue recognized in the quarter and an approximately \$1.0 million cash outflow for accounts payable and accrued liabilities due to the timing of payments, and a \$0.1 million cash outflow related to payments of the Company's operating lease.

Cash used in operating activities of \$10.1 million for the nine months ended September 30, 2022 reflects a \$10.5 million loss for the period adjusted for \$0.9 million of net cash inflows related to changes in operating assets and liabilities, and certain non-cash items including: (i) a \$1.1 million loss recognized from the issuance of the January 2022 Warrants, (ii) a \$2.4 million gain recognized for the change in the fair market value of the liability-classified warrants in the period, and (iii) a \$0.9 million non-cash expense recognized for stock-based compensation and related charges.

### **Net cash used in investing activities**

Cash used in investing activities for the nine months ended September 30, 2023 consists of payments for leasehold improvements. payments.

### **Net Cash Provided by Financing Activities**

For the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, cash provided by financing activities of **\$11.3 million** **approximately \$2.0 million** was **primarily** attributable to net cash proceeds of **\$9.4 million** **approximately \$2.2 million** from the exercise of common stock warrants in conjunction with the February 2024 Warrant Inducement, partially offset by payments made on the Company's insurance financing arrangements of approximately \$0.2 million.

For the three months ended March 31, 2023, cash provided by financing activities of approximately \$4.4 million was attributable to cash proceeds of approximately \$2.2 million from the January 2023 Offering **the April 2023 Offering** and **the September 2023 Offering**. Also contributing to the cash provided by financing activities in the period was **\$2.8 million** **approximately \$2.7 million** from the exercise of common stock purchase warrants, which includes the receipt in early January 2023 of a \$1.4 million other receivable from warrant exercises on December 30, 2022, partially offset by payments of equity issuance costs of **\$0.6 million** **approximately \$0.4 million** and payments made on the Company's insurance financing arrangements of **\$0.3 million** **approximately \$0.1 million**.

For the nine months ended September 30, 2022, cash provided by financing activities of \$13.5 million was attributable to net cash proceeds of \$1.8 million from the Company's registered direct equity offering completed in May of 2022 and net cash proceeds of \$12.6 million from the Company's public equity offering completed in August 2022, partially offset by payments of equity issuance costs of \$0.3 million in the period and payments made on the Company's insurance financing arrangements of \$0.5 million in the period.

## **Contractual Obligations**

### *Office Lease*

On May 12, 2022, the Company entered **We are party** a **new, to** non-cancelable facility operating lease (the "Corporate Office Lease") of office space for **its** **our** corporate headquarters, replacing its existing corporate headquarters lease that expired on July 31, 2022. The Corporate Office Lease is for 2,747 square feet of an office building in Carlsbad, California, **headquarters**. The initial contractual term is for 39-months commencing on June 1, 2022 and expiring on **August 31, 2025**. The Company has

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**August 31, 2025**. **We have** the option to renew the Corporate Office Lease for an additional 36-month period at the prevailing market rent upon completion of the initial lease term. **The Company has** **We have** determined **that** it is not **reasonably certain that it** **likely we** will exercise this renewal option.

Commencing on June 1, 2022, the Company is we are subject to contractual monthly lease payments of \$10,850, plus certain utilities, for the first 12 months with 3 percent escalations at the first, second and third lease commencement anniversaries. As of September 30, 2023 March 31, 2024, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately \$263,000, \$196,000, including imputed interest of \$24,000 \$13,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 1.9 1.4 years.

#### *Insurance Financing Arrangements*

Consistent with past practice, in June 2023, the Company we entered into an agreement to finance certain an insurance policies which policy that renewed in May 2023. The insurance financing arrangement is secured by the associated insurance policy. As We made the final principal payment of September 30, 2023, the aggregate remaining balance under the Company's insurance financing

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arrangements was approximately \$0.3 million arrangement during the three months ended March 31, 2024. Accordingly, there is no outstanding balance due as of March 31, 2024. We expect to renew the insurance policy, and is payable over a 9-month period with the first payment having commenced on June 30, 2023. enter into an associated insurance financing arrangement accordingly, in late May of 2024.

#### *Reduction in Workforce*

In order to better utilize the Company's our resources on the implementation of its our refocused business plans and corporate strategy, on October 27, 2023, the Company we committed to a reduction in workforce. This reduction-in-workforce on October 27, 2023 (the "2023 RIF"). The 2023 RIF consisted of a 25% reduction in our employee workforce, specifically research and development employees that were no longer deemed critical for the Company's our development of PALI-2108.

Associated with the reduction As of March 31, 2024, we have accrued \$35,000 in workforce, the Company will recognize costs of approximately \$0.2 million in the fourth quarter of 2023 consisting of severance and benefits payments pursuant to employment agreements and the execution of severance and release agreements, the majority of which is expected to be paid in cash prior related to the end of 2023. 2023 RIF and expect to make the remaining cash payments by June 30, 2024.

#### *Future Liquidity Needs*

The Company has We have incurred significant operating losses and negative cash flows from operations since our inception. To date, the Company has we have not been able to generate significant revenues nor achieve operating profitability. Based upon the Company's our cash and cash equivalents balance of \$15.3 million \$11.3 million as of September 30, 2023 March 31, 2024, the Company believes it has we believe we have sufficient cash to fund its our currently planned operations into through the first quarter of 2025. Notwithstanding, should the Company's our anticipated level of operations significantly change, the Company we may require additional financing sooner than the first quarter of

2025. Further, beyond 2024, Beyond the Company first quarter of 2025 we will require additional financing to continue at its our expected level of operations. If the Company fails we fail to obtain the needed capital, it we will be forced to delay, scale back, or eliminate some or all of its our development activities, or perhaps potentially cease our operations.

### **Critical Accounting Policies and Estimates**

The Company's Our condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires the Company us to make estimates, judgments, and assumptions that impact the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. The Company's Our estimates are based on historical experience, known trends, events and various other factors that it believes 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. In making estimates and judgments, management employs critical accounting policies. policies

The Company's Our significant accounting policies used in the preparation of the condensed consolidated financial statements are described in more detail in Note 2 to the notes to the condensed consolidated financial statements for the quarter ended September 30, 2023 March 31, 2024, included elsewhere in this Quarterly Report on Form 10-Q. The Company's Our critical accounting estimates are identified in Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of the Company's our most recently filed Form 10-K. The Company believes In the three months ended March 31, 2024, we determined that our accounting policy for Derivative Financial Instruments disclosed in the Form 10-K is no longer a critical accounting policy due to the insignificant impact our liability-classified warrants currently has on our financial statements. Other than the removal of our critical accounting policy for Derivative Financial Instruments, we believe there have been no significant changes in its our critical accounting policies and significant judgments and estimates since those disclosed in its our most recently filed Form 10-K.

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### **Recently Issued or Adopted Accounting Pronouncements**

See Note 2 to the notes to the condensed consolidated financial statements for the quarter ended September 30, 2023 March 31, 2024, included elsewhere in this Quarterly Report on Form 10-Q.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are not required to provide the information required by this item as we are considered a smaller reporting company, as defined by Rule 229.10(f)(1).

## ITEM 4. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and 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, who is also our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of **September 30, 2023** **March 31, 2024**. Based upon the evaluation, our Chief Executive Officer concluded that, as of **September 30, 2023** **March 31, 2024**, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness that existed in our internal control over financial reporting, as described below.

However, our management, including our Chief Executive Officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the condensed consolidated financial statements in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

### ***Material Weakness in Internal Control over Financial Reporting***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

As previously disclosed, during the quarter ended June 30, 2021, **the Company** **we** identified a material weakness in our internal controls over financial reporting due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. This material weakness contributed to a material weakness in our control activities based on the criteria set forth in the **Committee of Sponsoring Organizations** 2013 Framework. If not remediated, or if **the Company identifies** **we identify** further material weaknesses in its internal controls, **the Company's** **our** failure to establish and maintain effective disclosure controls and procedures and internal control over

financial reporting could result in material misstatements in its consolidated financial statements and a failure to meet its reporting and financial obligations.

As described below, management has begun designing the plan and executing the remediation actions to address the material weakness and further actions are ongoing as of September 30, 2023 March 31, 2024. The material weakness continues to be present as of September 30, 2023 March 31, 2024.

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### **Remediation Efforts related to the Material Weakness**

Management, with oversight from the Audit Committee of the Board of Directors, of the Company, is actively engaged in remediation efforts to address the material weaknesses identified in the management's evaluation of internal controls and procedures. The remediation efforts summarized below, which have been or are in the process of being implemented, are intended to address the identified material weakness.

- (i) The Company We will continue to hire additional finance, accounting and information technology employees appropriate experience, certification, education and training.
- (ii) The Company has We have implemented new accounting and finance management software effective July 1, 2024 which is intended to eliminate some of the existing deficiencies in the Company's internal control environment. The information technology general controls implemented with the new accounting and finance management software will be documented and tested for operating effectiveness.
- (iii) The Company is We are in the process of updating its formal accounting policies, procedures and controls including preparation and review of account reconciliations, review of journal entries, and controls over period financial reporting.

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- (iv) We have identified and remediated all segregation of duties deficiencies in our current control environment. The Company is developing a comprehensive plan controls established to identify and remediate all segregation of duties deficiencies in its current control environment. identified will be documented and tested for operating effectiveness.
  - (v) The Company is We are in the process of implementing additional key internal controls designed to address potential risks identified in its key business processes. Once fully implemented, these controls will be tested for operating effectiveness.
  - (vi) The Company engaged a third-party service provider to assist with the development, implementation and testing of its information technology general computer controls.
- We believe that the development, implementation and testing of its information technology general computer controls

The Company believes that the implementation of the above steps will allow it us to make progress on addressing a number of the deficient controls within its our internal control environment, which will help facilitate the remediation of the material weakness identified above. As the Company continues we continue to evaluate and work to improve its our internal control over financial reporting, it we will take additional measures to address control deficiencies, or it we may modify certain of the remediation measures described above. However, the Company requires we require additional time to complete the design and implementation of its our remediation plans and demonstrate the operating effectiveness of our remediation efforts. The material weakness cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

### Changes in Internal Control Over Financial Reporting

There were no changes in the Company's our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended September 30, 2023 March 31, 2024 that have materially affected, or are reasonably likely to materially affect, the Company's our internal control over financial reporting.

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## PART II OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

None.

### ITEM 1A. RISK FACTORS

On September 1, 2023, the Company announced that it had entered into a research collaboration and license agreement with Giiant Pharma Inc. ("Giiant") (the "Giiant License Agreement") for the exclusive worldwide license to Giiant's assets. As a result, the Company changed its strategic focus. To the extent that the risk factors contained herein contradict any risk factors contained in the Company's recent periodic reports, the risk factors contained herein shall supersede. The risk factors contained in the Company's recent periodic reports remain applicable to the Company.

