

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

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2025

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File Number 001-37471

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

Nevada
(State or other jurisdiction of
incorporation or organization)
125 Strafford Ave, Suite 360
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 Capital Market

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 May 9, 2025 was 11,055,665.

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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 for our programs, including QTORIN™ rapamycin, and research-stage opportunities, including their expected therapeutic potential and market opportunity;
- 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 discovery platform to develop a pipeline of product candidates to address unmet needs in rare skin disease 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;

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- our manufacturing, commercialization, and marketing capabilities and strategy;
- 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;
- 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 particular types of therapy;
- 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 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 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, 2024 (our “2024 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 2024 Form 10-K, which was filed with the SEC on March 31, 2025, 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.

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)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 75,626	\$ 83,602
Accounts receivable	—	358
German research and development tax credit receivable	1,978	1,978
Prepaid expenses and other current assets	1,835	2,296
Total current assets	79,439	88,234
Total assets	\$ 79,439	\$ 88,234
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,441	\$ 4,586
Derivative liabilities – contingent value right liability	1,978	1,978
Accrued expenses and other current liabilities	2,564	5,474
Total current liabilities	8,983	12,038
Royalty agreement liability	13,157	11,942
Derivative liabilities – royalty agreement	1,722	1,647
Total liabilities	23,862	25,627
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001; 10,000,000 shares authorized; 15,617 shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized; 11,021,389 and 11,012,105 shares issued and outstanding at March 31, 2025 and December 31, 2024	11	11
Additional paid-in capital	157,489	156,328
Accumulated other comprehensive (loss) income	(3)	3
Accumulated deficit	(101,920)	(93,735)
Total stockholders' equity	55,577	62,607
Total liabilities and stockholders' equity	\$ 79,439	\$ 88,234

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 March 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 4,074	\$ 984
General and administrative	3,797	775
Total operating expenses	7,871	1,759
Operating loss	(7,871)	(1,759)
Other (expense) income:		
Interest expense – royalty agreement	(1,215)	(805)
Fair value adjustments on derivative liabilities – royalty agreement	(75)	(58)
Interest income, net	752	86
Other income, net	224	—
Loss before income taxes	(8,185)	(2,536)
Income tax benefit (expense)	—	—
Net loss	<u>\$ (8,185)</u>	<u>\$ (2,536)</u>
Less: Cumulative Series D preferred dividends	—	(194)
Loss attributable to common stockholders	<u>\$ (8,185)</u>	<u>\$ (2,730)</u>
Other comprehensive loss:		
Foreign currency translation loss	(6)	—
Comprehensive loss	<u>\$ (8,191)</u>	<u>\$ (2,730)</u>
Net loss per share of common stock – basic and diluted	<u>\$ (0.74)</u>	<u>\$ (1.54)</u>
Weighted-average shares used in computing net loss per share of common stock – basic and diluted	<u>11,013,697</u>	<u>1,770,167</u>

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

PALVELLA THERAPEUTICS, INC.

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

(Unaudited)

(in thousands, except share amounts)

Three Months Ended March 31, 2025

	Preferred Stock		Common Stock		Additional	Accumulated Other	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in	Comprehensive	Deficit	Stockholders'
					Capital	Income (Loss)		Equity
Balance at December 31, 2024	15,617	\$ —	11,012,10	\$ 5	\$ 156,328	\$ 3	\$ (93,735)	\$ 62,607
Proceeds from the exercise of stock options	—	—	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	\$ —	11,021,38	\$ 9	\$ 157,489	\$ (3)	\$ (101,920)	\$ 55,577

Three Months Ended March 31, 2024

	Convertible Preferred Stock		Common Stock		Additional	Accumulated Other	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in	Comprehensive	Deficit	Stockholders'
					Capital	Income (Loss)		Deficit
Balance at December 31, 2023	15,360,78	\$ 70,603	1,770,167	\$ 2	\$ 1,816	\$ —	\$ (76,301)	\$ (74,483)
Stock-based compensation	—	—	—	—	146	—	—	146
Net loss	—	—	—	—	—	—	(2,536)	(2,536)
Balance at March 31, 2024	15,360,78	\$ 70,603	1,770,167	\$ 2	\$ 1,962	\$ —	\$ (78,837)	\$ (76,873)

