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 September 30, 2026

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.)**
4600 South Syracuse Street, Suite 900 Denver, Colorado[1]	**80237**
(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 November 6, 2026, there were 179,277,820 shares of common stock, $0.01 par value, outstanding. This number does not include 37,814,754 shares of common stock issuable upon the exercise of pre-funded warrants outstanding as of November 6, 2026 (which are immediately exercisable at an exercise price of $0.0001 per share of common stock, subject to beneficial ownership limitations).

[1] The Company does not currently maintain a physical headquarters but maintains a mailing address at 4600 South Syracuse Street, Suite 900, Denver, Colorado, 80237.

Palisade Bio, Inc.

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PART I
FINANCIAL INFORMATION

ITEM 1. UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 113,613	$ 133,385
Prepaid expenses and other current assets	3,860	836
Total current assets	117,473	134,221
Restricted cash	55	55
Other noncurrent assets	1,017	68
Total assets	$ 118,545	$ 134,344
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,445	$ 767
Accrued liabilities	3,608	2,187
Accrued compensation and benefits	773	1,298
Share liability	—	313
Insurance financing debt	—	71
Total current liabilities	5,826	4,636
Noncurrent liabilities	279	328
Total liabilities	6,105	4,964
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 September 30, 2026 and December 31, 2025	2	2
Common stock, $0.01 par value; 450,000,000 and 300,000,000 shares authorized; 174,442,971 and 159,444,017 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	1,744	1,594
Additional paid-in capital	298,216	280,509
Accumulated deficit	(187,522)	(152,725)
Total stockholders' equity	112,440	129,380
Total liabilities and stockholders' equity	$ 118,545	$ 134,344

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
License revenue	$ —	$ —	$ 500	$ —
Operating expenses:				
Research and development	10,579	1,394	24,376	4,019
General and administrative	5,121	1,528	14,270	4,056
Total operating expenses	15,700	2,922	38,646	8,075
Loss from operations	(15,700)	(2,922)	(38,146)	(8,075)
Other (expense) income:				
Interest expense	—	(5)	(1)	(8)
Other income, net	1,077	59	3,350	201
Total other income, net	1,077	54	3,349	193
Net loss	$ (14,623)	$ (2,868)	$ (34,797)	$ (7,882)
Basic and diluted weighted average shares used in computing basic and diluted net loss per common share	212,027,787	7,473,898	211,035,838	5,702,050
Basic and diluted net loss per common share	$ (0.07)	$ (0.38)	$ (0.16)	$ (1.38)

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 September 30, 2026						
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, June 30, 2026	200,000	$ 2	173,595,201	$ 1,735	$ 292,910	$ (172,899)	$ 121,748
Net loss	—	—	—	—	—	(14,623)	(14,623)
Stock-based compensation expense and related charges	—	—	—	—	5,065	—	5,065
Issuance of common stock for vesting of restricted stock units			675,224	7	(7)	—	—
Issuance of common stock in connection with exercise of warrants	—	—	133	—	—	—	—
Issuance of common stock in connection with Crohn's and Colitis Foundation Agreement (Note 5)	—	—	172,413	2	248	—	250
Balance, September 30, 2026	200,000	$ 2	174,442,971	$ 1,744	$ 298,216	$ (187,522)	$ 112,440

	Three Months Ended September 30, 2025						
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, June 30, 2025	200,000	$ 2	4,800,247	$ 48	$ 143,528	$ (140,958)	$ 2,620
Net loss	—	—	—	—	—	(2,868)	(2,868)
Stock-based compensation expense and related charges	—	—	—	—	47	—	47
Issuance of common stock in connection with July 2025 Warrant Inducement, net of issuance costs of $9,330 (Note 5)	—	—	4,318,905	43	3,370	—	3,413
Balance, September 30, 2025	200,000	$ 2	9,119,152	$ 91	$ 146,945	$ (143,826)	$ 3,212

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)

	Nine Months Ended September 30, 2026						
	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balance, December 31, 2025	200,000	$ 2	159,444,017	$ 1,594	$ 280,509	$ (152,725)	$ 129,380
Net loss	—	—	—	—	—	(34,797)	(34,797)
Stock-based compensation expense and related charges	—	—	—	—	14,147	—	14,147
Issuance of common stock to vendors	—	—	10,000	—	—	—	—
Issuance of common stock for vesting of restricted stock units	—	—	705,022	7	(7)	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	13,031	—	20	—	20
Issuance of common stock in connection with exercise of warrants	—	—	12,369,886	123	32	—	155
Issuance of common stock in connection with Crohn's and Colitis Foundation Agreement (Note 5)	—	—	364,130	4	559	—	563
Issuance of common stock in connection with stock purchase agreement, net of issuance costs of $28 (Note 5)	—	—	1,536,885	16	2,956	—	2,972
Balance, September 30, 2026	200,000	$ 2	174,442,971	$ 1,744	$ 298,216	$ (187,522)	$ 112,440

	Nine Months Ended September 30, 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	—	—	—	—	—	(7,882)	(7,882)
Stock-based compensation expense and related charges	—	—	—	—	185	—	185
Issuance of common stock under Employee Stock Purchase Plan	—	—	4,601	—	3	—	3
Issuance of common stock in connection with exercise of warrants	—	—	2,027,000	21	(20)	—	1
Issuance of common stock in connection with July 2025 Warrant Inducement, net of issuance costs of $9,330 (Note 5)	—	—	4,318,905	43	3,370	—	3,413
Balance, September 30, 2025	200,000	$ 2	9,119,152	$ 91	$ 146,945	$ (143,826)	$ 3,212

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

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

	Nine Months Ended September 30,	
	2026	**2025**
Net loss	$ (34,797)	$ (7,882)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	3
Non-cash operating lease expense	—	84
Recurring fair value measurements of liabilities	1	323
Write-off of deferred equity issuance costs	—	75
Stock-based compensation and related charges	14,147	228
Other	—	(61)
Changes in operating assets and liabilities:		
Prepaid and other current assets and other noncurrent assets	(4,223)	(537)
Accounts payable and accrued liabilities	2,145	255
Accrued compensation and benefits	(525)	(101)
Operating lease liabilities	—	(90)
Net cash used in operating activities	(23,252)	(7,703)
Cash flows from financing activities:		
Payments on insurance financing debt	(71)	(180)
Proceeds from issuance of common stock	3,450	—
Proceeds from the exercise of warrants	155	3,909
Payment of warrant inducement issuance costs	—	(445)
Payment of equity issuance costs	(74)	(178)
Proceeds from issuance of common stock under Employee Stock Purchase Plan	20	3
Net cash provided by financing activities	3,480	3,109
Net decrease in cash, cash equivalents and restricted cash	(19,772)	(4,594)
Cash, cash equivalents and restricted cash, beginning of year	133,440	9,847
Cash, cash equivalents and restricted cash, end of period	$ 113,668	$ 5,253
Reconciliation of cash, cash equivalents and restricted cash to the balance sheets:		
Cash and cash equivalents	$ 113,613	$ 5,227
Restricted cash	55	26
Total cash, cash equivalents and restricted cash	$ 113,668	$ 5,253
Supplemental disclosures of cash flow information:		
Interest paid	$ 1	$ 5
Supplemental disclosures of non-cash investing and financing activities:		
Warrant inducement costs included in accounts payable and accrued liabilities	$ —	$ 50
Payment of equity issuance costs previously included in accounts payable and accrued liabilities	46	—
Fair value of common shares issued in settlement of share liability (Note 4)	313	—
Fair value of common shares issued in settlement of derivative liability (Note 4)	50	—
Fair value of warrants issued to solicitation agent in warrant inducements (Note 5)	—	233
Insurance financing debt included in prepaid and other current assets and other noncurrent assets	—	312
Incremental fair value of modified warrants (Note 5)	—	8,602

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

Unless the context indicates or otherwise requires, “Palisade,” “Palisade Bio,” the "Company,” “we,” “us,” and “our” or similar designations in this Quarterly Report on Form 10-Q ("Form 10-Q"), 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 “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 "Seneca Merger"). Any reference to “Series A Preferred Stock” refers to the Company's Series A 4.5% Convertible Preferred Stock. Any reference herein that refers to preclinical studies also refers to nonclinical studies.

Description of Business

The Company is a clinical-stage biopharmaceutical company developing next-generation oral therapies for immune-mediated and fibrotic diseases. The Company's lead clinical product candidate, PALI-2108, is in Phase 2 clinical trials as a treatment for patients living with inflammatory bowel disease, including ulcerative colitis and Crohn’s disease.

Liquidity

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. 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 operating losses and negative cash flows from operations since its inception. The Company expects to continue to incur net 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 assurance that such profitability will ever be achieved. To fund its operations, the Company has historically relied primarily on equity financings.

On October 2, 2025, the Company closed on an equity offering for net proceeds to the Company of $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million (the "October 2025 Offering"), which significantly increased the Company's available working capital and its ability to fund its operations into the foreseeable future. Although the Company still anticipates incurring net operating losses and negative cash flows from operations into the foreseeable future, based on its current operating plan and based upon its cash and cash equivalents balance of $113.6 million as of September 30, 2026, management has concluded the Company has sufficient capital to fund its operations for at least a period of one year following the date that these condensed consolidated financial statements are issued.

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, 2025, which was filed with the SEC on March 20, 2026 ("Form 10-K").

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.

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 and nine months ended September 30, 2026 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's Form 10-K.

Comprehensive Loss

Comprehensive 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.

Reclassifications

Certain prior year amounts have been reclassified within the unaudited condensed consolidated financial statements to conform with current year presentation.

Recently Issued or Adopted Accounting Pronouncements

No new accounting pronouncements issued or adopted during the three and nine months ended September 30, 2026 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 consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Prepaid insurance	$ 541	$ 355
Other current receivables	3	264
Prepaid subscriptions and fees	377	145
Prepaid software licenses	104	60
Deferred equity issuance costs	70	—
Prepaid research and development expenses	2,765	7
Prepaid other	—	5
	$ 3,860	$ 836

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 nine months ended September 30, 2025, the Company expensed approximately $75,000 of previously deferred equity issuance costs associated with its shelf registration statement that expired in April of 2025 in general and administrative expenses in the condensed consolidated statements of operations. As of September 30, 2026, the entire balance of deferred equity issuance costs consists of legal, accounting and other direct and incremental costs directly attributable to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on May 21, 2026.

Other noncurrent assets as of September 30, 2026 consisted of the noncurrent portion of prepaid research and development expenses. Other noncurrent assets as of December 31, 2025 consisted of prepaid insurance, less the current portion.