## RISK FACTOR SUMMARY

The Company faces We face many risks and uncertainties, as more fully described in this Quarterly Report on Form 10-Q. Some of these risks and uncertainties are summarized below. 10-Q under the heading "Risk Factors." The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

### Risks Related to the Company's Our Development, Commercialization and Regulatory Approval of the Company's Our Investigational Therapies

- The Company's Our business depends on the successful pre-clinical and clinical development, regulatory approval and commercialization of its our recently licensed therapeutic compound, including our lead asset PALI-2108.
- There are substantial risks inherent in drug development, and, as a result, the Company we may not be able to successfully develop PALI-2108 for commercial use. PALI-2108.
- The Company depends We depend on its our license agreement with Giiant to permit the Company us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with obligations under this the license agreement could materially harm the Company's our business and prevent it us from developing or commercializing its PALI-2108, our lead product candidates. candidate.
- The Company expects We expect that its our operations and development of PALI-2108 will require substantially more capital than it we currently has, have, and the Company we cannot guarantee when or if it we will be able to secure such additional funding.
- There can be no assurance that the Company's our product candidates will obtain regulatory approval.
- If pre-clinical and clinical studies of PALI-2108 do not yield successful results, then we may decide to not continue. Company will be unable to commercialize its product candidates. development of PALI-2108.
- Even if the Company's our clinical studies are successful and achieve regulatory approval, the approved product may be more limited than the Company or analysts we anticipate, which could limit the commercial prospects of PALI-2108.
- The Company We may in the future conduct clinical trials for PALI-2108 outside the United States ("U.S."), and the FDA U.S. Food and Drug Administration ("FDA") and applicable foreign regulatory authorities may not accept data from such trials.
- The Company may rely We anticipate relying on third-party CROs Contract Research Organizations ("CROs") or other third parties to conduct and oversee its our pre-clinical studies and clinical trials. If these third parties do not meet the Company's our requirements or otherwise conduct the studies or trials as required, the Company we may not be able to satisfy its our contractual obligations or obtain regulatory approval for, or commercialize, its our product candidates.
- The Company has We have entered into a collaborative research agreement with Giiant related to pre-clinical development, which will require the efforts of Giiant and its personnel, which are out of the Company's our control.

### Risks Related to the Company's Our Business

- The Company has We have a very limited operating history and has have never generated any revenues from product sales.

sales.

- The Company's Our business model assumes revenue from, among other activities, marketing or out-licensing products the Company develops, we develop. PALI-2108 is in the early stages of development and because Company has we have a short

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development history with PALI-2108, there is a limited amount of information about the Company us upon which can evaluate its our business and prospects.

- The Company has Our common stock could be delisted from the Nasdaq Stock Market if we are unable to maintain compliance with the Nasdaq Stock Market's continued listing standards.
- We have received a delisting notification from the Nasdaq Stock Market based on that our audit committee does have three (3) independent members as a result of recent director resignations. If we fail to timely appoint independent director that meets the Company's Bid Price being under \$1.00 Nasdaq Stock Market Requirements thirty (30) consecutive trading days. If the Company is not able to regain compliance with the applicable continuing listing requirements or standards of The Nasdaq Capital Market, audit committees, Nasdaq could delist its common stock.
- The Company's Our success depends on the attraction attracting and retention retaining of senior management scientists with relevant expertise.
- The Company We may choose to discontinue developing or commercializing any of its our product candidates, or choose to not commercialize product candidates in approved indications, at any time during development or approval, which could adversely affect the Company us and its our operations.
- The Company's Our inability to successfully in-license, acquire, develop and market additional product candidate approved products would could impair its our ability to grow its our business.

#### Risks Related to the Company's Our Dependence on Third Parties

- The Company expects We expect to rely on collaborations with third parties for the successful development commercialization of its our product candidates.
- The Company anticipates We anticipate relying completely on third-party contractors to supply, manufacture distribute clinical drug supplies for its our product candidates.

#### Risks Related to the Company's Our Financial Operations

- The Company has We have expressed substantial doubt about its our ability to continue as a going concern.
- The Company has We have a history of net operating losses, and it expects we expect to continue to incur operating losses and may not never achieve or maintain profitability.
- Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in the Company's our consolidated financial statements.

## Risks Related to the Company's Intellectual Property

- The Company We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover its our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against the Company us.
- If the Company fails we fail to comply with its our obligations under its our intellectual property license agreements, it we could lose license rights that are important to its our business.

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## Other Risks Related to the Company's Securities

- The Company We will need to raise additional financing capital in the future to fund its our operations, which may not be available to it us on favorable terms or at all.
- The Our common stock price of the Company may be highly volatile.
- If the Company fails we fail to maintain proper and effective internal controls, its our ability to produce accurate financial statements on a timely basis could be impaired.
- The Company's Our Board of Directors has broad discretion to issue additional securities, which might dilute the tangible book value per share of its our common stock for existing stockholders.

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## RISK FACTORS

Investing in the Company's our common stock involves a high degree of risk. The Company has We have described below a number of uncertainties and risks which, that, in addition to uncertainties and risks presented elsewhere in this Quarterly Report on Form 10-Q, may adversely affect its our business, operating results and financial condition. The uncertainties and risks enumerated below as well as those presented elsewhere in this Quarterly Report on Form 10-Q should be considered carefully when evaluating the Company, its us, our business and the value of its our securities. To the extent the term "product candidate" or "product candidates" are used, it refers to the current and potential future products of the Company. To the extent the term "clinical trial" or "clinical trials" are used, it refers to the extent applicable, to pre-clinical and clinical trials of the Company. On September 1, 2023, the Company announced that it had entered into the Giant License Agreement with Giant for the exclusive worldwide license to Giant's assets. As a result, the Company changed its strategic focus. To the extent that the risk factors contained herein contradict any risk factors contained in the Company's recent periodic reports, the risk factors contained herein shall supersede. The risk factors contained in the Company's recent periodic reports remain applicable to the Company.

## Risks Related to the Company's Development, Commercialization and Regulatory Approval of the Company's Investigational Therapies

*The Company's business depends on the successful pre-clinical and clinical development, regulatory approval, and commercialization of its recently licensed therapeutic compound, including our lead asset PALI-2108.*

On September 1, 2023, the Company we announced that it we had entered into a research collaboration and license agreement with the Giiant License Agreement, pursuant to which the Company we exclusively licensed all of Giiant's current and future technologies, including PALI-2108. PALI-2108 is a pre-clinical asset and the Company's is our only asset being actively developed. The Our success of the Company depends on the development of PALI-2108, which is subject to a number of risks, including:

- the continued enforceability of the Company's our research collaboration and license agreement with Giiant;
- the successful completion of pre-clinical and Individual New Drug Application ("IND" our investigational new application ("IND")) or a Canadian Clinical Trial Application ("CTA") enabling studies and research;
- the submission and approval of an IND or CTA;
- the Company's our ability to develop and implement clinical trial designs and protocols;
- the successful initiation and completion of its our planned pre-clinical studies and clinical trials;
- the approval by the U.S. Food and Drug Administration ("FDA") FDA or other regulatory authority to commence marketing of the Company's our product candidates;
- the Company ability for us and its third-party contractors, third-parties, if applicable, achieving to achieve maintaining maintain compliance with their our contractual obligations and with applicable regulatory requirements;
- the ability of the Company's our contract manufacturers to manufacture sufficient supply of the Company's our product candidates to meet the required pre-clinical studies and clinical trial and commercial supplies;
- the ability of the Company's our contract manufacturers to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing facilities and processes that are compliant cGMP;
- the Company's our ability to obtain favorable labeling for its our product candidates through regulators that allow successful commercialization;

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- acceptance by physicians, insurers, and payors, and patients of the beneficial quality, benefits, safety and efficacy of the Company's our product candidates, if approved, including relative to alternative and competing treatments;
  - the Company's our ability to price its our product candidates to recover the Company's our development costs applicable milestone or royalty payments, and generate a satisfactory profit margin; and
  - the Company's our ability and its our applicable collaboration and licensing partners' ability to establish and enforce intellectual property rights related to the our product candidates and technologies.

If the Company does we do not achieve one or more of these factors, many of which are beyond its our control, in a timely manner or at all, the Company we could experience significant delays or an inability to obtain regulatory approvals or

commercialize **its our** proposed product candidate. Such delays may result in increased costs and the failure to complete any required regulatory activity. Even if regulatory approvals are obtained, **the Company we** may never be able to successfully commercialize **its our** product candidates. Accordingly, **the Company we** cannot make assurances that **it we** will ever be able to generate sufficient revenue through the sale of any product candidates, if approved, to internally fund **its our** business.

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***There are substantial risks inherent in drug development, and, as a result, **the Company we** may not be able to successfully develop **PALI-2108 for commercial use. PALI-2108.*****

**The Company's Our** research and development efforts are focused on a therapeutic based on PDE4 inhibitors. **The Company's Our** development of PALI-2108 is in the early stages. However, such technology's commercial feasibility and acceptance in **the Company's our** target indication of inflammatory bowel disease ("**IBD**") are unknown. Scientific research and development requires significant amounts of capital and takes a long time to reach commercial viability, if it can be achieved at all. During the research and development process, **the Company we** may experience technological barriers that **it we** may be unable to overcome. Further, certain underlying premises in **the Company's our** development programs **are have not been** proven. Because of these and similar uncertainties, it is possible that **the Company's our** product candidates will not reach commercialization. If **the Company is we are** unable to successfully develop and commercialize **its our** product candidates, **the Company we** will be unable to generate revenue or build a sustainable or profitable business.

***The Company depends We depend on **its our** license agreement with Giiant to permit **the Company us** to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with obligations under **this the license** agreement could materially harm **the Company's our** business and prevent **it us** from developing or commercializing **its PALI-2108, our lead product candidates. candidate.*****

**The Company is We are** a party to a license agreement with Giiant under which **the Company is we have been** granted rights to patents and patent applications that are important to **its our** business. **The Company relies We rely** on this license agreement **in order** to be able to use various proprietary technologies that are material to **its our** business, including certain **patents trade secrets** and patent applications that cover PALI-2108. **The Company's Our** rights to use **these patents and patent applications this intellectual property** and employ the inventions claimed in these **licensed patents patent applications and contained in the trade secrets** are subject to the continuation of and **its our** compliance with the terms of **its our** license agreement. If **the Company fails we fail** to comply with any of **its our** obligations under the license agreement with Giiant, Giiant may have the right to terminate the license agreement, in which event **the Company we** would not be able to continue the development of PALI-2108. Additionally, disputes may arise under the license agreement regarding the intellectual property that is subject to such license agreement. If disputes over intellectual property that **the Company**

has we have licensed, or in the future licenses, may license, prevent or impair its our ability to maintain any of its our license agreements on acceptable terms, the Company we may be unable to successfully develop and commercialize the affected product candidates and technologies.

***Pre-clinical and clinical drug development is very expensive, time-consuming and uncertain.***

The pre-clinical and clinical development of product candidates is very expensive, time-consuming, difficult to design and implement, and the outcomes are inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved, many do not cover their costs of development. In addition, the Company we, any partner with which it we may in the future collaborate, the FDA, or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, or institutional review boards ("IRB") at the Company's our trial sites, may suspend, delay, require modifications to or terminate the Company's our clinical trials, once begun, at any time.

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***The Company expects We expect that its our operations and development of PALI-2108 will require substantially more capital than it we currently has, have, and the Company we cannot guarantee when or if it we will be able to secure such additional funding.***

The Company has We have historically funded its our operations and prior development efforts through the sale of its our securities. Based on the Company's our existing cash resources and its our current or future business plan, of operations, the Company may we do not have adequate capital to complete its fund our anticipated pre-clinical or clinical operations through the completion of the development or fund operations. Moreover, the Company cannot guarantee that its cash resources are sufficient to provide for the Company's working capital needs and complete any anticipated pre-clinical and clinical research and studies of PALI-2108. As a result, the Company may we will need to secure additional financing funding. If the Company is we are not able to obtain financing additional capital in the future or on acceptable terms, it we may have to curtail its our research and development efforts as well as its our operations.

