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

November 5, 2026

FDA Accepts NDA for QTORIN™ Rapamycin and Grants Priority Review for Microcystic Lymphatic Malformations; PDUFA Target Action Date Set for February 28, 2027

QTORIN™ Rapamycin Could Become the First FDA-Approved Therapy for Microcystic Lymphatic Malformations, a Serious, Rare Lifelong Disease Affecting an Estimated More Than 30,000 Diagnosed Children and Adults in the U.S.

Palvella Advancing Preparations for Standalone U.S. Commercial Launch of QTORIN™ Rapamycin in First Half of 2027, if Approved

Additional QTORIN™ Programs Accelerating in Cutaneous Venous Malformations, Clinically Significant Angiokeratomas, and Disseminated Superficial Actinic Porokeratosis; Two Additional Programs Anticipated to be Announced by Year-End

Cash, Cash Equivalents and Short-Term Investments of $236.7 Million as of September 30, 2026

Palvella to Host Third Quarter 2026 Financial Results and Corporate Update Conference Call at 8:30 a.m. ET Today

WAYNE, Pa., Nov. 05, 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 anomalies for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, today reported financial results for the third quarter ending September 30, 2026 and provided a corporate update.

"With the FDA's acceptance of our NDA for QTORIN™ rapamycin in microcystic lymphatic malformations and granting of Priority Review, we believe we are closer than ever to bringing our first therapy to patients," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella Therapeutics. "Our commercial and medical leadership is now in place and we are actively recruiting additional top talent to shape an exceptional launch for the microcystic LM community, if approved by the FDA, with the goal of establishing QTORIN™ rapamycin as the first-line treatment and standard of care for this serious, lifelong disease. Our focus is clear: successfully obtain FDA approval and bring our first therapy to patients, advance multiple additional QTORIN™ programs to approval, and build the leading company addressing serious, rare skin diseases and vascular anomalies."

Recent Program Highlights

QTORIN™ rapamycin for microcystic lymphatic malformations (microcystic LMs)

- Completed the NDA submission for QTORIN™ rapamycin, which was accepted by the FDA with a February 28, 2027 PDUFA target action date.
- Advanced preparations for a standalone U.S. commercial launch in the first half of 2027, if approved, with key commercial, medical, and patient services capabilities established.
- Received a third year of FDA Office of Orphan Products Development grant funding to support the Phase 3 SELVA trial and ongoing open-label extension study.
- Presented two posters at Fall Clinical Dermatology 2026 highlighting Phase 3 SELVA participant-reported clinical benefits and treatment satisfaction, as well as low and stable systemic rapamycin exposure over 24 hours, with mean exposure at least 40-fold lower than reported exposure with oral sirolimus.
- Presented a Phase 3 SELVA poster at the 2026 Pediatric Dermatology Research Alliance (PeDRA) Annual Conference highlighting improvements in overall disease severity, lesion height, vesicle appearance, and leaking/bleeding in children with microcystic LMs.

QTORIN™ rapamycin for cutaneous venous malformations (cutaneous VMs)

- Phase 2 TOIVA poster presented at the 2026 Pediatric Dermatology Research Alliance (PeDRA) Annual Conference highlighted improvements in overall disease severity and reductions in lesion bleeding among pediatric participants with cutaneous VMs treated with QTORIN™ rapamycin.
- Phase 3 trial initiation remains on track for the fourth quarter of 2026.

QTORIN™ rapamycin for clinically significant angiokeratomas

- Enrolling 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)

- Presented a poster at Fall Clinical Dermatology 2026 featuring an analysis of U.S. claims data that identified an estimated 154,986 diagnosed DSAP patients in the U.S., providing the first real-world, claims-based characterization of the diagnosed DSAP population.
- Phase 2 trial initiation expected in the fourth quarter of 2026.

Pipeline expansion

- Palvella plans to announce the fourth target clinical indication for QTORIN™ rapamycin in the fourth quarter 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 fourth quarter of 2026.

Recent Corporate Highlights

- Appointed James R. Treat, M.D., a nationally recognized pediatric dermatologist with nearly 20 years of clinical, research, and academic experience, as Chief Medical Officer, effective December 21, 2026, bringing expertise in cutaneous vascular anomalies and prior experience as a Phase 3 SELVA and Phase 2 study investigator for QTORIN™ rapamycin in microcystic LM.
- Palvella Therapeutics Chief Scientific Officer Jeff Martini, Ph.D. was selected to provide public comment at an FDA public workshop on drug repurposing, discussing evidence frameworks and regulatory approaches for advancing repurposed therapies for patients with serious, rare diseases and significant unmet medical needs.

Third Quarter 2026 Financial Results

- Cash, cash equivalents, and short-term investments as of September 30, 2026 were $236.7 million.
- Research and development expenses for the three months ended September 30, 2026 were $10.8 million, as compared to $6.5 million for the three months ended September 30, 2025. The increase was primarily due to increased spending on manufacturing activities, the clinical development of QTORIN rapamycin for the treatment of angiokeratomas, costs associated with completion of the submission of the rolling NDA, and costs resulting from increased headcount and consulting services in 2026.
- General and administrative expenses for the three months ended September 30, 2026 were $11.9 million, as compared to $3.6 million for the three months ended September 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 $24.6 million, or $1.70 per basic and diluted share, for the three months ended September 30, 2026, as compared to net loss of $11.3 million, or $1.03 per basic and diluted share, for the three months ended September 30, 2025.
- Weighted average shares outstanding for calculation of EPS in Q3 2026 and nine months ended September 30, 2026 were 14,531,595 and 13,996,326 respectively. Shares outstanding were 15,844,715 as of November 2, 2026, including 14,618,457 shares of common stock and 1,226,258 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 third 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 anomalies 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 anomalies, 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 expectations with respect to the potential approval of the NDA for QTORIN™ rapamycin, the potential impact of Priority Review on the FDA's review timeline, any delays in the FDA's review of Palvella's accepted NDA, Palvella's commercial preparedness and the timing and execution of a potential launch following regulatory approval, 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 September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 10,824	$ 6,528	$ 32,631	$ 15,720
General and administrative	11,902	3,649	26,355	11,578
Total operating expenses	22,726	10,177	58,986	27,298
Loss from operations	(22,726)	(10,177)	(58,986)	(27,298)
Total other income (expense), net	(1,917)	(1,168)	(3,294)	(1,703)
Net loss	$ (24,643)	$ (11,345)	$ (62,280)	$ (29,001)
Net loss per share of Common Stock — basic and diluted	$ (1.70)	$ (1.03)	$ (4.45)	$ (2.63)
Weighted-average shares used in computing net loss per share of Common Stock — basic and diluted	14,531,595	11,064,282	13,996,326	11,043,758

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

	September 30, 2026	**December 31, 2025**
Assets		
Cash and cash equivalents	$ 193,297	$ 57,982
Short-term investments	43,383	—
Other current assets	2,287	1,005
Total current assets	238,967	58,987
Non-current assets	435	572
Total assets	$ 239,402	$ 59,559
Liabilities and Stockholders' Equity		
Current liabilities	$ 14,928	$ 11,344
Non-current liabilities	26,550	20,232
Total liabilities	41,478	31,576
Total stockholders' equity	197,924	27,983
Total liabilities and stockholders’ equity	$ 239,402	$ 59,559