Accrued liabilities consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued accounts payable	$ 392	$ 163
Accrued clinical trial expenses	1,002	801
Accrued chemistry, manufacturing and controls ("CMC") expenses	942	543
Accrued preclinical and translational science expenses	810	188
Accrued director stipends	81	59
Accrued other	381	433
	$ 3,608	$ 2,187

4. Fair Value Measurements

The following tables reflect the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2026 and December 31, 2025 (in thousands):

September 30, 2026	**Financial Statement Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:					
Money market funds	Cash and cash equivalents	$ 113,585	$ —	$ —	$ 113,585
Total		$ 113,585	$ —	$ —	$ 113,585
Liabilities:					
Derivative liability	Noncurrent liabilities	$ 12	$ —	$ —	$ 12
Contingent consideration obligation	Noncurrent liabilities	—	—	267	267
Total		$ 12	$ —	$ 267	$ 279

December 31, 2025	**Financial Statement Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:					
Money market funds	Cash and cash equivalents	$ 132,399	$ —	$ —	$ 132,399
Total		$ 132,399	$ —	$ —	$ 132,399
Liabilities:					
Share liability	Share liability	$ 313	$ —	$ —	$ 313
Derivative liability	Noncurrent liabilities	62	—	—	62
Contingent consideration obligation	Noncurrent liabilities	—	—	266	266
Total		$ 375	$ —	$ 266	$ 641

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 measures fair value based on quoted prices in active markets for identical assets.

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions and in money market accounts, and at times balances may exceed federally insured limits. Management believes that the Company is not

exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held and historically the Company has not experienced any losses in such accounts.

Share Liability and Derivative Liability

On December 17, 2025 (the "Execution Date"), the Company entered into a Research Program Funding Agreement with the Crohn's and Colitis Foundation (the "CCF"), in which the CCF agreed to provide up to a $0.5 million investment to support the Company's Phase 1b research program related to PALI-2108 in return for shares of the Company's common stock.

The funding is payable in three tranches ("CCF Milestone Amount") subject to the achievement of specified milestones. The first milestone ("CCF Milestone 1") in the amount of $250,000 was due to the Company within approximately 45 days of the Execution Date. Accordingly, as of December 31, 2025, the Company recognized a $250,000 other current receivable for the amount due from CCF in Prepaid and other current assets in the condensed consolidated balance sheets. Pursuant to Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480"), the Company also recognized CCF Milestone 1 as a financial instrument that requires liability classification initially recognized at fair value, with subsequent changes in fair value measured at each reporting period thereafter based on the market value of the Company's common stock, which is a level 1 input. Accordingly, as of December 31, 2025, the Company recognized the fair value of CCF Milestone 1 of $312,500 in Share liability in the condensed consolidated balance sheets. In the first quarter of 2026, CCF Milestone 1 was settled in cash, which reduced both the other current receivable and the Share liability to zero as of September 30, 2026. There was no change in the fair value of the Share liability prior to its cash settlement.

The second milestone ("CCF Milestone 2") is in the amount of $200,000 and was due based on achievement of certain research deliverables. The third milestone ("CCF Milestone 3") is in the amount of $50,000 and is due upon the final Phase 1b study report. Pursuant to ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* ("ASC 815-40"), CCF Milestone 2 and CCF Milestone 3 were determined to be derivative liabilities initially recognized at fair value, with subsequent changes in fair value measured at each reporting period thereafter based on the market value of the Company's common stock, which is a level 1 input. The fair value of each of CCF Milestone 2 and CCF Milestone 3, was recognized as a derivative liability and included in noncurrent liabilities in the condensed consolidated balance sheets.

During the three months ended September 30, 2026, it was determined that CCF Milestone 2 was met and the Company received the cash payment of $200,000 and issued to CCF shares of its common stock with a fair value of $250,000. Accordingly, the CCF Milestone 2 derivative liability was reduced to zero as of September 30, 2026. As of December 31, 2025, the fair value of the CCF Milestone 2 derivative liability was $50,000 and there was no change in the fair value prior to settlement.

As of September 30, 2026, CCF Milestone 3 has not been met. As of September 30, 2026 and December 31, 2025, the fair value of the CCF Milestone 3 derivative liability was determined to be $12,500. There was no change in the fair value of the derivative liability in the three and nine months ended September 30, 2026.

Contingent Consideration Obligation

On September 1, 2023, the Company and Giiant Pharma, Inc. ("Giiant") entered into a research collaboration and license agreement, as amended ("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 ASC 480, and accordingly has recognized it as a liability measured at its estimated fair value.

At the end of each reporting period, the Company re-measures the contingent consideration obligation to its estimated fair value and any resulting change is recognized in research and development expenses in the condensed consolidated statements of operations. The fair value of the contingent consideration obligation is determined using a probability-based model that estimates the likelihood of success in achieving each of the defined milestones that is then discounted to present value using the Company's incremental borrowing rate. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting hierarchy. The significant assumptions used in the calculation of the fair value as of September 30, 2026

included a discount rate of 26.2% 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 measured at its fair value on a recurring basis (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Contingent Consideration Obligation	**2026**	**2025**	**2026**	**2025**
Fair value at beginning of period	$ 259	$ 141	$ 266	$ 150
Change in fair value during the period	8	334	1	325
Fair value at end of period	$ 267	$ 475	$ 267	$ 475

As of September 30, 2026 and December 31, 2025, the entire amount of the contingent consideration obligation of approximately $267,000 and $266,000, respectively, was included in noncurrent liabilities in the condensed consolidated balance sheets since it is not expected to be settled within one-year of the respective balance sheet date.

Financial Instruments Not Required to be Remeasured at Fair Value

The Company's other financial assets and liabilities, including restricted cash, accounts receivable, other current receivables, accounts payable, and accrued liabilities are not remeasured to fair value, as the carrying amount of each approximates its fair value due to the short-term nature of these instruments. The carrying value of the Company’s insurance financing debt also approximated its fair value as of December 31, 2025 due to the short-term nature of the instrument and the market rate of interest, which is based on level 2 inputs.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

None of the Company’s non-financial assets or liabilities are recognized at fair value on a nonrecurring basis.

5. Stockholders’ Equity

Classes of Stock

Common Stock

On June 10, 2026, the Company held its annual meeting of stockholders at which time the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of the Company's $0.01 par value common stock from 300,000,000 shares to 450,000,000 shares. The Company subsequently amended its Amended and Restated Certificate of Incorporation to reflect the increase. As of September 30, 2026, the Company was authorized to issue 450,000,000 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.

Preferred Stock

As of September 30, 2026, 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 Transactions

Common Stock Purchase Agreement

On March 27, 2026, the Company issued and sold 1,536,885 shares of its common stock, par value $0.01 per share, to an investor for a total purchase price of $3.0 million, or $1.952 per share, pursuant to a common stock purchase agreement, dated March 27, 2026, by and between the Company and the investor. The Company recognized net equity issuance costs of approximately $28,000 against the additional paid-in capital recognized in this transaction.

Crohn's and Colitis Foundation Research Program Funding Agreement

The CCF has agreed to provide up to a $0.5 million investment to support the Company's Phase 1b research program related to PALI-2108. In the first quarter of 2026, the CCF settled CCF Milestone 1 in the amount of $250,000, and in the third quarter of 2026, the CCF settled CCF Milestone 2 in the amount of $200,000. Pursuant to the CCF Agreement, for each CCF Milestone payment received, within 30 days the Company must issue shares of its common stock equal to the CCF Milestone Amount divided by 80% of the closing price of the Company's common stock on the date of the respective milestone's cash receipt date. Accordingly, in the first quarter of 2026 and the third quarter of 2026, the Company issued 191,717 shares and 172,413 shares, respectively, of its common stock, par value $0.01 per share, to the CCF. As of September 30, 2026, CCF Milestone 3 has not yet been met.

October 2025 Offering

On October 2, 2025, the Company completed an underwritten offering of common stock and pre-funded warrants to purchase common stock for net proceeds of $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million.

Common Stock Warrants Outstanding and Warrant Activity

July 2025 Warrant Inducement

On July 23, 2025, the Company entered into a warrant inducement agreement (the "July 2025 Warrant Inducement Agreement") with an accredited and institutional holder (the "July 2025 Warrant Holder") of certain of the Company's outstanding common stock warrants (the "July 2025 Existing Warrants"), to exercise the July 2025 Existing Warrants to purchase up to an aggregate of 4,318,905 shares of the Company's common stock. Pursuant to the July 2025 Warrant Inducement Agreement, the exercise price of each July 2025 Existing Warrant exercised was reduced from $1.40 per share to $0.9047 per share. In consideration for the immediate exercise of the July 2025 Existing Warrants, the July 2025 Warrant Holder received new unregistered warrants (the "July 2025 Replacement Warrants") to purchase shares of common stock in a private placement. Pursuant to the July 2025 Warrant Inducement Agreement, the July 2025 Warrant Holder received two July 2025 Replacement Warrants for each July 2025 Existing Warrant exercised. The July 2025 Replacement Warrants are exercisable into an aggregate of up to 8,637,810 shares of common stock (the transaction in its entirety, the "July 2025 Warrant Inducement Transaction").

The July 2025 Warrant Holder exercised an aggregate of 4,318,905 July 2025 Existing Warrants and the Company issued an aggregate of 4,318,905 shares of its common stock and 8,637,810 July 2025 Replacement Warrants. The July 2025 Warrant Inducement closed on July 25, 2025 with the Company receiving net cash proceeds of approximately $3.4 million consisting of gross cash proceeds of $3.9 million, less cash equity issuance costs of approximately $0.5 million.

The July 2025 Warrant Inducement Transaction, which resulted in the lowering of the exercise price of the July 2025 Existing Warrants and the issuance of the July 2025 Replacement Warrants, is considered a modification of the July 2025 Existing Warrants under the guidance of ASC 815-40. 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 July 2025 Existing Warrants to cash exercise their July 2025 Existing Warrants, resulting in the imminent exercise of the July 2025 Existing Warrants, which raised equity capital and generated gross cash proceeds for the Company of approximately $3.9 million. As pursuant to the guidance of ASC 480 and ASC 815-40 the July 2025 Existing Warrants and 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 $8.6 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 July 2025 Existing Warrants and additional July 2025 Replacement Warrants issued as compared to the fair value of the original July 2025 Existing Warrants immediately prior to their modification.

Total equity issuance costs recognized in the July 2025 Warrant Inducement of $9.3 million include cash equity issuance costs of $0.5 million, non-cash warrant modification costs of approximately $8.6 million, and non-cash issuance costs of $0.2 million associated with 259,134 common stock warrants, with an exercise price of $1.49 per share, and a term of five years from issuance, that were issued to the solicitation agent in the transaction.

