UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2025

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

PALISADE BIO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2007292**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7750 El Camino Real, Suite 2A Carlsbad, California	**92009**
(Address of principal executive offices)	**(Zip Code)**

(858) 704-4900

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of May 8, 2025, there were 4,795,646 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)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,230	$ 9,821
Prepaid expenses and other current assets	657	673
Total current assets	7,887	10,494
Restricted cash	26	26
Property and equipment, net	2	3
Operating lease right-of-use asset	53	84
Other noncurrent assets	222	273
Total assets	$ 8,190	$ 10,880
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 745	$ 1,105
Accrued liabilities	1,856	1,240
Accrued compensation and benefits	118	722
Current portion of operating lease liability	58	90
Insurance financing debt	—	79
Total current liabilities	2,777	3,236
Warrant liability	2	2
Contingent consideration obligation	80	150
Total liabilities	2,859	3,388
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Series A Convertible Preferred Stock, $0.01 par value, 7,000,000 shares authorized; 200,000 issued and outstanding at March 31, 2025 and December 31, 2024	2	2
Common stock, $0.01 par value; 280,000,000 shares authorized; 4,396,646 and 2,768,646 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	43	27
Additional paid-in capital	143,460	143,407
Accumulated deficit	(138,174)	(135,944)
Total stockholders' equity	5,331	7,492
Total liabilities and stockholders' equity	$ 8,190	$ 10,880

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 March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 950	$ 2,214
General and administrative	1,360	1,459
Total operating expenses	2,310	3,673
Loss from operations	(2,310)	(3,673)
Other (expense) income:		
Interest expense	(1)	(1)
Other income, net	81	147
Total other income, net	80	146
Net loss	$ (2,230)	$ (3,527)
Net loss available to common stockholders	$ (2,230)	$ (3,527)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share	4,795,646	768,137
Basic and diluted net loss per common share	$ (0.47)	$ (4.59)

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

Palisade Bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Three Months Ended March 31, 2025						
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, December 31, 2024	200,000	$ 2	2,768,646	$ 27	$ 143,407	$ (135,944)	$ 7,492
Net loss	—	—	—	—	—	(2,230)	(2,230)
Stock-based compensation expense and related charges	—	—	—	—	69	—	69
Issuance of common stock in connection with exercise of warrants	—	—	1,628,000	16	(16)	—	—
Balance, March 31, 2025	200,000	$ 2	4,396,646	$ 43	$ 143,460	$ (138,174)	$ 5,331

	Three Months Ended March 31, 2024						
	Preferred Stock		Common Stock		Additional Paid-in Capital*	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares*	Amount*			
Balance, December 31, 2023	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, net of employee withholding tax liability	—	—	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)	—	—	—	—
Balance, March 31, 2024	200,000	$ 2	851,302	$ 8	$ 135,087	$ (125,033)	$ 10,064

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

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)

	Three Months Ended March 31,	
	2025	**2024**
Net loss	$ (2,230)	$ (3,527)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1	1
Non-cash operating lease expense	31	28
Recurring fair value measurements of liabilities	(1)	—
Loss on disposal of property and equipment	—	4
Stock-based compensation and related charges	69	118
Changes in operating assets and liabilities:		
Prepaid and other current assets and other noncurrent assets	67	174
Accounts payable and accrued liabilities	366	615
Accrued compensation and benefits	(604)	(565)
Operating lease liabilities	(32)	(28)
Net cash used in operating activities	(2,333)	(3,180)
Cash flows from financing activities:		
Payments on insurance financing debt	(80)	(158)
Proceeds from the exercise of warrants	—	2,503
Payment of warrant inducement issuance costs	—	(321)
Payment of equity issuance costs	(178)	—
Net cash (used in) provided by financing activities	(258)	2,024
Net decrease in cash, cash equivalents and restricted cash	(2,591)	(1,156)
Cash, cash equivalents and restricted cash, beginning of year	9,847	12,458
Cash, cash equivalents and restricted cash, end of period	$ 7,256	$ 11,302
Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:		
Cash and cash equivalents	$ 7,230	$ 11,276
Restricted cash	26	26
Total cash, cash equivalents and restricted cash	$ 7,256	$ 11,302
Supplemental disclosures of cash flow information:		
Interest paid	$ 1	$ 2
Supplemental disclosures of non-cash investing and financing activities:		
Warrant inducement and equity issuance costs included in accounts payable and accrued liabilities	$ —	$ 22
Fair value of warrants issued to solicitation agent	—	94
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)

1. Organization, Business and Financial Condition

As used in this Quarterly Report on Form 10-Q, unless the context indicates or otherwise requires, "Palisade," "Palisade Bio," the "Company," "we," "us," and "our" or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to "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" refers to the Company's operations prior to the completion of its merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any reference herein that refers to preclinical studies also refers to nonclinical studies.

Description of Business

The Company is a clinical-stage biopharmaceutical company focused on developing and advancing novel therapeutics for patients living with autoimmune, inflammatory, and fibrotic diseases. The Company's lead product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease, or IBD, including fibrostenotic Crohn's disease and ulcerative colitis.

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 net losses and negative cash flows from operations since its inception. As of March 31, 2025, the Company had an accumulated deficit of $138.2 million and cash and cash equivalents of approximately $7.2 million. The Company expects to continue to incur losses in the foreseeable future. The successful transition to achieving profitability is dependent upon achieving a level of revenues adequate to support the Company's 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 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 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 5, Stockholders' Equity, 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 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 occurrences could materially harm the Company's business, results of operations and future prospects.

2. Basis of Presentation and 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 ("U.S. GAAP") have been condensed or omitted pursuant to instructions, rules and regulations prescribed by the United States ("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 consolidated financial statements and notes included in the Company's financial statements filed in the Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 24, 2025.

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, 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 April 5, 2024, the Company effected a 1-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 stockholders received one share of common stock for every 15 shares such 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 were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split also affected the Company's outstanding 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-based awards 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 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 accrued research and development expenses and its contingent consideration 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.

Significant Accounting Policies

The Company's significant accounting policies used in the preparation of these condensed consolidated financial statements for the three months ended March 31, 2025 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 24, 2025.

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 Issued or Adopted Accounting Pronouncements

No new accounting pronouncements issued or adopted during the three months ended March 31, 2025 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 consists of the following (in thousands):

	March 31, 2025	December 31, 2024
Prepaid insurance	$ 279	$ 384
Other receivables	78	24
Prepaid subscriptions and fees	175	116
Prepaid software licenses	33	57
Deposits	12	12
Deferred equity issuance costs	75	75
Prepaid other	5	5
	$ 657	$ 673

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. 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 months ended March 31, 2024, the Company netted previously deferred equity issuance costs of approximately $37,000 against the additional paid-in capital recognized in conjunction with the warrant inducement transaction that closed on February 1, 2024 (see Note 5, Stockholders' Equity). There were no previously deferred equity issuance costs netted against additional paid-in capital during the three months ended March 31, 2025.

Accrued liabilities consists of the following (in thousands):

	March 31, 2025	December 31, 2024
Accrued accounts payable	$ 197	$ 109
Accrued clinical trial expenses	542	—
Accrued chemistry, manufacturing and controls ("CMC") expenses	626	606
Accrued director stipends	59	59
Accrued joint development expenses (Note 7)	138	223
Current portion of contingent consideration obligation (Note 4)	69	—
Accrued other	225	243
	$ 1,856	$ 1,240

4. Fair Value Measurements

The Company’s financial instruments consist principally of cash and cash equivalents, restricted cash, other current receivables, accounts payable, accrued liabilities, insurance financing debt, and a contingent consideration obligation. The carrying amounts of financial instruments such as restricted cash, other current receivables, accounts payable, and accrued liabilities approximate their relative fair values due to the short-term nature of these instruments. The carrying value of the Company’s insurance financing debt approximates its fair value as of December 31, 2024 due to the market rate of interest, which is based on level 2 inputs. The Company’s contingent consideration obligation is carried at fair value based on level 3 inputs. None of the Company’s non-financial assets or liabilities are recorded at fair value on a nonrecurring basis.

Cash and Cash Equivalents

The Company invests its excess cash in money market funds that are classified as level 1 in the fair value hierarchy, due to their short-term maturity of three months or less, and measured the fair value based on quoted prices in active markets for identical assets. The fair value of the Company's cash and cash equivalents invested in money market funds was $7.2 million and $9.8 million as of March 31, 2025 and December 31, 2024, respectively.

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 and historically the Company has not experienced any losses in such accounts.

Contingent Consideration Obligation

On September 1, 2023, the Company and Giiant Pharma, Inc. ("Giiant") entered into a research collaboration and license agreement ("Giiant License Agreement")(See Note 7, Collaborations and License Agreements). Pursuant to the Giiant License Agreement, the Company incurred a contingent consideration obligation related to future milestone payments. The Company has an obligation to make contingent consideration payments to Giiant, in either cash or shares of the Company's common stock solely at the Company's election, upon the achievement of development milestones (as set forth in the Giiant License 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 Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and accordingly has recognized it as a liability measured at its estimated fair value. On August 2, 2024, the Company and Giiant entered into an amendment to the Giiant License Agreement, which among other things, reduced the milestone payments due to Giiant upon the achievement certain development milestones (see Note 7, Collaborations and License Agreements, for further details).

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 hierarchy. The significant assumptions used in the calculation of the fair value as of March 31, 2025 included a discount rate of 11.3% and management's updated projections of the likelihood of success in achieving each of the defined milestones based on empirical, published industry data.

The following table summarizes the activity of the Company's Level 3 contingent consideration obligation, which is fair valued on a recurring basis (in thousands):

	Three Months Ended March 31,	
Contingent Consideration Obligation	**2025**	**2024**
Fair value at beginning of period	$ 150	$ 204
Change in fair value during the period	(1)	—
Fair value at end of period	$ 149	$ 204

As of March 31, 2025, approximately $69,000 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 and remaining amount of the contingent consideration liability of approximately $80,000 was recognized as a noncurrent liability. As of December 31, 2024, the entire amount of the contingent consideration obligation of approximately $150,000 was classified as a noncurrent liability in the condensed consolidated balance sheet as none of it was expected to be settled within one-year of the balance sheet date.