***There can be no assurance that the Company's our product candidates will obtain regulatory approval.***

The sale of human therapeutic products in the U.S. and foreign jurisdictions is subject to extensive and time-consuming regulatory approval, which requires, among other things:

- pre-clinical data required for the submission of an IND or CTA;
- controlled research and human clinical testing;
- establishment of the safety and efficacy of the product; proposed product candidate;
- government review and approval of a submission containing manufacturing, pre-clinical and clinical data; and
- adherence to cGMP regulations during production and storage.

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The proposed product candidate the Company we currently has have under development, PALI-2108, will require significant development, pre-clinical and clinical testing and the investment of significant funds to gain regulatory approval before it can be commercialized. The results of the Company's our research and human clinical testing of PALI-2108 may not meet regulatory requirements. If approved, PALI-2108 may also require the completion of post-market studies. There can be no assurance that PALI-2108 will be successfully developed and approved. The process of completing pre-clinical and clinical testing and obtaining the required approvals is expected to take a number of years and require the use of substantial resources. Further, there can be no assurance that PALI-2108 will be shown to be safe and effective in clinical trials or receive applicable regulatory approvals. If the Company fails we fail to obtain regulatory approvals, it will not be able to market PALI-2108 and its our operations may be adversely affected.

***If pre-clinical and clinical studies of PALI-2108 do not yield successful results, then we may decide to not continue the Company will be unable to commercialize its product candidates. development of PALI-2108.***

The Company We must demonstrate that PALI-2108 is safe and efficacious in humans through extensive pre-clinical and clinical testing. The Company's Our research and development programs are at an early stage of development. The Company We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any products, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in early human clinical trials, if approved, may not be indicative of results that obtained in later clinical trials;
- after reviewing test results, the Company we may abandon projects that it previously believed to be promising;
- the Company we or its our regulators may suspend or terminate our clinical trials because the participating subject patients are being exposed to unacceptable health risks; and
- PALI-2108 may not have the desired effects or may include undesirable side effects or other characteristics preclude regulatory approval or limit their commercial use if approved.

***It may take the Company us longer than it projects we estimate to complete pre-clinical studies and clinical trials, and the Company we may not be able to complete them at all.***

Although for planning purposes the Company projects we project the commencement, continuation and completion of its our pre-clinical studies and clinical trials; a number of factors, including scheduling conflicts with participating researchers

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and/or clinicians and research or clinical institutions, and difficulties in identifying or enrolling patients who meet trial eligibility criteria, may cause significant delays. The Company We may not commence or complete pre-clinical studies or clinical trials involving PALI-2108 as projected currently contemplated or may not be able to conduct them successfully.

**Even if the Company's our clinical studies are successful and achieve regulatory approval, the approved product label may be more limited than the Company or analysts we anticipate, which could limit the commercial prospects of PALI-2108.**

At the time therapeutic drugs are approved for marketing, they are given a "product label" from the FDA or other regulatory body. In most countries this label sets forth the approved indication for marketing, and identifies potential safety concerns for prescribing physicians and patients. While the Company intends we intend to seek as broad a product label as possible for PALI-2108, the Company we may receive a narrower label than is expected by either the Company us or third parties, such as stockholders and securities analysts. For example, any approved products may only be indicated to treat refractory patients (i.e., those who have failed some other first-line therapy). Similarly, it is possible that only a specific sub-set of patients safely responds to PALI-2108. As a result, even if successful in clinical trials, PALI-2108 could be approved only for a subset of patients. Additionally, safety considerations may result in contraindications that could further limit the scope of an approved product label. Any of these or other safety and efficacy considerations could limit the commercial prospects including market size, of PALI-2108.

**Even if PALI-2108 is approved for commercialization, future regulatory reviews or inspections may result in its suspension or withdrawal, closure of a facility or enforcement of substantial fines.**

If regulatory approval to sell PALI-2108 is received, regulatory agencies will subject PALI-2108, as well as the manufacturing facilities, to continual review and periodic inspection. If previously unknown problems with a product or manufacturing and laboratory facility are discovered, or the Company fails we fail to comply with applicable regulatory approval requirements, a regulatory agency may impose restrictions on PALI-2108 or the Company. us. The agency may require the withdrawal of PALI-2108 from the market, closure of the facility or enforcement of substantial fines.

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**We may in the future conduct clinical trials for PALI-2108 outside the United States, and the FDA and or applicable foreign regulatory authorities may not accept data from such trials.**

The Company We may in the future choose to conduct clinical trials outside of the U.S. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the U.S. or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of the Company's our business plan.

***The Company may rely We anticipate relying on third-party CROs and other third parties to conduct and oversee its our pre-clinical studies and clinical trials. If these third parties do not meet the Company's our requirements or otherwise conduct the studies or trials as required, the Company we may not be able to satisfy its our contractual obligations or obtain regulatory approval for, or commercialize, its our product candidates.***

The Company We may rely on third-party CROs to conduct and oversee its our anticipated pre-clinical studies and clinical trials and other aspects of product development. The Company We also expects expect to rely on various medical institutions, clinical investigators and contract laboratories to conduct its our trials in accordance with the Company's our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and good clinical practice ("GCP") requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties are expected to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. The Company expects We expect to rely heavily on these parties for the execution of its our clinical trials and pre-clinical studies and will control only certain aspects of their activities. The Company We and its our CROs and other third-party contractors

will be required to comply with GCP and good laboratory practice ("GLP") requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If the Company we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, any clinical data generated in the Company's our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require the Company us to perform additional clinical trials before approving the Company's our or the Company's our partners' marketing applications. The Company We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine whether or not any of the Company's our clinical or pre-clinical trials comply with applicable GCP and GLP requirements. In addition, the Company's our clinical trials generally must be conducted with compounds produced under cGMP regulations. The Company's Our failure to comply with these regulations and policies may require it to repeat clinical trials, which would be costly and delay the regulatory approval process. If any of the Company's our CROs were to terminate their involvement with the Company, us, there is no assurance that the Company we would be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms.

***The successful commercialization of PALI-2108, if approved, will depend in part on the extent to which government authorities and health insurers establish adequate reimbursement levels and pricing policies.***

Sales of any approved drug candidate will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations, who are increasingly challenging the price of medical products and services. Accordingly, coverage and reimbursement may be uncertain. Adoption of any drug by the medical community may be limited if third-party payers will not offer coverage. Additionally, significant uncertainty exists as to the reimbursement status of newly approved drugs. Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. The Company is We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers. Any denial of private or government payer coverage or inadequate reimbursement could harm the Company's our business or future revenues, if any. If the Company partners we partner with third parties with respect to any of its our product candidates, the Company we may be reliant on that partner to obtain reimbursement from government and private payors for the

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drug, if approved, and any failure of that partner to establish adequate reimbursement could have a negative impact on the Company's our revenues and profitability.

In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, regulations, and policies affecting coverage and reimbursement rates, which are designed to contain or reduce the cost of health care. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that the Company develops we develop and may further limit the Company's our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for the Company's our product candidates, if approved and commercialized, and the Company we cannot predict the scope of any future changes or the impact that those changes would have on its our operations.

If future reimbursement for PALI-2108, subject to approval, are substantially less than projected, or rebate obligations associated with them are substantially greater than expected, the Company's our future net revenue and profitability, if any, could be materially diminished.

***The Company faces We face potential product liability exposure, and if successful claims are brought against the Company, us, it may incur substantial liability for a product candidate and may have to limit its our commercialization.***

The use of the Company's our product candidates in clinical trials and the sale of any products for which the Company obtains we obtain marketing approval exposes it us to the risk of product liability claims. Product liability claims might be brought against the Company us by clinical trial participants, consumers, health-care providers, pharmaceutical companies, or others selling the Company's our products. If the Company we cannot successfully defend itself ourselves against these claims, it may incur substantial liabilities. Regardless of merit or eventual outcomes of such claims, product liability claims may result in:

- decreased demand for the Company's our product candidates;
- impairment of the Company's our business reputation;
- withdrawal of clinical trial participants;
- costs of litigation;
- substantial monetary awards to patients or other claimants; and

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- loss of revenues.

The Company's Our insurance coverage may not be sufficient to reimburse it for all expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, the Company we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses.

***Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.***

The commercial success of the Company's our product candidates, if approved, will depend significantly on attaining broad adoption and use of the drug by physicians and patients. The degree and rate of physician and patient adoption of a product, if approved, will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat the indication for which they are approved;
- the effectiveness of a product compared to other available therapies or treatment regimens;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration by physicians or patients;
- patient satisfaction with the results, administration and overall treatment experience;
- limitations or contraindications, warnings, precautions or approved indications for use different than those sought the Company us that are contained in the final FDA-approved labeling, or other authoritative regulatory body approved labeling, for the applicable product;
- any FDA requirement, or other authoritative regulatory body requirement, to undertake a risk evaluation and mitigation strategy;

- the effectiveness of the Company's our sales, marketing, pricing, reimbursement and access, government affairs, distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on way: commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If any of the Company's our product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, the Company's our operating results and financial condition will be adversely affected, which may delay, prevent or limit its our ability to generate revenue and continue its our business.

***The Company has We have entered into a collaborative research agreement with Giiant related to pre-clinical development, which will require the efforts of Giiant and its personnel, which are out of the Company's our control.***

The license agreement with Giiant provides for certain joint research and development of PALI-2108 related to pre-clinical studies and development. The Company's Our business strategy relies on such collaboration to shorten the time required to file and an IND and accelerate the knowledge transfer of trade secrets and other know-how associated with the licensed technologies. Overall, the success of the development PALI-2108 will depend on the Company's our ability to manage such relationship, and to a certain extent, to the efforts of Giiant, which are beyond our control. If we are not able to successfully manage such relationship, the Company's control. development of PALI-2108 may take longer and be more costly than previously anticipated.

#### **Risks Related to the Company's our Business**

***The Company has We have a very limited operating history and has have never generated any revenues from product sales.***

The Company is We are a pre-clinical biopharmaceutical company with a very limited operating history that may make it difficult to evaluate the success of its our business to date and to assess its our future viability. The Company was While we were initially formed in 2001, and its our operations, to date, have been limited to business planning, raising capital and other research and development activities related to its our product candidates. The Company has We additionally adopted a new business plan in September 2023 upon entering into the Giiant License Agreement. Accordingly, we have not yet demonstrated an ability to successfully complete

any clinical trials and **has have** never completed the development of any product candidate, nor **has it have we** ever generated any revenue from product **sales or otherwise. sales.** Consequently, **the Company has we have** no meaningful operations upon which to evaluate **its our** business, and predictions about **its our** future success or viability may not be as accurate as they could be if **it we** had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

***The Company's Our business model assumes revenue from, among other activities, marketing or out-licensing the products the Company develops. we develop. PALI-2108 is in the early stages of development and because the Company has we have a short development history with PALI-2108, there is a limited amount of information about the Company us upon which you can evaluate its our business and prospects.***

The Company has **We have** no approved drugs and thus have not begun to market or generate revenues from the commercialization of any products. **The Company We** recently in-licensed PALI-2108 and accordingly, **has we only have** a limited history upon which **one we** can evaluate **its our** ability to develop PALI-2108 as it is still at an early stage of development. Thus, **the Company has we have** limited experience and **has have** not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area.