Common Stock Warrants Outstanding and Warrant Activity

The following table summarizes the Company's outstanding and exercisable common stock warrants as of September 30, 2026:

Common Stock Warrants	Classification	Number of Warrants Outstanding and Exercisable	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
October 2025 Offering Pre-Funded Common Stock Warrants	Equity-classified	37,814,754	$ 0.0001	Perpetual [1]
July 2025 Warrant Inducement Replacement Common Stock Warrants	Equity-classified	8,637,810	0.9047	4.18
February 2024 Warrant Inducement Replacement Common Stock Warrants	Equity-classified	113,804	10.97	2.34
Series 2 Common Stock Warrants	Equity-classified	6,615	0.70	0.87
Placement Agent, Solicitor and Representative Common Stock Warrants	Equity-classified	5,084,891	1.70	3.94
All Other Common Stock Warrants	Equity-classified	258	28,526.86	0.70
Total Warrants Outstanding and Exercisable, September 30, 2026		51,658,132	0.48	4.07 [1]

[1] The pre-funded common stock warrants outstanding as of September 30, 2026 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 Common Stock 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 all common stock warrant activity during the nine months ended September 30, 2026:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Warrants outstanding, December 31, 2025	64,031,148	$ 0.53	4.81 [1]
Granted	—	—	
Exercised	(12,369,886)	0.0126	
Forfeited, expired or cancelled	(3,130)	2,866.88	
Warrants outstanding, September 30, 2026	51,658,132	0.48	4.07 [1]

[1] The pre-funded common stock warrants outstanding as of September 30, 2026 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 nine months ended September 30, 2026, the Company granted 7,440,708 RSUs at a weighted-average grant date fair value of $1.72 per RSU, and the Company granted 254,200 PSUs at a weighted-average grant date fair

value of $1.38 per PSU. The Company granted no stock options during the nine months ended September 30, 2026. During the nine months ended September 30, 2025, the Company granted 116,600 stock options at a weighted-average grant date fair value of $1.00 per stock option, and the Company granted 89,400 RSUs at a weighted-average grant date fair value of $1.13 per RSU. The Company granted no PSUs during the nine months ended September 30, 2025.

Employee Stock Purchase Plan

The Company offers its employees an opportunity to participate in its stockholder-approved Palisade Bio, Inc. 2021 Amended and Restated 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 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 was approximately $14,000 and $30,000 in the three and nine months ended September 30, 2026, respectively, and approximately $5,000 and $26,000 in the three and nine months ended September 30, 2025, respectively.

Share-Based Compensation Expense

The allocation of stock-based compensation for the Company's equity-based awards is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development expense	$ 2,085	$ 45	$ 6,120	$ 93
General and administrative expense	2,966	40	7,997	109
Total	$ 5,051	$ 85	$ 14,117	$ 202

As of September 30, 2026, the unrecognized compensation cost related to outstanding stock options was approximately $0.1 million, which is expected to be recognized over a weighted-average period of approximately 1.30 years, and the unrecognized compensation cost related to outstanding RSUs and PSUs was approximately $42.4 million, which is expected to be recognized over a weighted-average period of approximately 2.16 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.

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 development plan and development budget for the Giiant Licensed Assets (the “Giiant Development Plan”). 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.

For the three and nine months ended September 30, 2026, the Company recognized no expenses related to the joint development of the Giiant Licensed Assets pursuant to the Giiant Development Plan. For the three and nine months ended September 30, 2025, the Company recognized a net credit related to the joint development of the Giiant Licensed Assets of approximately $0.2 million and $0.8 million, respectively, which consisted primarily of funds received by the Company from Giiant. Both the expenses related to the joint development plan and any credits for funds received by the Company from Giiant are included in research and development expenses in the condensed consolidated statements of operations.

Pursuant to the Giiant License Agreement, the Company is (i) required to make certain payments 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. On October 16, 2025, the Company determined that the first of the development milestones pursuant to the Giiant License Agreement was achieved with the dosing of the first patient in the Company's exploratory Phase 1b clinical trial of PALI-2108 in a fibrostenotic Crohn's disease cohort. The Company settled this Giiant Milestone Payment in cash in the amount of $235,000 in the fourth quarter of 2025. As of September 30, 2026, one of the Giiant Milestone Payments remains, which could require the Company to make a payment in the low-seven-digit range upon the achievement of the one remaining development milestone. There have been no other Giiant Milestone Payments made pursuant to the Giiant License Agreement.

Co-Development and Distribution Agreement with Newsoara

Prior to the completion of the Seneca Merger, LBS entered into a co-development and distribution agreement with Newsoara, a joint venture established by 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 to 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 Newsoara Licensed Products only include the drug asset referred to as LB1148.

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 Newsoara Licensed Products, subject to adjustment to the royalty percentage in certain events, including a change of control, the expiration of certain patent rights, and royalties paid by Newsoara to third parties. To date, Newsoara has met all of its payment obligations under the Newsoara Co-Development Agreement.

During the nine months ended September 30, 2026, the Company recognized license revenue of $0.5 million earned upon Newsoara's achievement in the second quarter of 2026 of a development milestone pursuant to the Newsoara Co-Development Agreement. During the three months ended September 30, 2026, and the three and nine months ended September 30, 2025, the Company recognized no license revenue from Newsoara under the Newsoara Co-Development Agreement.

License Agreements with the Regents of the University of California

Prior to the Seneca Merger, the Company 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 September 30, 2026, 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 was 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 on certain milestone payments, of which none of the milestone payments that may result on this obligation remain. Additionally, pursuant to the 2015 UC License, the Company is obligated to pay a low-single-digit percentage of the tiered royalty payments on annual net sales of Newsoara Licensed Products that it receives from Newsoara, if any. During the three months ended September 30, 2026, the Company recognized no sublicense fees or license maintenance fees. During the nine months ended September 30, 2026, the Company recognized no sublicense fees and license maintenance fees of approximately $12,000 in research and development expenses in the condensed consolidated statements of operations. During the three and nine months ended September 30, 2025, the Company recognized no sublicense fees or license maintenance fees due to Regents.

Licensed Legacy Assets

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

Prior to the Seneca 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 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 mid-2027. 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. To date, the Company has recognized no net revenues from the licensing of NSI-532.IGF-1.

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 October 2025 Offering, on October 2, 2025, the Company issued pre-funded warrants to purchase one share of the Company's common stock, par value $0.01 per share (the "October 2025 Offering Pre-Funded Common Stock Warrants"). The October 2025 Offering Pre-funded Common Stock Warrants were determined to be

equity-classified in accordance with ASC 480 and ASC 815-40. As of September 30, 2026, 37,814,754 of the October 2025 Offering Pre-funded Common Stock 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 for the unexercised portion of the October 2025 Offering Pre-funded Common Stock Warrants have been included in the denominator for the calculation of basic and dilutive net loss per common share for the three and nine months ended September 30, 2026. There were no pre-funded warrants outstanding at September 30, 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 and nine months ended September 30, 2026 and September 30, 2025 were calculated using the if-converted and treasury stock methods. For both the three and nine months ended September 30, 2026 and September 30, 2025, basic and diluted net loss per common share were the same as all common stock equivalents other than the pre-funded warrants that were outstanding at September 30, 2026, as discussed above, were anti-dilutive for all the periods presented.

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Basic and diluted net loss per common share:				
Net loss	$ (14,623)	$ (2,868)	$ (34,797)	$ (7,882)
Weighted average shares used in calculating basic and diluted net loss per common share	212,027,787	7,473,898	211,035,838	5,702,050
Basic and diluted net loss per common share	$ (0.07)	$ (0.38)	$ (0.16)	$ (1.38)

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

	September 30,	
	2026	2025
Stock options	167,252	167,261
Service-based and performance-based restricted stock units	31,699,438	92,352
Common stock warrants	13,843,378	9,295,577
Series A Convertible Preferred Stock	8	8
Total	45,710,076	9,555,198

9. Commitments and Contingencies

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 currently pending against the Company, which will have, individually or in aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, legal proceedings or claims, however, are subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

Nexys Agreements

On September 22, 2026 (the "Execution Date"), the Company entered into a development funding agreement (the "DFA") and call option agreement (the "Call Option" and together with the DFA, the "Nexys Agreements") with Nexys Therapeutics, LLC. ("Nexys"). Under the DFA, the Company may fund up to $3.5 million in expenses related to the development of Nexys' assets, evidenced by a promissory note (the "Note") bearing simple interest at an annual rate of 4.01% and maturing on January 1, 2030.

During the call option period, as defined in the Call Option, the Company can exercise the Call Option to acquire all outstanding equity interests of Nexys, which would apply the aggregate principal and accrued interest outstanding under the Note toward the purchase consideration. If the Company elects not to exercise the Call Option, the Company

may elect for any outstanding principal and accrued interest under the Note to convert into equity interests of Nexys, subject to a 19.99% ownership limitation (the "conversion feature"). Unless certain events of default occur, the Note, including any principal and accrued interest due, will not be settled in cash and will be settled through the Call Option, the conversion feature, or forgiven if the Company does not elect the Call Option during the option period or the conversion feature prior to the maturity of the Note.

As both the Note and the Call Option are not readily convertible into cash, and are physically settled into the equity of Nexys, the Company has determined that both instruments fail the net-settlement provisions of ASC 815, *Derivatives and Hedging*, ("ASC 815"), and therefore do not meet the definition of a derivative.

Under the terms of the DFA, the Company is not obligated to fund any amounts under the Note until the related funding package is approved. As of both the Execution Date and September 30, 2026, the Company had not approved nor had any funding been advanced through the Note. Therefore, as of both the Execution Date and September 30, 2026, the Company has not recognized any financial impact resulting from the Nexys Agreements.

Other Commitments

On March 30, 2026, the Company entered into an agreement with a third party to support with site selection, activation, and enrollment for the Company's Phase 2 clinical trial of PALI-2108 for the treatment of UC. Per the terms of the agreement, the Company will pay a set amount per patient that is enrolled and randomized in the trial. The Company may also owe additional amounts based upon achievement of certain defined enrollment rate targets. The agreement includes a contract termination clause, requiring a payment of $2.0 million if the Company terminates the agreement after activation of the first site and prior to the earlier of the aggregate per-patient fees reaching $8.0 million or completion of the study. The first site subject to the agreement was activated in the third quarter of 2026. No patients were randomized as of September 30, 2026 and no amounts for this agreement were recognized as of September 30, 2026.

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 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 for the three and nine months ended September 30, 2026 and 2025 is included in the table below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
PALI-2108 program expenses	$ 7,250	$ 457	$ 15,372	$ 2,280
Legacy program expenses	1	13	75	(45)
Other research and development expenses	3,312	933	9,157	1,830
Other general and administrative expenses	5,137	1,519	14,042	4,010
Total operating expenses	$ 15,700	$ 2,922	$ 38,646	$ 8,075

PALI-2108 program expenses are those expenses directly related to 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 include primarily employee-related 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, legal fees, investor and public relations, accounting and audit services, taxes and 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 and nine months ended September 30, 2026 and 2025, the other segment items that the Company used to aggregate with Total operating expenses to arrive at Net Loss as shown on the condensed consolidated statement of operations may include 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 condensed 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 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 and nine months ended September 30, 2026 and 2025.
- *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 developing next-generation oral therapies for immune-mediated and fibrotic diseases. Our lead clinical product candidate, PALI-2108, is in Phase 2 clinical trials as a treatment for patients living with inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC") and Crohn's disease ("CD").

Despite the availability of multiple biologic and small-molecule therapies, many patients with UC and CD do not achieve durable remission, lose response over time, or discontinue treatment because of safety or tolerability limitations. We believe PALI-2108 has the potential to address these limitations through once-daily oral dosing, targeted lower-intestinal bioactivation, sustained pharmacologic exposure of its active metabolite, and broad phosphodiesterase-4 ("PDE4") mediated anti-inflammatory activity.