5. Stockholders' Equity

Classes of Stock

Common Stock

As of March 31, 2025, 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 a 1-for-15 reverse stock split of its issued and outstanding common stock (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 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 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 fractional shares was immaterial to the Company's financial statements.

As a result of the Reverse Stock Split, on April 5, 2024 the number of issued and outstanding shares of the Company's common stock was adjusted from 12,771,015 shares to 851,302 shares.

Preferred Stock

As of March 31, 2025, 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"), of which 200,000 are issued and outstanding and are convertible into an aggregate of 8 shares of the Company's common stock.

Recent Equity Offerings

December 2024 Offering

On December 13, 2024, the Company completed a underwritten offering of common stock, pre-funded warrants to purchase common stock, and common warrants to purchase common stock (the "December 2024 Offering"). Gross cash proceeds from the December 2024 Offering were $5.0 million and net cash proceeds were approximately $4.1 million after deducting cash equity issuance costs of approximately $0.9 million.

May 2024 Offering

On May 6, 2024, the Company completed a private placement of common stock, pre-funded warrants to purchase common stock, and warrants to purchase common stock (the "May 2024 Offering"). Gross cash proceeds from the May 2024 Offering were $4.0 million and net cash proceeds were approximately $3.5 million after deducting cash equity issuance costs of approximately $0.5 million.

Common Stock Warrants and Warrant Exercises

February 2024 Warrant Inducement

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 Warrant(s)"). Pursuant to the Warrant Inducement Agreements, the exercise price of each of the 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 one share of the Company's

common stock (the “Replacement Warrants”) for each Existing Warrant exercised (in its entirety, the "February 2024 Warrant Inducement").

The Replacement Warrants are exercisable immediately, have an exercise price per share of $10.97, and expire five years from the date of issuance, which was February 1, 2024.

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 and 228,162 Replacement Warrants. 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 the Existing Warrants and the issuance of the Replacement Warrants, is considered a modification of the Existing Warrants under the guidance of ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* ("ASC 815"). The modification is consistent with the Equity Issuance classification under that guidance as the reason for the modification was to induce the holders of the Existing Warrants to cash exercise their Existing Warrants, resulting in the imminent exercise of the 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 as the 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 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.

Common Stock Warrants Outstanding and Warrant Activity

The Company accounts for the 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 5,116,538 and 6,745,213 at March 31, 2025 and December 31, 2024, respectively.

The following table summarizes the Company's outstanding and exercisable common stock warrants as of March 31, 2025:

Common Stock Warrants	Classification	Number of Warrants Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
December 2024 Offering Pre-Funded Common Stock Warrants	Equity-classified	399,000	$ 0.0001	Perpetual
December 2024 Offering Common Stock Warrants	Equity-classified	3,278,688	1.40	4.70
May 2024 Offering Common Stock Warrants	Equity-classified	922,863	1.40	6.10
February 2024 Warrant Inducement Replacement Common Stock Warrants	Equity-classified	228,158	6.17	3.84
August 2022 Offering Series 2 Common Stock Warrants	Equity-classified	6,748	1.40	2.37
Bridge, January 2021, and July 2021 Common Stock Warrants	Liability-Classified	5,612	1,306.14	1.89
Placement Agent, Solicitor and Representative Common Stock Warrants	Equity-classified	274,693	10.98	4.41
All Other Common Stock Warrants	Equity-classified	776	11,614.97	2.20
Total Warrants Outstanding, March 31, 2025		5,116,538	5.20	4.91 (1)

(1) The pre-funded common stock warrants outstanding as of March 31, 2025 have a perpetual term and are therefore excluded from the calculation of the weighted-average remaining contractual life.

Of the outstanding common stock warrants, only the Series 2 Warrants include a down round feature whereby they are subject to price reset provisions in the event future sales of the Company's securities are sold at a price per share less than the exercise price of such warrants.

The following table summarizes warrant activity during the three months ended March 31, 2025:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2024	6,745,213	$ 4.53	5.16 (1)
Granted	—	—	—
Exercised	(1,628,000)	0.0001	—
Forfeited, expired or cancelled	(675)	5,863.33	—
Warrants outstanding, March 31, 2025	5,116,538	5.20	4.91 (1)

(1) The pre-funded common stock warrants outstanding as of the three months ended March 31, 2025 have a perpetual term and are therefore excluded from the calculation of the weighted-average remaining contractual life.

6. Equity Incentive Plans

Equity Incentive Plans

The Company’s stock-based compensation generally includes service-based restricted stock units (“RSUs”), stock options, and market-based performance RSUs (“PSUs”).

During the three months ended March 31, 2025, the Company granted 108,600 stock options at a weighted-average grant date fair value of $1.02 per stock option, and the Company granted 89,400 RSUs at a weighted-average grant date fair value of $1.13 per RSU. There were no stock options, RSUs, or other equity-based awards issued under any of the Company's equity incentive plans during the three months ended March 31, 2024.

Employee Stock Purchase Plan

The Company offers its employees an opportunity to participate in its shareholder approved Palisade Bio, Inc. 2021 Employee Stock Purchase Plan (the "ESPP"). 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 in a calendar year, or 5,000 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.

Compensation expense associated with the ESPP in the three months ended March 31, 2025 and the three months ended March 31, 2024 was approximately $12,000 and $5,000, respectively.

Share-Based Compensation Expense

The allocation of stock-based compensation for all stock option, RSU and PSU awards is as follows (in thousands):

	Three Months Ended March 31,	
	2025	2024
Research and development expense	$ 23	$ 47
General and administrative expense	34	66
Total	$ 57	$ 113

As of March 31, 2025, the unrecognized compensation cost related to outstanding stock options was approximately $0.3 million, which is expected to be recognized over a weighted-average period of approximately 1.91 years and the unrecognized compensation cost related to outstanding RSUs and PSUs was approximately $0.1 million, which is expected to be recognized over a weighted-average period of approximately 2.76 years.

7. Collaborations and License Agreements

Research Collaboration and License Agreement with Giiant

On September 1, 2023, the Company entered into the Giiant License Agreement whereby the Company 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 compound, and (ii) the PALI-1908 compound and the associated intellectual property around each of the foregoing (the “Giiant Licensed Assets”). The Giiant License Agreement has a perpetual term.

Pursuant to the Giiant License Agreement, the Company and Giiant established a joint development committee (“JDC”), consisting of one Giiant appointee and two Company appointees. The JDC 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 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 was 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 reimbursed or advanced Giiant up to an amount in the low seven-digit range for costs and expenses incurred by them. Upon reaching the Proof of Concept, which occurred in October of 2024, the Company became solely responsible for all costs and expenses incurred for the development, manufacturing, regulatory and commercialization of the Giiant Licensed Assets. The Company records expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection, pursuant to the terms of the Giiant License.

Expense payments made by the Company to Giiant pursuant to the terms of the Giiant License Agreement for qualifying development costs under the joint development plan are expensed only as the associated research and development costs are incurred or other aspects of the drug development or related activities are achieved. For the three months ended March 31, 2025, the Company recognized no expenses related to the joint development plan. For the three months ended March 31, 2024, the Company recognized expenses of approximately $1.6 million related to the joint development plan. In instances where the expense determined to be recognized exceeds the payments made

to the Giiant, the Company recognizes an accrual of joint development expenses. As of March 31, 2025 and December 31, 2024, the Company accrued joint development expenses of approximately $0.1 million and $0.2 million, respectively, in Accrued liabilities in the condensed consolidated balance sheets.

The Company records expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when Company receives the cash or has an undisputed claim to the cash that is probable of collection, pursuant to the terms of the Giiant License Agreement and the principles of ASC 450, *Gain Contingencies*. For the three months ended March 31, 2025, the Company recognized a reduction in net research and development expenses of approximately $0.7 million, which consisted primarily of funds received by the Company from Giiant pursuant to the joint development plan. There were no expense payments from Giiant recognized for the three months ended March 31, 2024. Both the expenses recognized and any reduction in expenses recognized are included in research and development expenses in the condensed consolidated statements of operations.

Pursuant to the Giiant License Agreement, as amended (see below) the Company will (i) make certain payments between the low 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 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"). 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*. The Company has made no Giiant License Payments since the commencement of the Giiant License Agreement.

On August 2, 2024, the Company and Giiant entered into an amendment to the Giiant License Agreement (the "Giiant License Agreement Amendment"). Pursuant to the Giiant License Agreement Amendment, the Company agreed to increase the amount it would reimburse or advance to Giiant prior to Proof of Concept under the Giiant Development Plan by an amount in the mid six-digit range. After taking into account such increase, the amount that Company will reimburse or advance Giiant for costs and expenses incurred by them will remain in the low seven-digit range. As consideration for the increase, Giiant agreed to (i) a reduction in the Giiant Milestone Payments that would be due to them upon the achievement certain development milestones, and (ii) a decrease to the Payment Cap applied to future Giiant License Payments, as set forth in the original Giiant License Agreement. The amount of the reduction in the Giiant Milestone Payment as a result of the Giiant License Agreement Amendment is in the high six-digit range and the decrease in the Payment Cap is in the mid-six digit range. There were no other changes to the terms of the original Giiant License Agreement as a result of the Giiant License Agreement Amendment that would have a material impact on the Company's results of operations, financial position or future cash flows.

The Company may unilaterally terminate the Giiant License Agreement for: (i) convenience, or (ii) a material breach by Giiant, that is not cured within the applicable notice period.

Giiant may unilaterally terminate the Giiant License Agreement only for a material breach by Company that is not cured within the applicable notice period provided however that upon the Payment Cap being achieved, that right will terminate and the Giiant License Agreement will become perpetual.

Co-Development and Distribution Agreement with Newsoara

LBS 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 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. The Company records the expense reimbursements from Newsoara for any research and development or manufacturing activities it performs under the Newsoara Co-Development Agreement as a reduction to research and development expenses once the reimbursement amount is approved for payment by Newsoara.

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 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 three months ended March 31, 2025 and 2024, the Company recognized no license revenue from Newsoara under the Newsoara Co-Development Agreement.