For example, to execute **the Company's our** business plan, **it we** will need **to successfully: to:**

- Execute product development activities using unproven technologies;
- Build, maintain, and protect a strong intellectual property portfolio;
- Demonstrate safety and efficacy of **the Company's our** drug candidates in multiple **pre-clinical animal studies** human clinical studies;
- Receive FDA approval and approval from similar foreign regulatory bodies;
- Gain market acceptance for the development and commercialization of any drugs **the Company develops develop;**
- Ensure **the Company's our** products are reimbursed by commercial and/or government payors at a rate that per commercial viability;

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- Develop and maintain successful strategic relationships with suppliers, distributors, and commercial licen partners;
  - Manage **the Company's our** spending and cash requirements as **its our** expenses will increase in the near term if **Company adds we add** programs and additional pre-clinical and clinical trials; and
  - Effectively market any products for which **the Company obtains we obtain** marketing approval.

If the company is we are unsuccessful in accomplishing these objectives, it we may not be able to develop our proposed products, raise sufficient capital to fund our operations, expand its our business or continue its our operations.

**The Company has received a delisting notification Our common stock could be delisted from the Nasdaq Stock Market based on the Company's Bid Price being under \$1.00 for thirty (30) consecutive trading days. If the Company is not able if we are unable to regain maintain compliance with the applicable Nasdaq Stock Market's continued listing standards.**

Our common stock is listed on the Nasdaq Stock Market. There are a number of continued listing requirements or standards of The Nasdaq Capital Market, Nasdaq could delist its common stock.

The Company's ability to publicly or privately sell equity securities and the liquidity of its common stock could be adversely affected if it is delisted from the Nasdaq Capital Market or if it is unable to transfer its listing to another stock market. In that we must satisfy in order to maintain this its listing it must satisfy minimum financial and other continued listing requirements and standards, on The Nasdaq Stock Market, including a the requirement to maintain a minimum bid price of at least \$1.00 (the "Bid Price Rule"). Although we are currently in compliance with the Company's Bid Price Rule, we have been unable to comply with this rule in the past. For example, in October 2023, we were notified that we were no longer in compliance with the Bid Price Rule and had 180 days to cure such deficiency. On April 5, 2024, we effected a 1-for-15 reverse stock split and we were notified by the Nasdaq Stock Market that as of April 19, 2024, we were back in compliance with the Bid Price Rule. Notwithstanding our current compliance with the Bid Price Rule, in the event that our common stock of trades below \$1.00 per share ("Minimum for 30 consecutive business days, we may again be subject to delisting. If we fail to comply with the Bid Price Requirement"). On October 19, 2023, Rule in the Company future, or any of the other continued listing requirements, there can be no assurance that we will be able to regain compliance. The delisting of our common stock would likely adversely affect the market liquidity and market price of our common stock and our ability to obtain financing for the continuation of our operations and/or result in the loss of confidence by investors.

**We have received notice (the "Notice") a notification from the Nasdaq Stock Market LLC ("Nasdaq") advising that our audit committee does not have three (3) independent members as a result of recent director resignations. If we fail to timely appoint an independent director that meets the Company Nasdaq Stock Market Requirements for audit committees, Nasdaq could delist our common stock.**

On March 22, 2024, we received a notice from the Nasdaq Stock Market stating that for 30 consecutive trading days preceding pursuant to the recent resignation of certain members of the Board of Directors ("Board"), we became noncompliant with the requirements set forth in Nasdaq Listing Rule 5605(c)(2)(A), which requires us to have an audit committee of at least three (3) independent directors. As of March 22, 2024, we had only two (2) independent directors serving on the Audit Committee.

The Notice states that, consistent with Nasdaq Listing Rule 5605(c)(4), Nasdaq will provide us with a cure period in order to regain compliance (i) until the earlier of the Company's next annual shareholders' meeting or March 4, 2025, or (ii) if the next annual shareholders' meeting is held before September 3, 2024, then we must evidence compliance no later than September 3, 2024.

On May 7, 2024, we appointed Margery Fischbein to serve as a member of the Board and our Audit Committee. We believe that Ms. Fischbein's appointment to the Audit Committee will cure such deficiency. However, as of the date of the Notice, the bid price of the Company's common stock had closed below \$1.00 per share minimum required for continued listing this Quarterly Report on the Form 10-Q, we have not received notice from Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has until April 16, 2024 to regain compliance with the Minimum Bid Price Requirement. If at any time during this period the closing bid price of the Company's common stock is at least \$1.00 for a minimum of 10 consecutive business days, the Company will regain compliance with the Minimum Bid Price Requirement and its common stock will continue to be eligible for listing on The Nasdaq Capital Market absent noncompliance with any other requirement for continued listing. In the event that the Company does not regain compliance by April 16, 2024, the Company may be eligible for an additional 180 calendar day grace period if the Company meets the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market with the exception of bid price, and the Company provides written notice to

Nasdaq of its intention to cure the Audit Committee deficiency during the second compliance period, by effecting a reverse stock split, if necessary. has been cured.

If the Company does we do not regain compliance within the allotted compliance period, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's our common stock will be subject to delisting. The Company We will then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing. The Company While we believe we are currently in compliance with all Nasdaq listing requirements, we cannot be sure that its share price we will be able to continue to comply with the requirements for continued listing of its shares on the Nasdaq Capital Market in the future or that it will comply with the such other continued listing requirements. requirements of Nasdaq.

**Notwithstanding, the Company cannot assure you that, in the future, its securities will meet the continued listing requirements to be listed on Nasdaq. If the Company's common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of its common stock, increased volatility in its common stock, reduced liquidity in its common stock, a limited availability of market quotations for the Company's common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of the Company's common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in its common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in the Company's securities at all. Delisting could also cause a loss of confidence from the Company's collaborators, vendors, suppliers and employees, which could harm its business and future prospects.**

If the Company's common stock is delisted by Nasdaq, its common stock may be eligible to trade on the OTC Bulletin Board, OTCQB or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of or obtain accurate quotations as to the market value of, its common stock. In addition, there can be no assurance that the

Company's common stock would be eligible for trading on any such alternative exchange or markets. Moreover, if the Company's common stock is delisted, it may come within the definition of "penny stock" under the Exchange Act, which imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For example, the Company and/or broker-dealers are required to make a special suitability determination for purchases of such securities and must receive a purchaser's written consent to the transaction prior to any purchase. Additionally, unless exempt, prior to a transaction involving a penny stock, the penny stock rules require the delivery of a disclosure schedule prescribed by the SEC relating to the penny stock market. The broker-dealer must also disclose the commissions payable to the broker-dealer, current quotations for the securities and, if the broker-dealer is the sole market-maker for the security, the fact that they are the sole market-maker and their presumed control over the market. Finally, monthly statements disclosing recent price information on the limited market in penny stocks must be sent to holders of such penny stocks. These requirements may reduce trading activity in the secondary market for the Company's common stock and may impact the ability or willingness of broker-dealers to sell its securities which could limit the ability of stockholders to sell their securities in the public market and limit the

***The Company's Our success depends on the attraction attracting and retention of retaining senior management and scientists with relevant expertise.***

The Company's Our future success depends to a significant extent on the continued services of its our key employees, including its our senior scientific, technical and managerial personnel. The Company does We do not maintain key person life insurance for any of its executives and it does not maintain employment agreements with many senior employees. our executives. Competition for qualified employees in the pharmaceutical industry is high, and the Company's our ability to execute its our strategy will depend in part on our ability to continue to attract and retain qualified scientists and management. If the Company is we are unable

to find, hire, and retain qualified individuals, it will have difficulty implementing its we may be unable to execute our business plan in a timely manner, or if at all.

***The Company We may choose to discontinue developing or commercializing any of its our product candidates, or may choose to not commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect the Company us and its our operations.***

At any time, the Company we may decide to discontinue the development of, or temporarily pause the development of, any of its our product candidates then in existence for a variety of reasons, including the appearance of new technologies that make its our product candidates obsolete, competition from a competing product product(s) or changes in or failure to comply with applicable regulatory requirements. If the Company we temporarily pauses pause or terminates terminate a

program in which **it has we have** invested significant resources, **the Company we** will not receive any return on **its our** investment and **it we** will have missed the

opportunity to have allocated those resources to potentially more productive uses, which could have an adverse effect on **the Company us** and **its our** business.

***The Company's Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products would could impair its our ability to grow its our business.***

PALI-2108 is currently **the Company's our** only product candidate being actively developed. **The Company We** may in-license, acquire, develop and market additional products and product candidates. Since **the Company's our** internal research and development capabilities are limited, **it we** may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to **it. us**. The success of this strategy depends partly on **the Company's our** ability to identify and select promising pharmaceutical product candidates and **approved** products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of identifying, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with **the Company us** for the license or acquisition of product candidates and approved products. Moreover, **the Company we** may devote resources to potential acquisitions or licensing opportunities that are never completed, or **the Company we** may fail to realize the anticipated benefits of such efforts. **The Company We** may not be able to acquire the rights to additional **approved products or** product candidates on terms that **it finds we find** acceptable, or at all.

Further, any product candidate that **the Company acquires we acquire** or licenses may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, **the Company we** cannot provide assurance that any approved products that **it acquires we acquire** will be manufactured or sold profitably or achieve market acceptance.

***The Company We may seek to avail itself ourselves of mechanisms to expedite the development or approval for product candidates it we may pursue in the future, such as Fast Track or breakthrough designation, but such mechanisms may not actually lead to a faster development or regulatory review or approval process.***

**The Company We** may seek to avail **itself ourselves** of Fast Track designation, breakthrough designation, or priority review for product candidates **it we** may pursue in the future. For example, if a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if **the Company believes we believe** a particular product candidate is eligible for any such

mechanism, **it we** cannot guarantee that the FDA would decide to grant it. Even if **the Company believes we believe** a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if **it does we do** obtain Fast Track or priority review designation or pursue an accelerated approval pathway, **the Company we** may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from **the Company's our** clinical development program.

#### **Risks Related to the Company's our Dependence on Third Parties**

***The Company expects We expect to rely on collaborations with third parties for the successful development and commercialization of its our product candidates.***

The Company expects We expect to rely upon the efforts of third parties for the successful development and commercialization of the Company's our product candidates. The clinical and commercial success of the Company's our product candidates may depend upon maintaining successful relationships with third-party partners, which are subject to a number of significant risks, including the following:

- the Company's our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner

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- reduced control over delivery and manufacturing schedules;
  - price increases;
  - manufacturing deviations from internal or regulatory specifications;
  - quality incidents;

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- the failure of partners to perform their obligations for technical, market or other reasons;
  - misappropriation of the Company's our product candidates; and
  - other risks in potentially meeting the Company's our product commercialization schedule or satisfying requirements of its our end-users.

The Company We cannot provide any assurance that **it we** will be able to establish or maintain third-party relationships in order to successfully develop and commercialize **its our** product candidates.

***The Company anticipates We anticipate relying completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for its our product candidates.***

The Company does We do not currently have, nor does it do we currently plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute pre-clinical, clinical or commercial quantities of drug substances or products. Additionally, the Company has we have not entered into a long-term commercial supply agreement to provide it us with such drug substances or products. As a result, the Company's our ability to develop its and commercialize, if approved, our product candidates is dependent and the Company's ability to supply its products commercially will depend, in part, on the Company's our ability to obtain the active pharmaceutical ingredients ("APIs") APIs and other substances and materials used in its our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for pre-clinical and clinical testing and commercialization. If the Company fails we fail to develop and maintain supply and other technical relationships with these third parties, it we may be unable to continue to develop or commercialize its our products and product candidates, which could adversely affect the Company us and its our business.

