

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 June 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 001-37471

Palvella Therapeutics, Inc.
(Exact name of Registrant as specified in its Charter)

Nevada
(State or other jurisdiction of
incorporation or organization)
353 W. Lancaster Ave, Suite 200
Wayne, Pennsylvania
(Address of principal executive offices)

30-0784346
(I.R.S. Employer
Identification No.)

19087
(Zip Code)

Registrant’s telephone number, including area code: (484) 253-1461

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, \$0.001 par value per share	PVLA	The Nasdaq Global Market

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

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

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

Large accelerated filer☐

Non-accelerated filer☒

Emerging growth company☐

Accelerated filer☐

Smaller reporting company☒

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

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

The number of shares of Registrant’s common stock outstanding as of July 31, 2026 was 14,408,407.

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GENERAL INFORMATION

Unless otherwise stated or the context requires otherwise, references in this Quarterly Report on Form 10-Q to “Palvella,” the “company,” the “Company,” “we,” “us,” “our” or similar designations refer to Palvella Therapeutics, Inc. (formerly Pieris Pharmaceuticals, Inc.) and its subsidiaries, taken together. All trademarks, service marks, trade names and registered marks used in this report are trademarks, trade names or registered marks of their respective owners.

References to “Pieris” refer to Pieris Pharmaceuticals, Inc., our predecessor company prior to the Merger (as defined below) and references to “Legacy Palvella” or “Palvella” refer to Palvella Therapeutics, Inc. prior to the Merger and our wholly owned subsidiary upon the consummation of the Merger (as defined below).

On December 13, 2024 (the “Closing Date”), Palvella Therapeutics, Inc., a Nevada corporation (the “Company” or “Palvella”) (previously named Pieris Pharmaceuticals, Inc. and our predecessor company (“Pieris”)), consummated the previously announced merger pursuant to the terms of that certain Agreement and Plan of Merger, dated as of July 23, 2024 (the “Merger Agreement”), by and among the Company, Polo Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Pieris (the “Merger Sub”), and Palvella Therapeutics, Inc., a Delaware corporation (“Legacy Palvella”). Pursuant to the Merger Agreement, on the Closing Date, (i) Merger Sub merged with and into Legacy Palvella, with Legacy Palvella as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly owned subsidiary of the Company (the “Merger”) and (ii) the Company’s name was changed from Pieris Pharmaceuticals, Inc. to Palvella Therapeutics, Inc.

Statements made in this Quarterly Report on Form 10-Q concerning the contents of any agreement, contract or other document are summaries of such agreements, contracts or documents and are not complete description of all of their terms. If we filed any of these agreements, contracts or documents as exhibits to this Quarterly Report on Form 10-Q or to any previous filing with the Securities and Exchange Commission (“SEC”), you may read the document itself for a complete understanding of its terms.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and the documents we incorporate by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements, other than statements of historical fact, included or incorporated in this report regarding, among other things, our management team’s expectations, hopes, beliefs, intentions or strategies regarding the future, are forward-looking statements. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements contained in this Quarterly Report on Form 10-Q may include, but are not limited to, statements about:

- the strategies, prospects, plans, expectations and objectives of management of our future operations;
- the potential of, and expectations regarding our programs, including QTORIN™ rapamycin, QTORIN™ pitavastatin, and research-stage opportunities, including their expected therapeutic potential and market opportunity;
- expectations regarding the timing of completion of the New Drug Application (“NDA”) submission;
- expectations regarding the timing of potential U.S. Food and Drug Administration (“FDA”), regulatory approval of our lead product candidate QTORIN™ rapamycin and, if approved, its subsequent commercial launch;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the ability to protect and enhance our products, proprietary technologies and intellectual property, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- developments and projections relating to our competitors or industry;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- expectations concerning our relationships and actions with third parties, including any licenses and collaborations with such third parties;
- future regulatory, judicial and legislative changes or uncertainties in our industry in the United States, Europe, and other jurisdictions, including due to uncertainty resulting from the recent change in U.S. administration and shift in government policy and the evolving regulatory environment;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates;
- our ability to utilize our proprietary drug development platform to develop a pipeline of product candidates to address unmet needs in rare skin disease and vascular malformation indications;
- the outcome of clinical trials of our product candidates, including the ability of those trials to satisfy relevant governmental and regulatory requirements;
- the timing of availability of data from our clinical trials;

- our plans to research, develop and commercialize our current and future product candidates;
- our reliance on contract manufacturers, contract research organizations and other third parties;
- our ability to develop and advance current product candidates and programs into clinical studies and to successfully complete those studies;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our ability and the ability of third-party manufacturers that we engage to optimize and scale manufacturing;
- the size of the market opportunity for our product candidates, including estimates of the number of patients who suffer from the diseases we are targeting;
- the benefits of orphan drug designation and potential benefit of orphan drug exclusivity in the future for QTORIN rapamycin for the treatment of microcystic lymphatic malformations;
- expectations regarding potential for accelerated approval or other expedited regulatory designations;
- degree of market acceptance of our product candidates, as well as the pricing and reimbursement of our product candidates, if approved;
- our competitive position and the success of competing therapies that are or may become available;
- estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and our expectations regarding various types of therapy;
- our expectations regarding the use of proceeds from recent and any future financings;
- the potential impact of healthcare reform in the U.S., including the Inflation Reduction Act of 2022, and measures being taken worldwide designed to reduce healthcare costs;
- the volatility of capital markets and other macroeconomic factors, including those due to inflationary pressures, tariffs and other trade restrictions or the threat of such actions, interest rate and currency rate fluctuations, economic slowdown or recession, banking instability, monetary policy changes, geopolitical tensions or the outbreak of hostilities or war, including from the ongoing Russia-Ukraine war, the current conflicts in Venezuela and the Middle East (including any escalation or expansion) and increasing tensions between China and Taiwan; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2025 (our “2025 Form 10-K”) and the other documents we file with the Securities and Exchange Commission (the “SEC”).

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth under Part I, Item 1A “Risk Factors” in our 2025 Form 10-K, which was filed with the SEC on March 31, 2026, and in our other disclosures and filings with the SEC. These factors and the other cautionary statements made in this Quarterly Report on Form 10-Q and the documents we incorporate by reference should be read as being applicable to all related forward-looking statements whenever they appear in this Quarterly Report on Form 10-Q and the documents we incorporate by reference. Information contained on or made available through our website or other websites mentioned in this Quarterly Report on Form 10-Q is not incorporated into and is not a part of this Form 10-Q, and any references to our website are intended to be inactive textual references only.

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In addition, any forward-looking statements represent our estimates only as of the date that this Quarterly Report on Form 10-Q is filed with the SEC and should not be relied upon as representing our estimates as of any subsequent date. All forward-looking statements included in this Quarterly Report on Form 10-Q are made as of the date hereof and are expressly qualified in their entirety by this cautionary notice. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as may be required by law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

PALVELLA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except share and per share amounts)

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 187,803	\$ 57,982
Short-term investments	62,781	—
Prepaid expenses and other current assets	2,444	1,005
Total current assets	253,028	58,987
Operating lease right-of-use assets, net	482	572
Total assets	\$ 253,510	\$ 59,559
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,785	\$ 4,595
Derivative liabilities – contingent value right liability	—	2,196
Current portion of operating lease liability	217	202
Accrued expenses and other current liabilities	4,945	4,351
Total current liabilities	11,947	11,344
Long-term portion of operating lease liability	318	431
Royalty agreement liability	22,107	17,760
Derivative liabilities – royalty agreement	2,271	2,041
Total liabilities	36,643	31,576
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized; 14,395,705 and 12,380,933 shares issued and outstanding at June 30, 2026 and December 31, 2025	14	12
Additional paid-in capital	389,851	163,338
Accumulated other comprehensive (loss) income	89	83
Accumulated deficit	(173,087)	(135,450)
Total stockholders' equity	216,867	27,983
Total liabilities and stockholders' equity	\$ 253,510	\$ 59,559

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

PALVELLA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 12,473	\$ 5,118	\$ 21,807	\$ 9,192
General and administrative	8,932	4,132	14,453	7,929
Total operating expenses	21,405	9,250	36,260	17,121
Operating loss	(21,405)	(9,250)	(36,260)	(17,121)
Other (expense) income:				
Interest expense – royalty agreement	(2,308)	(1,354)	(4,347)	(2,569)
Fair value adjustments on derivative liabilities – royalty agreement	(114)	(118)	(230)	(193)
Fair value adjustments on derivative liabilities – contingent value right liability	—	—	202	—
Interest income, net	1,965	690	3,038	1,442
Other (expense) income, net	(8)	561	(40)	785
Loss before income taxes	(21,870)	(9,471)	(37,637)	(17,656)
Income tax benefit (expense)	—	—	—	—
Net loss	<u>\$ (21,870)</u>	<u>\$ (9,471)</u>	<u>\$ (37,637)</u>	<u>\$ (17,656)</u>
Other comprehensive loss:				
Unrealized loss on investments	(30)	—	(26)	—
Foreign currency translation gain (loss)	24	(108)	32	(114)
Comprehensive loss	<u>\$ (21,876)</u>	<u>\$ (9,579)</u>	<u>\$ (37,631)</u>	<u>\$ (17,770)</u>
Net loss per share of Common Stock – basic and diluted	<u>\$ (1.52)</u>	<u>\$ (0.86)</u>	<u>\$ (2.74)</u>	<u>\$ (1.60)</u>
Weighted-average shares used in computing net loss per share of Common Stock – basic and diluted	<u>14,356,219</u>	<u>11,052,741</u>	<u>13,724,256</u>	<u>11,033,327</u>

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

PALVELLA THERAPEUTICS, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN PREFERRED
STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**

(Unaudited)

(in thousands, except share amounts)

Six Months Ended June 30, 2026

	Common Stock		Additional	Accumulated Other	Accumulated	Total
	Shares	Amount	Paid-in	Comprehensive	Deficit	Stockholders'
			Capital	Income (Loss)		Equity
Balance at December 31, 2025	12,380,933	\$ 12	\$ 163,338	\$ 83	\$ (135,450)	\$ 27,983
Issuance of common stock, net of expense	1,840,000	2	215,751	—	—	215,753
Exercise of common stock options for cash, net of expense	92,726	—	956	—	—	956
Stock-based compensation	—	—	3,376	—	—	3,376
Foreign currency translation gain	—	—	—	8	—	8
Unrealized gain on investments	—	—	—	4	—	4
Net loss	—	—	—	—	(15,767)	(15,767)
Balance at March 31, 2026	14,313,659	\$ 14	\$ 383,421	\$ 95	\$ (151,217)	\$ 232,313
Stock-based compensation	—	—	5,155	—	—	5,155
Issuance of 3,250 shares of common stock upon settlement of employee performance stock units and restricted stock units, net of shares withheld for taxes	2,293	—	—	—	—	—
Exercise of common stock options for cash, net of expense	79,753	—	1,280	—	—	1,280
Equity issuance costs	—	—	(5)	—	—	(5)
Foreign currency translation gain	—	—	—	24	—	24
Unrealized gain (loss) on investments	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(21,870)	(21,870)
Balance at June 30, 2026	14,395,705	\$ 14	\$ 389,851	\$ 89	\$ (173,087)	\$ 216,867

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

PALVELLA THERAPEUTICS, INC.