The Newsoara Co-Development Agreement will expire upon 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 related to LB1148. 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, 2025, the only license agreement remaining with Regents is that entered into with LBS in August of 2015, as amended in December of 2019 and September of 2022 (the "2015 UC License"). The 2015 UC License was retained for the 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 ranging from 30 percent to 35 percent of one-third of the upfront payment and milestone payments received from Newsoara. During both the three months ended March 31, 2025 and 2024, the Company recognized no sublicense fees or license maintenance fees due to Regents.

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 entitlement to receive CVR Payment Amounts expired on April 27, 2025, or 48-months following the closing of the Merger. There were no CVR Payments made to any of the CVR Holders pursuant to the CVR Agreement.

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 ATA, 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.

On October 22, 2024, Alto announced that its Phase 2b study of ALTO-100 in patients with major depressive disorder (MDD) did not meet its primary endpoint. Notwithstanding, ALTO-100 is being evaluated as an adjunctive treatment in a Phase 2b study in bipolar depression with topline data expected in 2026. Upon the enrollment of a patient in a Phase 3 clinical trial of ALTO-100, if it occurs, a milestone payment of $1.5 million will be due to the Company from Alto under the ATA.

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 preclinical 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.

8. Net Loss Per Share

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.

Pursuant to the December 2024 Offering the Company issued 3,120,688 pre-funded warrants with such pre-funded warrants being immediately exercisable, having an exercise price of $0.0001 per share, and a perpetual term. The pre-funded warrants were determined to be equity-classified in accordance with ASC 480 and ASC 815. As of March 31, 2025, 399,000 of these pre-funded warrants remained unexercised. Pursuant to the guidance of ASC 260-10, the Company concluded that because the equity-classified pre-funded warrants were immediately exercisable for little or

no cash consideration due to the non-substantive stated exercise price, all the necessary conditions for issuance of the underlying common shares had been met when the pre-funded warrants were issued. Therefore, the underlying common shares outstanding as of March 31, 2025, have been included in the denominator for both the calculation of basic and dilutive net loss per common share for the three months ended March 31, 2025.

As the Company was in a net loss position for all periods presented, basic and diluted net loss per common share for the three months ended March 31, 2025 and March 31, 2024 were calculated under the if-converted and treasury stock methods. For both the three months ended March 31, 2025 and March 31, 2024, basic and diluted net loss per common share were the same as all common stock equivalents other than the pre-funded warrants discussed above were anti-dilutive for both periods.

The following table presents the calculation of basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2025	2024
Basic and diluted net loss per common share:		
Net loss available to common stockholders - basic and diluted	$ (2,230)	$ (3,527)
Weighted average shares used in calculating basic and diluted net loss per common share	4,795,646	768,137
Basic and diluted net loss per common share	$ (0.47)	$ (4.59)

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

	March 31,	
	2025	2024
Stock options	159,274	41,937
Restricted stock units	92,352	20,833
Warrants for common stock	4,717,538	285,891
Series A Convertible Preferred Stock	8	8
Total	4,969,172	348,669

9. Commitments and Contingencies

Corporate Office Lease

The Company is party to non-cancelable facility operating lease (the "Corporate Office Lease") of office space for its corporate headquarters 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 will not exercise this renewal option.

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 was 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.

As of March 31, 2025, the Company recognized an operating right-of-use asset related to the Corporate Office Lease in the amount of $53,000, which is included in Operating lease right-of-use asset in the condensed consolidated balance sheets, and an operating lease liability in the amount of $58,000, all of which is classified in Current portion of operating lease liability in the condensed consolidated balance sheets. As of March 31, 2025, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately $59,000, including imputed interest of $1,000 calculated using a discount rate of 10.75%, will be paid in 2025 over the remaining lease term of approximately 0.4 years.

The Company recognized operating lease expense associated with its Corporate Office Lease of approximately $32,000 in both the three months ended March 31, 2025 and March 31, 2024.

Insurance Financing Arrangements

In June of 2024, the Company entered an agreement to finance insurance policies that renewed in May of 2024. The financing arrangement entered in June of 2024 has a stated annual interest rate of 8.42% and is payable over a 9-month period with the first payment payable on June 30, 2024. The insurance financing arrangement is secured by the associated insurance policy. As of March 31, 2025 and December 31, 2024, the aggregate remaining balance under the Company's insurance financing arrangements in place at each time was zero and approximately $0.1 million, respectively.

Restructuring Costs

In order to better utilize the Company's resources on the implementation of its refocused business plans and corporate strategy, the Company committed to a reduction-in-workforce on October 27, 2023 (the "2023 RIF"). 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.

The Company recognized no restructuring expenses related to the 2023 RIF for the three months ended March 31, 2025 and March 31, 2024. Total expenses related to the 2023 RIF through March 31, 2025 were approximately $0.2 million. The 2023 RIF was completed in the second quarter of 2024. Accordingly, the Company accrued no restructuring liabilities as of either March 31, 2025 or December 31, 2024.

The 2023 RIF was completed in the second quarter of 2024. Accordingly, the Company accrued no restructuring liabilities as of either March 31, 2025 or December 31, 2024. The following table summarizes the change in the Company's accrued restructuring liabilities under the 2023 RIF for the three months ended March 31, 2024, which consisted solely of employee compensation and benefits and is classified within accrued liabilities in the condensed consolidated balance sheets (in thousands):

Balance as of the beginning of period	$	131
Cash paid		(96)
Balance as of the end of period	$	35

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 March 31, 2025, 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.

10. Segment Information

The Company operates as one operating and reportable segment, focused on the research and development of novel therapeutics for patients, including the advancement of PALI-2108 through clinical trials. The Company did not aggregate multiple operating segments into its one operating segment. The Company's chief operating decision maker ("CODM") is its chief executive officer.

The Company's CODM uses Net loss that is reported on the condensed consolidated statements of operations and comprehensive loss for the purposes of assessing performance, allocating resources and planning, monitoring budget versus actual results, and forecasting future periods. The Company's CODM views specific program spend within research and development expenses, research and development spend that is not allocated to specific programs, as well as general and administrative expenses as significant segment expenses. As a pre-product revenue company, the CODM considers budget versus actual results for expenses that are deemed significant and cash forecast models for assessing performance and to decide the level of investment in the Company's operating and capital allocation activities.

In addition to significant expense categories included in Net loss, the Company regularly provides disaggregated significant expense amounts that comprise operating expenses to the CODM to assist when managing the Company's single reporting segment. A reconciliation to consolidated operating expenses as our single segment operating loss for three months ended March 31, 2025 and 2024 is included in the table below (in thousands):

	Three Months Ended March 31,	
	2025	2024
PALI-2108 program expenses	$ 568	$ 1,646
Legacy program (expense reimbursements) expenses	(58)	64
Other research and development expenses	453	587
Other general and administrative expenses	1,347	1,376
Total operating expenses	$ 2,310	$ 3,673

PALI-2108 program expenses are those expenses directly related with the development of the Company's only asset currently under development, PALI-2108. Legacy program expenses are those expenses directly related to its legacy assets, primarily LB1148, which the Company ceased developing in August of 2023. Other research and development expenses includes primarily employee-related expenses and research and development facility expenses, which are not allocated to specific programs, and non-cash losses associated with changes in the fair value of the Company's contingent consideration obligation. Other general and administrative expenses consist primarily of salary and employee-related costs and benefits, professional fees for legal, investor and public relations, accounting and audit services, insurance costs, director and committee fees, and general corporate expenses. Excluded from other general and administrative expenses are intellectual property expenses and business development expenses that are allocated to program expenses.

For the three months ended March 31, 2025 and 2024, the other segment items that the Company used to aggregate Total operating expenses to arrive at Net Loss as shown on the condensed consolidated statement of operations include, if applicable, License Revenue, Interest expense and Other income, net.

The Company does not provide separate segment asset information to the CODM because the CODM does not review segment assets at a different asset level or category than those shown on the consolidated balance sheets. All of the Company’s assets are located in the U.S.

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 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 on Form 10-Q entitled "Risk Factors" and elsewhere herein. 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.

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," "we," "us," and "our" or similar designations in this report refer to Palisade Bio, Inc., a Delaware Corporation, and its subsidiaries. Any reference to "common shares" or "common stock," refers to our $0.01 par value common stock. Any reference to "Series A Preferred Stock" refers to our Series A 4.5% Convertible Preferred Stock. Any reference to "Leading Biosciences, Inc." or "LBS" refers to our operations prior to the completion of our merger with Seneca Biopharma, Inc. ("Seneca") on April 27, 2021 (the "Merger"). Any technology that we currently own or may acquire the rights to in the future is referred to by us as either a "product candidate" or "product candidates". Additionally, any reference herein that refers to preclinical studies also refers to nonclinical studies.

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 our results of operations, financial condition and cash flows. The MD&A is organized as follows:

- *Executive Overview* — Discussion of our business and overall analysis of financial and other items affecting our Company in order to provide context for the remainder of MD&A.
- *Results of Operations* — Analysis of our financial results comparing the three months ended March 31, 2025 and 2024.
- *Liquidity and Capital Resources* — An analysis of cash flows and discussion of our financial condition and future liquidity needs.

Executive Overview

We are a clinical-stage biopharmaceutical company focused on developing and advancing novel therapeutics for patients living with autoimmune, inflammatory, and fibrotic diseases. Our lead product candidate, PALI-2108, is being developed as a treatment for patients living with inflammatory bowel disease ("IBD"), including fibrostenotic Crohn's disease ("FSCD") and ulcerative colitis ("UC").

Our Precision Medicine Approach

We are developing a biomarker-based patient selection approach that we believe may aid clinicians in identifying patients who may better respond to PALI-2108, thereby improving the rate of clinical response previously demonstrated with enzyme phosphodiesterase-4 ("PDE4") inhibitors. Our approach involves the use of clinical and multiomics data from large patient populations to identify PDE4-related biomarkers that are correlated with IBD, its severity, and which are modified with local PDE4-inhibitor therapy in the colon. Based on our research, we have initiated the development of corresponding biomarker assays for these PDE4-related biomarkers that we expect to use in our current and future clinical studies with the aim of developing regulatory approved tests for selecting potential responders to PALI-2108.