Our development strategy is focused on establishing PALI-2108 as a potentially differentiated oral monotherapy, while exploring its potential for use in future combination regimens with complementary mechanisms of action. We believe PDE4 inhibition may offer opportunities to address multiple aspects of disease pathophysiology, including inflammation, mucosal injury and fibrosis.

During 2026, we completed our Phase 1 clinical development program for PALI-2108. In June 2026, the U.S. Food and Drug Administration ("FDA") cleared our Investigational New Drug ("IND") application for ASCENTRA-UC, our global Phase 2 clinical trial, in which we dosed our first patient on October 27, 2026. ASCENTRA-UC represents our first large, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy and safety

of PALI-2108 in patients with moderately-to-severely active UC. In September 2026, the FDA cleared our IND for our global Phase 2 ASCENTRA-CD clinical trial in patients with moderate-to-severe CD.

Together, ASCENTRA-UC and ASCENTRA-CD are designed to evaluate the clinical efficacy, safety and pharmacology of PALI-2108 across the two major forms of IBD while generating data to inform subsequent clinical development and potential future therapeutic applications.

PALI-2108

Our lead clinical product candidate, PALI-2108, is a novel, once-daily, orally administered microbiota-activated prodrug designed for targeted delivery of PDE4 inhibition to the terminal ileum and colon. The prodrug is designed to remain pharmacologically inactive until it reaches the lower intestine, where bacterial enzymes convert it into the active PDE4 inhibitor at sites of inflammation and fibrosis.

This differentiated drug-delivery approach is designed to provide sustained intestinal exposure to the active metabolite with the goal of enabling measurable systemic exposure with moderated peak plasma concentrations. We believe these pharmacologic characteristics may improve the therapeutic index of PDE4 inhibition and potentially mitigate tolerability limitations historically associated with systemic PDE4 inhibitors, including headache and gastrointestinal adverse events such as nausea and diarrhea.

Our Translational and Precision Medicine Approach

We are advancing a translational medicine strategy designed to characterize the molecular and pharmacologic effects of PALI-2108, identify biomarkers associated with treatment response and support the development of potentially more effective therapeutic approaches for patients with IBD.

Our research incorporates clinical data, intestinal tissue analyses, pharmacodynamics ("PD") measurements and multiomics datasets to investigate PDE4-associated inflammatory pathways and molecular responses to treatment. These efforts are intended to improve our understanding of the mechanism of action of PALI-2108, identify candidate biomarkers potentially associated with therapeutic response and inform future clinical development, including exploratory biomarker analyses in our Phase 2 clinical programs.

Our Phase 1 clinical program incorporated measurements of intestinal tissue cAMP signaling, inflammatory biomarkers and molecular profiling to evaluate treatment-associated PD effects. We are using these findings, together with broader translational research, to investigate candidate biomarker signatures that may support future patient stratification and treatment optimization.

In addition, we are evaluating complementary molecular pathways that may be suitable for future combination approaches with PALI-2108. We believe this integrated strategy may support both the continued development of PALI-2108 as a monotherapy and the identification of potential future oral combination therapies.

Phase 1 Clinical Study of PALI-2108

The Phase 1 clinical study of PALI-2108 consisted of a single-center study evaluating the safety, tolerability, pharmacokinetics (“PK”) and PD of PALI-2108 in healthy volunteers, patients with UC and patients with fibrostenotic Crohn's disease ("FSCD"). The clinical study included five single ascending dose ("SAD") double-blind, placebo-controlled cohorts, four multiple ascending dose ("MAD") double-blind, placebo-controlled cohorts, a food effect ("FE") study, and open-label exploratory Phase 1b patient cohorts in UC and FSCD. In addition, to inform the dosing regimen selected for our Phase 2 study, we conducted a multiple-dosing, open-label study in three cohorts to evaluate safety, tolerability and PK in which each of the cohorts received a once-daily 15 mg, 30 mg or 45 mg dosing over a ten-day dosing period. The Phase 1 clinical study of PALI-2108 enrolled and completed dosing in 106 subjects across all cohorts.

On October 9, 2024, Health Canada issued a No Objection Letter for our Phase 1 human clinical study of PALI-2108. The study of the SAD, MAD and FE cohorts and the Phase 1b UC patient cohort commenced on November 7, 2024.

On May 27, 2025, we announced positive results from the SAD, MAD and FE cohorts in healthy volunteers. The double-blind, placebo-controlled study successfully met its primary endpoints of safety, tolerability, and PK.

On August 7, 2025 and September 17, 2025, we announced positive results from the open-label exploratory Phase 1b UC patient cohort portion of the study. All five patients met criteria for clinical response during treatment, including two patients who achieved clinical remission, as measured by the Modified Mayo score. Exploratory assessments also

identified improvements in inflammatory biomarkers and histologic measures. Although encouraging, these findings were obtained from a small, uncontrolled cohort and require confirmation in adequately powered randomized clinical trials.

On October 16, 2025, we dosed our first patients in the open-label exploratory Phase 1b FSCD patient cohort to evaluate the safety, tolerability, PK, and PD of once-daily oral dosing of PALI-2108 over a 14-day treatment period as well as evaluate tissue-level pharmacology and molecular responses using paired ileal biopsies and peripheral blood mononuclear cells. The study incorporated advanced molecular analyses, including cAMP quantification and RNA sequencing, to characterize treatment-induced changes in inflammatory and fibrotic signaling pathways.

On March 30, 2026, we announced positive results from the open-label exploratory Phase 1b FSCD patient cohort. In five treated patients, exploratory endoscopic assessments demonstrated a mean reduction of approximately 47.5% in the Simple Endoscopic Score for Crohn's Disease ("SES-CD") following 14 days of treatment, with two patients meeting criteria for both endoscopic response and endoscopic remission. The study also demonstrated PD evidence consistent with intestinal PDE4 pathway engagement, including an approximately 43% increase in ileal tissue cAMP, together with changes in inflammatory cellular populations and exploratory biomarkers associated with tissue remodeling. The study demonstrated favorable safety and tolerability, robust PD target engagement in ileal tissue, and encouraging early signals of clinical activity. We believe these findings support the continued development of PALI-2108 as a potential first therapy for both the inflammatory and fibrotic components of CD.

Global Phase 2 ASCENTRA-UC Clinical Trial of PALI-2108

On June 29, 2026, we announced that the FDA cleared our IND application for PALI-2108, enabling initiation of our global Phase 2 ASCENTRA-UC clinical trial for the treatment of moderately-to-severely active UC.

ASCENTRA-UC is a global, multi-center, randomized, double-blind, placebo-controlled, dose-ranging Phase 2 clinical trial designed to evaluate the efficacy, safety, tolerability, PK and PD of PALI-2108 in approximately 204 patients with moderately-to-severely active UC. Patients will be randomized to receive either PALI-2108 15 mg, PALI-2108 30 mg, or placebo administered orally once daily. The study includes patients with prior exposure to advanced therapies, enabling evaluation across a clinically relevant UC population.

The primary endpoint is clinical remission at week 12, as measured by the modified Mayo Score. Key secondary endpoints include clinical response, endoscopic improvement and histologic-endoscopic mucosal improvement (HEMI). Following the 12-week induction period, eligible patients will continue into a 36-week maintenance phase designed to evaluate durability of response through week 48.

We dosed our first patient in the ASCENTRA-UC clinical trial on October 27, 2026. Primary efficacy results for ASCENTRA-UC are expected in the fourth quarter of 2027.

Global Phase 2 ASCENTRA-CD Clinical Trial of PALI-2108

On September 22, 2026, we announced that the FDA cleared our IND application for PALI-2108, enabling initiation of our global Phase 2 ASCENTRA-CD clinical trial for the treatment of moderate-to-severe CD.

ASCENTRA-CD is a global, multi-center, open-label, single-arm Phase 2 study designed to evaluate the efficacy, safety, tolerability, PK and PD of PALI-2108 in approximately 60 adults with moderate-to-severe CD. Patients will receive PALI-2108 orally once daily, with dose titration to the target dose of PALI-2108 30 mg. The study includes a 12-week induction phase followed by a 36-week maintenance phase.

The primary endpoint is endoscopic response at week 12, as measured by at least a 50% reduction from baseline in the Simple Endoscopic Score for Crohn’s Disease ("SES-CD"), based on blinded central endoscopic review. Key secondary endpoints at week 12 include clinical remission, endoscopic remission, PRO-2 remission (a patient-reported outcome of abdominal pain and stool frequency), clinical response and combined clinical remission and endoscopic response, with additional maintenance assessments through week 48.

We anticipate initiating patient enrollment in the ASCENTRA-CD clinical trial in the first quarter of 2027, with primary efficacy results expected in the first quarter of 2028.

RESULTS OF OPERATIONS

License Revenue

We generated no revenues from the sale of our product candidates for any of the periods presented. For the nine months ended September 30, 2026, we recognized license revenue of approximately $0.5 million from the co-development and distribution agreement with Newsoara, a joint venture established by Biolead Medical Technology Limited, as amended, (the "Newsoara Co-Development Agreement"). For the three months ended September 30, 2026, and three and nine months ended September 30, 2025, we recognized no license revenue.

Research and Development Expenses

Our research and development expenses include:

- salaries and employee-related costs and benefits, 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.

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 development and manufacturing organizations ("CDMOs") and research laboratories in connection with our process development, manufacturing, preclinical and 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, (iii) drug manufacturing activities, and (iv) process development.

General and Administrative Expenses

Our general and administrative expenses consist primarily of (i) salary and employee-related costs and benefits, including stock-based compensation, (ii) professional fees for legal, intellectual property, investor and public relations, accounting and audit services, insurance costs, director and committee fees, and (iii) general corporate expenses.

Results of Operations

Comparison of the three months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Change	
	2026	2025	$	%
Operating expenses:				
Research and development	$ 10,579	$ 1,394	$ 9,185	659%
General and administrative	5,121	1,528	3,593	235%
Total operating expenses	15,700	2,922	12,778	437%
Loss from operations	(15,700)	(2,922)	(12,778)	437%
Other (expense) income:				
Interest expense	—	(5)	5	(100)%
Other income, net	1,077	59	1,018	1725%
Total other income, net	1,077	54	1,023	1894%
Net loss	$ (14,623)	$ (2,868)	$ (11,755)	410%

Research and Development Expenses

Our research and development expenses increased by approximately $9.2 million from approximately $1.4 million for the three months ended September 30, 2025 to approximately $10.6 million for the three months ended September 30, 2026. The increase is primarily attributable to an approximately $2.7 million increase in research and development employee-related expenses and an approximately $6.8 million net increase in PALI-2108 program expenses. These increases were partially offset by an approximately $0.3 million decrease in expenses associated with the fair value of the contingent consideration obligation pursuant to the research collaboration and license agreement, as amended ("Giiant License Agreement") entered with Giiant Pharma, Inc. ("Giiant").