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)

	Three Months Ended March 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (8,185)	\$ (2,536)
Adjustments to reconcile net loss income to net cash used in operating activities:		
Non-cash interest expense – royalty agreement	1,215	805
Change in fair value of derivative liabilities – royalty agreement	75	58
Stock-based compensation	1,094	146
Change in operating assets and liabilities:		
Accounts receivable	358	—
Prepaid expenses and other current assets	461	54
Accounts payable	1,124	85
Accrued expenses and other current liabilities	(2,910)	286
Net cash used in operating activities	(6,768)	(1,102)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment of transaction costs in connection with Reverse Merger	(1,269)	—
Proceeds from exercise of stock options	67	—
Net cash used in financing activities	(1,202)	—
Effect of exchange rate change on cash and cash equivalents	(6)	—
Net decrease in cash and cash equivalents	(7,976)	(1,102)
Cash and cash equivalents at beginning of period	83,602	7,350
Cash and cash equivalents at end of period	<u>\$ 75,626</u>	<u>\$ 6,248</u>

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 genetic skin diseases 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 two rare genetic skin disorders. Since inception, the Company has devoted substantially all of its resources to identifying, researching and conducting preclinical and clinical activities for its product candidates, acquiring 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”). See Note 3 for additional details.

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 three months ended March 31, 2025 and year ended December 31, 2024, the Company reported a net loss of \$8.2 million and \$17.4 million, respectively, and net cash used in operating activities of \$6.8 million and \$10.8 million, respectively. At March 31, 2025, the Company had an accumulated deficit of \$101.9 million.

Management does not expect to generate commercial revenue or operating cash flows for at least the next several years. 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 three months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ended December 31, 2025 or any other future period.

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, the Company is treated as the “acquired” company and Legacy Palvella is treated as the acquirer for financial reporting purposes. As a result, the consolidated assets, liabilities and results of operations prior to the Business Combination are those of Legacy Palvella.

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 U.S. Food and Drug Administration (“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.

Accounts Receivable

Accounts receivable are amounts due from our vendors as a result of research and development and other services provided, as well as the shipment of clinical product.

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 March 31, 2025 and December 31, 2024, 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 March 31, 2025 and December 31, 2024, 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 20.0%) is approximately \$28.3 million and \$26.6 million, respectively. The Company records its 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 4) 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 CVR Agreement related to the asset sales prior to the Reverse Merger qualified as derivatives under ASC 815. Upon such time that these payments are assessed a fair value, they would be 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. All of the stock-based awards are subject only to service-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.

Prior to the Reverse Merger, Legacy Palvella periodically estimated the fair value of the Company's common stock considering, among other things, valuations of its common stock prepared by management with the assistance of a third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

Following the Reverse Merger, 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 Capital 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

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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.

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, whereby the Company expects to receive approximately \$0.5 million through August 2025. During the three months ended March 31, 2025, the Company recognized \$0.1 million of grant income as a reduction to research and development costs in the accompanying condensed consolidated statements of operations.

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 months ended March 31, 2025 and 2024, 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 March 31, 2025 or December 31, 2024 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 March 31, 2025 and December 31, 2024, the Company had no uncertain tax positions.

German Research and Development Tax Credit Receivable

The Company recognizes income associated with research and development ("R&D") tax credits when the receipt of the R&D tax credit becomes probable. The Company evaluates the conditions of each R&D tax credit as of each reporting period to evaluate whether the Company has reached reasonable assurance of meeting the conditions of each R&D tax credit and that it is expected that the R&D tax credit will be received as a result of meeting the necessary conditions. R&D tax credits are recognized as a component of other income in the condensed consolidated statements of operations once it becomes probable that the amounts will be received. Specifically, income related to the receipt of R&D tax credits is not recorded until it is probable that amounts will be received.

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.

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 10 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 months ended March 31, 2025 and 2024, basic and diluted net loss per share are the same.

Recently Issued (Not Yet Adopted) Accounting Standards

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures (Topic 740)* ("ASU 2023-09"). The ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is also permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the impact of adopting ASU 2023-09.