PALI-2108

Our lead product candidate, PALI-2108, is a prodrug inhibitor designed to help treat UC and FSCD by targeting the key PDE4 in colon tissues and preventing it from breaking down cyclic Adenosine Monophosphate ("cAMP") molecules that regulate inflammation in the body. By inhibiting PDE4, intracellular cAMP molecule levels become elevated, which may lead to a reduction of inflammatory molecules and an increase of anti-inflammatory molecules within tissues of the colon. Additionally, we believe that PALI-2108 may help prevent the movement of inflammatory cells from the blood into colon tissues, thereby lowering the activity of certain proteins that contribute to fibrosis (a type of tissue scarring).

With a glucuronic-derived sugar moiety, PALI-2108 remains minimally absorbed until activated by the colonic bacterium enzyme β-glucuronidase. We believe that localized bioactivation may help focus the effects of PALI-2108 where it would be most beneficial to a patient suffering from IBD.

Phase 1 Clinical Study of PALI-2108

The Phase 1 clinical study of PALI-2108 is a single-center, randomized, double-blinded, placebo-controlled clinical study focused on safety, tolerability, and pharmacokinetics ("PK") in both healthy volunteers and UC patients. The clinical study includes an open-label UC patient cohort with multiple dosing arms in which we will evaluate the pharmacodynamics of PALI-2108 in healthy volunteers. We plan to complete enrollment of approximately 90 subjects across several arms of this Phase 1 clinical study including, (i) at five subject cohorts receiving a Single Ascending Dose ("SAD") with a crossover to evaluate food effects ("FE"), (ii) three or more subject cohorts receiving a Multiple Ascending Dose ("MAD"), and (iii) at least one multiple dose in a UC patient cohort. The primary objective of the study is to assess the safety and tolerability of single (healthy subjects) and repeated (healthy subjects and UC patients) oral doses of PALI-2108. Secondary objectives include determining plasma, urine, colon tissue, and fecal (MAD healthy subjects and UC patients only) PK, as well as the FE of PALI-2108 and its metabolites following a single oral dose in healthy subjects and repeated oral doses in both healthy subjects and UC patients. We anticipate announcing topline data from this study during the second quarter of 2025. If the trial meets its primary objectives, we plan to initiate a Phase 1b/2a clinical study in UC patients and FSCD patients in the first quarter of 2026.

Phase 1 Clinical Study of PALI-2108 in Canada

On October 9, 2024, Health Canada issued a No Objection Letter for our Phase 1 human clinical study of PALI-2108 for the treatment of UC. We officially began studying on November 7, 2024. To date, we have dosed all five SAD cohorts, all four MAD cohorts, and the FE crossover. Each of the SAD and MAD cohorts consisted of eight subjects, with six subjects receiving the drug and two subjects receiving a placebo. The FE study included two cohorts each of six subjects, of which one cohort was in a fasted state and the other cohort in a fed state. Finally, we have initiated the dosing of a cohort of UC patients, of which four patients have completed the study to date.

Planned Clinical Trial in the United States

In addition to conducting clinical studies in Canada, we anticipate submitting an Investigational New Drug Application ("IND") with the United States Food and Drug Administration ("FDA") during 2025. If our IND is approved, we anticipate commencing clinical trials of PALI-2108 in the U.S. during the first quarter of 2026.

RESULTS OF OPERATIONS

Research and Development Expenses

Our research and development costs include:

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

Through the majority of 2024, the nature of our research and development expenses incurred related primarily to the preclinical activities associated with our joint development of PALI-2108 with our collaboration partner, Giiant Pharma Inc. ("Giiant"). With the approval to commence the Phase 1 clinical trial of PALI-2108, which we received from Health Canada on October 9, 2024, pursuant to terms of the research and collaboration agreement that we have with Giiant ("Giiant License Agreement"), we have assumed all development, manufacturing, regulatory and commercialization activities and costs of PALI-2108. Therefore, we expect our clinical research and development costs directly attributable to the clinical trials of PALI-2108 to continue to increase through 2025 as compared to the prior year periods, offset by a decrease in joint development costs associated with the Giiant License Agreement.

Our 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, CROs, clinical sites, contract manufacturing organizations (“CMOs”) and research laboratories in connection with our preclinical development, process development, manufacturing, clinical development, and regulatory activities. We do not allocate employee costs and costs associated with our 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. As needed, we manage third parties that are engaged to conduct our (i) research activities, (ii) preclinical, clinical and translational science development activities, and (iii) process development. When we perform any research and development or manufacturing activities under a co-development agreement, 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 where we perform research and development activities under a joint development plan, such as our research and collaboration with Giiant, qualifying development costs are expensed as research and development costs as incurred. We recognize expense payments from Giiant, if any, as a reduction to research and development expense once the expense payments are realized or realizable, which is when we receive the cash or we have an undisputed claim to the cash that is probable of collection.

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 and committee fees, and general corporate expenses.

Going Concern

Our management has evaluated all conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that these financial statements are issued, including: (i) our available cash as of the date of this filing will not be sufficient to fund our anticipated level of operations for the next 12 months; (ii) we will require additional financing by the end of 2025 to continue at our expected level of operations; and (iii) if we fail to obtain the needed capital, we will be forced to delay, scale back, or eliminate some or all of our development activities or perhaps cease operations. In the opinion of management, these factors, among others, raise substantial doubt about our ability 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.

Results of Operations

Comparison of the three months ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,		Change	
	2025	2024	$	%
Operating expenses:				
Research and development	$ 950	$ 2,214	$ (1,264)	(57)%
General and administrative	1,360	1,459	(99)	(7)%
Total operating expenses	2,310	3,673	(1,363)	(37)%
Loss from operations	(2,310)	(3,673)	1,363	(37)%
Other (expense) income:				
Interest expense	(1)	(1)	—	—
Other income, net	81	147	(66)	(45)%
Total other income, net	80	146	(66)	(45)%
Net loss	$ (2,230)	$ (3,527)	$ 1,297	(37)%

Research and Development Expenses

The approximately $1.3 million, or 57%, decrease in research and development expenses for the three months ended March 31, 2025 compared to the three months ended March 31, 2024 is primarily attributable to an approximately $2.2 million decrease in expenses that were directly related to the preclinical joint development of PALI-2108 and a $0.1 million decrease in employee-related expenses, partially offset by an approximately $1.1 million increase in clinical trial costs associated with Phase 1 clinical trial of PALI-2018.

With the approval to commence the Phase 1 clinical trial of PALI-2108, which we received from Health Canada on October 9, 2024, pursuant to terms of the Giiant License Agreement, we have assumed all development, manufacturing, regulatory and commercialization activities and costs of PALI-2108. Accordingly, preclinical joint development costs were approximately $1.6 million for the three months ended March 31, 2024 compared to zero for the three months ended March 31, 2025. In addition, during the three months ended March 31, 2025 we recognized a reduction in joint development costs of $0.7 million that was related to funds received by us from Giiant pursuant to the joint development plan, resulting in a total net decrease in preclinical joint development expenses of approximately $2.2 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024.

We commenced our Phase 1 clinical trial of PALI-2108 in November of 2024. Accordingly, we recognized clinical trial-related costs of approximately $1.1 million during the three months ended March 31, 2025, compared to virtually none during the three months ended March 31, 2024. Preclinical joint development costs during the three months ended March 31, 2024 were higher than our clinical trial-related costs during the three months ended March 31, 2025 primarily due to higher investment in the manufacturing of the PALI-2108 drug substance during the three months ended March 31, 2024.

Finally, research and development employee-related costs decreased approximately $0.1 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024 due to lower bonus accrual and lower employee headcount.

General and Administrative Expenses

General and administrative expenses decreased by approximately $0.1 million, or 7%, for the three months ended March 31, 2025, compared to the three months ended March 31, 2024, primarily as result of (i) lower shareholder services expense due to a special shareholder meeting held in the first quarter of 2024, of which there was none in the first quarter of 2025, (ii) lower general and administrative employee-related expenses, due to lower bonus accrual and share-based compensation expense, (iii) lower insurance costs, due to lower insurance premiums, and (iv) lower other general administrative expenses. Partially offsetting these decreases was an increase in professional fees, which resulted from the timing of expense recognition.

Other (expense) income

Other income, net, for the three months ended March 31, 2025 and 2024 consists of dividend income from our investments of excess cash in money market funds with maturities of three months or less. The year-over-year decrease is due to a reduction in the cash balance invested during the three months ended March 31, 2025, compared to the three months ended March 31, 2024.

Liquidity and Capital Resources

Financial Condition

Since our inception, we have financed our operations through the sales of our securities, issuance of debt, the exercise of common stock warrants, and to a lesser degree, grants and research contracts as well as the licensing of 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 our ability to continue as a going concern.

Sources of Liquidity

We expect to incur substantial operating losses for the foreseeable future. We will need to raise additional capital through a combination of equity offerings, debt financings, collaborations, and other similar arrangements. Our ability to raise additional capital may be adversely impacted by: (i) general political or economic conditions, (ii) an economic slowdown or recession, (iii) inflation, (iv) tariffs, sanctions, trade restrictions, or other U.S. and foreign regulatory requirements, (v) rising interest rates, (vi) ongoing supply chain disruptions, (vii) the ongoing global conflicts, including those in the Ukraine and the Middle East, and (viii) limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry. In the event that we are unable to access additional capital, we may need to curtail or greatly reduce our operations, which could have a materially adverse impact on our business, financial condition, and results of operations.

Cash Flows

As of March 31, 2025, we had $7.3 million in cash, cash equivalents and restricted cash. The following table shows a summary of our cash flows for the three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,	
	2025	2024
Net cash used in operating activities	$ (2,333)	$ (3,180)
Net cash (used in) provided by financing activities	(258)	2,024

Net Cash Used in Operating Activities

Cash used in operating activities was approximately $2.3 million for the three months ended March 31, 2025, which reflects an approximately $2.2 million net loss adjusted for (i) approximately $0.2 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 attributable to a net cash outflow of approximately $0.6 million driven by the payment of annual employee cash bonuses in period, partially offset by an increase in accounts payable and accrued liabilities as of March 31, 2025, compared to December 31, 2024. The increase in accounts payable and accrued liabilities was primarily due to higher accrued clinical trial expenses partially offset by lower accrued joint development expenses associated with the Giiant License Agreement.