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN PREFERRED
STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) (CONTINUED)**

(Unaudited)

(in thousands, except share amounts)

Six Months Ended June 30, 2025

	Preferred Stock		Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in	Other	Deficit	Stockholders
					Capital	Comprehensive		Equity
						Income (Loss)		
Balance at December 31, 2024	15,617	\$ —	11,012,105	\$ 11	\$ 156,328	\$ 3	\$ (93,735)	\$ 62,607
Exercise of common stock options for cash, net of expense	—	—	9,284	—	67	—	—	67
Stock-based compensation	—	—	—	—	1,094	—	—	1,094
Foreign currency translation gain	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(8,185)	(8,185)
Balance at March 31, 2025	15,617	\$ —	11,021,389	\$ 11	\$ 157,489	\$ (3)	\$ (101,920)	\$ 55,577
Exercise of common stock options for cash, net of expense	—	—	38,276	—	349	—	—	349
Stock-based compensation	—	—	—	—	1,433	—	—	1,433
Foreign currency translation gain	—	—	—	—	—	(108)	—	(108)
Net loss	—	—	—	—	—	—	(9,471)	(9,471)
Balance at June 30, 2025	15,617	\$ —	11,059,665	\$ 11	\$ 159,271	\$ (111)	\$ (111,391)	\$ 47,780

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

PALVELLA THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2026	2025
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (37,637)	\$ (17,656)
Adjustments to reconcile net loss income to net cash used in operating activities:		
Non-cash interest expense – royalty agreement	4,347	2,569
Change in fair value of derivative liabilities – royalty agreement	230	193
Change in fair value of derivative liabilities – contingent value right liability	(202)	—
Stock-based compensation	8,531	2,527
Accretion on marketable securities	(335)	—
Non-cash lease operating expense	89	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,422)	1,318
Accounts payable	2,202	1,240
Accrued expenses and other current liabilities	586	(2,393)
Payments on operating lease liabilities	(98)	—
Net cash used in operating activities	(23,709)	(12,202)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(70,472)	—
Maturities of marketable securities	8,000	—
Net cash used in investing activities	(62,472)	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of transaction costs in connection with Reverse Merger	—	(1,269)
Proceeds from issuance of common stock in connection with equity financing	230,000	—
Payment of financing cost in connection with equity financing	(14,247)	—
Payment of contingent value right liability	(1,978)	—
Proceeds from exercise of stock options	2,236	416
Net cash provided by (used in) financing activities	216,011	(853)
Effect of exchange rate change on cash and cash equivalents	(9)	(114)
Net increase (decrease) in cash and cash equivalents	129,821	(13,169)
Cash and cash equivalents at beginning of period	57,982	83,602
Cash and cash equivalents at end of period	\$ 187,803	\$ 70,433

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

PALVELLA THERAPEUTICS, INC.**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)****Note 1. Description of Business, Organization and Liquidity*****Business***

Palvella Therapeutics, Inc. (the “Company,” or “Palvella”) (previously named Pieris Pharmaceuticals, Inc. (“Pieris”)), a Nevada corporation, is a late clinical-stage biopharmaceutical company committed to serving individuals suffering from serious, rare skin diseases and vascular malformations without approved therapies. The Company’s lead product candidate, QTORIN 3.9% rapamycin anhydrous gel (“QTORIN rapamycin”), is based on the Company’s patented QTORIN platform. QTORIN rapamycin is in clinical development for microcystic lymphatic malformations (“microcystic LMs”), cutaneous venous malformations (“cutaneous VMs”) and angiokeratomas. The Company is conducting IND-enabling development for QTORIN pitavastatin for disseminated superficial actinic porokeratosis (“DSAP”). Since inception, the Company has devoted substantially all of its resources to identifying, researching and conducting preclinical and clinical activities for its product candidates, and developing its platform technology, organizing and staffing the Company, business planning, raising capital and establishing its intellectual property portfolio. The Company’s principal executive offices are located in Wayne, Pennsylvania.

Reverse Merger

On December 13, 2024 (the “Closing Date”), the Company consummated the previously announced merger pursuant to the terms of that certain Agreement and Plan of Merger, dated as of July 23, 2024 (the “Merger Agreement”), by and among the Company, Polo Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Pieris (the “Merger Sub”), and Palvella Therapeutics, Inc., a Delaware corporation (“Legacy Palvella”). Pursuant to the Merger Agreement, on the Closing Date, (i) Merger Sub merged with and into Legacy Palvella, with Legacy Palvella as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly owned subsidiary of the Company (the “Reverse Merger”) and (ii) the Company’s name was changed from Pieris Pharmaceuticals, Inc. to Palvella Therapeutics, Inc. (the “Reverse Merger” and, together with the other transactions contemplated by the Merger Agreement, the “Business Combination”).

Liquidity

The Company follows the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess the Company’s ability to continue as a going concern within one year after the date the financial statements are issued.

Since inception, the Company has incurred net losses and negative cash flows from operations. During the six months ended June 30, 2026 and 2025, the Company reported a net loss of \$37.6 million and \$17.7 million, respectively, and net cash used in operating activities of \$23.7 million and \$12.2 million, respectively. At June 30, 2026, the Company had an accumulated deficit of \$173.1 million and cash and cash equivalents and short-term investments of \$250.6 million.

Management does not expect to generate commercial revenue or operating cash flows in the near-term. The Company’s ability to continue as a going concern in the near term is largely dependent on its existing cash and cash equivalents balance and ability to obtain additional sources of financing in order to fund operating expenses, complete development of its product candidates, obtain regulatory approvals, launch, and commercialize its product candidates, and continue research and development programs. Assuming no additional fund raising, the Company’s forecasted cash required to fund operations indicates that the Company has sufficient funds to support operations through at least the one-year period from the issuance date of these condensed consolidated financial statements.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”) for interim financial reporting. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States (“U.S. GAAP”) for complete financial statements as certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These condensed consolidated statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring adjustments and accruals) necessary to fairly present the results of the interim periods. The results of operations and cash flows for the six months ended June 30, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2026 or any other future period.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the reporting period. Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these condensed consolidated financial statements. Management must apply significant judgment in this process and actual results could differ materially from those estimates.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company holds cash at two accredited financial institutions in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. In addition, the Company also maintains cash in a German bank account in denominations of Euros and U.S. dollars. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company is dependent on contract manufacturing organizations (“CMOs”) to supply products for research and development of its product candidates, including pre-clinical and clinical studies, and for commercialization of its product candidates, if approved. The Company’s development programs could be adversely affected by any significant interruption in its CMOs’ operations or by a significant interruption in the supply of active pharmaceutical ingredients and other components.

Products developed by the Company require approval from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance the Company’s product candidates will receive the necessary approvals. If the Company is denied approvals, approvals are delayed, or it is unable to maintain approvals received, such events could have a materially adverse impact on the Company.

Comprehensive Loss and Accumulated Other Comprehensive (Loss) Income

Other comprehensive (loss) income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on investments and foreign currency translation gains and losses.

Cash and Cash Equivalents

Cash and cash equivalents are held in accounts at multiple independent financial institutions. Cash equivalents are defined as money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

Investments

The Company invests in fixed maturity securities including U.S. Treasury bills and bonds. The investments are classified as available-for-sale and reported at fair value. Unrealized gains or losses are determined by comparing the fair market value of the securities with their cost or amortized cost. Realized gains and losses on investments are recorded on the trade date and are included in the statement of operations. Unrealized gains and losses on investments are recorded in other comprehensive income (loss) on the consolidated statements of operations and comprehensive income (loss) and the consolidated statements of changes in preferred stock and stockholders' equity (deficit). The cost of securities sold is based on the specified identification method. Investment income is recognized as earned and discounts or premiums arising from the purchase of debt securities are recognized in investment income using the interest method over the remaining term of the security. Securities with an original maturity date greater than three months that mature within one year of the balance sheet date are classified as short-term, while investments with a maturity date greater than one year are classified as long-term.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies, and similar techniques.

At June 30, 2026 and December 31, 2025, the carrying amounts of financial instruments, which include cash and cash equivalents, accounts payable, and accrued expenses and other liabilities, approximate their fair value due to their short maturities. At June 30, 2026 and December 31, 2025, the fair value of the royalty agreement liability, which is based on Level 3 inputs (including probability-weighted cash flow estimates of the Company's potential future royalty payments and a weighted-average cost of capital of 16.0% and 18.0%, respectively) is approximately \$97.3 million and \$61.5 million, respectively. The Company records its investments and derivative liabilities at fair value.

Derivative Instruments

The Company evaluates its contracts to determine if those contracts qualify as derivatives under ASC 815, *Derivatives and Hedging*. For derivative financial instruments that are accounted for as assets or liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date. Any changes in fair value are recorded as other income or expense for each reporting period. Derivative instrument assets or liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is probable within the next 12 months from the balance sheet date.

The Company has milestone payments which may be required in connection with the royalty agreement (see Note 3) that were determined to be derivative liabilities. The valuation of the derivative liabilities is based on unobservable inputs and, therefore, represent Level 3 financial liabilities. The fair value of the derivative liabilities – royalty agreement was calculated using the present value of the potential payments using a weighted-average cost of capital and an assessment of the probability of the achievement of the milestones as well as an assessment of the timing of the potential milestone payments.

The derivative liabilities – royalty agreement was initially recorded at fair value, with gains and losses arising for changes in fair value of the derivative liabilities – royalty agreement recognized within the condensed consolidated statements of operations as fair value adjustments on the derivative liabilities at each financial reporting period.

The Company determined that certain contingent payments that may become payable under the Contingent Value Rights Agreement entered into on December 13, 2024 with a rights agent, immediately prior to the closing of the Reverse Merger (the “CVR Agreement”) related to the asset sales prior to the Reverse Merger qualify as derivatives under ASC 815. Upon such time that these payments were assessed a fair value, they were recorded as a liability on the balance sheet. These values are then remeasured for future expected payout or receipt, as well as the increase in fair value due to the time value of money. These gains or losses, if any, are recognized in the condensed consolidated statements of operations within other income, net.

The derivative liabilities – CVR agreement was initially recorded at fair value, with gains and losses arising from changes in fair value of the derivative liabilities – CVR recognized within the condensed consolidated statements of operations as fair value adjustments on the derivative liabilities at each financial reporting period.

Research and Development Expenses

Research and development costs are charged to expense as incurred. Research and development expenses include, among other costs, salaries and benefits of scientific personnel and the external cost of producing and testing the clinical material for clinical trials.

The Company has entered into various research and development and clinical trial-related contracts. The Company defers and capitalizes prepaid nonrefundable advance research and development payments to third parties for goods and services to be used in future research and development activities and recognizes to research and development expense over the period that the research and development activities are performed, or the services are provided. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and clinical trial costs. When determining the accruals, at the end of a reporting period, the Company analyzes progress of its studies and clinical trials, including the phase or completion of events, invoices received and contracted costs. Actual results could differ from the Company’s estimates.

Stock-Based Compensation

The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation – Stock Compensation* (“ASC 718”). ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the condensed consolidated statements of operations based on their fair values. Stock-based awards are subject to service-based or performance-based vesting conditions. Management estimates the fair value of the stock option awards using the Black-Scholes option pricing model, which requires the input of assumptions, including (a) the fair value of the Company’s common stock, (b) the expected stock price volatility, (c) the calculation of expected term of the award, (d) the risk-free interest rate and (e) expected dividends. Management estimates the fair value of the restricted stock awards using the fair value of the Company’s common stock. Forfeitures are recognized as they are incurred.

The fair value of the Company’s common stock is based on the closing stock price on the date of grant as reported on the Nasdaq Global Market. The expected life of the stock options in years is estimated using the “simplified method,” as prescribed in SEC’s Staff Accounting Bulletin (SAB) No. 107, as the Company has no historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of option grants. The risk-free rate is based on the U.S. Treasury yield curve commensurate with the expected life of the option. The expected dividend yield is zero as the Company has no history of paying dividends and no plans to do so in the near term.

Compensation cost related to restricted stock units (“RSUs”) and performance stock units (“PSUs”) is based on the fair market value at the time of the grant. The Company recognizes the compensation cost related to RSUs over the requisite service period as determined by the grant, amortized ratably or on a straight-line basis over the life of the

grant. The Company recognizes compensation cost for PSUs over the performance period, adjusting this cost based on the Company's estimate of the probability that performance metrics will be achieved.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner of the award recipient's payroll costs.

Government Grants

The Company recognizes grants from governmental agencies when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and the grant will be received. The Company evaluates the conditions of each grant as of each reporting period to evaluate whether the Company has reached reasonable assurance of meeting the conditions of each grant arrangement and that it is expected that the grant will be received as a result of meeting the necessary conditions. Grants are recognized in the condensed consolidated statements of operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, grant income related to research and development costs is recognized as such expenses are incurred. Grant income is recorded as a reduction of research and development costs in the condensed consolidated statements of operations. In September 2024, the Company received a grant award notice from the Department of Health and Human Services in connection with its ongoing Phase 3 clinical trial, SELVA. During the three and six months ended June 30, 2025, the Company recognized \$0.2 million and \$0.3 million, respectively, of grant income as a reduction to research and development costs in the accompanying condensed consolidated statements of operations. The Company did not recognize any grant income during the three and six months ended June 30, 2026.

Income Taxes

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three and six months ended June 30, 2026 and 2025, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. The Company has not recorded its net deferred tax asset as of either June 30, 2026 or December 31, 2025 because it maintained a full valuation allowance against all deferred tax assets as of these dates as management has determined that it is not more likely than not that the Company will realize these future tax benefits. As of June 30, 2026 and December 31, 2025, the Company had no uncertain tax positions.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act, modifications to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The Company evaluated the OBBBA and estimated its impact on the condensed consolidated financial statements to be immaterial.