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 024-03 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.

Note 3. Reverse Merger

As discussed in Note 1, on the Closing Date, the Company consummated the previously announced Business Combination with Legacy Palvella, as a result of which Legacy Palvella became a wholly-owned subsidiary of the Company. The Reverse Merger was contemplated and consummated, along with the PIPE Financing (defined below), to generate capital resources to support the advancement of the Company's pipeline and future operations.

At the consummation of the Merger Agreement on the Closing Date (the "Effective Time"), or immediately prior to where indicated, the following occurred:

- All of the then outstanding shares of Legacy Palvella common stock were converted into 1,770,167 shares of the Company's common stock, based on the exchange ratio of approximately 0.309469242 (the "Exchange Ratio").
- All of the then outstanding shares of Legacy Palvella's convertible preferred stock were converted into 4,753,650 shares of the Company's common stock, based on the Exchange Ratio. Refer to Note 7, *Convertible Preferred Stock*, for further detail on the conversion of the Company preferred stock.
- All outstanding 15,617 shares of Pieris preferred stock remained outstanding through the completion of the Reverse Merger, with no changes to their terms and conditions.
- All of the then outstanding Convertible Notes of Legacy Palvella plus accrued interest were converted into 1,179,163 shares of the Company's common stock and 168,503 prefunded warrants based on the Exchange ratio.
- All of the then outstanding stock options of Legacy Palvella were exchanged for options to purchase common stock of the Company, subject to the Exchange Ratio.

While the Company was the legal acquirer of Legacy Palvella in the business combination, for accounting purposes, the Reverse Merger is treated as a reverse recapitalization whereby Legacy Palvella is deemed to be the accounting acquirer, and the historical financial statements of Legacy Palvella became the historical consolidated financial statements of the Company upon the closing of the Reverse Merger. Under this method of accounting, the Company was treated as the "acquired" company and Legacy Palvella was treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Reverse Merger was treated as the equivalent of Legacy Palvella issuing stock for the net assets of the Company, accompanied by a recapitalization.

Based on the following factors, the Company determined under ASC 805, *Business Combinations*, that the Reverse Merger should be accounted for as a reverse recapitalization:

- The Company stockholders owned approximately 60% of the voting rights in the Company and thus had sufficient voting rights to exert influence over the Company.
- The Company designated a majority of the Company's board of directors and maintained a majority of the composition of management.
- At the time of Closing, Pieris did not meet the definition of a business and had nominal assets, meeting the definition of a public shell company. As such, the Reverse Merger was treated as a reverse recapitalization in which Palvella is issuing stock for the net assets of Pieris.

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The following table summarizes the fair value of identifiable assets acquired and liabilities assumed as part of the recapitalization (in thousands):

	As of December 13, 2024
Assets	
Current assets:	
Cash	\$ 13,781
Accounts receivable	377
Prepaid expenses and other current assets	595
Total current assets	14,753
Total assets	<u>\$ 14,753</u>
Liabilities	
Current liabilities:	
Accounts payable	\$ 142
Accrued expenses and other current liabilities	3,000
Total current liabilities	3,142
Total liabilities	<u>\$ 3,142</u>
Net assets acquired	<u>\$ 11,611</u>

In connection with the Reverse Merger, the Company incurred transaction costs of \$2.5 million. The \$2.5 million of transaction costs were initially recorded as deferred financing costs on the consolidated balance sheets and then were reclassified to offset to equity upon closing of the Reverse Merger.

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 the 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”).

Contingent Value Rights Agreement

On December 13, 2024, immediately prior to the Effective Time, Pieris entered into a contingent value rights agreement (the “CVR Agreement”) with a rights agent, pursuant to which holders of Pieris common stock prior to Closing received one non-transferable contingent value right (each, a “CVR”) for each outstanding share of Pieris common stock held by such stockholder immediately prior to Closing. Each CVR represents the contractual right to receive payments upon the receipt of payments by Pieris or any of its affiliates under certain strategic partner agreements, including existing collaboration agreements pursuant to which Pieris 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 Pieris 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. As no amounts related to the CVR Agreement were probable as of the time of the Reverse Merger, no contingencies for the CVR agreement had been recorded on the Closing Date.