The increase in research and development employee-related expenses for the three months ended September 30, 2026, compared to the three months ended September 30, 2025, was primarily due to an approximately $2.0 million increase in non-cash share-based compensation expense and an approximately $0.7 million increase in research and development salaries and benefits expense due to higher research and development headcount necessary to support our PALI-2108 development strategy.

We recognized PALI-2108 program expenses of approximately $7.3 million for the three months ended September 30, 2026, compared to PALI-2108 program expenses of approximately $0.4 million for the three months ended September 30, 2025. Included in these program expenses were (i) clinical operations costs, which increased from approximately $0.3 million for the three months ended September 30, 2025 to approximately $5.0 million for the three months ended September 30, 2026, (ii) chemistry, manufacturing and controls ("CMC") expenses, which increased from approximately $0.2 million for the three months ended September 30, 2025 to approximately $1.0 million for the three months ended September 30, 2026, (iii) other program expenses, which increased from an immaterial amount for the three months ended September 30, 2025 to approximately $0.2 million for the three months ended September 30, 2026, and (iv) preclinical and translational science expenses, which increased from a credit of approximately $0.1 million for the three months ended September 30, 2025 to approximately $1.1 million for the three months ended September 30, 2026. Preclinical and translational science expenses for the three months ended September 30, 2025 includes a credit of approximately $0.2 million related to funds received by us from Giiant pursuant to the Giiant License Agreement, that did not recur in the three months ended September 30, 2026.

The decrease in expense associated with the fair value of the contingent consideration obligation was driven by the recognition of an approximate $0.3 million non-cash loss on the fair value remeasurement of the contingent consideration obligation for the three months ended September 30, 2025, compared to an immaterial non-cash loss on the fair value remeasurement of the contingent consideration obligation for the three months ended September 30, 2026. Pursuant to the Giiant License Agreement, we owe Giiant certain payments upon the achievement of development milestones associated with PALI-2108. Concurrent with the expected dosing of our first patients in an exploratory Phase 1b cohort in FSCD, which occurred on October 16, 2025, we recognized an approximate $0.3 million non-cash loss in the three months ended September 30, 2025 with the fair value remeasurement of the associated contingent consideration liability.

General and Administrative Expenses

Our general and administrative expenses increased by approximately $3.6 million from approximately $1.5 million for the three months ended September 30, 2025 to approximately $5.1 million for the three months ended September 30, 2026. The increase was primarily as a result of (i) an approximately $3.1 million increase in general and administrative employee-related expenses driven by an approximately $2.9 million increase in non-cash share-based compensation expense and an approximately $0.2 million increase in general and administrative salaries and benefits, (ii) an approximately $0.4 million increase in professional fees, primarily legal fees, and (iii) an approximately $0.1 million increase in general operating costs.

Other (expense) income

Other income, net, for the three months ended September 30, 2026 and 2025 consists primarily of dividend income from our investments of excess cash in money market funds with maturities of three months or less. The increase of $1.0 million for the three months ended September 30, 2026, compared to the three months ended September 30, 2025, is due to the increased investment of excess cash in money market accounts after the October 2025 Offering, which is further described below.

Comparison of the nine months ended September 30, 2026 and 2025

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
License revenue	$ 500	$ —	$ 500	n/a
Operating expenses:				
Research and development	24,376	4,019	20,357	507%
General and administrative	14,270	4,056	10,214	252%
Total operating expenses	38,646	8,075	30,571	379%
Loss from operations	(38,146)	(8,075)	(30,071)	372%
Other (expense) income:				
Interest expense	(1)	(8)	7	(88)%
Other income, net	3,350	201	3,149	1567%
Total other income, net	3,349	193	3,156	1635%
Net loss	$ (34,797)	$ (7,882)	$ (26,915)	341%

License revenue

During the nine months ended September 30, 2026, we recognized license revenue of $0.5 million earned upon the achievement of a milestone under the Newsoara Co-Development Agreement. During the nine months ended September 30, 2025, we recognized no license revenue.

Research and Development Expenses

Our research and development expenses increased by approximately $20.4 million from approximately $4.0 million for the nine months ended September 30, 2025 to approximately $24.4 million for the nine months ended September 30, 2026. The increase is primarily attributable to (i) an approximately $7.7 million increase in research and development employee-related expenses, (ii) an approximately $12.9 million net increase in PALI-2108 program expenses, and (iii) an approximately $0.1 million net increase in legacy program expenses. These increases were partially offset by an approximately $0.3 million decrease in expenses associated with the fair value of the contingent consideration obligation pursuant to the Giiant License Agreement.

The increase in research and development employee-related expenses for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025, was primarily due to an approximately $6.0 million increase in non-cash share-based compensation expense and an approximately $1.7 million increase in research and development salaries and benefits expense due to higher research and development headcount necessary to support our PALI-2108 development strategy.

PALI-2108 program expenses were approximately $15.1 million for the nine months ended September 30, 2026, compared to PALI-2108 program expenses of approximately $2.2 million for the nine months ended September 30, 2025. Included in these program expenses were (i) clinical operations costs, which increased from approximately $2.1 million for the nine months ended September 30, 2025 to approximately $8.4 million for the nine months ended September 30, 2026, (ii) CMC expenses, which increased from approximately $0.6 million for the nine months ended September 30, 2025 to approximately $3.0 million for the nine months ended September 30, 2026, and (iii) other program expenses, which increased from approximately $0.1 million for the nine months ended September 30, 2025 to approximately $0.5 million for the nine months ended September 30, 2026, and (iv) preclinical and translational science expenses, which increased from a credit of approximately $0.6 million for the nine months ended September 30, 2025 to approximately $3.2 million for the nine months ended September 30, 2026. Preclinical and translational science expenses for the nine months ended September 30, 2025 includes a credit of approximately $0.8 million related to funds received by us from Giiant pursuant to the Giiant License Agreement, that did not recur in the nine months ended September 30, 2026.

The decrease in expense associated with the fair value of the contingent consideration obligation was driven by the recognition of an approximate $0.3 million non-cash loss on the fair value remeasurement of the contingent consideration obligation for the nine months ended September 30, 2025, compared to an immaterial non-cash loss on the fair value remeasurement of the contingent consideration obligation for the nine months ended September 30, 2026.

General and Administrative Expenses

Our general and administrative expenses increased by approximately $10.2 million from approximately $4.1 million for the nine months ended September 30, 2025 to approximately $14.3 million for the nine months ended September 30, 2026. The increase was primarily as a result of (i) an approximately $8.5 million increase in general and administrative employee-related expenses due to an approximately $7.9 million increase in non-cash share-based compensation expense and an approximately $0.6 million increase in general and administrative salaries and benefits, (ii) an approximately $1.2 million increase in professional fees, primarily legal fees, (iii) an approximately $0.2 million increase in patent-related costs, (iv) an approximately $0.1 million increase in taxes and insurance, and (v) an approximately $0.2 million increase in general corporate expenses.

Other (expense) income

Other income, net, for the nine months ended September 30, 2026 and 2025 consists primarily of dividend income from our investments of excess cash in money market funds with maturities of three months or less. The increase of $3.1 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025, is due to the increased investment of excess cash in money market accounts after the October 2025 Offering, which is further described below.

Liquidity and Capital Resources

We expect to incur substantial losses for the foreseeable future. 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.

The October 2025 Offering, as further described below, significantly increased our available working capital and our ability to fund our operations into the foreseeable future. Based on our current operating plan and our cash and cash equivalents balance of $113.6 million as of September 30, 2026, management believes that we have sufficient capital to fund our operations through major clinical development milestones including a primary efficacy readout of our Phase 2 ASCENTRA-UC clinical trial that is expected in the fourth quarter of 2027 and a primary efficacy readout of our Phase 2 ASCENTRA-CD clinical trial that is expected in the first quarter of 2028.

Future capital requirements will depend upon many factors, including the timing and extent of spending on research and development and market acceptance of our products, if approved for commercial sale. We may seek additional funding through public and private financings, debt financings, collaboration agreements, strategic alliances and licensing agreements. Although we have been successful in raising capital in the past, there is no assurance of success in obtaining such additional financing on terms acceptable to us, if at all, and there is no assurance that we will be able to enter into collaborations or other arrangements. If we are unable to obtain funding, it could force delays, reduce or eliminate research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our future business prospects, and the ability to continue operations.

Pursuant to the underwritten offering of common stock and pre-funded warrants we completed on October 2, 2025 (the "October 2025 Offering"), we issued and sold (a) 113,240,564 shares of our common stock, par value $0.01 per share, at a public offering price of $0.70 per share, and (b) 83,914,280 pre-funded warrants to purchase one share of our common stock, par value $0.01 per share, at a public offering price of $0.6999 per share. Net proceeds from the offering, including the full exercise of the underwriter's over-allotment option, were approximately $127.6 million, consisting of gross cash proceeds of $138.0 million less underwriting discounts and commissions and other cash equity issuance costs of approximately $10.4 million. We intend to use the net proceeds from the offering for working capital and general corporate purposes, including the development of PALI-2108 for the treatment of UC and CD.

Refer to Note 5, *Stockholders' Equity* in Part I Item 1 of this Quarterly Report on Form 10-Q for further details of our recent equity transactions.

Cash Flows

As of September 30, 2026, we had $113.7 million in cash, cash equivalents and restricted cash. The following table shows a summary of our cash flows for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (23,252)	$ (7,703)
Net cash provided by financing activities	3,480	3,109

Net Cash Used in Operating Activities

Cash used in operating activities was approximately $23.3 million for the nine months ended September 30, 2026, which reflects an approximately $34.8 million net loss adjusted for (i) approximately $2.6 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 $14.1 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 (i) a net cash outflow of approximately $4.2 million from an increase in prepaid and other current assets and other noncurrent assets that was primarily attributable to prepaid research and development expenses of approximately $3.8 million recognized during the period, and the timing of payments for certain services, and (ii) a net cash outflow of approximately $0.5 million driven by the payment of annual employee cash bonuses in the period, partially offset by the current period employee cash bonus accrual. These cash outflows were partially offset by an approximately $2.1 million cash inflow from an increase in accounts payable and accrued liabilities as of September 30, 2026, compared to December 31, 2025, primarily due to higher PALI-2108 program expenses in the period.