Related Party Transactions

The Company's board of directors reviews and approves transactions with directors, officers, and holders of 5% or more of its voting securities and their affiliates, each a related party. The material facts as to the related party's relationship or interest in the transaction are disclosed to its board of directors prior to their consideration of such transaction, and the transaction is not considered approved by its board of directors unless a majority of the directors who are not interested in the transaction approve the transaction.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

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The Company follows ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (“ASU 2023-07”) which applies to public entities with a single reportable segment and requires disclosures about each reportable segments’ significant expenses and other segment items on an interim and annual basis. See Note 9 for related disclosures.

Net Loss Per Share

Basic net loss per share is calculated by dividing net income loss by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, preferred stock, stock options and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. For the three and six months ended June 30, 2026 and 2025, basic and diluted net loss per share are the same.

Recently Issued (Not Yet Adopted) Accounting Standards

In November 2024, the Financial Account Standards Board (“FASB”) issued ASU 2024-03, *Income Statement – Disaggregation of Income Statement Expenses (DISE)*, which requires disaggregated disclosure of income statement expenses for public business entities (“PBEs”). The ASU does not change the expense captions an entity presents on the face of the income statement; rather, it requires disaggregation of certain expense captions into specified categories in disclosures within the footnotes to the consolidated financial statements. ASU 2024-03 is effective for all PBEs for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. The Company is currently evaluating the impacts the ASU has on its consolidated financial statements.

In December 2025, the FASB issued ASU No. 2025-10, *Government Grants (Topics 832) - Accounting for Government Grants Received by Business Entities*, which provides authoritative guidance for the recognition, measurement and presentation of government grants received by a business entity. The standard is effective for fiscal years beginning after December 15, 2028 and early adoption is permitted. The Company is currently evaluating the potential impact of this standard on its consolidated financial statements.

Note 3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table presents information about the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	June 30, 2026			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash and cash equivalents	\$ 187,803	\$ —	\$ —	\$ 187,803
U.S. Treasury	—	62,781	—	62,781
Total assets measured at fair value	<u>\$ 187,803</u>	<u>\$ 62,781</u>	<u>\$ —</u>	<u>\$ 250,584</u>
Liabilities:				
Derivative liabilities – royalty agreement	\$ —	\$ —	\$ 2,271	\$ 2,271
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,271</u>	<u>\$ 2,271</u>

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash and cash equivalents	\$ 57,982	\$ —	\$ —	\$ 57,982
Total assets measured at fair value	<u>\$ 57,982</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 57,982</u>
Liabilities:				
Derivative liabilities – royalty agreement	\$ —	\$ —	\$ 2,041	\$ 2,041
Derivative liabilities – contingent value right liability	—	—	2,196	2,196
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4,237</u>	<u>\$ 4,237</u>

Cash and cash equivalents as of June 30, 2026 and December 31, 2025 includes cash and investments in money market funds. Money market funds, which are cash equivalents, are highly liquid investments and are actively traded. The pricing information on the Company's money market funds is based on quoted prices in active markets for identical securities. This approach results in a classification of these securities as Level 1 of the fair value hierarchy.

There were no transfers between Levels during the period ended June 30, 2026. The Company uses the services of its investment manager, which uses widely accepted models for assumptions in valuing securities with inputs from major third-party data providers.

The Company classifies all of its investments in fixed maturity debt securities as available-for-sale and, accordingly, are carried at estimated fair value.

The amortized cost, gross unrealized gains and losses, and fair value of investments in fixed maturity securities as of June 30, 2026 are as follows:

	June 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury	\$ 62,807	\$ 195	\$ (221)	\$ 62,781
Total assets measured at fair value	<u>\$ 62,807</u>	<u>\$ 195</u>	<u>\$ (221)</u>	<u>\$ 62,781</u>

All of the Company's fixed maturity available-for-sale securities have maturities of less than one year.

The Company has evaluated the unrealized losses on the fixed maturity securities and determined that they are not attributable to credit risk factors. For fixed maturity securities, losses in fair value are viewed as temporary if the fixed maturity security can be held to maturity and it is reasonable to assume that the issuer will be able to service the debt, both as to principal and interest.

As of June 30, 2026, the Company had seven available-for-sale investment debt securities in an unrealized loss position without an allowance for credit losses. Unrealized losses on governmental debt securities have not been recognized into income because the issuers' securities are of high credit quality (rated AA+ or higher) and the decline in fair value is largely due to market conditions and or changes in interest rates. Management does not intend to sell and it is likely that management will not be required to sell the securities prior to the anticipated recovery of their amortized cost basis. The issuers continue to make timely payments on the securities. The fair value is expected to recover as the securities approach maturity.

As of June 30, 2026, accrued interest receivable on available-for-sale investment debt securities totaling \$0.4 million is excluded from the estimate of credit losses and is included in prepaid expenses and other current assets.

Assumptions Used in Determining Fair Value of Derivative Liabilities

The key assumptions used to determine the fair value of the derivative liabilities – royalty agreement at June 30, 2026 and December 31, 2025 are as follows:

	June 30, 2026	December 31, 2025
Discount rate	16.0%	18.0%
Probability rate of achieving FDA approval of a product ⁽¹⁾	56.6%	56.6%
Expected term to FDA regulatory approval of a product	1.0 years	1.5 years

⁽¹⁾ Source: *Clinical Development Success Rates and Contributing Factors 2011-2020* study of drug approval success from February 2021. The probability assumption used reflects the study's estimate of the likelihood of approval of a Phase 3 drug that has not yet submitted its full NDA.

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

The following table provides a reconciliation of the liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

Derivative Liabilities – Royalty Agreement

	2026
Derivative liabilities - royalty agreement	
Balance at January 1	\$ 2,041
Fair value adjustments on derivative liabilities	230
Balance at June 30	<u>\$ 2,271</u>

	2025
Derivative liabilities - royalty agreement	
Balance at January 1	\$ 1,647
Fair value adjustments on derivative liabilities	394
Balance at December 31	<u>\$ 2,041</u>

The derivative liabilities – royalty agreement is classified as long term on the Company's condensed consolidated balance sheets according to the estimated timing of the occurrence of the potential payments.

Derivative Liabilities – Contingent Value Right Liability

	2026
Derivative liabilities - contingent value right liability	
Balance at January 1	\$ 2,196
Settlement of contingent value right	(1,994)
Fair value adjustments on derivative liabilities	(202)
Balance at June 30	<u>\$ —</u>

	2025
Derivative liabilities - contingent value right liability	
Balance at January 1	\$ 1,978
Fair value adjustments on derivative liabilities	218
Balance at December 31	<u>\$ 2,196</u>

The derivative liabilities – contingent value rights is classified as short term on the Company's condensed consolidated balance sheets according to the estimated timing of the occurrence of the potential payments.

The Company applies a scenario-based method and weighs them based on the possible likelihood of certain contingencies triggering payments due under the contingent value right ("CVR") for the liability recognized. The fair value measurements are based on significant inputs not observable in the market and thus represent a Level 3 measurement as defined in ASC 820, *Fair Value Measurement*. The estimated value of the CVR is based upon available information and certain assumptions, which the Company's management believes are reasonable under the circumstances. In January 2026, the Company paid out approximately \$2.0 million to holders of CVRs in accordance with the CVR Agreement entered into immediately prior to closing of the Merger on December 13, 2024. As of June 30, 2026, the fair value adjustment for the CVR is driven from foreign currency translation. The change in fair value has been recorded in fair value adjustments on derivative liabilities - contingent value right liability on the condensed consolidated statement of operations.

Note 4. Strategic Agreements

Ligand Development Funding Agreement

The Company is party to a Development Funding and Royalties Agreement with Ligand Pharmaceuticals, Inc. ("Ligand"), dated December 13, 2018, as amended May 22, 2020 and November 28, 2023 (the "Ligand Agreement"). Under the Ligand Agreement, Ligand has made payments totaling \$15.0 million to fund the development of QTORIN rapamycin. As partial consideration for the funding received, the Company granted Ligand the right to receive up to \$8.0 million in milestone payments upon the achievement of certain corporate, financing and regulatory milestones by the Company related to QTORIN rapamycin for the treatment of any and all indications. In addition, the Company is currently obligated to pay to Ligand tiered royalties ranging from 8.0% to 9.8% of any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. On a licensed product-by-licensed product and country-by-country basis, the royalty period is from the date of first commercial sale of such licensed product in a country until the latest of (i) the expiration of the last valid claim within the licensed patent rights covering such licensed product in the country in which such licensed product is made, used or sold, (ii) the expiration of the regulatory exclusivity term conferred by the applicable regulatory authority in such country with respect to such licensed product, and (iii) the fifteenth anniversary of the first commercial sale of such licensed product in such country.

The Ligand Agreement may be terminated by the earlier of a mutual written agreement of the parties or when the royalties contemplated by the agreement are paid to Ligand. Additionally, Ligand may terminate the agreement for (i) any or no reason upon a 90-day notice to the Company, or (ii) cause in connection with a material breach that the Company does not cure within a certain period of time.

The total amount of potential future milestone payments remaining under the arrangement was \$5.0 million as of June 30, 2026. The potential future milestone payments represent derivative liabilities with a fair value of \$2.3 million and \$2.0 million as of June 30, 2026 and December 31, 2025, respectively, which are classified as "derivative liabilities – royalty agreement" on the accompanying condensed consolidated balance sheets. See Note 3 for fair value measurements.

The Company's obligation to pay tiered royalties under the Ligand Agreement was determined to be a debt instrument based on the likelihood of repaying the amounts provided to fund the development of QTORIN rapamycin and that the Company has significant continuing involvement in the generation of the cash flows potentially due to Ligand. This obligation is reflected as royalty agreement liability which is classified as a long-term liability on the accompanying condensed consolidated balance sheets and was \$22.1 million and \$17.8 million as of June 30, 2026 and December 31, 2025, respectively. Interest expense with respect to the royalty agreement liability is determined using the effective interest method based upon probability-adjusted cash flow estimates of the Company's potential future royalty payments under the Ligand Agreement, yielding an effective interest rate of 45.1% and 44.9% as of June 30, 2026 and December 31, 2025, respectively. Changes in these estimates impact the amount of interest expense recognized through the accompanying condensed consolidated statements of operations. The Company incurred non-cash interest expense of \$2.3 million and \$1.4 million for the three months ended June 30, 2026 and 2025, respectively, and \$4.3 million and \$2.6 million for the six months ended June 30, 2026 and 2025, respectively, all of which is a component of the royalty agreement liability on the accompanying condensed consolidated balance sheets.

The Ligand Agreement requires the Company to make certain estimates and assumptions about future development, FDA approval, commercialization, and net sales of any product containing QTORIN rapamycin. These estimates and assumptions are subject to significant variability and are thus subject to significant uncertainty. Therefore, these estimates and assumptions are likely to change as the Company develops and commercializes products containing QTORIN rapamycin. This may result in significant future adjustments to the royalty agreement liability, the derivative liabilities, and the accretion of interest expense.

Note 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2026	December 31, 2025
Research and development expenses	\$ 1,635	\$ 1,200
Compensation expense	1,469	1,915
Professional fees	597	531
Other	1,244	705
Total accrued expenses and other current liabilities	<u>\$ 4,945</u>	<u>\$ 4,351</u>

Note 6. Stockholders' Equity

Authorized Capital

Upon closing of the Reverse Merger, pursuant to the terms of the Amendment to the Company's Amended and Restated Articles of Incorporation with the Nevada Secretary of State, the Company was authorized to issue up to 200,000,000 shares of common stock, par value \$0.001 per share ("Common Stock"). As of June 30, 2026 and December 31, 2025, 14,395,705 and 12,380,933 shares of Common Stock were issued and outstanding, respectively.

The Company is authorized to issue up to 10,000,000 shares of preferred stock, par value \$0.001 per share ("Preferred Stock"). As of December 31, 2025, BVF has fully converted its shares of Preferred Stock to shares of Common Stock and no shares of Preferred Stock were outstanding as of June 30, 2026.

Common Stock, Preferred Stock, and Pre-Funded Warrants

Each share of Common Stock is entitled to one vote and all shares rank equally as to voting and other matters. Dividends may be declared and paid on the Common Stock from funds legally available therefore, if, as and when determined by the Board of Directors.