Note 4. 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):

	March 31, 2025			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash and cash equivalents	\$ 75,626	\$ —	\$ —	\$ 75,626
Total assets measured at fair value	<u>\$ 75,626</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 75,626</u>
Liabilities:				
Derivative liabilities – royalty agreement	\$ —	\$ —	\$ 1,722	\$ 1,722
Derivative liabilities – contingent value right liability	—	—	1,978	1,978
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,700</u>	<u>\$ 3,700</u>
	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash and cash equivalents	\$ 83,602	\$ —	\$ —	\$ 83,602
Total assets measured at fair value	<u>\$ 83,602</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 83,602</u>
Liabilities:				
Derivative liabilities – royalty agreement	\$ —	\$ —	\$ 1,647	\$ 1,647
Derivative liabilities – contingent value right liability	—	—	1,978	1,978
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,625</u>	<u>\$ 3,625</u>

Cash and cash equivalents as of March 31, 2025 and December 31, 2024 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.

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 March 31, 2025 and December 31, 2024 are as follows:

	March 31, 2025	December 31, 2024
Discount rate	20.0 %	20.0 %
Probability rate of achieving FDA approval of a product	56.6 %	56.6 %
Expected term to FDA regulatory approval of a product	2.25 years	2.50 years

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

	2025	2024
Derivative liabilities - royalty agreement		
Balance at January 1	\$ 1,647	\$ 1,014
Fair value adjustments on derivative liabilities	75	58
Balance at March 31	<u>\$ 1,722</u>	<u>\$ 1,072</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

	2025	2024
Derivative liabilities - contingent value rights		
Balance at January 1	\$ 1,978	\$ —
Fair value adjustments on derivative liabilities	—	—
Balance at March 31	<u>\$ 1,978</u>	<u>\$ —</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 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.

Note 5. 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 March 31, 2025. The potential future milestone payments represent derivative liabilities with a fair value of \$1.7 million and \$1.6 million as of March 31, 2025 and December 31, 2024, respectively, which are classified as “derivative liabilities – royalty agreement” on the accompanying condensed consolidated balance sheets. See Note 4 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. 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 39.9% as of March 31, 2025 and December 31, 2024. 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 \$1.2 million and \$0.8 million for the three months ended March 31, 2025 and 2024, 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 6. Accrued Expenses and Other Current Liabilities

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

	March 31, 2025	December 31, 2024
Professional fees	\$ 497	\$ 808
Compensation expense (1)	500	3,073
Research and development expenses	742	404
Other	825	1,189
Total accrued expenses and other current liabilities	<u>\$ 2,564</u>	<u>\$ 5,474</u>

(1)Includes accrued severance, bonus, and retention payments of \$2.1 million for current and former Pieris employees as of December 31, 2024.

Note 7. 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 March 31, 2025 and December 31, 2024, 11,021,389 and 11,012,105 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”), of which 85 shares have been designated as Series A Convertible Preferred Stock, 4,026 shares have been designated as Series B Convertible Preferred Stock, 3,506 shares have been designated as Series C Convertible Preferred Stock, 3,000 shares have been designated as Series D Convertible Preferred Stock, and 5,000 shares have been designated as Series E Convertible Preferred Stock.

In connection with the Reverse Merger, 15,617 shares of Preferred Stock remain outstanding and convert on a factor of 13.34 common shares for each preferred share, and consists of the following as of March 31, 2025 and December 31, 2024:

- Series A Convertible Preferred Stock, 85 shares issued and outstanding
- Series B Convertible Preferred Stock, 4,026 shares issued and outstanding
- Series C Convertible Preferred Stock, 3,506 shares issued and outstanding
- Series D Convertible Preferred Stock, 3,000 shares issued and outstanding
- Series E Convertible Preferred Stock, 5,000 shares issued and outstanding

Common Stock and Pre-Funded Warrants

Each share of the Company's 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 therefor, if, as and when determined by the Board of Directors.

The Company has pre-funded warrants outstanding to purchase an aggregate of 2,466,456 shares of common stock as of March 31, 2025 and December 31, 2024. 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.