Cash used in operating activities was approximately $7.7 million for the nine months ended September 30, 2025, which reflects an approximately $7.9 million net loss adjusted for (i) approximately $0.5 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 (a) an approximately $0.3 million non-cash expense recognized for the fair value remeasurement of liabilities, mainly our contingent consideration liability, (b) an approximately $0.2 million non-cash expense recognized for stock-based compensation and related charges, (c) an approximately $0.1 million non-cash operating lease expense, and (d) an approximately $0.1 million non-cash expense related to the write-off of certain deferred equity issuance costs associated with our shelf registration statement that expired in April of 2025. The net cash outflow from operating assets and liabilities was primarily attributable to (i) a net cash outflow of approximately $0.5 million from an increase in prepaid and other current assets and other noncurrent assets that was due to the deferral of issuance costs in the amount of approximately $0.6 million associated with the equity offering that closed on October 2, 2025 and a significant prepaid research and development expense of approximately $0.4 million recognized in the period, (ii) a cash outflow of approximately $0.1 million driven by the payment of annual employee cash bonuses in the first quarter of 2025, and (iii) an approximately $0.1 million cash outflow related to payments of our operating lease. These net cash outflows were partially offset by an approximately $0.3 million cash inflow from an increase in accounts payable and accrued liabilities as of September 30, 2025 compared to December 31, 2024, primarily due to higher clinical trial-related expenses as a result of increased clinical trial activity, partially offset by lower accrued joint development expenses associated with the Giiant License Agreement.

Net Cash Provided by Financing Activities

For the nine months ended September 30, 2026, cash provided by financing activities of approximately $3.5 million was primarily attributable to net cash proceeds of approximately $3.5 million from the issuance of our common stock to an investor and the issuance of our common stock in association with the Crohn's and Colitis Foundation Research Program Funding Agreement, both of which are described in Note 5, *Stockholders' Equity* in Part I Item 1 of this Quarterly Report on Form 10-Q, and net cash proceeds of approximately $0.2 million from the exercise of our common stock purchase warrants by certain investors. These cash proceeds were partially offset by the payment of equity issuance costs of approximately $0.1 million related to certain recently completed financings and payments of approximately $0.1 million made on our insurance financing arrangement, which expired in the second quarter of 2026 and was not renewed.

For the nine months ended September 30, 2025, cash provided by financing activities of approximately $3.1 million was primarily attributable to net cash proceeds of approximately $3.5 million from the exercise of common stock warrants in conjunction with the July 2025 Warrant Inducement, partially offset by the payment of equity issuance

costs of approximately $0.2 million in the period, primarily related to our underwritten equity offering completed in December of 2024, and payments made on our insurance financing arrangement of approximately $0.2 million.

Contractual Obligations and Commitments

In the normal course of business, we enter into services agreements with CROs, CDMOs, and other third parties. These agreements generally provide for termination upon notice, with amounts owed based on the timing of termination and the terms of the agreement. The actual amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of the services to be provided.

Other than commitments disclosed in Note 9, Commitments and Contingencies, in Part 1 Item 1 of this Quarterly Report on Form 10-Q, we have no material non-cancellable commitments or contractual obligations.

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 $113.6 million as of September 30, 2026, we believe we have sufficient capital to fund our operations through major clinical development milestones including a primary efficacy readout of our Phase 2 ASCENTRA-UC clinical trial that is expected in the fourth quarter of 2027 and a primary efficacy readout of our Phase 2 ASCENTRA-CD clinical trial that is expected in the first quarter of 2028. Notwithstanding, should our anticipated level of operations significantly change, we may require additional financing sooner than anticipated. Further, beyond the readout expected in the first quarter of 2028, we will require additional financing to continue at our expected level of operations, which would include a potential Phase 3 clinical trial and possible commercialization of PALI-2108 for the treatment of UC and CD.

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 discussed 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 and include estimates related to accrued research and development expenses and our contingent consideration obligation. We believe there have 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 in Part 1 Item 1 of this Quarterly Report on Form 10-Q.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer

and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer, who is also our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. Based upon the evaluation, our Chief Executive Officer concluded that, as of September 30, 2026, 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 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 condensed consolidated financial statements and a failure to meet our reporting and financial obligations.

As described below, management has begun designing the plan and executing the remediation actions to address the material weakness and further actions are ongoing as of September 30, 2026. The material weakness continues to be present as of September 30, 2026.

Remediation Efforts related to the Material Weakness

Management, with oversight from the Audit Committee of our Board of Directors, 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 have hired or contracted with additional finance and accounting 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 known 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 will continue to implement, as needed, additional key internal controls designed to address the potential risks identified in our business processes. Our existing and any additional controls implemented will be tested for operating effectiveness.

We believe that remediation steps taken to date have allowed us to address a number of the deficient controls within our internal control environment. However, the material weakness identified above will not be considered remediated

until we complete the design and implementation of our remediation plans and demonstrate the operating effectiveness of our remediation efforts over 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 September 30, 2026 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 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 clinical 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 clinical product candidate.
- ASCENTRA-UC is our first large randomized, placebo-controlled clinical trial, and we may be unable to conduct it, or our planned ASCENTRA-CD clinical trial, as planned or to show a statistically significant treatment effect.
- We have not yet obtained authorization from all foreign regulatory authorities outside of the U.S. and Canada to conduct our global Phase 2 ASCENTRA-UC clinical trial, and foreign regulatory authorities may not accept data from our may not accept data generated from our clinical trials of PALI-2108.
- 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 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 clinical 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.
- PALI-2108 depends on activation by gut bacteria, and differences in patients' intestinal bacteria, disease activity, medications or anatomy could reduce its efficacy, increase side effects or complicate its development.
- Systemic PDE4 inhibitors have been limited by gastrointestinal and other adverse effects, and if PALI-2108 causes similar effects at doses needed for efficacy, it may not be differentiated from other therapies, and those effects could complicate the interpretation of our clinical trial results.
- 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.

•Topline, interim or preliminary data that we announce from our clinical trials may differ from final results, and others may interpret our data differently than we do.

•We face substantial competition in IBD, and our competitors may develop, obtain approval for or commercialize therapies that are more effective, safer, more convenient or less expensive than PALI-2108, or do so before we do.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

•Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.

•Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Risks Related to Our Business

•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.

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

Risks Related to Our Dependence on Third Parties

•We currently rely on and we intend to continue to rely 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.

Risks Related to Our Financial Operations

•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 condensed 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.

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 reporting 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 lead asset PALI-2108.

On October 9, 2024, Health Canada issued a No Objection Letter for 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. On May 27, 2025, we announced positive results from the SAD, MAD and FE cohorts in healthy volunteers and on August 7, 2025 and September 17, 2025, we announced positive results from the UC cohort portion of the study. The clinical study successfully met its primary endpoints of safety, tolerability, and PK. On October 16, 2025, we dosed our first patients in an exploratory Phase 1b cohort in FSCD to evaluate the safety, tolerability, PK, and PD of once-daily oral dosing of PALI-2108 over a 14-day treatment period as well as evaluate tissue-level pharmacology and molecular responses using paired ileal biopsies and peripheral blood mononuclear cells. On March 30, 2026, we announced positive results from the exploratory Phase 1b cohort in FSCD. The study demonstrated favorable safety and tolerability, robust PD target engagement in ileal tissue, and encouraging early signals of clinical activity in the five patients with FSCD that were dosed. On June 29, 2026, we announced that the FDA has cleared our Investigational New Drug ("IND") application for PALI-2108, enabling initiation of our global Phase 2 ASCENTRA-UC clinical trial and on September 22, 2026, we announced that the FDA has cleared our IND application for PALI-2108, enabling initiation of our global Phase 2 ASCENTRA-CD clinical trial. On October 27, 2026, we dosed the first patient in our Phase 2 ASCENTRA-UC clinical trial.

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 produce 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/or completion of our current and planned clinical trials and any additional required preclinical studies;
- our ability to retain third-party CROs on terms acceptable to us for the conduct and oversight of our current and anticipated clinical trials;
- our ability to fund the development costs related to PALI-2108's clinical development;
- the approval by the FDA, 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. We must also 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 clinical product candidate, PALI-2108.

We have commenced our Phase 2 clinical trials of PALI-2108 for the treatment of UC, and we expect to initiate patient enrollment in our Phase 2 clinical trial of PALI-2108 for the treatment of CD in the first quarter of 2027. 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 clinical 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 clinical 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, the FDA, Health Canada, or 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.

ASCENTRA-UC is our first large randomized, placebo-controlled clinical trial, and we may be unable to conduct it, or our planned ASCENTRA-CD clinical trial, as planned or to show a statistically significant treatment effect.

Our clinical experience with PALI-2108 to date consists of Phase 1 studies in healthy volunteers and small, open-label cohorts of patients with UC and FSCD. ASCENTRA-UC is a global, multi-center, randomized, double-blind, placebo-controlled, dose-ranging Phase 2 clinical trial designed to enroll approximately 204 patients with moderately-to-severely active UC, and we dosed the first patient on October 27, 2026. We also expect to initiate patient enrollment in ASCENTRA-CD, an open-label, single-arm Phase 2 clinical trial in approximately 60 patients with moderate-to-severe CD, in the first quarter of 2027. Running two global Phase 2 clinical trials at the same time will place significant demands on our small organization and on the CRO managing both trials. IBD clinical trials can show meaningful placebo response rates, which may vary with patient population, region, assessment methods and concomitant medications. A higher-than-expected placebo response, or inconsistent disease assessments across sites and countries, could prevent ASCENTRA-UC from showing a statistically significant difference from placebo even if PALI-2108 is active. In a dose-ranging trial, neither dose, or only one dose, may separate from placebo, or the results may not support dose selection for later clinical trials. Because ASCENTRA-CD does not include a placebo or active comparator arm, its results may be more difficult to interpret, and regulators may not view them as sufficient to support later-stage development without additional controlled clinical trials. Slower site activation or enrollment, protocol deviations or higher discontinuation rates could delay the primary efficacy readouts, which we currently expect in the fourth quarter of 2027 for ASCENTRA-UC and in the first quarter of 2028 for ASCENTRA-CD, increase our costs and shorten our cash runway.

Outside of the U.S., we have not yet obtained authorization from all foreign regulatory authorities to conduct our global Phase 2 ASCENTRA-UC clinical trial, and these foreign regulatory authorities may not accept data from our clinical trials of PALI-2108.

We recently completed a Phase 1 clinical trial of PALI-2108 in Canada and have received approvals from the FDA to conduct Phase 2 clinical trials of PALI-2108 for the treatment of both UC and CD in the U.S. and approval from Health Canada and one other foreign regulatory authority to conduct a Phase 2 clinical trial of PALI-2108 for the treatment of UC in those countries, respectively. However, our Phase 2 clinical trials of PALI-2108 for the treatment of both UC and CD are designed as a global trials, and we have not received authorization from all other foreign regulatory authorities to commence any clinical trials outside of the U.S., and there is no guarantee that we will be able to obtain such authorization in a timely manner, if at all. If we do not obtain these authorizations on our expected timeline, we may need to conduct ASCENTRA-UC and/or ASCENTRA-CD at fewer sites or in fewer countries than planned, which could slow enrollment and delay the primary efficacy readout that we currently expect in the fourth quarter of 2027. Although requirements vary by jurisdiction, the 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 foreign regulatory authority can validate the trial data through on-site inspections or other means. Moreover, the foreign regulatory authority will assess whether the trial design, patient population, endpoints, and other factors meet the standards expected for clinical trials conducted within that foreign jurisdiction.

In addition, regulatory approval for clinical trials and eventual drug approval in foreign jurisdictions can be influenced by several factors, including:

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

There can be no assurance that we will successfully obtain all foreign regulatory authority authorizations needed to conduct our Phase 2 clinical trials 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.