The Company has pre-funded warrants outstanding to purchase an aggregate of 1,394,761 shares of Common Stock as of June 30, 2026 and December 31, 2025. The pre-funded warrants are exercisable at any time for an exercise price of \$0.001, except that the pre-funded warrants cannot be exercised by the holders if, after giving effect thereto, the holders would beneficially own more than 9.99% or 4.99% of the outstanding Common Stock, depending on the investor and subject to certain exceptions. However, any holder may increase or decrease such percentage to any other percentage (not in excess of 19.99%) upon at least 61 days' prior notice from the holder to the Company. The holders of the pre-funded warrants will not have the right to vote the shares underlying the pre-funded warrants on any matter except to the extent required by Delaware law. These warrants were classified as equity.

Prior to the Reverse Merger, Legacy Pieris had issued multiple series (Series A through E) of Preferred Stock to certain entities affiliated with Biotechnology Value Fund, L.P. ("BVF"). In each case, each share Preferred Stock is convertible into 13.34 shares of Common Stock (subject to adjustment as provided in the Certificate of Designation for each series) at any time at the option of the holder, provided that the holder is prohibited from converting the Preferred Stock into shares of Common Stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of Common Stock then issued and outstanding, or the Beneficial Ownership Limitation. The holder may reset the Beneficial Ownership Limitation to a higher or lower number, not to exceed 19.99% of the total number of common shares issued and outstanding immediately after giving

effect to a conversion, upon providing written notice to the Company. Any such notice providing for an increase to the Beneficial Ownership Limitation will be effective 61 days after delivery to the Company.

Series A, Series B, Series C, Series D and Series E Preferred Stock rank senior to Common Stock; senior to any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as junior to the five series of Preferred Stock; in parity with each other and with any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as in parity with the existing five series of Preferred Stock; and junior to any class or series of capital stock of the Company created after the designation of and specifically ranking by its terms as senior to the existing five series of Preferred Stock. In the event of the Company's liquidation, dissolution or winding up, subject to the rights of holders of Preferred Stock, holders are entitled to receive a payment equal to \$0.001 per share of Preferred Stock pursuant to the rights and preferences discussed above, plus an additional amount equal to any dividends declared but unpaid on such shares. However, if the assets of the Company are insufficient to comply with the preceding sentence, then all remaining assets of the Company shall be distributed ratably to holders of the shares of the existing five series of Preferred Stock.

For each series of Preferred Stock, the Company designated the requisite number of shares of its authorized and unissued preferred stock as a specific series of Preferred Stock and filed a Certificate of Designation with the Nevada Secretary of State.

Shares of Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Preferred Stock is required to amend the terms of the Certificate of Designation for each respective series of Preferred Stock. Holders of Preferred Stock are entitled to receive any dividends payable to holders of the Company's common stock subject to the rights and preferences discussed above, in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up whether voluntarily or involuntarily and/or the right to receive dividends.

Equity Financing

On February 25, 2026, the Company entered into an underwriting agreement (the "Underwriting Agreement") with TD Securities (USA) LLC, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated, as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to an underwritten public offering of 1,600,000 shares of its Common Stock, at a price to the public of \$125.00 per share. Under the terms of the Underwriting Agreement, the Company granted the underwriters an option to purchase up to an additional 240,000 shares of Common Stock at the same price. The option was exercised in full and the offering closed on February 27, 2026.

The offering resulted in net proceeds of \$215.8 million, after deducting underwriting discounts and commissions and other offering expenses.

Note 7. Equity Incentive Plans

In connection with the Reverse Merger, the Company stockholders approved the 2024 Equity Incentive Plan (the "2024 Plan") on December 13, 2024. The 2024 Plan provides for the grant of incentive stock options, nonqualified stock options, and stock awards, any of which may be performance-based, and for incentive bonuses, which may be paid in cash, Common Stock or a combination thereof.

On June 10, 2026, the Company stockholders approved Amendment No. 1 to the 2024 Plan, which increased the number of shares reserved for issuance under the 2024 Plan by 750,000 shares. Accordingly, the number of shares reserved for issuance under the 2024 Plan is equal to 4,205,433 shares of Common Stock as of June 30, 2026.

As of June 30, 2026, 2,794,172 options were outstanding under the 2024 Plan.

In connection with the Reverse Merger, all of the options outstanding under the Company's 2019 Equity Incentive Plan (the "2019 Plan") were adjusted with respect to the number of shares and exercise price to reflect the Exchange Ratio. As of June 30, 2026, 477,811 shares of Common Stock were outstanding under the 2019 Plan and no further grants will be made under the 2019 Plan.

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For incentive stock options and non-statutory stock options, the option exercise price may not be less than 100% of the estimated fair value on the date of grant. Options granted to employees typically vest over a four-year period but may be granted with different vesting terms. The options expire ten years from the grant date.

The following table summarizes stock option activity for the Company's equity incentive plans for the six months ended June 30, 2026:

	Common Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (in years)
Outstanding at December 31, 2025	<u>2,917,143</u>	\$ 20.69	8.5
Granted	548,686	\$ 88.39	
Exercised	(172,479)	\$ 12.96	
Forfeited / Cancelled	(21,367)	\$ 140.03	
Outstanding at June 30, 2026	<u>3,271,983</u>	\$ 31.67	8.5
Exercisable at June 30, 2026	<u>1,135,878</u>	\$ 16.01	7.7

The aggregate intrinsic value of options outstanding and options exercisable as of June 30, 2026 was \$396.8 million and \$155.8 million, respectively.

Total stock-based compensation expense recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2026 and 2025 is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	\$ 1,745	\$ 510	\$ 3,202	\$ 900
General and administrative	3,410	923	5,329	1,627
Total stock-based compensation expense	<u>\$ 5,155</u>	<u>\$ 1,433</u>	<u>\$ 8,531</u>	<u>\$ 2,527</u>

As of June 30, 2026, there was approximately \$55.2 million of unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over a remaining weighted-average service period of 2.75 years.

The weighted average fair value of stock options granted during the six months ended June 30, 2026 was \$60.61 per share which was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

Expected volatility	72.43% - 76.17%
Risk-free interest rate	3.05% - 4.36%
Expected term (years)	5.50 - 6.08
Expected dividend yield	—

Performance Stock Unit and Restricted Stock Unit Activity

The Company grants time-based restricted stock unit ("RSU") awards and performance-based restricted stock unit ("PSU") awards to certain employees. RSU awards vest over a four-year period subject to the employee's continued employment or service with the Company through the vesting date. PSU awards have a performance period of one year and vest depending on the Company's achievement of predetermined performance goals. For the three and six months ended June 30, 2026, the Company recorded \$0.8 million and \$5 thousand of stock compensation expense for PSUs and RSUs, respectively, included in general and administrative expense in the statement of operations.

The following table summarizes the activities related to the Company's unvested RSUs and PSUs:

	Shares	Weighted Average Grant Date Fair Value (per share)
Outstanding PSU and RSU Grants at December 31, 2025	-	\$ -
PSUs Granted	13,000	\$ 119.86
RSUs Granted	2,291	\$ 112.59
PSUs Released ⁽¹⁾	(3,250)	\$ 119.86
PSUs Cancelled	-	\$ -
RSUs Cancelled	-	\$ -
Outstanding PSU and RSU Grants at June 30, 2026	12,041	\$ 118.48

⁽¹⁾Amount includes 3,250 PSU awards (2,293 shares, net of employee tax withholdings, paid in shares) that vested based on the achievement of performance goals during the performance period ended June 30, 2026.

Note 8. Commitments and Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when future expenditures are probable and such expenditures can be reasonably estimated.

Legal Proceedings

From time to time, the Company may face legal claims or actions in the normal course of business. The Company is not currently subject to any material legal proceedings.

Note 9. Segment Information

The Company is comprised of one reportable segment, the Company operations. As of June 30, 2026, the Company operations segment has not generated any product revenue since inception, as it does not yet have approved products for sale. However, the Company operations segment anticipates future revenue generation upon the successful development and commercialization of product candidates either independently or through partnerships.

The Company expects to primarily generate revenue in North America, with its long-lived assets also concentrated in this region, and manages its business activities on a consolidated basis. Decisions concerning the allocation of the Company's resources are made by the Company's CODM, which is the Company's CEO. The CODM views the Company's operations as a single operating segment which is the business of discovering and developing products for individuals with serious and rare skin diseases.

The Company's significant segment expenses that are regularly provided to the CODM are related to:

- *Research and Development Expenses:* These expenses include costs incurred in conducting research and development activities for the specific clinical trials including facilities costs, license fee and other costs incurred in connection with preclinical research and development activities. Research and development also encompass non-program specific costs such as salaries and stock-based compensation costs, third party consulting fees, and other related costs.
- *General and Administrative Expenses:* These expenses include costs associated with the overall administration and management of the Company, including salaries and benefits for administrative personnel, professional service fees (e.g., accounting and legal services) and other office expenses.

The CODM assesses performance for the Company operations segment and decides how to allocate resources based on net income or loss that is also reported on the income statement as consolidated net income or loss and the measure

of segment assets as reported on the balance sheet as total consolidated assets. Net income or loss is used to monitor budget versus actual results as well as to assess the general performance of the segment in a given period.

The following table reconciles segment direct profit or loss to the Company's consolidated results:

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development:				
QTORIN CMC	\$ 3,308	\$ 1,517	\$ 5,135	\$ 2,289
QTORIN rapamycin for microcystic LM	865	1,235	2,400	2,389
QTORIN rapamycin for angiokeratomas	749	—	1,201	—
QTORIN rapamycin for cutaneous VM	712	354	1,157	700
QTORIN rapamycin for microcystic LM - Government grant income	—	(212)	—	(339)
Non-program specific and unallocated research and development expenses:				
Salaries and stock-based compensation	3,697	1,501	6,887	2,823
Consultants	2,081	385	3,434	632
Other	1,061	338	1,593	698
Total research and development	\$ 12,473	\$ 5,118	\$ 21,807	\$ 9,192
General and administrative:				
Salaries and stock-based compensation	\$ 5,147	\$ 1,744	\$ 8,429	\$ 3,197
Consultants	1,977	914	2,693	1,910
Other	1,808	1,474	3,331	2,822
Total general and administrative	\$ 8,932	\$ 4,132	\$ 14,453	\$ 7,929
Loss from operations	\$ (21,405)	\$ (9,250)	\$ (36,260)	\$ (17,121)

Note 10. Subsequent Events

Subsequent events have been evaluated through August 4, 2026, which is the date the accompanying condensed consolidated financial statements were issued.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and accompanying notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and our consolidated audited financial statements and accompanying notes thereto included in our 2025 Form 10-K filed with the Securities and Exchange Commission on March 31, 2026, as well as the information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2025 Form 10-K.

In addition to historical information, this discussion and analysis includes forward-looking statements that are subject to risks and uncertainties, including those discussed in the section titled "Risk Factors," set forth in Part I, Item 1A of our 2025 Form 10-K, that could cause actual results to differ materially from historical or anticipated results.

Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "the Company," "we," "us," and "our" refer to the business and operations of Palvella Therapeutics, Inc., a Delaware corporation (referred to as "Legacy Palvella") prior to the Merger, and the business and operations of Palvella Therapeutics, Inc., a Nevada Corporation (previously Pieris Pharmaceuticals, Inc., referred to as "Pieris") and its consolidated subsidiaries following the Merger.

Overview

We are a clinical-stage biopharmaceutical company whose vision is to become the leading rare disease biopharmaceutical company focused on developing and, if approved, commercializing novel therapies to treat patients suffering from serious, rare skin diseases and vascular malformations for which there are no FDA-approved therapies. We envision a future treatment paradigm in which individuals suffering from serious, rare skin diseases and vascular malformations, and the physicians treating those diseases, have significantly improved treatment options which address the underlying causes of those diseases. We intend to leverage our versatile QTORIN platform to minimize the challenges and timelines typically associated with generating novel topical product candidates that penetrate the deep layers of the skin to locally treat a broad spectrum of rare skin diseases and vascular malformations. Our lead product candidate, QTORIN 3.9% rapamycin anhydrous gel ("QTORIN rapamycin"), is currently in clinical development for microcystic lymphatic malformations ("microcystic LMs"), cutaneous venous malformations ("cutaneous VMs"), and clinically significant angiokeratomas. QTORIN rapamycin contains the active pharmaceutical ingredient ("API") rapamycin, also known as sirolimus, which is an inhibitor of mTOR, a kinase that has been known to play a key role in cell growth and proliferation. We introduced a new QTORIN product candidate, QTORIN pitavastatin, for the treatment of disseminated superficial actinic porokeratosis ("DSAP"), which leverages our proprietary QTORIN platform and is designed to be the first pathogenesis-directed therapy for DSAP.

