Palvella Therapeutics Reports Full Year 2025 Financial Results and Provides Corporate Update

March 31, 2026

New Drug Application (NDA) for QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations (microcystic LMs) on track for planned submission in second half of 2026

Accelerating U.S. launch readiness for QTORIN™ rapamycin for microcystic LMs; potential to become the first FDA-approved therapy and first-line, standard-of-care treatment for serious, lifelong disease affecting an estimated more than 30,000 diagnosed patients in the U.S.

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

Initiation of Phase 2 trial of QTORIN™ rapamycin for the treatment of clinically significant angiokeratomas planned for second quarter of 2026

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

Pro forma cash of approximately $274 million as of December 31, 2025 reflects net proceeds from a February 2026 equity financing; cash and cash equivalents of $58.0 million as of December 31, 2025

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

WAYNE, Pa., March 31, 2026 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc. (Palvella or "the Company") (Nasdaq: PVLA), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from 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 full year ending December 31, 2025 and provided a corporate update.

"2025 was a landmark year for Palvella, and we carried that momentum into 2026 with positive Phase 3 SELVA results in microcystic lymphatic malformations, marking a major milestone for the company and putting us on a path toward our first potential FDA approval in the first half of 2027," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "Following SELVA results, we significantly strengthened our balance sheet through an oversubscribed $230.0 million financing, enabling us to accelerate U.S. launch readiness and continue advancing novel topical product candidates from our QTORIN™ platform. Supported by Breakthrough Therapy, Fast Track, and Orphan designations, we are now focused on advancing QTORIN™ rapamycin toward an NDA submission while preparing for a planned standalone U.S. commercial launch. We believe this momentum positions us to advance our vision of building the leading rare disease biopharmaceutical company addressing serious, rare skin diseases and vascular malformations with no FDA-approved therapies."

Recent Research and Development Highlights

QTORIN™ rapamycin for microcystic LMs

- In February 2026, reported positive topline results from the Phase 3 SELVA study:
  - Primary endpoint met with statistically significant improvement (mean change of +2.13; p<0.001) on the Microcystic Lymphatic Malformation Investigator Global Assessment (mLM-IGA)
  - Achieved statistical significance on pre-specified key secondary endpoint (p<0.001) and all four secondary efficacy endpoints (all p<0.001)
  - 95% of trial participants aged 6 years and older who completed the efficacy evaluation period improved on the mLM-IGA at Week 24
  - 86% of trial participants aged 6 years and older who completed the efficacy evaluation period were rated as "Much Improved" (+2) or "Very Much Improved" (+3) on the mLM-IGA at Week 24
  - QTORIN™ rapamycin was well-tolerated, with no drug-related serious adverse events reported and systemic rapamycin levels below 2ng/mL at all timepoints for all participants
  - 98% of participants who completed the efficacy evaluation period elected to continue to receive QTORIN™ rapamycin in the ongoing treatment extension period
- In Q4 2025, FDA awarded year two non-dilutive proceeds from the FDA Orphan Products Grant program to support the

SELVA trial.
- In March 2026, submitted Pre-NDA meeting request to FDA, with meeting anticipated in the second quarter of 2026.
- NDA planning is underway, with submission on track for the second half of 2026.

QTORIN™ rapamycin for cutaneous venous malformations (cutaneous VMs)

- In December 2025, announced positive topline efficacy results from the Phase 2 TOIVA study, achieving statistical significance on multiple pre-specified clinician-reported and patient-reported efficacy endpoints, including dynamic change endpoints and static severity endpoints.
    - 73% of trial participants (11/15 participants) improved on the Overall Cutaneous Venous Malformations Investigator Global Assessment (Overall cVM-IGA) at Week 12; 67% of trial participants (10/15 participants) rated as “Much Improved” (+2) or “Very Much Improved” (+3) on the Overall cVM-IGA at Week 12.
- Recently completed a Preliminary Breakthrough Therapy Designation Advice meeting with the FDA; plan to file for Breakthrough Therapy Designation in the second quarter of 2026.
- Initiation of Phase 3 trial planned for the second half of 2026.

