Palvella Therapeutics Reports Second Quarter 2026 Financial Results and Provides Corporate Update

August 4, 2026

First module of the rolling NDA for QTORIN™ rapamycin for microcystic lymphatic malformations submitted to FDA, with completion of the NDA submission on track for the second half of 2026

Preparing for a planned standalone U.S. commercial launch of QTORIN™ rapamycin for microcystic lymphatic malformations in the first half of 2027, if approved

Initiation of Phase 3 trial of QTORIN™ rapamycin for the treatment of cutaneous venous malformations planned for the fourth quarter of 2026

Initiation of Phase 2 trial of QTORIN™ pitavastatin for the treatment of disseminated superficial actinic porokeratosis planned for the second half of 2026

Topline results from the Phase 2 LOTU trial of QTORIN™ rapamycin for clinically significant angiokeratomas expected in the second half of 2027

Cash, cash equivalents and short-term investments of $250.6 million as of June 30, 2026

Company to host conference call at 8:30 a.m. ET today

WAYNE, Pa., Aug. 04, 2026 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc. (Palvella or "the Company") (Nasdaq: PVLA), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies for serious, rare skin diseases and vascular malformations for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, today reported financial results for the second quarter ending June 30, 2026 and provided a corporate update.

"We made significant progress during the second quarter, completing our pre-NDA meeting with FDA and initiating the rolling NDA submission for QTORIN™ rapamycin in microcystic lymphatic malformations," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "We are working closely with FDA under the program's Breakthrough Therapy and Fast Track designations to expedite development and review, with the objective of potentially introducing the first approved therapy to pediatric and adult patients living with this serious, lifelong disease. Completion of the NDA submission remains on track for the second half of 2026, and we are preparing for a planned standalone commercial launch in the first half of 2027, if approved. We have recruited commercial and medical affairs leaders with deep experience in rare disease and dermatology who are now in the field executing key pre-launch activities, while we continue to advance our other rare disease programs and pursue additional opportunities across the QTORIN™ platform."

Recent Research and Development Highlights

QTORIN™ rapamycin for microcystic lymphatic malformations (microcystic LMs)

- James Treat, M.D., of Children's Hospital of Philadelphia presented additional Phase 3 SELVA data during a late-breaking session at the International Society for the Study of Vascular Anomalies World Congress (ISSVA), including a statistically significant improvement in the 6–11-year-old cohort and other supportive findings showing improvements in clinical signs and patient-reported outcomes with QTORIN™ rapamycin.
- Completed an in-person pre-New Drug Application (NDA) meeting with FDA which addressed nonclinical, clinical pharmacology, clinical information, and the planned evidence package for the NDA.
- Following the pre-NDA meeting, FDA granted Palvella's request for Rolling Review of the QTORIN™ rapamycin NDA for microcystic LMs, allowing the Agency to begin reviewing completed portions of the application before submission of the full NDA.
- Submitted the first module of its rolling NDA to the FDA seeking approval of QTORIN™ rapamycin for the treatment of microcystic LMs.
- The Company remains on track to complete the NDA submission in the second half of 2026.

QTORIN™ rapamycin for cutaneous venous malformations (cutaneous VMs)

- In May 2026, at the 83rd Annual Meeting of the Society for Investigative Dermatology (“SID”), Palvella presented new data from our Phase 2 TOIVA trial of QTORIN™ rapamycin for the treatment of cutaneous VMs highlighting that 100% of patients with bleeding at baseline demonstrated improvement on the Cutaneous Venous Malformations Investigator Global Assessment Bleeding scale at Week 12.
- Dr. Treat presented additional Phase 2 TOIVA data, including 24-week results, at ISSVA demonstrating statistically significant improvements in both cVM-MCSS Height/Engorgement and cVM-MCSS Appearance at all measured time points, with increasing clinical response observed with longer duration of QTORIN™ rapamycin therapy.
- Phase 3 trial initiation remains on track for the fourth quarter of 2026 following completion of the planned End-of-Phase 2 meeting.

QTORIN™ rapamycin for clinically significant angiokeratomas

- Dosed the first patients in LOTU, a multicenter Phase 2 trial evaluating Fast Track-designated QTORIN™ rapamycin for clinically significant angiokeratomas, a rare, chronic and debilitating isolated lymphatic malformation affecting an estimated more than 50,000 diagnosed patients in the U.S. and for which there are no FDA-approved therapies.
- Topline results from LOTU are expected in the second half of 2027.