We announced positive topline results for two clinical trials: (i) SELVA, a Phase 3, single-arm, baseline-controlled study evaluating the safety and efficacy of QTORIN rapamycin for the treatment of microcystic LMs in patients 3 years and older and (ii) TOIVA, a Phase 2, single-arm, open-label, baseline-controlled study evaluating the safety and efficacy of QTORIN rapamycin for the treatment of cutaneous VMs in patients 6 years and older. We also have preclinical research programs based on our QTORIN platform for the treatment of serious, rare skin diseases for which we believe there are significant unmet needs. As we work to expand our pipeline into additional rare skin diseases, we plan to generate new product candidates based on our QTORIN platform.

Recent Developments

- In April 2026, we dosed our first patients in the Phase 2 LOTU trial, a baseline-controlled clinical study of QTORIN rapamycin administered topically once daily for the treatment of clinically significant angiokeratomas. Topline results are expected in the second half of 2027.
- In April 2026, we announced the appointment of John D. Doux, M.D., M.B.A. to the Board of Directors.
- In April 2026, we submitted an application to the FDA for Breakthrough Therapy Designation for our cutaneous venous malformation program. Following the FDA's recent decision in July 2026 to not grant the

designation at this time, we are currently planning a resubmission incorporating TOIVA patient interview transcripts and new 24-week data.

- In May 2026, at the 83rd Annual Meeting of the Society for Investigative Dermatology (“SID”), we presented new data from our Phase 2 TOIVA trial of QTORIN rapamycin for the treatment of cutaneous VMs demonstrating 100% of patients with bleeding at baseline demonstrated improvement on the Cutaneous Venous Malformations Investigator Global Assessment Bleeding scale (“cVM-IGA Bleeding”) at Week 12.
- In May 2026, additional clinical data from our Phase 3 SELVA and Phase 2 TOIVA studies was presented by James Treat, MD at the International Society for the Study of Vascular Anomalies (“ISSVA”) World Congress 2026, which demonstrated that QTORIN rapamycin produced clinical improvements across multiple efficacy measures in patients with microcystic lymphatic malformations and cutaneous VMs.
- In May 2026, a patent that we exclusively licensed from Yale University was granted by the United States Patent and Trademark Office, further supporting the QTORIN pitavastatin program for porokeratosis.
- In May 2026, we completed a pre-NDA meeting with the FDA. The pre-NDA meeting addressed nonclinical, clinical pharmacology, and clinical information for the planned NDA and included an in-person discussion with FDA and receipt of official meeting minutes.
- In June 2026, the FDA granted rolling review of our NDA for QTORIN rapamycin for the treatment of microcystic LMs. Rolling review is an FDA regulatory feature available to programs with Fast Track or Breakthrough Therapy designation and is intended to facilitate expedited FDA review of applications for therapies addressing serious conditions with unmet medical need.
- In June 2026, we submitted the first module of our rolling NDA. We remain on track to submit the remaining modules and complete the NDA submission in the second half of 2026.
- In June 2026, we announced the appointment of Matthew Pauls, J.D., M.B.A. to the Board of Directors.

Our Novel Product Candidate: QTORIN rapamycin

Overview

We are developing QTORIN rapamycin, a novel, 3.9% anhydrous topical gel formulation containing rapamycin, for the treatment of microcystic LMs, cutaneous VMs, clinically significant angiokeratomas and other mTOR-driven skin diseases. If approved, we believe QTORIN rapamycin has the potential to become the first line therapy and the standard of care in each of these diseases.

QTORIN rapamycin for the treatment of microcystic LMs

Microcystic LM is a serious, chronically debilitating, and lifelong genetic disease of the lymphatic system characterized by lymphorrhea and acute cellulitis. It is estimated that there are more than 30,000 diagnosed patients in the United States with microcystic LMs. The specific pathophysiology of microcystic LMs is primarily the result of somatic activating mutations in PIK3CA that result in increased activation of the PI3K/mTOR pathway and subsequent lymphatic hyperplasia. Because microcystic LMs have a well-understood pathophysiology and a well-defined disease course, we believe an appropriate clinical study for this rare disease is a baseline-controlled Phase 3 study using clinician assessments.

We recently completed SELVA, a Phase 3, single-arm, baseline-controlled clinical trial evaluating once-daily QTORIN rapamycin in individuals aged ≥ 3 years with microcystic LMs and announced positive topline results. Of the 51 participants enrolled, 50 initiated treatment, including 49 participants aged ≥ 6 years and 1 participant in the exploratory 3- to 5-year-old cohort. In accordance with the statistical analysis plan, efficacy results were reported for participants aged ≥ 6 years, which constituted the Intent-to-Treat (“ITT”) population. The study was originally designed to enroll 40 participants across leading U.S. vascular anomaly centers and exceeded its target enrollment.

The primary endpoint, the microcystic lymphatic malformation Investigator Global Assessment (“mLM-IGA”), is a 7-point clinician-assessed dynamic scale measuring change in disease severity from baseline ranging from “Very Much Worse” (-3) to “Very Much Improved” (+3). On the mLM-IGA in the ITT population (n=49), QTORIN rapamycin demonstrated a mean improvement of +2.13 points, meeting the study’s primary endpoint (p<0.001). Of the participants aged ≥ 6 who completed the efficacy evaluation period, 95% (41/43) demonstrated at least a 1-point improvement, and 86% (37/43) were either “Much Improved” (+2) or “Very Much Improved” (+3). In the 3- to 5-year-old cohort, one participant enrolled and was “Very Much Improved” (+3) on the mLM-IGA at Week 24.

Similar to previous clinical trials of QTORIN rapamycin, in the Phase 3 SELVA study, QTORIN rapamycin was well-tolerated. Amongst the 50 participants who initiated treatment, 35 participants (70%) experienced treatment-emergent adverse events (“TEAEs”). Four experienced serious adverse events, of which one experienced a severe TEAE; all were deemed unrelated to study drug by investigators. Amongst the TEAEs, a total of 17 participants experienced treatment-related adverse events (“TRAEs”), all of which were rated mild or moderate. The most common TRAEs included application site acne, application site discoloration, and application site pruritus (all n=3, 6%). Rapamycin levels were below 2 ng/mL in systemic circulation for all participants at all timepoints in the study.

In May 2026, we presented new microcystic LM data from our Phase 3 SELVA study demonstrating that QTORIN rapamycin produced significant improvements across multiple efficacy measures in patients with microcystic LMs, at the ISSVA. 100% of participants (13/13) aged 6–11 years were rated as “Much Improved” (+2) or “Very Much Improved” (+3) on the Microcystic Lymphatic Malformation Investigator Global Assessment (mLM-IGA) scale at Week 24, with a mean improvement of +2.46 (p<0.001). 87% of participants (20/23) in SELVA with moderate or worse leaking/bleeding at baseline were rated as “Much Improved” (+2) or “Very Much Improved” (+3) on the mLM-IGA Leaking/Bleeding at Week 24, with a mean improvement of +2.48 (p<0.001). 100% of SELVA participants who completed the efficacy evaluation period (43/43) were at least somewhat satisfied with QTORIN™ rapamycin on the TSQM-9 overall satisfaction item at Week 24, with 84% reporting extremely satisfied, very satisfied, or satisfied. A blinded independent review demonstrated pre-treatment stability during the 8-week run-in period, followed by marked improvement on QTORIN™ rapamycin, supporting SELVA’s single-arm, baseline-controlled design.

We previously announced topline Phase 2 clinical trial results from our multi-center, open-label, baseline-controlled study of 12 subjects receiving QTORIN rapamycin administered once daily for 12 weeks for the treatment of microcystic LMs. The Phase 2 clinical trial featured multiple pre-specified efficacy assessments, including clinician and patient global impression assessments as well as assessments of individual clinical manifestations that are important disease burdens for individuals living with microcystic LMs. All participants in the Phase 2 clinical trial demonstrated improvements on the Clinician Global Impression of Change scale, a 7-point clinician-rated change scale, with all participants in the study rated as either “Much Improved” (n=7, 58%) or “Very Much Improved” (n=5, 42%) after 12-weeks of treatment compared to the pre-treatment baseline period.

We have received Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation from the FDA for QTORIN rapamycin for the treatment of microcystic LMs. Orphan Drug Designation has also been granted by the European Medicines Agency. In addition, we have been awarded an FDA Products Clinical Trials Grant for up to \$2.6 million supporting the SELVA Phase 3 study and have received \$1.1 million to date.

In June 2026, we completed a pre-NDA meeting with the FDA which addressed nonclinical, clinical pharmacology, and clinical information for the planned NDA and included an in-person discussion with FDA and receipt of official meeting minutes. Subsequent to the pre-NDA meeting, the FDA granted rolling review of our NDA for QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations.

In June 2026, we submitted the first module of our rolling NDA. We remain on track to submit the remaining modules and complete the NDA submission in the second half of 2026. We are preparing for a planned standalone U.S. commercial launch of QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations in the first half of 2027, subject to obtaining FDA approval.

QTORIN rapamycin for the treatment of cutaneous VMs

Cutaneous venous malformation is a serious disease with a high unmet need characterized by dysregulated growth of malformed veins impacting the skin, causing functional impairment and deformity. It is estimated that there are more than 75,000 diagnosed patients in the United States with cutaneous VMs.

In December 2025, we announced positive topline efficacy results from TOIVA, a multicenter, single-arm, open-label, baseline-controlled, Phase 2 clinical trial designed to evaluate the safety and efficacy of QTORIN rapamycin for the treatment of cutaneous VMs. The study enrolled 16 participants, ages six and older, at leading vascular anomaly centers across the U.S. Key findings from among the study's pre-specified efficacy endpoints at Week 12 demonstrated nominally statistically significant ($p < 0.001$) improvements at Week 12 on several of the clinically relevant and important efficacy endpoints evaluated when compared to pre-treatment (baseline), including many of the static and impression of change global instruments evaluated, including the Overall Cutaneous VM Investigator Global Assessment ("Overall cVM-IGA"). The Overall cVM-IGA is a 7-point, clinician-assessed, single-item efficacy endpoint measuring change in severity from baseline, with the numeric rating scale ranging from "Very Much Worse" (-3) to "Very Much Improved" (+3). On the Overall cVM-IGA at Week 12, 73% (11/15) participants improved, with 67% (10/15) either "Much Improved" (+2) or "Very Much Improved" (+3). No trial participants (0/15) were "Minimally Worse" (-1), "Much Worse" (-2), or "Very Much Worse" (-3).

Similar to previous clinical trials of QTORIN rapamycin, in the Phase 2 TOIVA study QTORIN rapamycin was generally well-tolerated, with the most common treatment-emergent adverse events being application site reactions (erythema, 25%). All treatment-related adverse events were moderate or mild, with no unexpected adverse events reported. Rapamycin levels were below 2 ng/mL in systemic circulation for all participants at all timepoints in the study.

In May 2026, at the 83rd Annual Meeting of the Society for Investigative Dermatology ("SID"), we presented new data from our Phase 2 TOIVA trial of QTORIN rapamycin for the treatment of cutaneous VMs demonstrating 100% of patients with bleeding at baseline demonstrated improvement on the Cutaneous Venous Malformations Investigator Global Assessment Bleeding scale ("cVM-IGA Bleeding") at Week 12 (+2.5 point mean improvement).

In May 2026, at the ISSVA World Congress 2026, James Treat, MD presented additional data from our Phase 2 TOIVA study demonstrating statistically significant improvements in both cVM-MCSS Height and cVM-MCSS Appearance at all time points measured, with increasing clinical response observed with longer duration of QTORIN rapamycin therapy.

After completing our Preliminary Breakthrough Therapy Designation Advice meeting with the FDA, we applied to the FDA for Breakthrough Therapy Designation in the second quarter of 2026. Following the FDA's decision in July 2026 to not grant the designation at this time, we are currently planning a resubmission incorporating TOIVA patient interviews and new 24-week data.

We are planning for our End-of-Phase 2 meeting with FDA and expect to commence a Phase 3 pivotal study in the fourth quarter of 2026.

We have received Fast Track Designation from the FDA for our cutaneous VMs program.

QTORIN rapamycin for the treatment of Clinically Significant Angiokeratomas

In September 2025, we announced the expansion of our QTORIN rapamycin development program into clinically significant angiokeratomas. No FDA-approved therapies currently exist for the estimated more than 50,000 diagnosed patients in the U.S.

Clinically significant angiokeratomas are superficial vascular malformations of lymphatic origin which can cause bleeding, pain, functional impairment, and risk of infection, with no tendency for spontaneous regression. Angiokeratomas were classified as an isolated lymphatic malformation in 2025 by ISSVA. Current treatment options include potentially destructive procedural interventions that carry significant risks of pain, scarring, and recurrence. Despite the substantial disease burden, there are currently no FDA-approved treatments available for clinically significant angiokeratomas.