Preferred Stock

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., or BVF. In each case, each share Preferred Stock is convertible into 13.34 shares of the Company's 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 the Company's 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 the Company's 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.

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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.

Note 8. 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, Company common stock or a combination thereof.

The number of shares reserved for issuance under the 2024 Plan is equal to 3,455,433 shares of the Company's common stock.

As of March 31, 2025, 1,853,292 shares of the Company's common stock were issued 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 March 31, 2025, 655,788 shares of the Company's common stock were outstanding under the 2019 Plan and no further grants will be made under the 2019 Plan.

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 three months ended March 31, 2025:

	Common Shares Underlying Stock Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (Years)
Outstanding at December 31, 2024	<u>1,673,352</u>	\$ 11.55	8.6
Granted	892,827	\$ 14.56	
Exercised	(9,284)	\$ 7.14	
Forfeited / Cancelled	(47,800)	\$ 13.60	
Outstanding at March 31, 2025	<u>2,509,095</u>	\$ 12.60	9.0
Exercisable at March 31, 2025	<u>498,578</u>	\$ 9.16	6.5

The aggregate intrinsic value of options outstanding and options exercisable as of March 31, 2025 was \$38.6 million and \$9.4 million, respectively.

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Total stock-based compensation expense recognized in the condensed consolidated statements of operations for the three months ended March 31, 2025 and 2024 is as follows (in thousands):

	Three Months Ended March 31,			
	2025		2024	
Research and development	\$	390	\$	133
General and administrative		704		13
Total stock-based compensation expense	\$	<u>1,094</u>	\$	<u>146</u>

As of March 31, 2025, there was approximately \$18.0 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 3.5 years.

The weighted average fair value of stock options granted during the three months ended March 31, 2025 was \$10.02 per share which was estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

Expected volatility	73.37% – 74.59%
Risk-free interest rate	4.29% – 4.47%
Expected term (years)	6.05
Expected dividend yield	—

Note 9. 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 10. Segment Information

The Company is comprised of one reportable segment, the Company operations. As of March 31, 2025, 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 Chief Operating Decision Maker (CODM), which is the Company's Chief Executive Officer (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 genetic 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 March 31,	
	2025	2024
Research and development:		
QTORIN rapamycin for microcystic LM	\$ 1,154	\$ 3
QTORIN rapamycin for microcystic LM - Government grant income	(127)	—
QTORIN rapamycin for cutaneous VM	321	—
QTORIN rapamycin CMC	785	113
Non-program specific and unallocated research and development expenses:		
Salaries and stock-based compensation	1,322	647
Consultants	247	173
Other	372	48
Total research and development	\$ 4,074	\$ 984
General and administrative:		
Salaries and stock-based compensation	\$ 1,453	\$ 346
Consultants	1,062	223
Other	1,282	206
Total general and administrative	\$ 3,797	\$ 775
Loss from operations	<u>\$ (7,871)</u>	<u>\$ (1,759)</u>

Note 11. Subsequent Events

Subsequent events have been evaluated through May 15, 2025, 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 2024 Form 10-K filed with the Securities and Exchange Commission on March 31, 2025, as well as the information contained under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our 2024 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 2024 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 genetic skin diseases for which there are no FDA-approved therapies. We intend to leverage our versatile QTORIN platform to treat these patients. The QTORIN platform is designed to generate potential new therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of rare genetic skin diseases. Our lead product candidate, QTORIN 3.9% rapamycin anhydrous gel ("QTORIN rapamycin"), is currently in clinical development for microcystic lymphatic malformations ("microcystic LMs") and cutaneous venous malformations ("cutaneous VMs"). 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 currently have two ongoing 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 additional preclinical research programs based on our QTORIN platform for the treatment of serious, rare genetic 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.

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, and other mTOR-driven skin diseases. If approved, we believe QTORIN rapamycin has the potential to become the standard of care in each of these diseases.

QTORIN rapamycin for the treatment of microcystic LMs

Microcystic LMs are a rare, chronically debilitating, and lifelong genetic disease of the lymphatic system characterized by lymphorrhea, which is the persistent discharge of internal lymph fluid from disrupted lymphatic vessels, and acute cellulitis, or a bacterial infection of the skin underlying tissues. The specific pathophysiology of microcystic LMs is primarily the result of somatic activating mutations in the PIK3CA gene 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. There are currently no FDA-approved treatments for the estimated more than 30,000 individuals in the U.S. with microcystic LMs.