Identifying and qualifying subjects to participate in our currently planned 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.

We expect that our operations and development of PALI-2108 will require 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. We believe we currently have sufficient capital to fund our operations through major clinical development milestones including a primary efficacy readout of our ASCENTRA-UC clinical trial that is expected in the fourth quarter of 2027 and a primary efficacy readout of our ASCENTRA-CD clinical trial that is expected in the first quarter of 2028. Notwithstanding the foregoing, we may 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 clinical 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 the FDA, or comparable regulatory authorities like Health Canada.

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 the FDA, or comparable regulatory authorities like Health Canada, 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.

PALI-2108 depends on activation by gut bacteria, and differences in patients' intestinal bacteria, disease activity, medications or anatomy could reduce its efficacy, increase side effects or complicate its development.

PALI-2108 is a prodrug designed to remain inactive until bacterial β-glucuronidase in the terminal ileum and colon converts it into an active PDE4 inhibitor. Our expectation that PALI-2108 may be better tolerated than systemic PDE4 inhibitors depends on this activation occurring predictably at the intended sites. The composition and activity of intestinal bacteria vary among individuals and can change with disease activity, diet, intestinal transit time, age, geography and medications, including antibiotics and other drugs commonly used by patients with IBD. Patients with UC and CD often have altered intestinal bacteria compared to healthy individuals, and patients with active diarrhea, prior bowel resection or strictures may differ from the subjects we have studied. Our data on this mechanism come from preclinical studies and small, open-label cohorts of patients, and it has not been evaluated in a large randomized, placebo-controlled clinical trial. If activation is lower or less consistent than expected, PALI-2108 may not reach effective concentrations at sites of inflammation, and some patients may not respond to treatment. If activation occurs earlier in the intestine or to a greater extent than expected, systemic exposure could be higher than intended, which could increase the risk of the side effects that have limited other PDE4 inhibitors. These factors could require us to narrow eligibility criteria, restrict concomitant medications, adjust doses or conduct additional studies, such as drug interaction studies with antibiotics, and could make it harder to select doses, increase variability in our clinical trial results or reduce the likelihood that ASCENTRA-UC or ASCENTRA-CD meets its primary endpoint. Even if PALI-2108 is approved, its label could restrict use in patients taking certain medications or with certain medical histories, which could limit its commercial potential.

Systemic PDE4 inhibitors have been limited by gastrointestinal and other adverse effects, and if PALI-2108 causes similar effects at doses needed for efficacy, it may not be differentiated from other therapies, and those effects could complicate the interpretation of our clinical trial results.

The use of PDE4 inhibitors has been constrained by tolerability limitations, including diarrhea, nausea and headache, and most systemic PDE4 inhibitors have shown dose-limiting toxicity. PALI-2108 is designed to reduce peak plasma levels of the active drug and limit these effects, but we have not yet shown in a large controlled clinical trial that it does so at the doses we are evaluating in ASCENTRA-UC and in ASCENTRA-CD. Several of these effects overlap with symptoms of IBD, and stool frequency and abdominal symptoms are used to measure disease activity, including in the modified Mayo Score used for the primary endpoint of ASCENTRA-UC and the patient-reported outcomes used for secondary endpoints of ASCENTRA-CD. Drug-related gastrointestinal effects could make a treatment benefit harder to detect, increase discontinuations or contribute to unblinding in ASCENTRA-UC. If PALI-2108 causes PDE4-class adverse effects at a frequency or severity similar to systemic PDE4 inhibitors, regulators could require lower doses, additional monitoring or restrictive labeling, physicians and patients may prefer other therapies, and the commercial potential of PALI-2108 could be substantially reduced. New safety findings or class-wide warnings for other PDE4 inhibitors could also affect how regulators, physicians and patients view PALI-2108.

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 and clinical data required for the submission of an IND or CTA;
- controlled research and human clinical testing;
- establishment of the safety and efficacy of the 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 the FDA recently cleared our INDs to conduct our Phase 2 clinical trials of PALI-2108 for the treatment of UC and CD, there can be no assurance that the FDA, or any other regulatory agency, will permit us to conduct Phase 3 clinical trials in the U.S., or other foreign jurisdictions. 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 throughout our 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:

- safety and efficacy results attained in preclinical and clinical studies to date may not be indicative of results that are obtained in our future 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/or complete our clinical trials involving PALI-2108 as currently contemplated, they may not be successful.

Topline, interim or preliminary data that we announce from our clinical trials may differ from final results, and others may interpret our data differently than we do.

We have announced, and expect to continue to announce, topline and other preliminary results from clinical trials of PALI-2108, including results from small, open-label cohorts such as the five patients dosed in our exploratory Phase 1b cohort in FSCD. These announcements are based on analyses performed before all data have been collected, cleaned, audited and verified, and they reflect our judgment about what information is material or otherwise appropriate to disclose. Final results may differ materially once additional data, quality review or full statistical analyses are complete. Results from small or open-label cohorts are especially variable and may not predict results in larger randomized, placebo-controlled clinical trials such as ASCENTRA-UC. We expect to report primary efficacy results from the 12-week induction period of each of our Phase 2 clinical trials before the 36-week maintenance phase is complete, and later results may not confirm or may be less favorable than the induction results. Because ASCENTRA-CD is open-label, any interim data we report from it may be subject to investigator and patient bias. Regulators, investigators, analysts and investors may interpret our data differently, weigh endpoints differently or disagree with our conclusions. Any of these outcomes could impair our ability to obtain regulatory approval for PALI-2108, raise capital or sustain the market price of our common stock.

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.

We face substantial competition in IBD, and our competitors may develop, obtain approval for or commercialize therapies that are more effective, safer, more convenient or less expensive than PALI-2108, or do so before we do.

Patients with moderate-to-severe UC and CD can be treated with multiple approved therapies, including TNF, IL-12/23 and IL-23 antibodies, an alpha4beta7 integrin antibody, JAK inhibitors and S1P receptor modulators. Many of these are marketed by large pharmaceutical companies with far greater resources than ours, and biosimilars of several are available. Numerous public and private companies are developing additional IBD therapies, including oral small molecules and new antibodies and antibody combinations. If competing products show better efficacy or safety, more convenient dosing or lower cost, or reach the market first, our commercial opportunity and the pricing and reimbursement of PALI-2108 could be reduced. Once-daily oral dosing and targeted delivery may not be enough to differentiate PALI-2108, particularly as more oral therapies are approved. Competition also affects our ability to enroll ASCENTRA-UC, ASCENTRA-CD and any future clinical trials, because eligible patients may choose approved therapies or other investigational trials, and it affects our ability to attract clinical sites, investigators and personnel. See "Business—Competition" in our Annual Report on Form 10-K for the year ended December 31, 2025.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Recent and future changes in healthcare legislation and regulations may increase the difficulty and cost to obtain marketing approval for a drug candidate, increase the costs to commercialize an approved product, and adversely affect the price set for such product.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact the future results of our operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels with the stated objective to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. The ACA and its implementation continue to evolve as a result of legislative, administrative, and judicial developments. Further changes remain possible, which may potentially negatively affect pricing, coverage, or reimbursement for any product candidates that we may commercialize in the future, including PALI-2108.

In addition to the ACA, U.S. governments continue to seek to adopt healthcare policies and reforms intended to curb healthcare costs, such as federal or state controls on payment for drugs (including under Medicare, Medicaid, and commercial health plans). For example, the Budget Control Act of 2011 resulted in aggregate reductions, or sequestration, of Medicare payments to providers. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, adjusted Medicare payments to several types of

providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

More recently, the IRA requires, among other things, the U.S. Secretary of the Department of HHS to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high spend Medicare Part B and D drugs and biologicals per year (the Maximum Fair Price), with prices taking effect starting in 2026. The IRA also makes several changes to the Medicare Part D benefit, including capping patient out-of-pocket spending at $2,000 beginning in 2025, subject to annual increases tied to aggregate Part D expenditures, while imposing new discount obligations for pharmaceutical manufacturers and payors (and sunsetting the coverage gap and coverage gap discount program), which could negatively affect our business and financial condition. If we are not in compliance with obligations under the Medicare Part D benefit redesign, we could be subject to civil monetary penalties. In addition, the IRA establishes Medicare Part B and Part D inflation rebate schemes, under which manufacturers will owe rebates to Medicare if, generally speaking, the average sales price of a Part B drug, or the annualized average manufacturer price of a Part D drug, increases faster than the pace of inflation. The failure to timely pay an inflation rebate may result in a civil monetary penalty. Since the IRA was enacted, the CMS has taken various steps to implement the drug pricing provisions of the law. This includes, on a quarterly basis, releasing a list of Medicare Part B products that had an adjusted coinsurance rate based on the inflationary rebate provisions of the IRA, as well as guidance and regulations governing the same issuing guidance detailing the requirements and parameters of the first rounds of price negotiations and effectuation of the Maximum Fair Price, negotiating the Maximum Fair Price for the first 10 drugs subject to negotiation and releasing the list of the next 15 drugs. While it remains to be seen how the drug pricing provisions imposed by the IRA will affect the broader pharmaceutical industry (including orphan drug development), several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against federal agencies challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. The IRA and any other similar laws introduced in the future may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our future revenues and results of operations.

Individual states in the United States have also become increasingly aggressive in seeking to pass legislation and implementing regulations designed to control pharmaceutical and biological product pricing. Such measures could harm our business, results of operations, financial condition, and prospects. For example, an emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost". We expect that additional state reform measures will be adopted in the future, any of which could limit the amounts that state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates, or additional pricing pressures.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, customers, and others will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with contractors, investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates, as well as our customer support and physician consulting arrangements. Such laws include:

- the U.S. federal Anti-Kickback Statute, a criminal law which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or anything of value), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs (such as Medicare and Medicaid). A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Anti-Kickback Statute has been interpreted to apply

to arrangements between pharmaceutical manufacturers or their agents and prescribers, purchasers and formulary or benefit managers, among other parties;

•the U.S. federal false claims and civil monetary penalties laws, including the FCA, which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, any claims submitted as a result of a violation of the Anti-Kickback Statute constitute false claims and are subject to enforcement under the FCA. Pharmaceutical manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA can be enforced by the U.S. Department of Justice or through whistleblower or qui tam actions filed by private citizens on behalf of the federal government;

•certain criminal provisions enacted as part of HIPAA prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters, regardless of the payor (e.g., public or private). Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•HIPAA and the respective implementing regulations, which impose, among other things, specified requirements relating to privacy, security and breaches of individually identifiable health information by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the creation, receipt, maintenance, or transmission of protected health information. HIPAA provides for criminal penalties, as well as civil monetary penalties, and is enforced by the Office of Civil Rights within the HHS as well as state attorneys general, which can file civil actions for damages or injunctions in federal courts and seek attorneys' fees and costs associated with pursuing federal civil actions;