We received written feedback from the FDA in February 2026 on the proposed design of a Phase 2 study of approximately 10-20 patients to evaluate QTORIN rapamycin for the treatment of clinically significant angiokeratomas. In April 2026, we dosed our first patients in the Phase 2 LOTU trial, a baseline-controlled clinical study of QTORIN rapamycin administered topically once daily for the treatment of clinically significant angiokeratomas. Topline results are expected in the second half of 2027.

Fast Track Designation from the FDA has been granted for our angiokeratomas program.

QTORIN pitavastatin for the treatment of Disseminated Superficial Actinic Porokeratosis

In November 2025, we announced a new product candidate, QTORIN pitavastatin, for the treatment of DSAP. QTORIN pitavastatin was developed leveraging our QTORIN platform.

DSAP is a premalignant genetic skin disease that presents as persistent, often extensive lesions that enlarge and increase in size, number, and extent over time, causing chronic loss of skin integrity which can severely impact quality-of-life; no FDA-approved therapies currently exist for the estimated more than 50,000 diagnosed patients in the U.S.

We received written feedback from the FDA in the first quarter of 2026 on the proposed design of a Phase 2 study to evaluate QTORIN pitavastatin for the treatment of DSAP. Trial initiation is anticipated in the second half of 2026.

The Business Combination

On December 13, 2024 (the “Closing Date”), we consummated the previously announced business combination contemplated by that certain Agreement and Plan of Merger, dated July 23, 2024 (the “Merger Agreement”), by and among the Company, Polo Merger Sub, Inc. (“Merger Sub”), and Palvella Therapeutics, Inc. (“Legacy Palvella”). Pursuant to the Merger Agreement, on the Closing Date, (i) Merger Sub merged with and into Legacy Palvella, with Legacy Palvella as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly owned subsidiary of the Company (the “Merger” and, together with the other transactions contemplated by the Merger Agreement, the “Business Combination”) and (ii) the Company’s name was changed from Pieris Pharmaceuticals, Inc. to Palvella Therapeutics, Inc.

Contingent Value Rights Agreement

On December 13, 2024, immediately prior to closing of the Merger, we entered into a Contingent Value Rights Agreement (the “CVR Agreement”) with a rights agent, pursuant to which our pre-Merger capital stockholders received one contingent value right (each, a “CVR”) for each outstanding share of our Common Stock held by such stockholder, or share of Common Stock underlying preferred stock held by such stockholder, on such date. Each CVR represents the contractual right to receive payments upon the receipt of payments by us or any of its affiliates under certain strategic partner agreements, including existing collaboration agreements pursuant to which we may be entitled to milestones and royalties in the future and other out-licensing agreements for certain of Pieris’ legacy assets, and upon the receipt of certain research and development tax credits in favor of us or any of its affiliates, in each case as set forth in, and subject to and in accordance with the terms and conditions of, the CVR Agreement. There can be no assurance that holders of CVRs will receive any amounts with respect thereto. In January 2026, we paid out \$2.0 million to holders of CVRs in accordance with the CVR Agreement entered into immediately prior to closing of the Merger on December 13, 2024.

Ligand Development Funding and Royalties Agreement

We are party to a Development Funding and Royalties Agreement with Ligand Pharmaceuticals, Inc. (“Ligand”), dated December 13, 2018, as amended May 22, 2020 and November 28, 2023 (the “Ligand Agreement”). Under the Ligand Agreement, Ligand has made payments totaling \$15.0 million to fund the development of QTORIN rapamycin. As partial consideration for the funding received, we granted Ligand the right to receive up to \$8.0 million in milestone payments upon the achievement of certain corporate, financing and regulatory milestones by us related to QTORIN rapamycin for the treatment of any and all indications, of which \$5.0 million of potential future milestone payments remain under the arrangement. In addition, we agreed to pay to Ligand tiered royalties ranging from 8.0% to 9.8% of any aggregate annual worldwide net product sales of any products based on QTORIN rapamycin. See Note 4 of the accompanying notes to the condensed consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q.

Impact of Global and Macroeconomic Events

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including increases in inflation, increased

U.S. trade tariffs and retaliatory tariffs, interest rate and currency rate fluctuations, new laws and regulations enacted by the Trump administration, including, but not limited to, the One Big Beautiful Bill Act, economic slowdown or recession, banking instability, monetary policy changes, and geopolitical factors, including the ongoing conflict between Russia and Ukraine, the current conflicts in Venezuela and the Middle East (including any escalation or expansion) and increasing tensions between China and Taiwan, rapid changes in our regulatory landscape in the United States, including significant staffing reductions and unexpected shifts in leadership of certain federal agencies, and an uncertain legislative environment and supply chain disruptions. While our management is closely monitoring the impact of the current macroeconomic conditions on all aspects of our business, including the impacts on its participants in its clinical trials, employees, suppliers, vendors and business partners, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside our control and could exist for an extended period of time. Management will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources. For additional information, see Part I, Item 1A “Risk Factors” of our 2025 Form 10-K.

Components of Operating Results

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

We expect to continue to incur significant operating losses for the foreseeable future and to incur increased expenses as we continue to advance our product candidates through clinical trials and regulatory submissions. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that Legacy Palvella did not incur as a private company. If we receive regulatory approval for QTORIN rapamycin for treatment of microcystic LMs, cutaneous VM, clinically significant angiokeratomas, QTORIN pitavastatin for the treatment of disseminated superficial actinic porokeratosis or any future product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Our losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- costs related to production of preclinical and clinical materials, including CMC fees paid to CMOs;
- personnel costs, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions, including medical affairs;
- vendor expenses related to the execution of preclinical studies and clinical trials;
- expenses incurred under agreements with consultants that conduct research and development activities on our behalf;
- costs related to compliance with regulatory requirements; and
- allocated overhead, including rent, equipment and information technology costs.

We expense all research and development expenses in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and other service providers. This process involves reviewing open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Any nonrefundable advance payments that we make for goods or

services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Our indirect research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs to identify and develop product candidates.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in advancing our programs and conducting clinical trials. In particular, we expect to incur substantial research and development expenses to continue late-stage clinical development and pursue regulatory approvals of QTORIN rapamycin for the treatment of microcystic LMs, venous malformations and the development of our preclinical programs. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development.

Because of the numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and may depend substantially upon the performance of certain third-party contractors;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any, or experienced by competitors who are developing topical rapamycin products or who are targeting the same indications in the rare skin diseases space;
- the ability of CMOs upon which we rely to manufacture clinical supplies of our product candidates or any future product candidates to remain in good standing with relevant regulatory authorities and to develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- our ability to retain patients who have enrolled in a clinical study but may be prone to withdraw due to the rigors of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest;
- our ability to establish and enforce intellectual property rights in and to our current product candidates and any future product candidates; and
- minimizing and managing any delay or disruption to our ongoing or planned clinical trials.

A change in the outcome of any of these factors with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate.

We may never succeed in achieving regulatory approval for any of our product candidates. Our preclinical studies and clinical trials may be unsuccessful. We may elect to discontinue, suspend or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct additional clinical trials beyond those that we currently anticipate will be required for the completion of any of our product candidates' clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or

clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development for such product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of the following costs:

- personnel costs, including salaries, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions; and
- professional fees for legal, intellectual property, information technology, financial, human resources, consulting, audit and accounting services not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase substantially in the future as we increase our headcount to support our organizational growth. Following the completion of the Merger, we also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with our operations as a public company. In addition, if we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing organization to support product sales, marketing and distribution activities.

Other (Expense) Income

Our other (expense) income for the three and six months ended June 30, 2026 and 2025 primarily consists of: (i) non-cash interest (expense) income related to our obligation to make future royalty payments pursuant to the Amended Ligand Agreement, which was determined to be a debt instrument; (ii) fair value adjustments related to our obligation to make future milestone payments under the Amended Ligand Agreement, which was determined to be a derivative liability; (iii) fair value adjustments related to the CVRs, which met the definition of a derivative; and (iv) interest income, net.

Our other (expense) income is subject to variability due to changes in the fair value of the derivative liabilities as well as the potential variability of the royalty agreement liability, both of which are based on significant estimates regarding the timing and success of future development and commercialization activities.

Income Taxes

Since May 2018, we have not recorded any income tax benefits for net operating losses (“NOLs”). We believe, based upon the weight of available evidence, that it is more likely than not that all of our NOLs and tax credits will not be realized. Accordingly, we have established a valuation allowance against such deferred tax assets for all periods since inception.

We assess our income tax positions and record tax benefits based upon management’s evaluation of the facts, circumstances, and information available at the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, we record the amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions for which it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the consolidated financial statements.

We had no provision for income taxes for the three and six months ended June 30, 2026 and 2025.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2026 and 2025

The following sets forth our results of operations (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	\$ Change	2026	2025	\$ Change
Operating expenses:						
Research and development	\$ 12,473	\$ 5,118	\$ 7,355	\$ 21,807	\$ 9,192	\$ 12,615
General and administrative	8,932	4,132	4,800	14,453	7,929	6,524
Total operating expenses	21,405	9,250	12,155	36,260	17,121	19,139
Operating loss	(21,405)	(9,250)	(12,155)	(36,260)	(17,121)	(19,139)
Other (expense) income:						
Interest expense – royalty agreement	(2,308)	(1,354)	(954)	(4,347)	(2,569)	(1,778)
Fair value adjustments on derivative liabilities – royalty agreement	(114)	(118)	4	(230)	(193)	(37)
Fair value adjustments on derivative liabilities – contingent value right liability	—	—	—	202	—	202
Interest income, net	1,965	690	1,275	3,038	1,442	1,596
Other income (expense), net	(8)	561	(569)	(40)	785	(825)
Loss before income taxes	(21,870)	(9,471)	(12,399)	(37,637)	(17,656)	(19,981)
Income tax benefit (expense)	—	—	—	—	—	—
Net loss	<u>\$ (21,870)</u>	<u>\$ (9,471)</u>	<u>\$ (12,399)</u>	<u>\$ (37,637)</u>	<u>\$ (17,656)</u>	<u>\$ (19,981)</u>

Research and Development Expenses

The table below summarizes our research and development expenses incurred by development program (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2026	2025	\$ Change	2026	2025	\$ Change
QTORIN CMC	\$ 3,308	\$ 1,517	\$ 1,791	\$ 5,135	\$ 2,289	\$ 2,846
QTORIN rapamycin for microcystic LM	865	1,235	(370)	2,400	2,389	11
QTORIN rapamycin for angiokeratomas	749	—	749	1,201	—	1,201
QTORIN rapamycin for cutaneous VM	712	354	358	1,157	700	457
QTORIN rapamycin for microcystic LM - Government grant income	—	(212)	212	—	(339)	339
Non-program specific and unallocated research and development expenses:						
Salaries and stock-based compensation	3,697	1,501	2,196	6,887	2,823	4,064
Consultants	2,081	385	1,696	3,434	632	2,802
Other	1,061	338	723	1,593	698	895
Total research and development expenses	<u>\$ 12,473</u>	<u>\$ 5,118</u>	<u>\$ 7,355</u>	<u>\$ 21,807</u>	<u>\$ 9,192</u>	<u>\$ 12,615</u>

Research and development expenses for the three months ended June 30, 2026 were \$12.5 million, as compared to \$5.1 million for the three months ended June 30, 2025. Research and development expenses for the six months ended June 30, 2026 were \$21.8 million, as compared to \$9.2 million for the three months ended June 30, 2025. The increase in research and development expenses was primarily due to increased spending on clinical, manufacturing and controls (“CMC”) activities, the clinical development of QTORIN rapamycin for the treatment of angiokeratomas, costs associated with the submission of the first module of our rolling NDA, and costs resulting from increased headcount and consulting services in 2026.

General and Administrative Expenses

General and administrative expenses for the three months ended June 30, 2026 were \$8.9 million, as compared to \$4.1 million for the three months ended June 30, 2025. General and administrative expenses for the six months ended June 30, 2026 were \$14.5 million, as compared to \$7.9 million for the six months ended June 30, 2025. The increase in general and administrative expenses was primarily due to increased headcount in 2026, as well as increased professional services related to operating as a publicly-traded company.