The Company is We are dependent on its our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMPs cGMP for production of both APIs our proposed products and finished products. API. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, the Company we may not be able to commercialize or obtain regulatory approval for the affected product or product candidates successfully, and the Company we may be held liable for injuries sustained as a result.

The Company expects We expect to continue to depend on third-party contract suppliers and manufacturers. The Company's Our supply and manufacturing agreements do not guarantee that a contract supplier or manufacturer will provide services adequate for its our needs. Additionally, any damage to or destruction of the Company's our third-party manufacturer's manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair the Company's our ability to have its our products and product candidates manufactured on a timely basis. The Company's Our reliance on contract manufacturers and suppliers further exposes it us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate the Company's our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of the Company's our suppliers may be located outside of the United States. This may give rise to difficulties in importing the Company's our products or product candidates or their components into the United States or other countries.

### Risks Related to the Company's Our Financial Operations

**The Company has We have expressed substantial doubt about its our ability to continue as a going concern.**

Management has determined that there is substantial doubt about the Company's our ability to continue as a going concern for a period of one year following the issuance of this report. This determination was based on conditions and events, considered in the aggregate, that raise substantial doubt about the Company's our ability to continue as a going concern within one year after the date that the financial statements are issued, including: (i) including the probability that significant changes to the Company's our anticipated level of operations, due to factors that are within or outside of the Company's our control, would cause the Company's our available cash as of the date of this filing to not be sufficient to fund its our anticipated level of operations for the next 12 months; and (ii) the uncertainties of the cost and timing of the Company's efforts to in-license or acquire a new product candidate. The Company's months. Our future consolidated financial statements may include a similar qualification about its our ability to continue as a going concern. The Company's Our year-

end and interim consolidated financial statements were prepared assuming that it will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

If the Company seeks we seek additional financing to fund its our business activities in the future and there remains substantial doubt about its our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to the Company us on commercially reasonable terms or at all.

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**The Company has We have a history of net operating losses, and it expects we expect to continue to incur net operating losses and may not never achieve or maintain profitability.**

The Company has We have incurred net operating losses since our inception, including inception. We expect that our net losses of \$14.3 million and \$9.3 million for the year ended December 31, 2022 and the nine months ended September 30, 2023, respectively. The Company expects that its operating losses will continue for the foreseeable future as it continues its our drug development and discovery efforts. To achieve profitability, it we must, either directly or through licensing and/or partnering relationships, meet certain milestones, successfully develop and obtain regulatory approval for one or more drug candidates and effectively manufacture, market and sell any drugs we successfully develop. Even if the Company is we are able to successfully commercialize product candidates that receive regulatory approval, it we may not be able to realize revenues at a level that would allow it us to achieve or sustain profitability. Accordingly, the Company we may never generate significant revenue and, even if it does we do generate significant revenue, it we may never achieve profitability.

**Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in the Company's our consolidated financial statements.**

The Company's Our management has identified a material weakness in its our internal control over financial reporting. The material weakness was due to a lack of controls in the financial closing and reporting process, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. Additionally, the Company's management identified a material weakness in its internal control over the fair value calculation of options granted during the quarter ended June 30, 2021, although management concluded that this material weakness has been remediated in the year ended December 31, 2022.

If the Company's our remaining material weakness, which management concluded is still present as of the date of these financial statements, is not remediated, or if the Company identifies we identify further material weaknesses in its our internal controls, the Company's our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in its our consolidated financial statements and a failure to meet its our reporting and financial obligations.

***Changing circumstances and market conditions, some of which may be beyond the Company's our control, could impair its our ability to access our existing cash and cash equivalents and investments and to timely pay key vendors and others.***

Changing circumstances and market conditions, some of which may be beyond the Company's our control, could impair its our ability to access its our existing cash and cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was placed into receivership with the Federal Deposit Insurance Corporation ("FDIC"), which resulted in all funds held at SVB being temporarily inaccessible by SVB's customers. Although the Company does we do not have any funds at SVB, if other banks and financial institutions with whom the Company has we have banking relationships enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, the Company we may be unable to access, and the Company we may lose, some or all of its our existing cash and cash equivalents to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances the Company we might not be able to timely pay key vendors and others. The Company We regularly maintains maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. Any delay in the Company's our ability to access its our cash and cash equivalents (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on the Company's our operations and cause it to need to seek additional capital sooner than planned.

#### **Risks Related to the Company's Our Intellectual Property**

***The Company We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover its our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against the Company. us.***

The Company's Our success with respect to its our current and future product candidates will depend, in part, on its our ability to obtain and maintain patent protection in both the U.S. and other countries, to preserve its our trade secrets and to prevent third parties from infringing on its our proprietary rights. The Company's Our ability to protect its our product candidates from unauthorized or infringing use by third parties depends in substantial part on its our ability to obtain and maintain valid and enforceable patents around the world. in certain countries.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and the Company we and its our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable

patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that the Company we or its our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of the Company's our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of its our business. Moreover, the Company's our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to the Company our

patents that would not constitute infringement. Any of these outcomes could impair the Company's our ability to enforce the exclusivity of its any issued or pending patents effectively, we may have or the

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ability to obtain future patent protections, which may have an adverse impact on its our business, financial condition and operating results.

The Company's Our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across varying countries. Accordingly, rights under any existing patents or any patents the Company we might obtain or license may not cover its our product candidates or may not provide the Company us with sufficient protection for its our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, the Company we cannot guarantee that any patents or other intellectual property rights will issue be issued from any pending or future patent or other similar applications owned by or licensed to the Company. us. Even if patents or other intellectual property rights have issued or will issue, the Company we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide the Company us with any significant protection against competitive products or otherwise be commercially valuable to the Company us in every country of commercial significance that the Company we may target.

The Company's Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between its our technology and the prior art allow its our technology to be patentable over the prior art. The Company does We do not have outstanding issued patents covering all of the recent developments in its our technology and is are unsure of the patent protection that it we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents the Company owns we own or licenses, license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents the Company holds we hold or pursues pursue with respect to its our product candidates is are challenged, it could dissuade companies from collaborating with the Company us to develop or threaten its our ability to commercialize or finance its our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U.S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. If the Company encounters we encounter such difficulties in protecting or are otherwise precluded from effectively protecting its our intellectual property in foreign jurisdictions, its our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to the Company's our business. Although the Company has we have taken steps to protect its our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property assignment and protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding such agreements will not be breached or enforced by courts, that the Company we would have adequate remedies for any breach, including injunctive and other equitable relief, or that its our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by the Company us or its our agents and representatives, or be independently discovered by its our competitors. If our trade secrets are independently discovered, the Company we would not be able to prevent their use and if the Company and its we or our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, the Company we may not be allowed to retrieve these trade secrets and/or unpatented know-how and maintain the exclusivity it we previously held.

***The Company We may not be able to protect its our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on the Company's our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States, especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, the Company we may not be able to prevent third parties from practicing its our inventions in all countries outside the United States and even in launching an identical version of the Company's our product notwithstanding the Company has we have a valid patent in that country. Competitors may use the Company's our technologies in jurisdictions where it has we have not obtained patent protection, to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where the Company has we have patent protection but enforcement on infringing activities is inadequate or where

the Company has we have no patents. These products may compete with the Company's our products, and the Company's our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

***In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patent holder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, the Company may have limited remedies if its patents are infringed or if the Company is compelled to grant a license to its patents to a third party, which could also materially diminish the value of those patents. This would limit its potential revenue opportunities. Accordingly, the Company's efforts to enforce its***

**intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that the Company owns or licenses, especially in comparison to what it enjoys from enforcing its intellectual property rights in the United States. Finally, the Company's ability to protect and enforce its intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.**

**Obtaining and maintaining the Company's our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and its our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trade Office ("USPTO") and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, procedures, including certain documentary, fee payment and other similar provisions during the patent application process. While an inadvertent

lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay a prosecution fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If the Company we or its our licensors fail to maintain the patents and patent applications covering its our product candidates for any reason, the Company's our competitors might be able to enter the market, which would have an adverse effect on the Company's our business.

**If the Company fails we fail to comply with its our obligations under its our intellectual property license agreements, it we could lose license rights that are important to its our business.**

The Company has We have entered into an in-license agreement the Giiant License Agreement, with respect to its current our lead product candidate. This license agreement candidate, PALI-2108 and other assets of Giiant. The Giiant License Agreement imposes various diligence, milestone, royalty, insurance, expense reimbursement, and other obligations

on the Company. From time to time, the Company may be delayed in various diligence or other obligations upon it. us. If the Company fails we fail to comply with these obligations, the licensor may have the ability to terminate the license. The loss of such rights would materially adversely affect its license, subject to certain requirements as more fully set forth in the Giiant License Agreement. In the event that license granted thereunder terminates, our business, financial condition, operating results, and prospects, prospects would be materially adversely affected.

***The Company We may be subject to patent infringement claims, which could result in substantial costs, and liability liabilities and prevent us from commercializing our potential products.***

Because the intellectual property landscape in the fields in which the Company participates we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess its our freedom to operate without infringing on third-party rights. If any patent infringement claims are brought against the Company, us, whether or not successful, it we may incur significant expenses and divert the attention of its our management and key personnel from other business concerns. These This could negatively affect the Company's our results of operations and prospects. The Company We cannot be certain that patents owned or licensed by it us will not be challenged, potentially successfully, by others.

In addition, if the Company's our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against its our customers, licensees and other parties with whom the Company has we have business relationships, and it we may be required to indemnify those parties for any damages they suffer as

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a result of these such claims. The claims may require the Company us to initiate or defend protracted and costly litigation on behalf of customers, licensees, and other parties regardless of the merits of these claims. If any of these claims succeed, the Company we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. If the Company we cannot obtain all necessary licenses on commercially reasonable terms, it we may be unable to continue selling such products.

***The Company We may be subject to claims that its our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.***

As is common in the biotechnology and pharmaceutical industries, certain of the Company's our employees were formerly employed by other biotechnology or pharmaceutical companies, including its our competitors or potential competitors. Moreover, the Company engages we engage the services of consultants to assist us in the development of the Company's our product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including the Company's our competitors or potential competitors. The Company We may be subject to claims that these our employees and or consultants or the Company has have inadvertently or otherwise wrongfully used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although the Company has we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend

against any such claims. Even if the Company is we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to its our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

#### Other Risks Related to the Company Our Securities

**The Company We will need to raise additional financing capital in the future to fund its our operations, which may not be available to it us on favorable terms or at all.**

The Company We will require substantial additional capital to fund its our operations and conduct the costly and time-consuming research and development, pre-clinical studies, and clinical trials work necessary to pursue regulatory approval of product candidates. The Company's Our future capital requirements will depend upon a number of factors, including: the number and timing of product candidates in the pipeline; progress with and results from pre-clinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete pre-clinical and clinical trials; the costs involved in preparing,

filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain, and could significantly dilute stockholders' given our limited cash reserves and the significant amount of capital that we will likely need to fund our operations and business plan, our stockholders will likely experience significant dilution to their ownership interests or inhibit the Company's our ability to achieve its our business objectives. If the Company raises we raise additional funds through public or private equity offerings, sales of our securities, the terms of these securities may include liquidation or other preferences that adversely impact the rights of its our common stockholders. Further, to the extent that the Company raises we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, its our stockholders' ownership percentage in the Company will be diluted. decreased. In addition, any debt financing may subject the Company us to fixed payment obligations and covenants limiting or restricting its our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If the Company raises we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, the Company we may have to relinquish certain valuable intellectual property or other rights to its our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. us. Even if the Company were to we obtain sufficient additional funding, there can be no assurance that it will be available on terms acceptable to the Company us or its our stockholders.