Cash used in operating activities was approximately $3.2 million for the three months ended March 31, 2024, which reflects an approximately $3.5 million net loss adjusted for (i) approximately $0.2 million of net cash inflows 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 inflow from operating assets and liabilities was driven by a cash outflow of approximately $0.6 million from the payment of annual 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 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 Giiant License Agreement and the timing of

accounts payable payments that were partially offset by accrued severance payments and lower accrued director stipends.

Net Cash Provided by Financing Activities

For the three months ended March 31, 2025, cash used in financing activities of approximately $0.3 million was attributable to the payment of equity issuance costs of approximately $0.2 million, primarily related to our underwritten equity offering completed in December of 2024, and payments made on our insurance financing arrangements of approximately $0.1 million.

For the three months ended March 31, 2024, cash provided by financing activities of approximately $2.0 million was attributable to net cash proceeds of approximately $2.2 million from the exercise of common stock warrants in conjunction with warrant inducement agreements entered into between us and certain investors in February of 2024, partially offset by payments made on the Company's insurance financing arrangements of approximately $0.2 million.

Contractual Obligations

Office Lease

We are party a to non-cancelable facility operating lease (the "Corporate Office Lease") of office space for our corporate headquarters. The initial contractual term is for 39-months commencing on June 1, 2022 and expiring on 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. We have determined that we will not exercise this renewal option.

Commencing on June 1, 2022, 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 March 31, 2025, the total remaining future minimum lease payments associated with the Corporate Office Lease of approximately $59,000, including imputed interest of approximately $1,000 calculated using a discount rate of 10.75%, will be paid over the remaining lease term of approximately 0.4 years.

Insurance Financing Arrangement

In June of 2024, we entered into an agreement to finance insurance policies that renewed in May of 2024. The insurance financing arrangement is secured by the associated insurance policy. We made the final principal payment required by the insurance financing arrangement during the three months ended March 31, 2025. Accordingly, there is no outstanding balance due as of March 31, 2025. We expect to renew the insurance policy, and enter into an associated insurance financing arrangement accordingly, in late May of 2025.

Future Liquidity Needs

We have incurred significant operating losses and negative cash flows from operations since our inception. To date, we have not been able to generate significant revenues nor achieve operating profitability. Based upon our cash and cash equivalents balance of $7.2 million as of March 31, 2025, we believe we have sufficient cash to fund our currently planned operations through the fourth quarter of 2025. Notwithstanding, should our anticipated level of operations significantly change, we may require additional financing sooner than anticipated. Beyond the fourth quarter of 2025 we will require additional financing to continue at our expected level of operations. If we fail to obtain the capital needed, we will be forced to delay, scale back, or eliminate some or all of our development activities, or potentially cease our operations.

Critical Accounting Policies and Estimates

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 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. Our estimates are based on historical experience, known trends, events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

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 our most recently filed Annual Report on Form 10-K include the discussion of estimates used for accrued research and development expenses and our contingent consideration obligation. We believe there has been no significant changes in our critical accounting policies and significant judgments and estimates since those disclosed in our most recently filed Annual Report on Form 10-K.

Recently Issued or Adopted Accounting Pronouncements

See Note 2 to the notes to the condensed consolidated financial statements for the quarter ended March 31, 2025, 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 March 31, 2025. Based upon the evaluation, our Chief Executive Officer concluded that, as of March 31, 2025, 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, 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 we identify further material weaknesses in its internal controls, our failure to establish and maintain effective disclosure controls and procedures and internal control over financial reporting could result in material misstatements in our 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 March 31, 2025. The material weakness continues to be present as of March 31, 2025.

Remediation Efforts related to the Material Weakness

Management, with oversight from our Audit Committee of the Board, 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)We will continue to hire or contract with additional finance, accounting and information technology employees with appropriate experience, certification, education and training.

(ii)We have implemented new accounting and finance management software effective July 1, 2022, which is intended to eliminate some of the existing deficiencies in our 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)We are in the process of updating our formal accounting policies, procedures and controls, including preparation and review of account reconciliations, review of journal entries, and controls over period end financial reporting.

(iv)We have identified and implemented controls to address all segregation of duties deficiencies in our current control environment. The controls implemented to remediate all segregation of duties deficiencies identified will be documented and tested for operating effectiveness.

(v)We are in the process of implementing additional key internal controls designed to address the potential risks identified in our business processes. Once fully implemented, these controls will be tested for operating effectiveness.

We believe that the implementation and testing of the above steps will allow us to make progress on addressing a number of the deficient controls within our internal control environment, which will help facilitate the remediation of the material weakness identified above. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. However, we require additional time to complete the design and implementation of 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 our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II
OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

RISK FACTOR SUMMARY

The Company faces many risks and uncertainties, as more fully described in this Quarterly Report on Form 10-Q under the heading "Risk Factors." Some of these risks and uncertainties are summarized below. 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 the section entitled "Risk Factors."

Risks Related to Our Development, Commercialization and Regulatory Approval of Our Product Candidates

- Our business depends on the successful clinical development, regulatory approval, and commercialization of our therapeutic compounds, including our lead asset PALI-2108.
- There are substantial risks in drug development, and, as a result, we may not be able to successfully develop any product candidate, including our lead product candidate, PALI-2108.
- We depend on our license agreement with Giiant Pharma Inc. ("Giiant") to permit us to use patents and patent applications relating to PALI-2108. Termination of these rights or the failure to comply with our obligations under the license agreement could materially harm our business and prevent us from developing or commercializing PALI-2108, our lead product candidate.
- We are currently conducting a Phase 1 clinical trial of PALI-2108 in Canada, and the U.S. Food and Drug Administration ("FDA") or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U.S.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.
- We expect that our operations and development of PALI-2108 will require substantially more capital than we currently have, and we cannot guarantee when or if we will be able to secure such additional funding.
- Our product candidates, including our lead product candidate PALI-2108, may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.
- There can be no assurance that our product candidates will obtain regulatory approval.
- If clinical studies of PALI-2108 do not yield successful results, we may discontinue the development of PALI-2108.
- It may take us longer than we estimate to complete clinical trials, and we may not be able to complete them at all.
- 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 substantial fines.
- 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.
- We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and we may need to limit our commercialization.
- 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.

Risks Related to Our Business

- We have a limited operating history and have never generated any revenues from product sales.
- Our business model assumes revenue from, among other activities, marketing or out-licensing the products we develop. PALI-2108 is in the early stages of clinical development, and because we have a short development history with PALI-2108, there is a limited amount of information about us upon which you can evaluate our business and prospects.
- We may choose to discontinue the development or commercialization of any of our product candidates, or may choose not to commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.
- Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.
- Changes in funding for the FDA and, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

Risks Related to Our Dependence on Third Parties

- We anticipate relying on third-party Contract Research Organizations ("CROs") and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations for, obtain regulatory approval for, or commercialize our product candidates.
- We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI-2108. Insufficient availability of the API or other raw materials necessary to manufacture PALI-2108, or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms, could adversely impact our business, results of operations and financial condition.
- We expect to rely on collaborations with third parties for the successful development and commercialization of our product candidates.
- We currently rely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

Risks Related to Our Financial Operations

- We have expressed substantial doubt about our ability to continue as a going concern.
- We have a history of net operating losses, and we expect to continue to incur net operating losses and may never achieve profitability.
- Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements.

Risks Related to Our Intellectual Property

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

Other Risks Related to Our Securities

- 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.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before investing in our securities, you should carefully consider the risks and uncertainties discussed under "Risk Factors" in our latest annual report on Form 10-K and subsequent quarterly reports on Form 10-Q and current reports on Form 8-K. Before making an investment decision, you should carefully consider each of the following risks described below, together with all other information set forth in or incorporated in this Quarterly Report on Form 10-Q, including the condensed consolidated financial statements and the related notes. The risks described in this Quarterly Report on Form 10-Q are not the only ones we face, but those that we consider to be material. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations and could result in a complete loss of your investment. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of the following risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the market price of our common stock to decline, and you could lose all or part of your investment.

Risks Related to Our Development, Commercialization and Regulatory Approval of Our Product Candidates

Our business depends on the successful clinical development, regulatory approval, and commercialization of our therapeutic compounds, including our lead asset PALI-2108.

On October 9, 2024, Health Canada approved our Canadian Clinical Trial Application ("CTA") to commence a Phase 1 clinical trial for PALI-2108 in Canada. On November 7, 2024, we commenced the Phase 1 clinical trial of PALI-2108. Our success depends on the development and clinical success of PALI-2108, which is subject to a number of risks, including:

- the continued enforceability of our research collaboration and license agreement with Giiant;
- timely and successful completion of required clinical trials, which may be significantly slower or costlier than we anticipate and/or produces results that do not achieve the primary or secondary endpoints of the trial(s);
- our ability to develop and implement clinical trial designs and protocols;
- the successful initiation and completion of our current planned clinical trials and any additionally required preclinical studies, if any;
- our ability to retain third-party CROs on terms acceptable to us for the conduct and oversight of our anticipated clinical trials, including our Phase 1 clinical trial for PALI-2108;
- our ability to fund the development costs related to PALI-2108's clinical development;
- the approval by Health Canada or other regulatory authorities to commence the marketing of our product candidates;
- the ability for us and third-parties, if applicable, to achieve and maintain compliance with our contractual obligations and applicable regulatory requirements;
- the ability of our contract manufacturers to manufacture sufficient supply of our product candidates to meet the required clinical trial supplies and any additional required preclinical studies;
- the ability of our contract manufacturers to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing facilities and processes that are compliant with cGMP regulations;
- our ability to obtain favorable labeling for our product candidates through regulators that allows for successful commercialization;
- acceptance by physicians, insurers, payors, and patients of the beneficial quality, safety and efficacy of our product candidates, if approved, including relative to alternative and competing treatments;
- our ability to price our product candidates to recover our development costs and applicable milestone or royalty payments, and generate a satisfactory profit margin; and

•our ability and our applicable collaboration and licensing partners' ability to establish and enforce intellectual property rights related to our product candidates and technologies.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our proposed product candidates. For example, we are currently enrolling and dosing subjects in our initial Phase 1 clinical trial of PALI-2108 in Canada. We may experience delays or difficulties in finding suitable trial subjects, or in completing enrollment. Such delays may result in increased costs and the failure to complete the Phase 1 clinical trial of PALI-2108 in Canada in a timely manner. Even if successfully completed, we must complete a number of additional clinical trials prior to obtaining regulatory approval to commercialize our product candidates. Accordingly, we cannot make assurances that we will ever be able to generate sufficient revenue through the sale of any product candidates, if approved, to internally fund our business.