Total Other (Expense) Income

Total other (expense) income, net for the three months ended June 30, 2026 was \$0.5 million, as compared to \$0.2 million of expense for the three months ended June 30, 2025. Total other (expense) income, net for the six months ended June 30, 2026 was \$1.4 million, as compared to \$0.5 million of expense for the six months ended June 30, 2025. The significant components of other (expense) income are more fully described below.

Interest expense – royalty agreement

During the three months ended June 30, 2026, we recorded interest expense of approximately \$2.3 million, as compared to approximately \$1.4 million for the three months ended June 30, 2025. During the six months ended June 30, 2026, we recorded interest expense of approximately \$4.3 million, as compared to approximately \$2.6 million for the six months ended June 30, 2025. Interest expense recorded in all periods related to the change in fair value of our royalty agreement liability.

Fair value adjustments on derivative liabilities – royalty agreement

During the three months ended June 30, 2026 and 2025, we recorded a non-cash loss on derivative liabilities of approximately \$0.1 million. During the six months ended June 30, 2026 and 2025, we recorded a non-cash loss on derivative liabilities of approximately \$0.2 million. The non-cash loss recorded in all periods related to the change in fair value of our obligation to make future milestone payments under the Amended Ligand Agreement, which was determined to be a derivative liability.

Fair value adjustments on derivative liabilities – contingent right liability

During the six months ended June 30, 2026, we recorded non-cash income of approximately \$0.2 million related to fair value adjustments related to the CVRs which were issued in 2024 in connection with the Business Combination and determined to be derivative liabilities.

Interest income, net

During the three months ended June 30, 2026, we recorded interest income, net of \$2.0 million, as compared to \$0.7 million for the three months ended June 30, 2025. During the six months ended June 30, 2026, we recorded interest income, net of \$3.0 million, as compared to \$1.4 million for the six months ended June 30, 2025. The increase during each of the three and six months ended June 30, 2026, as compared to the corresponding periods in 2025, was primarily due to increases in the average balances held in interest-bearing cash and money market funds.

Net Loss

As a result of the factors discussed above, our net loss applicable to common stockholders for the three months ended June 30, 2026 and 2025 was \$21.9 million and \$9.5 million, respectively, and our net loss applicable to common stockholders for the six months ended June 30, 2026 and 2025 was \$37.6 million and \$17.7 million, respectively.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have incurred substantial losses, and have primarily funded our operations with proceeds from the Amended Ligand Agreement and the sale of debt and equity securities, including common stock, convertible preferred stock and convertible notes. During the six months ended June 30, 2026, we incurred a net loss of \$37.6

million and reported net cash used in operating activities of \$23.7 million. As of June 30, 2026, we had an accumulated deficit of \$173.1 million and cash and cash equivalents and short-term investments of \$250.6 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and, to a lesser extent, general and administrative expenditures.

We do not expect to generate commercial revenue or operating cash flows in the near-term. Our ability to continue as a going concern in the near term is largely dependent on our existing cash balance and our ability to obtain additional sources of financing in order to fund operating expenses, complete development of our product candidates, obtain regulatory approvals, launch, and commercialize our product candidates, and continue research and development programs.

Equity Financing

On February 25, 2026, we entered into an underwriting agreement (the “Underwriting Agreement”) with TD Securities (USA) LLC, Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated, as representatives (the “Representatives”) of the several underwriters named therein (the “Underwriters”), pursuant to which we agreed to issue and sell an aggregate of 1,600,000 shares (the “Firm Shares”) of our Common Stock, at a price to the public of \$125.00. Under the terms of the Underwriting Agreement, we granted the Underwriters an option to purchase up to an additional 240,000 shares of our Common Stock at the public offering price, less underwriting discounts and commission. The option was exercised and the offering closed on February 27, 2026. The offering resulted in net proceeds of \$215.8 million, after deducting underwriting discounts and commissions and other offering expenses.

PIPE Financing

Concurrently with the execution of the Merger Agreement on July 23, 2024, Pieris entered into a securities purchase agreement (the “Purchase Agreement”) with certain investors, including BVF Partners, L.P., an existing stockholder of Pieris (the “PIPE Investors”), pursuant to which, among other things, on the Closing Date and immediately following the consummation of the Merger, the PIPE Investors purchased (either for cash or in exchange for the termination and cancellation of outstanding convertible promissory notes issued by Legacy Palvella), and the Company issued and sold to the PIPE Investors, (i) 3,168,048 shares of Common Stock and (ii) Pre-Funded Warrants, exercisable for 2,466,456 shares of Common Stock, at a purchase price of \$13.9965 per share or \$13.9955 per Pre-Funded Warrant, which represents the per share purchase price of Common Stock less the \$0.001 per share exercise price for each Pre-Funded Warrant, for an aggregate purchase price of approximately \$78.9 million, consisting of approximately \$60.0 million in cash and the conversion of approximately \$18.9 million of principal and interest under outstanding convertible notes issued by Legacy Palvella (the “PIPE Financing”). As of June 30, 2026, the Company has pre-funded warrants outstanding to purchase an aggregate of 1,394,780 shares of Common Stock.

Convertible Notes

On June 6, 2024, Legacy Palvella initiated a sequence of convertible notes with certain investors via a Convertible Note Purchase Agreement, pursuant to which the Company issued convertible notes in the aggregate principal amount of approximately \$18.4 million (the “Convertible Notes”) between June 2024 and December 2024. Simple interest accrued on the outstanding principal amount of the Convertible Notes at an annual rate of SOFR plus 2.0% per annum. Unless earlier converted, the maturity date of the Convertible Notes was the earliest to occur of (i) the date that Legacy Palvella received approval of an NDA by the FDA of QTORIN rapamycin in the United States, or (ii) June 3, 2027. Upon the closing of the PIPE Financing, the entire outstanding principal amount and unpaid accrued interest on the convertible notes automatically converted into an aggregate of 1,179,163 shares of Common Stock and 168,503 pre-funded warrants with all such pre-funded warrants remaining outstanding as of June 30, 2026.

Future Funding Requirements

We have not generated product revenue or achieved profitability since our inception and expect to continue to incur net losses for the foreseeable future. As of June 30, 2026, we had approximately \$250.6 million in cash and cash equivalents and short-term investments. Based on our current business plans, we believe that our existing cash and cash equivalents will be sufficient to fund our planned operations for at least the one year period following the date of the filing of this Quarterly Report on Form 10-Q. Moreover, we expect our losses to increase as we continue to advance our product candidates through clinical trials and regulatory submissions. We may also incur expenses in connection

with the in-licensing or acquisition of additional product candidates and to build our commercial organization in preparation for the launch of our lead product candidate, QTORIN rapamycin for the treatment of microcystic LM, which is currently under review at the FDA, which may not be currently contemplated in our planned operations. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our primary uses of capital have been, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, license payments or milestone obligations that may arise, manufacturing costs, legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that our cash and cash equivalents and short-term investments on hand as of June 30, 2026 will be sufficient to fund our operating expenses for at least the next twelve months from the date of this Quarterly Report on Form 10-Q. To continue to finance our operations beyond that point, we may need to raise additional capital, the success of which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. If we receive regulatory approval for QTORIN rapamycin for the treatment of microcystic LM, cutaneous VMs, clinically significant angiokeratomas, QTORIN pitavastatin for the treatment of disseminated superficial actinic porokeratosis, or any of our future product candidates, we expect to incur significant commercialization expenses related to manufacturing, sales, marketing, and distribution, or from any out-licensing of the product. We are also responsible for up to \$5.0 million in milestone payments to Ligand under the Amended Ligand Agreement upon the achievement of certain regulatory milestones by us related to QTORIN rapamycin, which may be triggered prior to the commercialization of any of our product candidates and ability to generate revenue.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences detrimental to the rights of our common stockholders. Any agreements for future debt or preferred equity financings, if available, may involve 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 funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we has sufficient funds for our current or future operating plans.

Our future funding requirements depend on many factors, including, but not limited to:

- timing and outcome of regulatory review for QTORIN rapamycin for the treatment of microcystic LM, or our other product candidates;
- the cost of commercialization and manufacturing activities for QTORIN rapamycin and QTORIN pitavastatin, and our ability to successfully commercialize these product candidates, if approved;
- the scope, progress, results and costs of researching and developing QTORIN rapamycin, QTORIN pitavastatin, or any future product candidates, and conducting preclinical studies and clinical trials;
- the number and scope of clinical programs we decide to pursue;
- the cost of manufacturing our product candidates and any products we commercialize, including costs associated with developing our supply chain;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the timing and sales of any future approved products, if any;

- the potential size of the markets, degree of market acceptance, as well as the pricing and reimbursement for our approved products, if any;
- the timing and amount of milestone or royalty payments due under the Ligand Agreements or under similar arrangements with any future collaboration or licensing partners;
- the expenses needed to attract and retain skilled personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, and other costs associated with being a public company; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio.

Further, our development and commercialization operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities and commercialization of QTORIN rapamycin, if approved. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we may be unable to accurately estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2026 and 2025 (in thousands):

	Six Months Ended June 30,	
	2026	2025
Net cash used in operating activities	\$ (23,709)	\$ (12,202)
Net cash used in investing activities	(62,472)	—
Net cash provided by (used in) financing activities	216,011	(853)
Effect of exchange rate change on cash and cash equivalents	(9)	(114)
Net increase (decrease) in cash and cash equivalents	<u>\$ 129,821</u>	<u>\$ (13,169)</u>

Net cash used in operating activities

Net cash used in operating activities for the six months ended June 30, 2026 and 2025 consisted of net loss for the period adjusted for non-cash items and changes in components of operating assets and liabilities. The primary use of cash was to fund our operations related to the development of our product candidates, including general and administrative support, which increased due to greater research and development efforts in 2026, increased costs to operate as a public company, as well as the timing of payments and increase in accounts payable.

Net cash used in investing activities

For the six months ended June 30, 2026, net cash used in investing activities was \$62.5 million, consisting of the purchase and maturities of marketable securities.

Net cash provided by (used in) financing activities

For the six months ended June 30, 2026, net cash provided by financing activities was \$216.0 million, consisting of proceeds from the issuance of common stock in connection with the equity financing in February 2026, the payment to holders of CVRs in accordance with the CVR Agreement entered into immediately prior to closing of the Merger on December 13, 2024, and proceeds from the exercise of stock options.

For the six months ended June 30, 2025, net cash used in financing activities was \$0.9 million, consisting primarily of payments of transaction costs incurred in connection with the Business Combination and proceeds from the exercise of stock options.

Contractual Obligations and Commitments

During the six months ended June 30, 2026, there were no material changes outside the ordinary course of our business to our contractual obligations and cash requirements, as disclosed in our 2025 Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. On an ongoing basis, management evaluates its estimates and judgments, including, but not limited to, those related to (i) research and development expenses and accruals, (ii) the Amended Ligand Agreement, including the related royalty agreement liability and derivative liability, (iii) the CVR Agreement, including contingent value right liability, (iv) stock-based compensation, and (v) the valuation allowance for deferred income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" if:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and
- the impact of the estimates and assumptions on financial condition or operating performance is material.

During the six months ended June 30, 2026, there were no material changes to our critical accounting policies or in the methodology used for estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2025 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

a) Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2026. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of June 30, 2026, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

b) Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 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.

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business. We are not currently a party to any material legal proceedings, and are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties discussed within “Item 1A. Risk Factors” of our 2025 Form 10-K, together with all of the other information in this Quarterly Report on Form 10-Q, including the section “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our unaudited condensed consolidated financial statements and related notes, before deciding whether to purchase any of our securities.

There have been no material changes in our risk factors from those disclosed in our 2025 Form 10-K.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

- (a) None.
- (b) None.
- (c) Consistent with Item 408 of Regulation S-K, the following table reflects Rule 10b5-1 trading arrangements and non-Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K) entered into by any director or officer (as defined in Rule 16a-1(f) of the Exchange Act) during the quarter ended June 30, 2026:

<u>Name</u>	<u>Type of Trading Arrangement</u>	<u>Date of Adoption</u>	<u>Expiration Date of Trading Arrangement</u>	<u>Aggregate Number of Securities to Be Purchased or Sold</u>
George Jenkins Director	Rule 10b5-1 Trading Plan	June 12, 2026	May 12, 2027 or such earlier date upon completion of all trades under the plan (or expiration of the orders relating to such trades without execution) or the occurrence of such other termination events as specified in the plan.	Sale of up to 55,000 shares of Common Stock

Our officers and directors from time to time may adopt trading plans to transact in our securities for reasons such as satisfying vesting-related income tax requirements, investment diversification, or other personal reasons. On June 12, 2026, George Jenkins, a member of our Board of Directors, entered into a Rule 10b5-1 trading plan that provides for the potential future sale of a limited portion of his Common Stock, as part of Mr. Jenkins long-term financial planning objectives. The plan was adopted during an open trading window, at a time when Mr. Jenkins was not in possession

of material non-public information and was reviewed and approved in accordance with the Company's Insider Trading Policy. The plan establishes fixed criteria for potential transactions and removes discretion over the timing of trades.