**The Our common stock price of the Company may be highly volatile.**

Since the completion of the Merger merger with Seneca on April 27, 2021, the Company's our stock price has already been subject to significant fluctuation. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile and may be subject even to large daily price swings. Some of the factors that may cause the market price of our shares of the Company to fluctuate include, but are not limited to:

- failure of the Company our product candidates to show safety and/or efficacy in its our pre-clinical or clinical trials;
- the our ability of the Company to obtain timely regulatory approvals for its our product candidates, and delay failures to obtain such approvals;

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- the results of pre-clinical or clinical trials, of product candidates, including the Company's our decision to pause terminate any such trials;
- failure of the Company's our product candidates, if approved, to achieve commercial success;
- the entry into, or termination of, or breach by partners parties of key agreements, including key commercial partnerships agreements; the Giant License Agreement, and employment agreements with our named executive officers;
- the initiation of, material developments in, or conclusion of any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the thereof, of, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of the Company's our stock by analysts; and
- the loss of key personnel.

Moreover, the stock markets in general have experienced substantial volatility in the biotechnology industry, particularly in the micro-capitalization space, that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of the Company's our shares. In the past, following periods of volatility in the market price of a company's securities, shareholders stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the Company's our profitability and reputation.

***The Company takes We take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in its our common stock being less attractive to investors.***

As of June 30, 2023, the last business day of the Company's our most recently completed second fiscal quarter, the our public float of the Company is less than \$250 million and therefore, the Company qualifies we qualify as a smaller reporting company under SEC rules. As a smaller reporting company, the Company is able to we can take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its our SEC filings. Decreased Such reduced disclosures in the Company's our SEC filings due to its status as a smaller reporting company may make it harder for investors to analyze its our results of operations and financial

prospects. The Company We cannot predict if investors will find the Company's our common stock less attractive if it relies we rely on these exemptions. If some investors find its our common stock less attractive as a result, there may be a less active trading market for its our common stock and its

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our stock price may be more volatile. The Company We may take advantage of the reporting exemptions applicable to a smaller reporting company until it is we are no longer a smaller reporting company, which status would end once it has we have a public float greater than \$250 million. In that event, the Company we could still be a smaller reporting company if its our annual revenues were are below \$100 million and it has we have a public float of less than \$700 million.

**The Company does We do not anticipate paying any dividends in the foreseeable future.**

The current expectation is that We do not anticipate paying any dividends in the Company will foreseeable future. We currently plan to retain its our future earnings, if any, to fund the development and growth of its our business. As a result, capital appreciation, if any, of the our shares of the Company will likely be your sole source of gain, if any, for the foreseeable future.

**If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the Company, its us, our business or its our market, its our stock price and trading volume could decline.**

The trading market for the Company's our common stock is and will be influenced by the research and reports that equity research analysts publish about it us and its our business. Equity research analysts may elect not to provide research coverage of the Company's our common stock, and such lack of research coverage may adversely affect the market price of its our common stock. In the event it does have equity research analyst coverage, the Company we will not have any control over the analysts, or the content and opinions included in their reports. The price of the Company's our common stock could decline if one or more equity research analysts downgrade its our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of the Company us or fails to publish reports on it us regularly, demand for its our common stock could decrease, which in turn could cause its our stock price or trading volume to decline.

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**Future sales of substantial amounts of the Company's our common stock, or the possibility that such sales could occur, could adversely affect the market price of its our common stock.**

Future sales in the public market of shares of the Company's our common stock, including shares issued upon exercise of its our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the

market price of its our common stock or make it difficult for it us to raise additional capital.

***The Company's Our business could be negatively affected as a result of the actions of activist stockholders, and such activism could impact the trading value of its our securities.***

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on the Company's our Board of Directors ("Board") and management. Activist campaigns that contest or conflict with the Company's our strategic direction or seek changes in the composition of its our Board could have an adverse effect on its our operating results and financial condition. A proxy contest would require the Company us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by the Company's our Board and management, diverting their attention from the pursuit of its our business strategy. Any perceived uncertainties as to the Company's our future direction and control, its our ability to execute on its our strategy, or changes to the composition of its our Board or senior management team arising from a proxy contest could lead to the perception of a change in the direction of its our business or instability, which may result in the loss of potential business opportunities, make it more difficult to pursue the Company's our strategic initiatives, or limit its our ability to attract and retain qualified personnel and business partners, any of which could adversely affect its our business and operating results. If individuals are ultimately elected to the Company's our Board with a specific agenda, it may adversely affect the Company's our ability to effectively implement its our business strategy and create additional value for our stockholders. The Company We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to its our Board and management and would require the Company us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in the Company's our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of its our business.

***Securities class action litigation could divert our management's attention and harm our business and could subject us to significant liabilities.***

The stock markets have from time to time time-to-time experienced significant price and volume fluctuations that have affected the market prices for the equity securities of life sciences and biotechnology companies. These broad market fluctuations may cause the market price of the Company's our common shares to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for the Company us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. Even if the Company is we are successful in defending claims that may be brought in the future, such litigation could result in substantial costs and may be a distraction to the Company's our management and may lead to an unfavorable outcome that could adversely impact its our financial condition and prospects.

***Anti-takeover provisions in the Company's our charter documents and under Delaware law could make an acquisition of the Company us more difficult and may prevent attempts by the Company our stockholders to replace or remove the Company our management.***

Provisions in the Company's our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because the Company is we are incorporated in Delaware, it is we are governed by the provisions of Section 203 of the DGCL, Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of the our outstanding Company voting stock from merging or combining with the Company us. Although the Company believes we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with the Company's our Board, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by the Company's our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of management.

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***If the Company fails we fail to maintain proper and effective internal controls, its our ability to produce accurate financial statements on a timely basis could be impaired.***

The Company is We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that the Company we maintain effective disclosure controls and procedures and internal control over financial reporting. The Company We must perform system and process evaluation and testing of its our internal control over financial reporting to allow management to report on the effectiveness of its our internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. our periodic reports. This has required that the Company reporting will require us to incur substantial professional fees and internal costs to expand its our accounting and finance functions and that it as to expend significant management efforts. The Company may experience difficulty in meeting these reporting requirements in a timely manner.

The Company may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its consolidated financial statements. Prior to the Merger, LBS's Our management identified a material weakness in its our internal control over financial reporting. The material weakness was due to a lack of controls in the financial closing and reporting process for LBS, including a lack of segregation of duties and the documentation and design of formalized processes and procedures surrounding the creation and posting of journal entries and account reconciliations. If the Company does we do not remediate this material weakness, or if the Company identifies we identify further material weaknesses in its our internal controls, the Company's our failure to establish and maintain effective internal financial and accounting controls and procedures could result in material misstatements in its our consolidated financial statements and a failure to meet its our reporting and financial obligations.

If the Company is we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is we are unable to maintain proper and effective internal controls, the Company we may not be able to produce timely and accurate consolidated financial statements. If that were to happen, the market price of its our common stock could decline and it we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

**The Company's Our Board of Directors has broad discretion to issue additional securities, which might dilute the net tangible book value per share of its our common stock for existing stockholders.**

The Company is We are entitled under its our certificate of incorporation, as amended, to issue up to 280,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of the Company's our blank check preferred stock provide its our Board with broad authority to determine voting, dividend, conversion, and other rights. rights of such preferred stock. As of September 30, 2023 March 31, 2024, the Company we had outstanding, common stock or securities convertible into common stock, totaling 9,210,751 1,202,005 shares. As a result, the Company is we are authorized to issue up to an additional 270,789,249 278,797,995 shares of common stock or common stock equivalents under its our certificate of incorporation as amended. Additionally, pursuant to the initial issuance of (i) 1,000,000 shares of Series A 4.5% Convertible Preferred Stock, of which 200,000 shares are outstanding and (ii) 1,460 shares of Series B Convertible Preferred Stock, of which no shares are outstanding, the Company is we are authorized to issue up to an additional 6,800,000 shares of preferred stock. The Company expects We expect that significant additional capital may will be needed in the future to continue its our planned operations. To the extent the Company raises we raise additional capital by issuing equity securities, its our existing shareholders may stockholders will likely experience substantial dilution. The Company We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner the Company determines that we determine from time to time. If the Company sells we sell common stock, convertible securities or other equity securities in more than one transaction, investors may will likely be materially diluted by the initial and subsequent sales. These sales may also result in material dilution to the Company's existing shareholders, and Additionally, new investors could may gain rights superior to existing shareholders. stockholders, depending on the terms of such transactions and types of securities. Pursuant to the Company's our equity incentive plans and employee stock purchase plan, management is authorized to grant stock options, restricted stock units and other equity-based awards to employees, directors and consultants, and to sell common stock to employees, respectively. Any increase in the number of shares outstanding as a result of the exercise of outstanding options, the vesting or settlement of outstanding stock awards, or the purchase of shares pursuant to the employee stock purchase plan will cause shareholders stockholders to experience additional dilution, which could cause the our stock price to fall.

## General Risk Factors

**The Our business could be adversely affected by the effects of health pandemics or epidemics, such as the COVID-19 pandemic, which could cause significant disruptions in our operations and those of our current or future CMOs, CROs, and other third parties upon whom we rely.**

Health pandemics or epidemics, such as the COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies, or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators, and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs, and other third-party service providers to assist us in managing, monitoring, and otherwise carrying out certain of our pre-clinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or epidemics, such as the COVID-19 pandemic, may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and/or disrupted. As a similar pandemic, epidemic, or outbreak of an infectious disease, result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may materially be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and adversely affect our business, financial condition, results of operations, and prospects. In addition, impact on the Company's operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated.

**Unstable economic and market conditions may have serious adverse consequences on our business, financial condition, and stock price.**

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the Company's financial results past several years, including severely diminished liquidity and could cause a disruption credit availability, rising inflation and monetary supply shifts, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the development ongoing Russia-Ukraine and Israel-Hamas conflict). The financial institutions in which we hold our cash and cash equivalents are subject to risk of failure. For example, recent events surrounding certain banks, including Silicon Valley Bank, First Republic Bank, and Signature Bank, created temporary uncertainty on their customers' cash deposits in

excess of Federal Deposit Insurance Corporation limits prior to actions taken by governmental entities. While we do not expect any developments with any such banks to have a material impact on our cash and cash equivalents balance, expected results of operations, or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash and cash equivalents would adversely affect our business.

The extent of the Company's product candidates.

Public health crises, such as pandemics or similar outbreaks, could adversely impact the Company's business. The impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the COVID-19 pandemic and the efforts to mitigate it, resulted in and will likely continue to result in disruptions to the global economy, expected timeframe, as well as businesses and capital markets around the world. The Company

experienced delays in its development activities as a result that of the COVID-19 pandemic, primarily due to temporary and partial shutdowns at certain of the Company's CROs and trial sites that have since resumed operations, and due to governmental responses to the pandemic. Additionally, the emergence of new variants, which could prove resistant to existing vaccines, could again result in major disruptions to businesses and markets worldwide. The extent to which the COVID-19 pandemic will continue to impact the Company's operations or those of its consultants and collaborators, third parties upon whom we rely, will depend on future developments including which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the global macroeconomic effects of the virus.