There are substantial risks in drug development, and, as a result, we may not be able to successfully develop any product candidate. including our lead product candidate, PALI-2108.

We have initiated a Phase 1 clinical trial of PALI-2108 in our target indication of inflammatory bowel disease, or IBD. Drug development requires a significant amount of capital and can take a long time to reach commercial viability, if it can be achieved at all. During the development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs have not been proven. Because of these and similar uncertainties, it is possible that our product candidates will not reach commercialization. If we are unable to successfully develop and commercialize our product candidates, including our lead product candidate, PALI-2108, we will be unable to generate revenue or build a sustainable or profitable business.

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

We are a party to the Giiant License Agreement under which we have been granted rights to patents and patent applications that are important to our business. We rely on this license agreement to be able to use various proprietary technologies that are material to our business, including patents, and patent applications that cover PALI-2108. Our rights to PALI-2108 are subject to the continuation of, and our compliance with, the terms of the Giiant License Agreement. If we fail to comply with any of our obligations under the Giiant License Agreement, Giiant may have the right to terminate the Giiant License agreement, in which event we would not be able to continue the development or our proposed commercialization of PALI-2108. Additionally, disputes may arise under the Giiant License Agreement regarding the intellectual property that is subject to such agreement. If disputes over intellectual property that we have licensed, or in the future may license, prevent or impair our ability to maintain any of our license agreements, including the Giiant License Agreement, on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and technologies.

Clinical drug development is expensive, time-consuming and uncertain.

The 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 generate sufficient revenue to cover their costs of development. In addition, we, any partner with which we may collaborate, Health Canada, any similar regulatory authority, state and local agencies, counterpart agencies in foreign countries, or the applicable Institutional Review Board ("IRB") at our trial sites, may suspend, delay, require modifications to or terminate our clinical trials, once begun, at any time.

We are currently conducting a Phase 1 clinical trial of PALI-2108 in Canada, and the FDA or applicable foreign regulatory authorities may not accept data from such trials, or any other trial we conduct outside of the U.S.

We have commenced a Phase 1 clinical trial for ulcerative colitis in Canada. However, we have not received approval from the FDA to commence any clinical trials in the U.S., and there is no guarantee that we will be able to obtain such approval in a timely manner, if at all. If our Phase 1 clinical trial is successful and we seek to initiate a Phase 2 clinical trial in the U.S, there is no certainty that the FDA will accept the data generated from our Canadian trial. The FDA's acceptance of foreign clinical data is subject to certain conditions, including whether the trial was conducted in accordance with good clinical practices ("GCP") and whether the FDA can validate the trial data through on-site inspections or other means. Moreover, the FDA will assess whether the trial design, patient population, endpoints, and other factors meet the standards expected for clinical trials conducted within the U.S.

In addition, regulatory approval for clinical trials and eventual drug approval in the U.S. is a complex process, influenced by several factors, including:

- the adequacy and relevance of the Phase 1 trial data in supporting progression to Phase 2, as evaluated by the FDA;
- the ability of the trial to meet safety, efficacy, and other scientific requirements set by the FDA, which may differ from those of Health Canada;
- whether the foreign clinical trial was conducted under an FDA-recognized regulatory authority, and whether FDA oversight is possible through monitoring or inspection of clinical sites; and
- the FDA's consideration of the risk-benefit ratio for continuing clinical development in the U.S., particularly based on data from a non-U.S. population.

Furthermore, while the FDA does have the ability to approve drugs that have undergone clinical trials in foreign jurisdictions, including Canada, approval is generally contingent on demonstrating that the trial data align with FDA standards and regulatory expectations. It is also possible that we may be required to conduct additional trials in the U.S. to address any concerns regarding the applicability of the foreign trial data to the U.S. population or regulatory environment. There can be no assurance that we will successfully obtain FDA approval to initiate a Phase 1 clinical trial in the U.S. or that if our Canadian trial is successful, a subsequent Phase 2 trial.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

We are currently enrolling subjects in the Phase 1 clinical trial of PALI-2108 in Canada. Identifying and qualifying subjects to participate in our current and anticipated future clinical trials is critical to our success. Our inability to enroll patients in our clinical trials on a timely basis could result in the trials being delayed or never completed.

Patient enrollment and trial completion are affected by numerous additional factors, including the:

- process for identifying patients;
- design of the trial protocol;
- eligibility and exclusion criteria;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- severity of the disease under investigation;
- proximity and availability of clinical trial sites for prospective patients;
- ability to obtain and maintain patients' consents;
- risk that enrolled patients will drop out before completion of the clinical trial;
- patient referral practices of physicians; and,
- ability to monitor patients adequately during and after treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects. There can be no assurances that we will be able to complete enrollment for our anticipated Phase 1 clinical trial for PALI-2108, and if we fail to do so, we may not be able to complete the trial on a timely basis, or at all.

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

We have historically funded our operations and prior development efforts through the sale of our securities. Based on our existing cash resources and our current business plan, we do not have adequate capital to fund our anticipated operations through the completion of the development of PALI-2108. As a result, we will need to secure additional funding. If we are not able to obtain additional capital in the future or on acceptable terms, we may need to curtail our anticipated clinical trials as well as our operations.

Our product candidates, including our lead product candidate, PALI-2108, may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from PALI-2108 could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by Health Canada, or comparable regulatory authorities like the FDA.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and Health Canada or comparable regulatory authorities, like the FDA, could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may have an adverse material effect on our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by a product after obtaining regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

There can be no assurance that 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:

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

PALI-2108 will require significant development, clinical testing, possibly additional preclinical studies, and the investment of significant funds to gain regulatory approval before it can be commercialized. Although we commenced a Phase 1 clinical trial in Canada, there can be no assurances that gaining regulatory approval in Canada will result in regulatory approval from any other regulatory agency, including the FDA of the U.S. The results of our human clinical testing of PALI-2108 may not meet applicable regulatory requirements. If approved in a jurisdiction, PALI-2108 may also require the completion of post-market studies. The process of completing 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.

On June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision will have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

If we fail to obtain regulatory approvals, or if there are significant changes in regulatory policies that result in increased litigation and judicial scrutiny leading to unexpected delays and increased cost, we may not be able to market PALI-2108 and our operations will be adversely affected.

If clinical studies of PALI-2108 do not yield successful results, we may discontinue the development of PALI-2108.

We must demonstrate that PALI-2108 is safe and efficacious in humans through extensive clinical testing. 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 preclinical studies that we have completed may not be indicative of results that will be obtained in human clinical trials;
- safety and efficacy results attained in preclinical studies may not be indicative of results that are obtained in our clinical trials;
- after reviewing early clinical trial results, we may abandon projects that we previously believed to be promising;
- we or our regulators may suspend or terminate our clinical trials because the participating subjects or 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 that preclude regulatory approval or limit their commercial use if approved.

It may take us longer than we estimate to complete clinical trials, and we may not be able to complete them at all.

Although for planning purposes we project the commencement, continuation and completion of our clinical trials; a number of factors, including scheduling conflicts with participating researchers and/or CROs, clinicians and research or clinical institutions, and difficulties in identifying or enrolling patients who meet trial eligibility criteria, may cause significant delays. Even if we were to commence and complete our clinical trials involving PALI-2108 as currently contemplated, they may not be successful.

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 substantial fines.

If regulatory approval to market and commercialize 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 we fail to comply with applicable regulatory approval requirements, a regulatory agency may impose restrictions on PALI-2108 or us. The agency may require the withdrawal of PALI-2108 from the market, closure of the facility or substantial fines.

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 in the applicable jurisdiction, including, for example, Medicare and Medicaid in the U.S., 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. 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 our business or future revenues, if any. If we partner with third parties with respect to any of our product candidates, we may be reliant on that partner to obtain reimbursement from government and private payors for the drug, if approved, and any failure of that partner to establish adequate reimbursement could have a negative impact on our revenues and profitability.

In addition, both the federal and state governments in the U.S. 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 we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

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

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and we may need to limit our commercialization.

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

- decreased demand for our product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of litigation;
- substantial monetary awards to patients or other claimants; and
- loss of revenues.

Our insurance coverage may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us 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 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 by us that are contained in the final approved labeling;
- any requirement of an authoritative regulatory body to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and 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 ways to 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 our product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Risks Related to Our Business

We have a limited operating history and have never generated any revenues from product sales.

We are a biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business and to assess our future viability. While we were initially formed in 2001, our operations have historically been limited to business planning, raising capital and other research and development activities related to our product candidates. We additionally adopted a new business plan in September of 2023 upon entering into the Giiant License Agreement. Since that time, we have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, nor have we ever generated any revenue from product sales. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

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

We have no approved drugs and thus have not begun to market or generate revenues from the commercialization of any products. We only have a limited history upon which we can evaluate our ability to develop PALI-2108. We commenced our initial Phase 1 clinical trial of PALI-2108 in November of 2024. Thus, we have limited experience and 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 our business plan, we will need to:

- execute product development activities using unproven technologies;
- build, maintain, and protect a strong intellectual property portfolio;
- Demonstrate safety and efficacy of our drug candidates in multiple human clinical studies;
- receive approval from Health Canada and/or approval from similar foreign regulatory bodies, such as the FDA;
- retain qualified CROs to oversee and manage our Phase 1 clinical trial for PALI-2108 and future clinical trials;
- gain market acceptance for the development and commercialization of any drugs we develop;
- ensure our products are reimbursed by commercial and/or government payors at a rate that permits commercial viability;
- develop and maintain successful strategic relationships with suppliers, distributors, and commercial licensing partners;
- manage our spending and cash requirements as our expenses will increase in the near term if we add programs and additional preclinical and clinical trials; and
- effectively market any products for which we obtain marketing approval.