•Under, section 5 of the Federal Trade Commission ("FTC") Act ("FTC Act"), the FTC expects a company's data privacy and security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Failure to meet these standards may constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records;

•the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;

•federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

•the U.S. federal Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, along with others, to track and report annually to the government information related to certain payments and other transfers of value to U.S.-licensed physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by certain physicians and their immediate family members in the manufacturer;

•the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial monetary penalties against an entity, such as a pharmaceutical manufacturer, that engage in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

•analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information that require the tracking of gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the CCPA, as amended by the CPRA, establishes certain requirements for data use and sharing transparency and provides California consumers (as defined in the law) certain rights concerning the use, disclosure, and retention of their personal data. Such rights include rights to access and delete personal information, opt out of certain personal information sharing, and receive detailed information about how personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches —involving certain types of personal information—that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Numerous other states, such as Virginia, Colorado, Utah, New York, and Connecticut, have enacted privacy laws similar to the CCPA, and some states, like Washington and Nevada, have enacted health privacy specific laws that grant heightened rights with respect to health information;

•similar healthcare laws and regulations in the EU, and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information, such as, where applicable, the General Data Protection Regulation, including as implemented in the UK, or GDPR, which imposes obligations and restrictions on the processing of personal data relating to individuals located in the EU and the European Economic Area ("EEA") (including health data); and

•laws and regulations prohibiting bribery and corruption such as the FCPA, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with healthcare providers, could be subject to challenge under one or more such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to actions including the imposition of civil, criminal, and administrative penalties, damages (potentially up to treble damages), disgorgement, monetary fines, exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements, or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be adversely affected.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release, and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds, and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Exports of our products are further subject to export controls and sanctions laws and regulations imposed by the U.S. government and administered by the U.S. Departments of State, Commerce, and Treasury. U.S. export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, U.S. economic sanctions laws include restrictions or prohibitions on engaging in any transactions or dealings, including receiving investment or financing from, or engaging in the sale or supply of products and services to, U.S. sanctioned countries, governments, persons and entities.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any changes in Trade Laws could result in a decreased ability to export or sell our solutions to existing or potential customers with international operations. Future changes in Trade Laws and enforcement could also result in increased compliance requirements and related costs which could materially adversely affect our business, results of operations, financial condition and/or cash flows.

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 have never completed the development of any product candidate through to commercialization, 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. We dosed the first patient in our

Phase 2 clinical trial of PALI-2108 for the treatment of UC on October 27, 2026 and we expect to initiate patient enrollment in our Phase 2 clinical trial of PALI-2108 for the treatment of CD in the first quarter of 2027. While we have completed the Phase 1 clinical trial, commenced our Phase 2 clinical trial for the treatment of UC and expect to initiate enrollment in our Phase 2 clinical trial for the treatment of CD, 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 product candidates in multiple human clinical studies;
- obtain clearance from the FDA and/or authorization from similar foreign regulatory bodies to conduct future clinical trials as necessary;
- retain qualified CROs to oversee and manage the continued development of PALI-2108 through current 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 the 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, or disruptions at, the FDA, the SEC and, other government agencies or comparable foreign regulatory authorities, including from government shutdowns or reductions in force, 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 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, including recently from October 1, 2025 through November 12, 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees from the FDA, SEC, and other government offices, halting critical activities. In addition, federal employees, including at the FDA, have recently been subject to termination in connection with cost reductions efforts by the federal government. If another prolonged government shutdown, or a significant reduction in force at the FDA or other agencies, occur, it could significantly impact the ability of the FDA and other governmental agencies to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business. Furthermore, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Dependence on Third Parties

We currently rely on and we intend to continue 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 retained a CRO to oversee our Phase 1 clinical trial for PALI-2108 in Canada and we have retained a leading global CRO in IBD to manage the execution of our Phase 2 clinical trials of PALI-2108, including our global Phase 2 clinical trials of PALI-2108 for the treatment of UC and CD. We intend to continue 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 clinical trials 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 any of our anticipated clinical trials, it would delay planned clinical operations and result in additional cost and expense. Additionally, if any of our CROs that we retain currently or 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.

In addition, foreign CDMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, in December of 2025 the BIOSECURE Act was enacted, which prohibits U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of that contract. It would also prohibit loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a "biotechnology company of concern" in the performance of the government grant or loan. The BIOSECURE Act restricts the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing certain services or equipment from certain Chinese biotechnology companies.

The BIOSECURE Act does not specifically name WuXi AppTec, including its subsidiary, STA Pharmaceutical Hong Kong Limited ("WuXi STA") our current CDMO for the manufacture and supply of API for PALI-2108, or Crystal Formulation Services, our drug product vendor, as "biotechnology companies of concern." However, the BIOSECURE Act provides a mechanism for Chinese companies to be designated as a "biotechnology company of concern" in the future should they be designated through existing national security mechanisms. In June 2026, the U.S. Department of Defense, pursuant to Section 1260H of the National Defense Authorization Act, added WuXi AppTec to its published list of "Chinese military companies" operating in the U.S. On August 7, 2026, a federal court enjoined the Department of Defense from enforcing, implementing or otherwise giving effect to that designation, and the litigation remains ongoing. If the injunction is lifted or the designation is otherwise given effect, WuXi AppTec, and potentially its subsidiaries, could become subject to the BIOSECURE Act's restrictions. Our API is manufactured by WuXi STA, a subsidiary of WuXi AppTec. WuXi STA has not itself been named on the Section 1260H list, and it is uncertain whether the BIOSECURE Act's restrictions, if they become effective as to WuXi AppTec, would extend to WuXi STA as a subsidiary or affiliate of WuXi AppTec, or whether WuXi STA would need to be separately designated. In addition, the Office of Management and Budget is required to publish an initial list of biotechnology

companies of concern by December 18, 2026, and may designate companies, including WuXi AppTec or its affiliates, such as WuXi STA, without regard to the Section 1260H list. It is possible that Crystal Formulation Services will receive a similar designation in the future. If WuXi AppTec or its affiliates become biotechnology companies of concern, while we continue to use WuXi AppTec or WuXi STA, we may be restricted from contracting with, or receiving grants or loans from, U.S. federal agencies for work in which its services are used, and we could face similar restrictions if Crystal Formulation Services or other suppliers or partners are identified as "biotechnology companies of concern." Potential collaborators, licensees, acquirers and investors may also view our reliance on a supplier that has been, or may be, designated unfavorably or require us to change suppliers as a condition of a transaction. The designation has not, to date, interrupted our supply of API.

In addition to the BIOSECURE Act, any additional executive action, legislative action, or potential sanctions with China could materially impact our work with these Chinese companies. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

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, one of which is WuXi STA, located in China, which currently supplies all of our API. Our second qualified supplier is located in Canada. 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. If WuXi STA becomes subject to restrictions under the BIOSECURE Act or other U.S. laws, as described above, we may need to shift API supply to our second qualified supplier, which may not have sufficient capacity to meet our needs, or to a new supplier, either of which could result in supply interruptions, delays in our clinical trials and increased costs.

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, such as the conflict involving the U.S., Israel and Iran, and other hostilities in the Middle East, 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 health authority 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 supply agreement to provide us with such drug substances or products for our ongoing clinical trials, 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, including the BIOSECURE Act, 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 API manufacturer, WuXi STA, 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 trials.

Risks Related to Our Financial Operations

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

We have incurred net operating 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 product 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 condensed 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 this quarterly report on Form 10-Q 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 condensed 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, 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, including our Phase 2 clinical trials, 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. Although we believe our existing cash and cash equivalents will be sufficient to fund our operations through the expected primary efficacy readouts of our Phase 2 clinical trials, we will need significant additional capital to fund our operations and business plan beyond those readouts, including any Phase 3 clinical trials and potential commercialization of PALI-2108, and as a result, 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 LLC ("Nasdaq"). There are a number of continued listing requirements that we must satisfy in order to maintain our listing on Nasdaq, including the requirement to maintain a minimum bid price of at least $1.00 (the "Bid Price Rule"). Although we are in compliance with the Bid Price Rule as of the date of this Quarterly Report on Form 10-Q, we have been unable to comply with this rule in the past. For example, 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 that as of April 19, 2024, we were back in compliance with the Bid Price Rule. On April 30, 2025, we were notified again that we were no longer in compliance with the Bid Price Rule and had 180 calendar days to cure such deficiency. On August 5, 2025, the bid price of our common stock did close above $1.00 for 10 consecutive trading days, however, we were notified on August 6, 2025 that Nasdaq was exercising its discretion to continue monitoring our stock price beyond this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). As of October 15, 2025, the bid price of our common stock again closed above $1.00 for 10 consecutive days and we received a minimum bid price compliance letter from Nasdaq confirming that we regained compliance with Listing Rule 5550(a)(2), and that the matter is now closed.

We can provide no assurances that we will continue to comply with the Bid Price Rule or the other continued listing requirements of Nasdaq. The delisting of our common stock by Nasdaq could adversely affect the liquidity of our common stock, our ability to raise capital, create increased volatility in our common stock, and result in a loss of

current or future coverage by analysts and/or diminish the interest of institutional investors to invest in our common stock. Delisting could also result in a loss of confidence of our collaborators, vendors and employees, which could harm our business and future prospects. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on the OTC Bulletin Board, OTCQB, OTCQX, or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of or obtain accurate quotations as to the market value of our common stock. Moreover, if our common stock is delisted, it may come within the definition of "penny stock" under the Securities Exchange Act of 1934, as amended, which imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. These requirements may reduce the trading activity in the secondary markets for our common stock and may impact the ability or willingness of broker-dealers to sell our securities which could limit the ability of stockholders to sell their securities in the public market and limit our ability to attract and retain qualified employees or raise additional capital in the future.

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, although our public float was greater than $75 million, because our annual revenues are less than $100 million and we have a public float of less than $700 million, we qualify as a smaller reporting company under the low-revenue exemption of the 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 and annual revenues in excess of $100 million, or we have a public float of greater 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 condensed consolidated financial statements and a failure to meet our reporting and financial obligations.

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 450,000,000 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 September 30, 2026, we had outstanding, common stock or securities convertible into common stock, totaling 257,967,801 shares. As a result, we are authorized to issue up to an additional 192,032,199 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 CDMOs, 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 CDMOs' 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, conflicts, such as the conflict involving the U.S., Israel and Iran, and other hostilities in the Middle East, 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.

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

On September 25, 2026, we issued and sold 172,413 shares of our common stock, par value $0.01 per share, to the Crohn's & Colitis Foundation (the "CCF") for a total purchase price of $200,000, or a discounted stock price of $1.16 per share, pursuant to the Research Program Funding Agreement, which we entered into with the CCF on December 17, 2025.

The sale of the securities described above was exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. No underwriters were involved in the sales.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of document
10.1+	Offer Letter with Julien E. Capers, dated September 17, 2026.
10.2+	Amended and Restated Employment Agreement with Mitchell Jones, dated October 7, 2026.
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.

SIGNATURES

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

PALISADE BIO, INC.

Date: November 10, 2026

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