QTORIN™ pitavastatin for disseminated superficial actinic porokeratosis (DSAP)

- Palvella's second product candidate, QTORIN™ pitavastatin, is for the treatment of disseminated superficial actinic porokeratosis, a premalignant genetic skin disease that presents as persistent, often extensive lesions that enlarge and increase in size, number, and extent over time, causing chronic loss of skin integrity which can severely impact quality-of-life; no FDA-approved therapies currently exist for the estimated more than 50,000 diagnosed patients in the U.S.
- Strengthened the intellectual property position supporting QTORIN™ pitavastatin through the issuance of U.S. Patent No. 12,636,273, exclusively licensed from Yale University and building on pioneering work by Keith Choate, M.D., Ph.D. The issued claims cover the topical administration of HMG-CoA reductase inhibitors, including pitavastatin, for the treatment of porokeratosis, including DSAP, and provide protection into 2043.
- Phase 2 trial initiation expected in the second half of 2026.

QTORIN™ rapamycin and QTORIN™ platform expansion

- Palvella plans to announce the fourth target clinical indication for QTORIN™ rapamycin in the second half of 2026. The expansion of QTORIN™ rapamycin into additional indications is supported by a growing body of published literature highlighting the broad potential of rapamycin in several difficult-to-treat, mTOR-driven skin diseases while advocating for targeted, topical approaches suited to improve tolerability and safety.
- Palvella plans to announce the third product candidate from the QTORIN™ platform in a serious, rare disease with no FDA-approved therapies in the second half of 2026.

Recent Corporate Highlights

- Appointed accomplished rare disease biotech executive and commercial leader Matt Pauls, J.D., M.B.A., to the Board of Directors, further strengthening the Board with extensive experience in rare disease drug development, commercialization, and corporate strategy from executive and Board roles at Savara Inc., Soleno Therapeutics, Strongbridge Biopharma, and Insmed Incorporated.
- Awarded “Healthcare & Life Sciences Company of the Year” at the 2026 Philadelphia Alliance for Capital and Technology Ecosystem Awards, recognizing Palvella's leadership in advancing innovative therapies for rare diseases and its contributions to the region's life sciences ecosystem.
- Completed the uplisting to the Nasdaq Global Market, providing increased visibility within the investment community and reflecting the Company’s continued growth and achievement of key corporate milestones.

Second Quarter 2026 Financial Results

- Cash, cash equivalents, and short-term investments as of June 30, 2026 were $250.6 million.
- Research and development expenses for the three months ended June 30, 2026 were $12.5 million, as compared to $5.1 million for the three months ended June 30, 2025. The increase was primarily due to increased spending for manufacturing activities, clinical development of QTORIN rapamycin for the treatment of angiokeratomas, costs associated with the submission of the first module of the rolling NDA, and costs resulting from increased headcount and consulting services in 2026.
- General and administrative expenses for the three months ended June 30, 2026 were $8.9 million, as compared to $4.1 million for the three months ended June 30, 2025. The increase was primarily due to increased headcount in 2026, as well as increased professional services related to operating as a publicly-traded company.
- Net loss was $21.9 million, or $1.52 per basic and diluted share, for the three months ended June 30, 2026, as compared to net loss of $9.5 million, or $0.86 per basic and diluted share, for the three months ended June 30, 2025.

- Weighted average shares outstanding for calculation of EPS in Q2 2026 and YTD 2026 were 14,356,219 and 13,724,256 respectively. Shares outstanding were 15,802,768 as of July 31, 2026, including 14,408,007 shares of common stock and 1,394,761 common share equivalents assuming conversion of outstanding pre-funded warrants.

Conference Call Details

Palvella will host a conference call and live audiovisual webcast to discuss the Company's second quarter 2026 financial results and provide a corporate update at 8:30 a.m. ET today. To access the live webcast, including presentation slides, please click here or visit the “Events & Presentations” section of Palvella’s website. To access the conference call by phone, register using this link, and you will be provided with dial-in details. A replay of the webcast will be available approximately two hours after the conclusion of the call and will remain archived for 90 days under the “Events & Presentations” section of the Company's website at www.palvellatx.com.