If we are unsuccessful in accomplishing these objectives, we may not be able to develop our proposed products, raise capital, expand our business or continue our operations.

Our success depends on attracting and retaining senior management and scientists with relevant expertise.

Our future success depends to a significant extent on the continued services of our key employees, including our senior scientific, technical and managerial personnel. We do not maintain key person life insurance for any of our executives. Competition for qualified employees in the pharmaceutical industry is high, and our ability to execute our strategy will depend in part on our ability to continue to attract and retain qualified scientists and management. If we are unable to find, hire, and retain qualified individuals, we may be unable to execute our business plan in a timely manner, if at all.

We may choose to discontinue development or commercialization any of our product candidates, or may choose not to commercialize product candidates in approved indications, at any time during development or after approval, which could adversely affect us and our operations.

At any time, we may decide to discontinue the development of, or temporarily pause the development of, any of our product candidates then in existence for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from competing product(s) or changes in or failure to comply with applicable regulatory requirements. If we temporarily pause or terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses, which could have an adverse effect on us and our business.

Our inability to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.

PALI-2108 is currently our only product candidate being actively developed. We may in-license, acquire, develop and market additional products and product candidates. Since our internal research and development capabilities are limited, we may be dependent on pharmaceutical companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on 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 us for the license or acquisition of product candidates and approved products. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional approved products or product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire or license may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the applicable 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, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Changes in funding for the FDA and, other government agencies or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent these agencies or authorities from performing normal business functions on which the operations of our business may rely, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key leadership and other personnel, the sufficiency of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies or comparable foreign regulatory authorities on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other, other government agencies or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

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

We have retained a CRO to oversee our Phase 1 clinical trial for PALI-2108 in Canada. We are likely to rely on third-party CROs to conduct and oversee our other anticipated clinical trials and other aspects of product development. We also expect to rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and 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. We expect to rely heavily on these parties for the execution of our clinical trials and any additionally required preclinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with GCP and GLP regulations, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, such as Health Canada, with respect to our Phase 1 clinical trial for PALI-2108. Regulatory authorities enforce these GCP or GLP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP regulations, or reveal noncompliance from an audit or inspection, any clinical data generated in our clinical trials may be deemed unreliable, and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority such regulatory authority will determine whether any of our clinical trials comply with applicable GCP or GLP regulations. In addition, our clinical trials generally must be conducted with compounds produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would be costly and delay the regulatory approval process. In the event that we are unable to retain a qualified CRO for our Phase 1 clinical trial for PALI-2108, or any other anticipated clinical trial, it would delay planned clinical operations and result in additional cost and expense. Additionally, if our current CRO for our Phase 1 clinical trial in Canada or if any of our CROs that we retain in the future were to terminate their involvement with us, there is no assurance that we would be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms.

We depend on two qualified suppliers for the active pharmaceutical ingredient used in the clinical trials of PALI-2108. Insufficient availability of the API or other raw materials necessary to manufacture PALI-2108, or the inability of our suppliers to manufacture and supply our products on commercially reasonable terms, could adversely impact our business, results of operations and financial condition.

We have two qualified suppliers for the API used in PALI-2108. We do not have, and we do not intend to establish in the foreseeable future, internal manufacturing capabilities. Instead, we intend to use the facilities of third-party manufacturers to produce the materials used in our clinical trials. Our dependence on third parties for the supply and manufacture of PALI-2108 and any future product candidates may adversely affect our ability to obtain our products in a timely or competitive manner, if at all.

Any supply shortages, quality concerns, or failure to obtain sufficient API, excipients, or components from our suppliers, including disruptions caused by, among other things, supply chain delays, public health emergencies, climate events, or political unrest would adversely affect our business, results of operations and financial condition. In particular, our suppliers may be impacted by epidemics, pandemics or other disease outbreaks or public health emergencies and general macroeconomic conditions, including inflationary pressures, economic slowdown or recession, relatively high interest rates, imposed tariffs, changes in monetary policy, potential U.S. federal government shutdowns, geopolitical conflicts and financial institution instability, all of which may result in supply delays and cost increases.

The manufacturing process for pharmaceutical products is highly regulated, and regulatory agencies may from time to time shut down facilities that they believe do not comply with regulations. Our third-party manufacturers and suppliers are subject to numerous FDA and Health Canada regulations, including those governing manufacturing processes, stability testing, record keeping, product serialization, and quality standards. Similar regulations apply in other jurisdictions where we may conduct business. Our third-party manufacturers and suppliers are independent entities who are subject to their own operational and financial risks which are out of our control.

If we, our third-party manufacturers, or our suppliers fail to comply with these regulations, our ability to deliver adequate supplies of PALI-2108 for clinical trials in a timely and cost-effective manner may be adversely affected. Should any of these risks materialize and adversely affect such third-party manufacturers' and/or suppliers' performance obligations to us, and we are unable to secure sufficient of the API used in the manufacture of PALI-2108 on commercially acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers or suppliers, our business, results of operations and financial condition could be adversely affected.

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

We currently rely on and expect to continue to rely upon the efforts of third parties for the successful development and commercialization of our product candidates. The clinical and commercial success of 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:

- our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;
- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of our product candidates; and
- other risks in potentially meeting our product commercialization schedule or satisfying the requirements of our end-users.

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

We currently rely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates.

We do not currently have, nor do we currently plan to acquire, the infrastructure or capability to supply, store, manufacture or distribute clinical or commercial quantities of drug substances or products. Although we have entered into a commercial supply agreement to provide us with such drug substances or products for our current Phase 1 clinical trial, our future ability to develop and commercialize, if approved, our product candidates is dependent on our ability to obtain the APIs and other substances and materials used in 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 preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates, which could adversely affect us and our business.

We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMP regulations for production of our proposed products and 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, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidates successfully, and we may be held liable as a result.

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

We currently have agreements in place with foreign third parties in China and other countries to provide the necessary clinical supply of our API. Termination of or limitations on our relationships with foreign third parties that

manufacture the API used in PALI-2108 may arise if U.S. legislation, tariffs, sanctions, trade restrictions, or other U.S. and foreign regulatory requirements, or prohibitions restrict our ability to engage with these foreign third parties. Further, any such actions could adversely impact our current and future arrangements with our foreign suppliers, including our current Chinese drug manufacturer, which could increase the cost or reduce the supply of material available to us or delay the procurement or supply of such material used in our clinical trial.

Risks Related to Our Financial Operations

We have expressed substantial doubt about our ability to continue as a going concern.

Management has determined that there is substantial doubt about our ability to continue as a going concern for a period of one year following the issuance of this Quarterly Report on Form 10-Q. This determination was based on conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued, including our available cash as of the date of this filing, which is not sufficient to fund our anticipated level of operations for the next 12 months. Our future consolidated financial statements may include a similar qualification about our ability to continue as a going concern. Our year-end and interim consolidated financial statements were prepared assuming that we will continue as a going concern and do not include any adjustments that may result from the outcome of this uncertainty.

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

We have a history of net losses, and we expect to continue to incur net losses and may never achieve profitability.

We have incurred net losses since our inception. We expect that our operating losses will continue for the foreseeable future as we continue our drug development and discovery efforts. To achieve profitability, 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 we are able to successfully commercialize product candidates that receive regulatory approval, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. Accordingly, we may never generate significant revenue and, even if we generate significant revenue, we may never achieve profitability.

Failure to remediate a material weakness in internal controls over financial reporting could result in material misstatements in our consolidated financial statements.

Our management has identified a material weakness in 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.

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

Risks Related to Our Intellectual Property

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

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

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and 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 we or our current, or future licensors and 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 our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of any issued or pending patents we may have or the ability to obtain future patent protections, which may have an adverse impact on our business, financial condition and operating results.

Our ability to obtain, maintain and/or enforce patents is uncertain and involves complex legal and factual questions, especially across varying countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for 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, we cannot guarantee that any patents or other intellectual property rights will be issued from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, 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 us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target.

Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and prior art make it patentable. We do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents are successfully issued, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates are challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance 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 we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect 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 such agreements will not be breached or enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If our trade secrets are independently discovered, we would not be able to prevent their use and if we or our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, we may not be allowed to retrieve these trade secrets and/or unpatented know-how and maintain the exclusivity we previously held.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability vary between countries, particularly developing nations. In addition, the laws of some countries do not protect intellectual property rights to the same extent as the laws of all other countries or jurisdictions, especially when it comes to granting use and other types of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from using our inventions or even in launching an identical version of our product even if we hold a valid patent. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, or they may produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement against such activities is inadequate or where we have no patents. These products could compete with ours, and our patents or other intellectual property rights may not prevent them from competing.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and 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 applicable patent agencies, which require compliance with a number of procedures, including certain documentary, fee payment and other similar provisions during the patent application process. 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. 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. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

The Giiant License Agreement pursuant to which we license PALI-2108, and other assets of Giiant, contains certain requirements related to diligence, milestone, royalty, insurance, expense reimbursement, and other obligations. If we fail to comply with these obligations, Giiant may have the ability to terminate the license, subject to certain requirements as more fully set forth in the Giiant License Agreement. If the license granted thereunder were to be terminated, our business, financial condition, operating results, and prospects would be materially adversely affected.

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

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

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our customers, licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of such claims. The claims may require 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, 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 we cannot obtain all necessary licenses on commercially reasonable terms, we may be unable to continue selling such products.

We may be subject to claims that 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 our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of 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 our competitors or potential competitors. We may be subject to claims that our employees or consultants 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 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 we are successful in defending against any such claims, the related litigation could be protracted, expensive, a distraction to our management team, and not viewed favorably by investors and other third parties.