QTORIN™ rapamycin for clinically significant angiokeratomas

- Expanded the development of QTORIN™ rapamycin into clinically significant angiokeratomas, a superficial lymphatic malformation which can cause bleeding, pain, functional impairment, and risk of infection, with no tendency for spontaneous regression; no FDA-approved therapies currently exist for the estimated more than 50,000 diagnosed U.S. patients.
- In December 2025, the U.S. FDA granted Fast Track Designation to QTORIN™ rapamycin for angiokeratomas.
- Received written feedback from FDA on the proposed design of a Phase 2 study in approximately 10-20 patients; trial is expected to initiate in the second quarter of 2026, earlier than prior guidance of 2H 2026.

QTORIN™ pitavastatin for disseminated superficial actinic porokeratosis (DSAP)

- In November 2025, Palvella announced a new QTORIN™ product candidate, QTORIN™ pitavastatin, for the treatment o DSAP, 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.
- QTORIN™ pitavastatin leverages Palvella’s proprietary QTORIN™ platform and is designed to be the first pathogenesis-directed therapy for DSAP by directly inhibiting the causal mevalonate pathway.
- Received written feedback from FDA on the proposed design of a Phase 2 study; trial is expected to initiate in the second half of 2026.

QTORIN™ rapamycin and QTORIN™ platform expansior

- Plan to announce the fourth clinical indication for QTORIN™ rapamycin in the second half of 2026. The expansion of QTORIN™ rapamycin into additional indications is supported by comprehensive publications which highlight 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.
- Plan 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

- Closed an upsized and oversubscribed public offering of common stock generating $230.0 million in gross proceeds, including the full exercise of the underwriters’ option to purchase additional shares.
- Strengthened Palvella's leadership team with the recent appointment of Jennifer McDonough, Senior Vice President of Market Access & Patient Services (previously contributed to the successful launch of VYJUVEK® at Krystal Biotech), and Sarah Foster, Senior Vice President of Human Resources (previously Senior Vice President, People, at Mineralys Therapeutics).

Full Year 2025 Financial Results

- Pro forma cash of approximately $274 million as of December 31, 2025 reflects approximate net proceeds of $215.8 million from a February 2026 equity financing; cash and cash equivalents as of December 31, 2025 were $58.0 million.
- Research and development expenses for the year ended December 31, 2025 were $22.8 million, as compared to $8.2 million for the year ended December 31, 2024. The increase was primarily due to increased spending on the clinical development of QTORIN™ rapamycin to conduct our Phase 3 SELVA and Phase 2 TOIVA trials, which were initiated in 2024. Additional increases include CMC costs for all programs and costs as a result of increased headcount in 2025.
- General and administrative expenses for the year ended December 31, 2025 were $15.8 million, as compared to $5.9 million for the year ended December 31, 2024. The increase was primarily due to increased headcount in 2025, as well as increased professional services related to operating as a publicly-traded company.

- Net loss attributable to common stockholders was $41.7 million, or $3.71 per basic and diluted share, for the year ended December 31, 2025, as compared to net loss attributable to common stockholders of $17.4 million, or $7.83 per basic and diluted share, for the year ended December 31, 2024.
- Shares outstanding were 15,708,420 as of March 25, 2026, including 14,313,659 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 full year 2025 financial results and provide a corporate update at 8:30 a.m. ET today. To access the live webcast of the call with slides please click here or visit the "Events & Presentations" section of Palvella's website. To access the call by phone, please use this registration link, and you will be provided with dial in details. A replay of the webcast will be available approximately 2 hours after the conclusion of the call and 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 suffering from 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, Palvella's plans to pursue Breakthrough Therapy Designation, Palvella's plans to meet with regulatory authorities, 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 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)

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 22,841	$ 8,151
General and administrative	15,761	5,944
Total operating expenses	38,602	14,095
Loss from operations	(38,602)	(14,095)
Total other income (expense), net	(3,113)	(3,339)
Net loss	$ (41,715)	$ (17,434)
Net loss per share of Common Stock — basic and diluted	$ (3.71)	$ (7.83)
Weighted-average shares used in computing net loss per share of Common Stock — basic and diluted	11,251,250	2,225,934

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

	December 31, 2025	**December 31, 2024**
Assets		
Cash and cash equivalents	$ 57,982	$ 83,602
Other current assets	1,005	4,632
Total current assets	58,987	88,234
Non-current assets	572	—
Total assets	$ 59,559	$ 88,234
Liabilities and Stockholders' Equity		
Current liabilities	$ 11,344	$ 12,038
Non-current liabilities	20,232	13,589
Total liabilities	31,576	25,627
Total stockholders' equity	27,983	62,607
Total liabilities and stockholders’ equity	$ 59,559	$ 88,234