**Global, market current equity and economic conditions, including inflation, may negatively impact the Company's business, financial condition and share price.**

Concerns over inflation, geopolitical issues, the U.S. financial markets, foreign exchange rates, capital and exchange controls, unstable global credit markets and financial conditions and the COVID-19 pandemic, have led to periods of significant economic instability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, and increased unemployment rates. The Company's general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, to complete, more costly, and more dilutive. In addition, there is a risk that one or more of Furthermore, our current or future service providers, manufacturers, suppliers and other partners could be negatively affected by difficult economic times, which could adversely affect the Company's ability to attain our operating goals on schedule and on budget or meet our business and financial objectives.

In addition, the Company faces several risks associated with international business and are subject to global events beyond its control, including war, public health crises, such as pandemics and epidemics, trade disputes, economic

sanctions, trade wars and their collateral impacts and other international events. Any of these changes could have a material adverse effect on the Company's reputation, business, financial condition or results of operations. There stock price may be changes decline due in part to the Company's business if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions announced by the U.S. and other countries, following Russia's invasion of Ukraine against Russia to date include restrictions on selling or importing goods, services or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business and financial organizations in Russia. The U.S. and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact the Company's business, financial condition and results of operations.

***The Company may be adversely affected by natural disasters and other catastrophic events and by man-made problems such as terrorism that could disrupt its business operations, and its business continuity and disaster recovery plans may not adequately protect it from a serious disaster.***

The Company's headquarters and main research facility are located in the greater San Diego area, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, health pandemics or epidemics, terrorism and similar unforeseen events beyond its control, including for example the ongoing COVID-19 pandemic, prevented it from using all or a significant portion of its headquarters or research facility, it may be difficult or, in certain cases, impossible for the Company to continue its business for a substantial period of time. The Company does not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result volatility of the absence or limited nature of stock market and the Company's internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with its lack of earthquake insurance, could have a material adverse effect on its business. Furthermore, integral parties in the Company's supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect its supply chain, it could have a material adverse effect on the Company's ability to conduct clinical trials, its development plans and its business. general economic downturn.

***If the Company's our information systems or data, or those of third parties upon which it relies, we rely, are or were compromised, the Company we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.***

In the ordinary course of the Company's our business, it may process, as defined above, proprietary, confidential, and sensitive data, including personal data (such as health-related patient data), intellectual property, and trade secrets (collectively, sensitive information). The Company We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, employee email, CROs, and other functions. The Company's Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. The Company We may share or receive sensitive information with or from third parties.

The risk of a security breach or disruption, particularly through cyber-attacks, cyber-intrusion, malicious internet-based activity, and online and offline fraud, are prevalent and have generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. These threats are becoming increasingly difficult to detect and come from a variety of sources, including traditional computer hackers, threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt the Company's our systems and operations, supply chain, and ability to produce, sell and distribute the Company's our products.

The Company We and the third parties upon which the Company relies we rely may be subject to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, natural disasters, terrorism, war, and telecommunication and electrical failures. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but the Company we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity.

Furthermore, the COVID-19 pandemic and our remote workforce poses increased risks to the Company's our information technology systems and data, as more most of the Company's our employees work from home, utilizing network connections outside our premises.

Any of the previously identified or similar threats could cause a security breach or disruption. While the Company has we have not experienced any such security breach or other disruption to date, if such an event were to occur, it could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information and cause interruptions in the Company's our operations, including material disruptions of its our development programs and business operations.

The Company We may expend significant resources or modify its our business activities (including our clinical trial activities) to try to protect against security breaches and disruptions. Certain data privacy and security obligations may require the Company us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While the Company has we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. The Company We may be unable in the future to detect vulnerabilities in its our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security breach or disruption has occurred. Despite the Company's our efforts to identify and remediate vulnerabilities, if any, in its our information technology systems, its our efforts may not be successful. Further, the Company we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require the Company us to notify relevant stakeholders parties of certain security breaches and disruptions. Such disclosures are costly, and the disclosure or the failure to comply with such

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requirements could lead to adverse consequences. If the Company we (or a third party upon whom it relies) experience a security breach or other disruption, or are perceived to have experienced such events, the Company we may experience adverse consequences, including: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data);

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litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in the Company's our operations (including availability of data); financial loss; and other similar harms. In particular, since the Company sponsors we sponsor clinical trials, any breach or disruption that compromises patient data and identities could generate significant reputational damage, which may affect trust in the Company us and its our ability to recruit for future clinical trials. Additionally, the loss of clinical trial data from completed or future clinical trials

could result in delays in the Company's our regulatory approval efforts and significantly increase its our costs to recover or reproduce the data.

The Company's Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in its our contracts are sufficient to protect it us from liabilities, damages, or claims related to its our data privacy and security obligations. Furthermore, the Company we cannot be sure that its our insurance coverage will be adequate or sufficient to protect it us from or to mitigate liabilities arising out of its our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

***The Company's Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in its cyber-security. our cybersecurity.***

Despite the implementation of security measures, the Company's our internal computer systems, and those of its our current and future CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Although the Company has we have not suffered any material incidents to date, the risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While the Company has we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in the Company's our operations, it could result in a material disruption of its our development programs and its our business operations. In addition, since the Company sponsors we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in the Company us to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in the Company's our regulatory approval efforts and significantly increase its our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, the Company's our data or applications or inappropriate disclosure of confidential or proprietary information, the Company we could incur liability and the further development and commercialization of its our products and product candidates could be delayed.

## **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

**None.**

## **ITEM 3. DEFAULT UPON SENIOR SECURITIES**

**None.**

## **ITEM 4. MINE SAFETY DISCLOSURE**

**Not Applicable.**

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

Exhibit Number	Description of document
2.1†	<a href="#">Agreement and Plan of Merger, dated as of December 16, 2020, by and among Seneca Biopharma, Inc., Leading BioSciences, Inc. and Townsgate Acquisition Sub 1, Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).</a>
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 27, 2021).</a>
3.2	<a href="#">Certificate of Designation of Series A 4.5% Convertible Preferred Stock (Incorporated by reference to Exhibit 3.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 12, 2016 March 6, 2024).</a>
3.3	<a href="#">Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.3 3.1 to the Registrant's Registration Statement Current Report on Form S-1 Amendment 5, 8-K, filed with the SEC on August 11, 2022 March 6, 2024).</a>
3.4	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).</a>
3.5	<a href="#">Amendment to Amended and Restated Certificate of Incorporation of Palisade Bio, Inc., effective November 15, 2022 (Incorporated by reference to Exhibit 3.01(i) to the Registrant's Current Report on Form 8-K, filed with the SEC on November 16, 2022).</a>

3.6	<a href="#">Amendment to the Amended and Restated Certificate of Incorporation of Palisade Bio, Inc. effective April 5, 2024 (Incorporated by reference to Exhibit 3.01(i) to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).</a>
4.1	Reference is made to Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> and <a href="#">3.3</a> .
4.2	<a href="#">Description of Securities (incorporated by reference to Exhibit 4.2 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).</a>
4.3	<a href="#">Specimen Common Stock Certificate. (Incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 17, 2022).</a>
4.4	<a href="#">Form of Series A Preferred Stock Certificate (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 12, 2016).</a>
4.5	<a href="#">Form of Consulting Warrant issued January 2011 and March 2012 (Incorporated by reference to Exhibit 4.01 to the Registrant's Registration Statement on Form S-3 (File No. 333-188859) original filed with the SEC on May 24, 2013</a>
4.6	<a href="#">Form of Common Stock Purchase Warrant from August 2017 Public Offering Dated August 1, 2017 (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 28, 2017).</a>
4.7	<a href="#">Form of Common Stock Purchase Warrant from October 2018 Offering (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 29, 2018).</a>
4.8	<a href="#">Form of Placement Agent Common Stock Purchase Warrant from October 2018 Offering (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on October 29, 2018).</a>
4.9	<a href="#">Consultant Warrant for Hibiscus BioVentures, LLC issued January 2019 (Incorporated by reference to Exhibit 4.40 to the Registrant's Form 10-Q, originally filed with the SEC on May 14, 2019).</a>
4.10	<a href="#">Form of Series M and Series N warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrant's Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019).</a>
4.11	<a href="#">Letter Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020).</a>

4.12	<a href="#">Form of Series O Pre-Funded Warrant from July 2019 Offering (Incorporated by reference to Exhibit 4.45 to the Registrant's Registration Statement on Form S-1/A (File No. 333-232273), filed with the SEC on July 24, 2019).</a>
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4.13	<a href="#">Form of Series Q Replacement Warrant issued in January 2020 Offering (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)</a>
4.14	<a href="#">Form of Placement Agent Agreement from January 2020 Offering (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)</a>
4.15	<a href="#">Form of Placement Agent Warrant issued in January 2020 Offering (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on January 22, 2020)</a>
4.16	<a href="#">Form of Placement Agent Warrant issued in May 2020 Offering (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on May 27, 2020)</a>
4.17	<a href="#">Form of Securities Purchase Agreement with Investors from May 2020 Offering (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, originally filed with the SEC on May 27, 2020)</a>
4.18	<a href="#">Form of Warrant to Purchase Shares of Common Stock of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.30 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended)</a>
4.19	<a href="#">Form of Bridge Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020)</a>
4.20	<a href="#">Form of Equity Warrant of Leading BioSciences, Inc. (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020)</a>
4.21†	<a href="#">Registration Rights Agreement, by and between Seneca Biopharma, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020)</a>
4.22	<a href="#">Waiver Agreement, dated as of July 21, 2021, by and between Palisade Bio, Inc. and Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 22, 2021)</a>
4.23	<a href="#">Warrant, dated as of July 21, 2021, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 22, 2021)</a>
4.24	<a href="#">Waiver Agreement, dated as of January 31, 2022, by and between Palisade Bio, Inc. and Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2022)</a>
4.25	<a href="#">Warrant, dated as of January 31, 2022, issued to Altium Growth Fund, LP (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2022)</a>

4.26	<a href="#">Securities Purchase Agreement, dated as of August 19, 2021, by and between Palisade Bio, Inc. and Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2021).</a>
4.27	<a href="#">Warrant, dated as of August 19, 2021, issued to Yuma Regional Medical Center (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 24, 2021).</a>
4.28	<a href="#">Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).</a>
4.29	<a href="#">Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).</a>
4.30	<a href="#">Form of Series 1 Common Stock Warrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).</a>
4.31	<a href="#">Form of Series 2 Common Stock Warrant (Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).</a>

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4.32	<a href="#">Warrant Agency Agreement dated August 16, 2022, by and between Palisade Bio, Inc. and American Stock Transfer and Trust Company, LLC. (Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 16, 2022).</a>
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4.33	<a href="#">Form of Series B Preferred Stock Certificate of Registrant (Incorporated by reference to Exhibit 4.33 to the Registrant's Registration Statement on Form S-1/A, filed with the SEC on August 9, 2022)</a>
4.34	<a href="#">Form of Underwriter Warrant issued August 16, 2022 (Incorporated by reference to Exhibit 4.33 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 14, 2022).</a>
4.35	<a href="#">Form of Registered Prefunded Warrant issued in January 2023 Registered Offering (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).</a>
4.36	<a href="#">Form of Prefunded Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).</a>
4.37	<a href="#">Form of Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).</a>