Other Risks Related to Our Securities

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

We have used and we intend to use the proceeds from our previous offerings and any future offerings, to, among other things, advance PALI-2108 through preclinical and clinical development and into INDs or their equivalent in foreign jurisdictions, fund our research and development activities, and for general working capital needs. We will require substantial additional capital to fund our operations and conduct the costly and time-consuming research and development and clinical work necessary to pursue regulatory approval of product candidates. 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 preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete clinical trials or any additional preclinical studies required; 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, which could inhibit our ability to achieve our business objectives. 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. If we raise additional funds through public or private equity sales of our securities, the terms of these securities may include liquidation or other preferences that adversely impact the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership percentage will be decreased. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may need to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we obtain additional funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Our common stock price may be highly volatile.

Since the completion of the merger with Seneca on April 27, 2021, the price of our common stock has 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 to large daily price swings. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to:

- failure of our product candidates to show safety and/or efficacy in our clinical trials;
- our ability to obtain timely regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- the results of our clinical trials, including our decision to pause or terminate any such trials;
- failure of our product candidates, if approved, to achieve commercial success;
- the entry into, or termination of, or breach by partners of key agreements, including the Giiant 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 lack of, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of 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-cap and nano-cap companies, 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 our shares. In the past, following periods of volatility in the market price of a company's securities, 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 our profitability and reputation.

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.

Our common stock is listed on the Nasdaq Stock Market. There are a number of continued listing requirements that we must satisfy in order to maintain our listing on The Nasdaq Stock Market, including the requirement to maintain a minimum bid price of at least $1.00 (the "Bid Price Rule"). In October of 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. On April 30, 2025, we received the Notice from Nasdaq advising us that we were no longer in compliance with the Bid Price Rule. The Notice has no effect on the listing of our common stock at this time, and our common stock continues to trade on The Nasdaq Capital Market under the symbol "PALI." If at any time during the Compliance Period the closing bid price of our common stock is at least $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the Bid Price Rule and our common stock will continue to be eligible for listing on The Nasdaq Capital Market absent noncompliance with any other requirement for continued listing. If we do not regain compliance with the Bid Price Rule by the end of the Compliance Period, we may be afforded an Additional Compliance Period if on the last day of the Compliance Period we are in compliance with the market value of publicly held shares requirement for continued listing as well as all other standards for initial listing of its common stock on The Nasdaq Capital Market (other than the Minimum Bid Price Requirement), unless we do not indicate our intent to cure the deficiency, or if it appears to Nasdaq that it is not possible for us to cure the deficiency. If we do not regain compliance with the Bid Price Rule by the end of the Compliance Period, or the Additional Compliance Period, if applicable, our common stock will be subject to delisting. 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 intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options to regain compliance with the Bid Price Rule.

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

As of the last business day of our most recently completed second fiscal quarter, our public float was less than $250 million and therefore, we qualify as a smaller reporting company under SEC rules. As a smaller reporting company, we can take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Such reduced disclosures in our SEC filings may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues are below $100 million and we have a public float of less than $700 million.

We do not anticipate paying any dividends in the foreseeable future.

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

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

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

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

Future sales in the public market of shares of our common stock, including shares issued upon exercise of our outstanding stock options or warrants, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

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

Provisions in our certificate of incorporation, as amended ("Certificate of Incorporation"), and bylaws, as amended ("Bylaws") may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our Board of Directors ("Board" or "Board of Directors"), 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 our stockholders to replace or remove management by making it more difficult for stockholders to replace members of the Board, which is responsible for appointing the members of management.

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

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 we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This has required that we incur substantial professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may experience difficulty in meeting these reporting requirements in a timely manner.

Our management identified a material weakness in our internal control over financial reporting. If we do not remediate this material weakness, or if we identify further material weaknesses in our internal controls, our failure to establish and maintain effective internal financial and accounting controls and procedures could result in material misstatements in our consolidated financial statements and a failure to meet our reporting and financial obligations.

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

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

We are entitled under our Certificate of Incorporation to issue up to 280,000,000 shares of common stock and 7,000,000 "blank check" shares of preferred stock. Shares of our blank check preferred stock provide our Board with broad authority to determine voting, dividend, conversion, and other rights of such preferred stock. As of March 31, 2025, we had outstanding, common stock or securities convertible into common stock, totaling 9,764,636 shares. As a result, we are authorized to issue up to an additional 270,235,364 shares of common stock or common stock equivalents under our Certificate of Incorporation. 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, we are authorized to issue up to an additional 6,800,000 shares of preferred stock. We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our existing stockholders will likely experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner that we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors will likely be materially diluted by the initial and subsequent sales. Additionally, new investors may gain rights superior to existing stockholders, depending on the terms of such transactions and types of securities. Pursuant to 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 stockholders to experience additional dilution, which could cause our stock price to fall.

General Risk Factors

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 preclinical 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 result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may 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 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.

Global economic conditions may have an adverse effect on our business.

Financial instability or a general decline in economic conditions in the U.S. and other countries, caused by political instability, conflict, and economic challenges resulting from general health crises, has led to market disruptions, including significant volatility in commodity prices, credit and capital market instability, and supply chain interruptions. Such volatility, instability, and interruptions have contributed to record inflation globally and could adversely affect our operations. Increased inflation may result in higher operating costs (including labor costs), reduced liquidity, and limitations on our ability to access credit or raise capital on acceptable terms, if at all. Existing free trade laws and regulations, such as the United States-Mexico-Canada Agreement, provide certain beneficial duties and tariffs for qualifying imports and exports, subject to compliance with applicable classification and other requirements. However, changes in trade laws or policies, particularly increased trade restrictions, tariffs, or taxes on imports from countries where we manufacture products, such as Canada, China, and Mexico, could have a material adverse effect on our business and financial results. Since February of 2025, the U.S. government has enacted, and continues to enact, a series of new tariffs, including a tariff on all imports and additional "reciprocal" tariffs targeting imports from specified countries. These tariffs and other changes in U.S. trade policy have triggered, and could continue to trigger, retaliatory actions by affected countries, including retaliatory measures on U.S. goods and other protectionist measures that could limit our ability to offer our products and services outside of the U.S. The tariff policy environment has been and can be expected to continue to be dynamic. The ultimate impact of these newly enacted and potential future tariffs or other restrictions on international trade will depend on various factors, including the ultimate levels of such tariffs, how long such tariffs remain in place, and how other countries respond to the U.S. tariffs. Consequently, we cannot assure that any strategies we implement to mitigate the effects of such tariffs or trade actions will be successful. In addition, the U.S. Federal Reserve has raised, and may continue to raise, interest rates in response to concerns about inflation. Inflation, combined with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten associated risks. Economic conditions and uncertainty regarding the broader macroeconomic environment are beyond our control and may make obtaining necessary debt or equity financing more difficult, costly, and dilutive. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, an economic downturn or a significant

increase in expenses could necessitate additional financing under less favorable conditions, including unattractive interest rates or excessively dilutive terms for existing stockholders. Failure to secure necessary financing in a timely manner and on favorable terms could materially and adversely affect our stock price and force us to delay or abandon clinical development plans.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. If there are significant employee reductions at the FDA or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future reductions in force and government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025. In addition, federal employees recently have been subject to termination in connection with cost reduction efforts by the federal government. If a prolonged government shutdown or significant reduction in force of federal employees occurs, including those working for the FDA, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and cost-cutting efforts could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If our information systems or data, or those of third parties upon which we rely, are or were compromised, 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 our business, we 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). 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. 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. 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 our systems and operations, supply chain, and ability to produce, sell and distribute our products.

We and the third parties upon which 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 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, our remote workforce poses increased risks to our information technology systems and data, as most of 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 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 our operations, including material disruptions of our development programs and business operations.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security breaches and disruptions. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may be unable in the future to detect vulnerabilities in 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 our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, 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 us to notify relevant parties of certain security breaches and disruptions. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security breach or other disruption, or are perceived to have experienced such events, 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); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. In particular, since we sponsor clinical trials, any breach or disruption that compromises patient data and identities could generate significant reputational damage, which may affect trust in us and 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 our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Furthermore, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of 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.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems, and those of 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 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 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 our operations, it could result in a material disruption of our development programs and our business operations. In addition, since 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 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 our regulatory approval efforts and significantly increase 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, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of 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.

ITEM 6. EXHIBITS

Exhibit Number	Description of document
3.1	Certificate of Designation of Preferences, Rights and Limitations 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).
3.2	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).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	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).
4.3	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).
4.4	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).
4.5	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).
4.6	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).
4.7	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).
4.8	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).
4.9	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).

4.10	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).
4.15	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).
4.16	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).
4.17	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).
4.18	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).
4.19	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).
4.20	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).
4.21	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).
4.22	Form of Five-Year Common Stock Purchase Warrant issued in December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 4.02 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
4.23	Form of Warrant Agency Agreement by and between Palisade Bio, Inc. and Equiniti Trust Company LLC (Incorporated by reference to Exhibit 4.03 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
10.1#	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).
10.2#	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).
10.3	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).
10.4+	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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	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).
10.11+	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).
10.12+	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).
10.13+	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).
10.14†	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).
10.15	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).
10.16	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).
10.17	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).
10.18	Form of Placement Agency Agreement, dated December 30, 2022, by and between the Company and Ladenburg Thalmann & 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).
10.19	Form of Placement Agency Agreement by and among the Company and Ladenburg Thalmann & 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).
10.20#	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.
10.21	Form of Placement Agency Agreement dated September 7, 2023, by and among the Company and Ladenburg Thalmann & 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).
10.23	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).
10.24	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.

10.25#	Amendment to Research Collaboration and License Agreement with Giiant Pharma, Inc. dated August 2, 2024 (Incorporated by reference to Exhibit 10.48 to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2024).
10.26+	Form of Employment Agreement with J.D. Finley, dated September 25, 2024 (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 27, 2024).
10.27	Form of Underwriting Agreement by and between Palisade Bio, Inc. and Ladenburg Thalmann & Co. Inc. (Incorporated by reference to Exhibit 1.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
10.28	Form of Warrant Amendment Agreement entered into Pursuant to the December 2024 Underwritten Public Offering (Incorporated by reference to Exhibit 10.01 to the Registrant's Current Report on Form 8-K filed with the SEC on December 16, 2024).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
32.1**	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.
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.
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.
† Schedules and exhibits to the Agreement 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: May 12, 2025

/s/ J.D. Finley
J.D. Finley, Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and Principal Financial Officer)