Other than as disclosed above, no director or officer (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as defined in Item 408 of Regulation S-K) during the quarter ended June 30, 2026.

(d) On August 3, 2026, the Board of Directors approved the Change in Control Acceleration Policy (the "Policy"), effective August 3, 2026, to provide for accelerated equity vesting benefits to eligible employees in the event of certain qualifying terminations following a Change in Control (as defined in the Policy), subject to the employee signing a general release of claims. Participants under the Policy include all Vice Presidents and above, including the Company's current named executive officers (the "Eligible Employees").

Under the Policy, in the event of an Eligible Employee's termination (i) by the Company or its successor without Cause or (ii) by the Eligible Employee for Good Reason (as such terms are defined in the Policy) during the period beginning three months prior to the effective date of a Change in Control (as defined in the Policy) and continuing for the 12 months immediately following such Change in Control (the "Change in Control Period"), subject to (i) the Eligible Employee signing a general release of claims (the "Release"), and (ii) the Release becoming effective within 60 days after the date of the Eligible Employee's termination (the "Date of Termination"), all then unvested and outstanding equity awards (collectively, the "Equity Awards"), shall become fully vested; provided that, any awards subject to performance-based vesting shall vest based on target performance unless otherwise explicitly set forth in the applicable award agreement.

If the Release has not become effective as of such Date of Termination, then acceleration of vesting shall be tolled until the earlier of (x) the effective date of the Release, at which point the Equity Awards will be automatically fully vested, or (y) the date upon which the Release can no longer become fully effective, at which time the unvested portion of the Eligible Employee's Equity Awards will be forfeited. The forfeiture of such awards shall be delayed until the earlier of (A) the effective date of the Release or (B) the date that the Release can no longer become fully effective.

The foregoing description of the Policy does not purport to be complete and is qualified in its entirety by reference to the full text of the Policy, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2026.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth in the Exhibit Index below, which is incorporated herein by reference.

Exhibit Index

Exhibit Number	Description
10.1#	Amendment No. 1 to the Palvella Therapeutics, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on June 16, 2026).
10.2*#	Form of Notice of Grant of Performance-Based Restricted Stock Unit Award under the Palvella Therapeutics, Inc. 2024 Equity Incentive Plan.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** This certification is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Registrant specifically incorporates it by reference.

Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Palvella Therapeutics, Inc.

Date: August 4, 2026	By: /s/ Wesley H. Kaupinen Wesley H. Kaupinen <i>President, Chief Executive Officer and Director</i> <i>(Principal Executive Officer)</i>
Date: August 4, 2026	By: /s/ Matthew E. Korenberg Matthew E. Korenberg <i>Chief Financial Officer and Treasurer</i> <i>(Principal Financial Officer and Principal Accounting Officer)</i>

PALVELLA THERAPEUTICS, INC.

2024 EQUITY INCENTIVE PLAN

NOTICE OF GRANT OF PERFORMANCE-BASED RESTRICTED STOCK UNITS AWARD

Palvella Therapeutics, Inc. (the “Company”), pursuant to its 2024 Equity Incentive Plan (the “Plan”), hereby grants to the individual listed below (the “Participant”) this award of Performance-Based Restricted Stock Units. The Performance-Based Restricted Stock Units described in this Notice of Grant of Performance-Based Restricted Stock Units Award (the “Notice”) are subject to the terms and conditions set forth in the Award Agreement attached hereto as Exhibit A (the “Agreement”) and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, capitalized terms used in this Notice and the Agreement will have the meanings defined in the Plan.

Participant:	
Grant Date:	
Total Number of Performance-Based Restricted Stock Units:	
Vesting:	Subject to the continued service of the Participant through the applicable vesting date, the Performance-Based Restricted Stock Units shall vest as set forth on Appendix A.

By Participant’s signature and the Company’s signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Notice. Participant has reviewed the Plan, the Agreement and this Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Notice and fully understands all provisions of this Notice, the Performance-Based Restricted Stock Unit Agreement and the Plan. This document may be executed, including by electronic means, in multiple counterparts, each of which will be deemed an original, and all of which together will be deemed a single instrument.

PALVELLA THERAPEUTICS, INC.

PARTICIPANT

Name:
Title:

Name:

EXHIBIT A

PERFORMANCE-BASED RESTRICTED STOCK UNIT AWARD AGREEMENT

1. **Grant of Award**. Effective as of the Grant Date set forth in the Notice, the Company has granted to the Participant the number of Performance-Based Restricted Stock Units set forth in the Notice (the "**Award**"), subject to the restrictions and on the terms and conditions set forth in the Notice, the Plan, and this Agreement. Each Performance-Based Restricted Stock Unit represents the right to receive one Share, subject to the terms and conditions set forth herein.

2. **Vesting of Award**.

(a) Subject to the continued service of the Participant with the Company through the relevant vesting date(s) or event(s), the Performance-Based Restricted Stock Units shall become vested in such amounts and at such times as set forth in Appendix A.

(b) Upon the cessation of the Participant's service with the Company for Cause (or a resignation by the Participant at such time as the Company could have terminated the Participant's service for Cause), (i) any unvested Performance-Based Restricted Stock Units will be forfeited automatically and (ii) any vested Performance-Based Restricted Stock Units for which Shares have not yet been delivered will also be forfeited automatically, and the Participant will have no further rights hereunder.

(c) Unless otherwise provided in the Participant's employment agreement or in the discretion of the Committee, upon the cessation of the Participant's service with the Company for any other reason, any unvested Performance-Based Restricted Stock Units will be forfeited automatically and the Participant will have no further rights hereunder.

(d) Solely for purposes of this Agreement, service with the Company will be deemed to include service with an Affiliate of the Company (for only so long as such entity remains an Affiliate of the Company).

3. **Settlement of Award**.

(a) One Share will be delivered with respect to each vested Performance-Based Restricted Stock Unit within sixty (60) days following the applicable vesting date or event.

(b) The award of Performance-Based Restricted Stock Units constitutes an unfunded and unsecured obligation of the Company. The Participant shall not have any stockholder rights with respect to the Shares underlying the Performance-Based Restricted Stock Units, in each case, unless and until a Performance-Based Restricted Stock Unit vests and a Share is delivered with respect thereto.

(c) Notwithstanding the foregoing, to the extent provided in Prop. Treas. Reg. § 1.409A-1(b)(4)(ii) or any successor provision, the Company may delay settlement of Performance-Based Restricted Stock Units if it reasonably determines that such settlement would violate federal securities laws or any other Applicable Law.

4. **Non-Transferability of Award**. Except for the forfeiture to the Company, the Performance-Based Restricted Stock Unit and this Award may not be sold, pledged, assigned, hypothecated, gifted, transferred or disposed of in any manner either voluntarily or involuntarily by operation of law or otherwise, other than by will or by the laws of descent and distribution.

5. **Section 409A**. The Award is intended to be exempt from Section 409A of the Code and should be interpreted accordingly. Nonetheless, the Company does not guarantee the tax treatment of the Award.

6. **Acknowledgements**. The Company may require that certain agreements, undertakings, representations, certificates, legends and/or information or other matters, as the Company may deem necessary or advisable, be executed, agreed to and/or provided to the Company to assure compliance with all such Applicable Laws. Participant

further acknowledges that the Plan is intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Award is granted, only in such a manner as to conform to such Applicable Laws.

7. **Tax Consequences.** Participant acknowledges that the Company has not advised Participant regarding Participant's income tax liability in connection with the Award and that the Company does not guarantee any particular tax treatment. Participant acknowledges that Participant has reviewed with their own tax advisors the tax treatment of this Award and is relying solely on those advisors in that regard. Participant understands that Participant (and not the Company) will be responsible for their own tax liabilities arising in connection with this Award.

8. **Clawback Provisions.** In consideration for the grant of the Award, the Participant agrees to be subject to (i) any compensation, clawback, recoupment or similar policies of the Company or its Affiliates covering the Participant that may be in effect from time to time, whether adopted before or after the Grant Date, and (ii) to such other clawback measures as may be required by Applicable Law ((i) and (ii) together, the "**Clawback Provisions**"). The Participant understands that the Clawback Provisions are not limited in their application to the Award, or to any equity or cash the Participant may receive in connection with the Award.

9. **Other Company Policies.** The Participant agrees, in consideration for the grant of the Award, to be subject to any policies of the Company and its Affiliates regarding stock ownership, securities trading, anti-hedging and anti-pledging of securities, and other similar policies, that may be in effect from time to time, or as may otherwise be required by Applicable Law.

10. **Entire Agreement.** The Notice and this Agreement, together with the Plan, represent the entire agreement between the parties with respect to the subject matter hereof and supersede any prior agreement, written or otherwise, relating to the subject matter hereof. The Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee with respect to questions arising under the Plan, the Notice, or this Agreement.

11. **Amendment.** The Notice and this Agreement may only be amended by a writing signed by each of the parties hereto. To the extent permitted by Applicable Laws, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Laws.

12. **Successors and Assigns.** This Agreement and the Notice shall be binding upon the heirs, executors, administrators and successors of the parties hereto. Neither this Agreement nor any rights or interest hereunder shall be assignable by the Participant, his or her beneficiaries or legal representatives, and any purported assignment in violation hereof shall be void ab initio and of no force or effect.

13. **Waiver.** Either party's failure to enforce any provision or provisions of this Agreement shall not in any way be construed as a waiver of any such provision or provisions, nor prevent that party thereafter from enforcing each and every other provision of this Agreement. The rights granted both parties herein are cumulative and shall not constitute a waiver of either party's right to assert all other legal remedies available to it under the circumstances.

14. **No Right to Continued Service.** Neither the Plan nor this Agreement will confer upon Participant any right to continue in the service of the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge Participant at any time, with or without Cause and with or without notice.

15. **Tax Withholding.** The Company is hereby authorized to withhold from any consideration payable or property transferable to Participant any taxes required to be withheld by applicable law in connection with the grant or settlement of this Award. The Company shall have the right to require the Participant to remit to the Company an amount sufficient to satisfy any federal, state and local withholding tax requirements prior to the issuance of any Shares. The Participant may satisfy the applicable withholding tax obligations by paying the amount of any taxes in cash, or, to the extent permitted by the Committee, Shares or other securities may be delivered to the Company or deducted from the number of Shares to be issued to the Participant pursuant to this Agreement to satisfy the obligation in full or in part as long as such withholding of Shares does not violate any applicable laws, rules, or regulations of

federal, state, or local authorities (including Section 16 of the Securities Exchange Act of 1934, and the rules promulgated thereunder, if applicable). The Participant shall make such payment or arrangement no later than the date as of which an amount first becomes includible in the gross income of the Participant for federal income tax purposes with respect to any Shares. The obligations of the Company under the Plan are conditioned on such payment or arrangement and the Company, to the extent permitted by law, has the right to deduct any such taxes from any distribution of any kind otherwise due to the Participant.

16. **Governing Law; Severability.** This Agreement shall be construed and interpreted in accordance with the laws of the State of Delaware, without regard to the principles of conflicts of law thereof. Should any provision of this Agreement be determined by a court of law to be illegal or unenforceable, the other provisions shall nevertheless remain effective and shall remain enforceable.

17. **Electronic Delivery of Documents.** The Company may, in its sole discretion, decide to deliver any documents related to the Notice, the Plan or this Agreement or any notices required by applicable law or the Company's Articles of Incorporation or Bylaws by email or any other electronic means. The Participant hereby consents to (i) conduct business electronically, (ii) receive such documents and notices by such electronic delivery and (iii) sign documents electronically and agrees to participate through an on-line or electronic system established and maintained by the Company or a third party designated by the Company.

Appendix A

For purposes hereof, the “Performance Goals” shall mean the following:

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**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Wesley Kaupinen, certify that:

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

Date: August 4, 2026

By: /s/ Wesley H. Kaupinen
Wesley H. Kaupinen
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Matthew Korenberg, certify that:

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

Date: August 4, 2026

By: /s/ Matthew E. Korenberg
Matthew E. Korenberg
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Wesley H. Kaupinen
Wesley H. Kaupinen
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Palvella Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 4, 2026

By: /s/ Matthew E. Korenberg
Matthew E. Korenberg
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)