4.38	<a href="#">Form of Placement Agent Warrant issued in January 2023 Private Placement (Incorporated by reference to Exhibit 4.04 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).</a>
4.39	<a href="#">Form of Prefunded Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).</a>
4.40	<a href="#">Form of Warrant issued in April 2023 Private Placement (Incorporated by Reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).</a>
4.41	<a href="#">Form of Placement Agent Warrant issued in April 2023 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on April 5, 2023).</a>
4.42	<a href="#">Form of Placement Agent Warrant issued in September 2023 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on September 11, 2023).</a>
4.43	<a href="#">Form of Replacement Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2024).</a>
4.44	<a href="#">Form of Placement Agent Warrant issued in February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on February 1, 2024).</a>
4.45	<a href="#">Form of Prefunded Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.01 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).</a>
4.46	<a href="#">Form of Common Stock Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).</a>
4.47	<a href="#">Form of Placement Agent Warrant issued in May 2024 Private Placement (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on May 3, 2024).</a>
10.1## +	<a href="#">Seneca Biopharma 2019 Equity Incentive Plan (Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement, originally filed with the SEC on April 29, 2019).</a>
10.2## +	<a href="#">Form of Restricted Option Grant from 2019 Equity Incentive Plan (Incorporated by reference to Exhibit 4.43 to the Registrant's Registration Statement on Form S-1 (File No. 333-232273), originally filed with the SEC on June 21, 2019, originally filed with the SEC on June 21, 2019).</a>
10.3#	<a href="#">License Agreement, by and between Leading BioSciences, Inc. and The Regents of the University of California, dated August 19, 2015, as amended on December 20, 2019 (Incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</a>
10.4#	<a href="#">License Agreement, by and between Leading BioSciences, Inc. and The Regents of the University of California, dated April 1, 2020 (Incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</a>

10.5#	<a href="#"><u>License Agreement, by and between Palisade Bio, Inc. and The Regents of the University of California, dated July 6, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).</u></a>
10.6#	<a href="#"><u>Co-Development and Distribution Agreement, by and between Leading BioSciences, Inc. and Newsoara Biopharma Co., Ltd. (as successor-in-interest to Biolead Medical Technology Limited), dated February 17, 2018, as amended on November 27, 2018 (Incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</u></a>
10.7	<a href="#"><u>Form of Seneca Biopharma, Inc. Support Agreement, dated as of December 16, 2020, by and between Leading BioSciences, Inc. and each of the parties named in each agreement therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).</u></a>
10.8	<a href="#"><u>Form of Leading BioSciences, Inc. Support Agreement, dated as of December 16, 2020, by and between Seneca Biopharma, Inc. and each of the parties named in each agreement therein (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).</u></a>

10.9†	<a href="#"><u>Securities Purchase Agreement, by and between Leading BioSciences, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).</u></a>
10.10†	<a href="#"><u>Securities Purchase Agreement, by and among Seneca Biopharma, Inc., Leading BioSciences, Inc. and the investor party thereto, dated December 16, 2020 (Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 21, 2020).</u></a>
10.11	<a href="#"><u>Amendment Agreement to Securities Purchase Agreement by and among, the Company, Leading BioSciences, Inc. and Altium Growth Fund, LP, dated May 3, 2021 (Incorporated by reference to Exhibit 10.03 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 14, 2021).</u></a>
10.12	<a href="#"><u>Form of Separation Agreement with Seneca Biopharma, Inc. Executives (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 18, 2021).</u></a>
10.13†	<a href="#"><u>Contingent Value Rights Agreement, dated as of April 27, 2021, by and among the Company, American Stock Transfer &amp; Trust Company, LLC and Raul Silvestre (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 27, 2021).</u></a>

10.14+	<a href="#">Form of Indemnification Agreement (incorporated by reference from Exhibit 10.03 to the Registrant's Current Report on Form 8-K filed with the SEC on December 18, 2018).</a>
10.15+	<a href="#">Leading BioSciences, Inc. Amended and Restated 2013 Employee, Director and Consultant Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise of Stock Option thereunder (Incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</a>
10.16+	<a href="#">Palisade Bio, Inc. 2021 Equity Incentive Plan, as amended (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 9, 2023).</a>
10.17+	<a href="#">Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 23, 2021).</a>
10.18+	<a href="#">Form of Non-Employee Director Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Palisade Bio, Inc. 2021 Equity Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 23, 2021).</a>
10.19+	<a href="#">Palisade Bio, Inc. Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on June 9, 2023).</a>
10.20+	<a href="#">Palisade Bio, Inc. 2021 Inducement Incentive Plan, as Amended August 7, 2023 (Incorporated by reference to Exhibit 10.20 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 10, 2023).</a>
10.21+	<a href="#">Form of Restricted Stock Unit Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Inducement Incentive Plan (Incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021).</a>

10.22+	<a href="#">Form of Stock Option Grant Notice and Award Agreement under the Palisade Bio, Inc. 2021 Inducement Incentive Plan (Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-261196), filed with the SEC on November 19, 2021).</a>
10.23+	<a href="#">Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).</a>
10.24+	<a href="#">Amended and Restated Executive Employment Agreement, by and between Leading BioSciences, Inc. and JD Finley, dated January 24, 2021 (Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</a>

10.25+	<a href="#"><u>Executive Employment Agreement, by and between Leading BioSciences, Inc. and Thomas Hallam, Ph.D., dated December 16, 2020 (Incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</u></a>
10.26+	<a href="#"><u>Executive Employment Agreement, by and between Leading BioSciences, Inc. and Michael Dawson, M.D., dated December 16, 2020 (Incorporated by reference to Exhibit 10.21 to the Registrant's</u></a>

	<a href="#"><u>Registration Statement on Form S-4 (File No. 333-251659), originally filed with the SEC on December 23, 2020, as amended).</u></a>
10.27+	<a href="#"><u>Asset Transfer Agreement, by and between Alto Neuroscience, Inc. and Palisade Bio, Inc., dated October 18, 2021 (incorporated by reference to Exhibit 10.27 to the Registrant's Form 10-K, filed with the SEC on March 17, 2022).</u></a>
10.28	<a href="#"><u>Office Lease Between AP Beacon Carlsbad, LP, and Palisade Bio, Inc., dated May 12, 2022 (Incorporate by reference to Exhibit 10.1 to the Registrant's Form 10-Q filed with the SEC on May 13, 2022).</u></a>
10.29	<a href="#"><u>First Amendment dated July 14, 2022 to the Office Lease Between AP Beacon Carlsbad, LP, and Palisade Bio, Inc., dated May 12, 2022 (Incorporated by reference to Exhibit 10.2 to the Registrants Form 10-Q filed with the SEC on August 15, 2022).</u></a>
10.30	<a href="#"><u>Form of Securities Purchase Agreement, dated May 6, 2022, by and among the Company and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 6, 2022).</u></a>
10.31+	<a href="#"><u>Separation Agreement and Release with former Chief Executive Officer (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K filed with the SEC on October 14, 2022).</u></a>
10.32	<a href="#"><u>Form of Securities Purchase Agreement dated December 30, 2022, by and among the Company and the purchasers named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current report on Form 8-K, filed with the SEC on January 4, 2023).</u></a>
10.33	<a href="#"><u>Form of Registration Rights Agreement, dated December 30, 2022, by and among the Company and signatories named therein (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).</u></a>
10.34	<a href="#"><u>Form of Placement Agency Agreement, dated December 30, 2022, by and between the Company and Ladenburg Thalmann &amp; Co Inc. (Incorporated by reference to Exhibit 10.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 4, 2023).</u></a>
10.35+	<a href="#"><u>Form of First Amendment Consulting Agreement dated January 25, 2023 by and between Dr. Herbert Slade and the Company (Incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).</u></a>

10.36+	<a href="#">Form of Consulting Agreement dated April 7, 2023 by and between Dr. Herbert Slade and the Company. (Incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K filed with the SEC on March 22, 2023).</a>
10.37	<a href="#">Form of Securities Purchase Agreement dated April 3, 2023, by and among the Company and the purchasers named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).</a>
10.38	<a href="#">Form of Registration Rights Agreement dated April 3, 2023, by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).</a>

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10.39	<a href="#">Form of Placement Agency Agreement dated April 3, 2023, by and among the Company and Ladenburg Thalmann &amp; Co Inc. (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2023).</a>
10.40#***	<a href="#">Form of Research, Collaboration, and License Agreement with Giiant Pharma (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 8, 2023).</a>
10.41	<a href="#">Form of Securities Purchase Agreement dated September 7, 2023, by and among the Company and the signatories named therein (Incorporated by Reference to Exhibit 10.01 to the Registrant's Current report on Form 8-K, filed with the SEC on September 11, 2023).</a>
10.42	<a href="#">Form of Placement Agency Agreement dated September 7, 2023, by and among the Company and Ladenburg Thalmann &amp; Co Inc. (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 11, 2023).</a>
10.43	<a href="#">Form of Employment Agreement with Mitchell Jones, dated September 5, 2023 (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 11, 2023).</a>

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19.1 10.44	<a href="#">Registrant's Insider Trading Policy</a> <a href="#">Form of Warrant Inducement Agreement entered into pursuant to February 2024 Warrant Inducement Transaction (Incorporated by reference to Exhibit 19.1 10.01 to the Registrant's Annual Current Report on Form 10-K 8-K, filed with the SEC on March 22, 2023 February 1, 2024).</a>
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10.45	<a href="#">Form of Securities Purchase Agreement entered into pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).</a>
10.46	<a href="#">Form of Registration Right Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.02 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).</a>
10.47	<a href="#">Form of Placement Agency Agreement entered into Pursuant to the May 2024 Private Placement (Incorporated by reference to Exhibit 10.03 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 3, 2024).</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.</a>
31.2*	<a href="#">Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.</a>
32.1**	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.</a>
101.INS*	Inline XBRL Instance Document-the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101).

\* Filed herewith

\*\* Furnished herewith.

+ Indicates management contract or compensatory plan.

# Certain portions of this exhibit (indicated by "[\*\*\*]") have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

† Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

## SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the Registrant has caused this report to be signed by the undersigned hereunto duly authorized.

### PALISADE BIO, INC.

Date: November 9, 2023 May 13, 2024

/s/ J.D. Finley

J.D. Finley, Chief Executive Officer and Chief  
Financial Officer

*(Principal Executive Officer and Principal Financial  
Officer)*

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Exhibit 31.1

## SECTION 302

### CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER

I, J.D. Finley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Palisade Bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material 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 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 being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023 May 13, 2024

By: /s/ J.D. Finley

J.D. Finley

Chief Executive Officer

*Principal Executive Officer*

**SECTION 302**  
**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER**

I, J.D. Finley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Palisade Bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023 May 13, 2024

By: /s/ J.D. Finley

J.D. Finley

Chief Financial Officer

Principal Financial Officer

Exhibit 32.1

## CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), J.D. Finley, Chief Financial Officer and Chief Executive Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023 March 31, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2023 May 13, 2024

IN WITNESS WHEREOF, the undersigned has set their hand hereto as of the date indicated above.

/s/ J.D. Finley

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J.D. Finley

Chief Executive Officer and

Chief Financial Officer

*(Principal Executive Officer and Principal Financial  
Officer)*

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*This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing."*

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## DISCLAIMER

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