About Palvella Therapeutics

Founded and led by rare disease biotech veterans, Palvella Therapeutics, Inc. (Nasdaq: PVLA) is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients living with serious, rare skin diseases and vascular malformations for which there are no FDA-approved therapies. Palvella is developing a broad pipeline of product candidates based on its patented QTORIN™ platform, with an initial focus on serious, rare skin diseases and vascular malformations, many of which are lifelong in nature. Palvella’s lead product candidate, QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin), is currently being developed for the treatment of microcystic lymphatic malformations, cutaneous venous malformations, and clinically significant angiokeratomas. Palvella’s second product candidate, QTORIN™ pitavastatin, is currently being developed for the treatment of disseminated superficial actinic porokeratosis. For more information, please visit www.palvellatx.com or follow Palvella on LinkedIn or X (formerly known as Twitter).

QTORIN™ rapamycin and QTORIN™ pitavastatin are for investigational use only and neither has been approved by the FDA o by any other regulatory agency for any indication.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (Securities Act)). These statements may discuss goals, intentions, and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Palvella, as well as assumptions made by, and information currently available to, the management of Palvella. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “anticipate,” “plan,” “likely,” “believe,” “estimate,” “project,” “intend,” and other similar expressions or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Statements that are not historical facts are forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding the expected timing of the presentation of data from clinical trials, Palvella’s clinical development plans and related anticipated development milestones and anticipated timing of regulatory submissions, Palvella’s plans with respect to the timing of, and anticipated FDA review process for, the NDA for QTORIN™ rapamycin, Palvella’s plans to pursue Breakthrough Therapy Designation, Palvella’s plans to meet with regulatory authorities, Palvella’s expectations regarding the benefits of orphan drug designation and potential benefit of orphan drug exclusivity for QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations, Palvella’s cash, financial resources and expected runway, Palvella’s expectations regarding its programs, including QTORIN™ rapamycin and QTORIN™ pitavastatin, and its research-stage opportunities, including its expected therapeutic potential and market opportunity. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the ability to raise additional capital to finance operations; the ability to advance product candidates through preclinical and clinical development; the ability to make regulatory submissions on anticipated timelines; the ability to obtain regulatory approval for, and ultimately commercialize, Palvella’s product candidates, including QTORIN™ rapamycin and QTORIN™ pitavastatin; the outcome of early clinical trials for Palvella’s product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements; the fact that data and results from clinical studies may not necessarily be indicative of future results; Palvella’s limited experience in designing clinical trials and lack of experience in conducting clinical trials; Palvella’s limited experience in commercial manufacturing; the ability to identify and pivot to other programs, product candidates, or indications that may be more profitable or successful than Palvella’s current product candidates; the substantial competition Palvella faces in discovering, developing, or commercializing products; the negative impacts of global events on operations, including ongoing and planned clinical trials and ongoing and planned preclinical studies; the ability to attract, hire, and retain skilled executive officers and employees; the ability of Palvella to protect its intellectual property and proprietary technologies; reliance on third parties, contract manufacturers, and contract research organizations; and the risks and uncertainties described in the filings made by Palvella with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that

Palvella may face. Except as required by applicable law, Palvella does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. This press release contains hyperlinks to information that is not deemed to be incorporated by reference into this press release.

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PALVELLA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 12,473	$ 5,118	$ 21,807	$ 9,192
General and administrative	8,932	4,132	14,453	7,929
Total operating expenses	21,405	9,250	36,260	17,121
Loss from operations	(21,405)	(9,250)	(36,260)	(17,121)
Total other income (expense), net	(465)	(221)	(1,377)	(535)
Net loss	$ (21,870)	$ (9,471)	$ (37,637)	$ (17,656)
Net loss per share of Common Stock — basic and diluted	$ (1.52)	$ (0.86)	$ (2.74)	$ (1.60)
Weighted-average shares used in computing net loss per share of Common Stock — basic and diluted	14,356,219	11,052,741	13,724,256	11,033,327

PALVELLA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION
(in thousands)

	June 30, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 187,803	$ 57,982
Short-term investments	62,781	—
Other current assets	2,444	1,005
Total current assets	253,028	58,987
Non-current assets	482	572
Total assets	$ 253,510	$ 59,559
Liabilities and Stockholders' Equity		
Current liabilities	$ 11,947	$ 11,344
Non-current liabilities	24,696	20,232
Total liabilities	36,643	31,576
Total stockholders' equity	216,867	27,983
Total liabilities and stockholders’ equity	$ 253,510	$ 59,559