In the third quarter of 2024, we initiated SELVA, a 24-week, Phase 3, single-arm, baseline-controlled clinical trial of QTORIN rapamycin administered topically once daily for the treatment of microcystic LMs. The primary efficacy endpoint is the change from baseline in the overall microcystic LM Investigator Global Assessment, a 7-point clinician rated changes scale, at week 24. In the first quarter of 2025, we announced the expansion of our SELVA trial to include patients ages 3 to 5 years old. Previously, trial participants were required to be at least 6 years old. We expect to report top-line data for the Phase 3 study in approximately 40 participants with microcystic LMs in the first quarter of 2026.

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 Orphan Products Clinical Trials Grant for up to \$2.6 million supporting the SELVA Phase 3 study.

QTORIN rapamycin for the treatment of cutaneous VMs

Cutaneous VMs are a serious, rare condition characterized by the overgrowth of veins that protrude through the skin and are characterized by deformities, functional impairment and hemorrhaging. They present as dilated, tortuous vessels that manifest as bluish or purplish patches or nodules on the skin. These malformations result from developmental errors in venous morphogenesis during embryogenesis, leading to abnormal connections between veins and capillaries. Cutaneous VMs cause functional impairment, significantly impact quality of life and are associated with severe long-term complications. There are currently no FDA-approved treatments for the estimated more than 75,000 individuals in the U.S. with cutaneous VMs.

In the first quarter of 2025, we announced the first patients have recently been dosed in 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. We expect to report top-line data for the TOIVA study in approximately 15 participants with cutaneous VMs in the fourth quarter of 2025.

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

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.

The Business Combination was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). Under this method of accounting, Pieris was treated as the “acquired” company and Legacy Palvella is treated as the acquirer for financial reporting purposes as more fully explained in Note 3 of the accompanying notes to the condensed consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q.

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.

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 5 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 and geopolitical factors, including the ongoing conflict between Russia and Ukraine and the responses thereto, 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 Phase 3 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 2024 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, venous malformations 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 its 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;
- 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 genetic 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 months ended March 31, 2025 and 2024 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; and (iii) 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 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 months ended March 31, 2025 and 2024.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

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

	Three Months Ended March 31,			Change	%
	2025	2024	\$		
Operating expenses:					
Research and development	\$ 4,074	\$ 984	\$ 3,090		314%
General and administrative	3,797	775	3,022		390%
Total operating expenses	7,871	1,759	6,112		347%
Operating loss	(7,871)	(1,759)	(6,112)		347%
Other (expense) income:					
Interest expense – royalty agreement	(1,215)	(805)	(410)		51%
Fair value adjustments on derivative liabilities – royalty agreement	(75)	(58)	(17)		29%
Interest income, net	752	86	666		774%
Other income, net	224	—	224		100%
Loss before income taxes	(8,185)	(2,536)	(5,649)		223%
Income tax benefit (expense)	—	—	—		0%
Net loss	<u>\$ (8,185)</u>	<u>\$ (2,536)</u>	<u>\$ (5,649)</u>		<u>223%</u>

Research and Development Expenses

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

	Three Months Ended March 31,			Change	%
	2025	2024	\$		
QTORIN rapamycin for microcystic LM	\$ 1,154	\$ 3	\$ 1,151		38,367%
QTORIN rapamycin for microcystic LM - Government grant income	(127)	—	(127)		100%
QTORIN rapamycin for cutaneous VM	321	—	321		100%
QTORIN rapamycin CMC	785	113	672		595%
Non-program specific and unallocated research and development expenses:					
Salaries and stock-based compensation	1,322	647	675		104%
Consultants	247	173	74		43%
Other	372	48	324		675%
Total research and development expenses	<u>\$ 4,074</u>	<u>\$ 984</u>	<u>\$ 3,090</u>		<u>314%</u>

The increase in research and development expenses during the 2025 period, as compared to 2024, was primarily due to increased spending on the clinical development of QTORIN rapamycin for the treatment of microcystic LMs and cutaneous venous malformations, including conducting our Phase 3 SELVA and Phase 2 TOIVA trials, which were initiated in 2024. Additional increases include CMC costs for all programs and increased compensation costs as a result of headcount additions in late 2024 and early 2025.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2025 were \$3.8 million, compared to \$0.8 million for the three months ended March 31, 2024. The increase in general and administrative expenses during the 2025 period, as compared to 2024, was primarily due to increased employee compensation expense due to headcount additions, 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 March 31, 2025 was \$0.3 million of expense, as compared to \$0.8 million of expense for the three months ended March 31, 2024. The significant components of other (expense) income are more fully described below.

Interest expense – royalty agreement

During the three months ended March 31, 2025, we recorded interest expense of approximately \$1.2 million, compared to interest expense of approximately \$0.8 million for the three months ended March 31, 2024, related to the change in fair value of our royalty agreement liability.

Fair value adjustments on derivative liabilities – royalty agreement

During each of the three months ended March 31, 2025 and 2024, we recorded a non-cash loss of approximately \$0.1 million 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.

Interest income, net

During the three months ended March 31, 2025, we recorded \$0.8 million of interest income, net, compared to \$0.1 million for the three months ended March 31, 2024. The increase during the 2025 period, as compared to 2024, was primarily due to increases in the average balances held in interest-bearing cash and money market funds.

Net Loss Applicable to Common Stockholders

As a result of the factors discussed above, our net loss applicable to common stockholders for the three months ended March 31, 2025 and 2024 was \$8.2 million and \$2.5 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 three months ended March 31, 2025, we incurred a net loss of \$8.2 million and reported net cash used in operating activities of \$6.8 million. As of March 31, 2025, we had an accumulated deficit of \$101.9 million and cash and cash equivalents of \$75.6 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 for at least the next several years. 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.

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 the 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”).

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 (defined below), 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 prefunded warrants.

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 March 31, 2025, we had approximately \$75.6 million in cash and cash equivalents. 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, 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

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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 on hand as of March 31, 2025 will be sufficient to fund our operating expenses into the second half of 2027. 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, 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 our ability to successfully commercialize this product candidate, if approved;
- the scope, progress, results and costs of researching and developing QTORIN rapamycin, 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 three months ended March 31, 2025 and 2024 (in thousands):

	Three Months Ended March 31,			
	2025		2024	
Net cash used in operating activities	\$	(6,768)	\$	(1,102)
Net cash used in financing activities		(1,202)		—
Effect of exchange rate change on cash and cash equivalents		(6)		—
Net decrease in cash and cash equivalents	\$	(7,976)	\$	(1,102)

Net cash used in operating activities

Net cash used in operating activities for the three months ended March 31, 2025 and 2024 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 2025, increased costs to operate as a public company, as well as the timing of payments and increase in accounts payable.

Net cash used in financing activities

For the three months ended March 31, 2025, net cash used in financing activities was \$1.2 million, consisting primarily of payments of transaction costs incurred in connection with the Business Combination.

Contractual Obligations and Commitments

During the three months ended March 31, 2025, there were no material changes outside the ordinary course of our business to our contractual obligations and cash requirements, as disclosed in our 2024 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 three months ended March 31, 2025, 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 2024 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 March 31, 2025. 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 March 31, 2025, 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 SEC'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 March 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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 2024 Form 10-K, together with all of the other information in this Annual 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 2024 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)None of our directors or “officers,” as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the period covered by this report.

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
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.

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: May 15, 2025

By:

/s/ Wesley H. Kaupinen

Wesley H. Kaupinen

President, Chief Executive Officer and Director

Date: May 15, 2025

By:

/s/ Matthew E. Korenberg

Matthew E. Korenberg

Chief Financial Officer and Treasurer

**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: May 15, 2025

By:

/s/ Wesley H. Kaupinen
Wesley H. Kaupinen
President and Chief 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: May 15, 2025

By:

/s/ Matthew E. Korenberg
Matthew E. Korenberg
Chief Financial Officer and Treasurer

**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 March 31, 2025, 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: May 15, 2025

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 March 31, 2025, 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: May 15, 2025

By:

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