Palvella Therapeutics Reports Third Quarter 2025 Financial Results and Provides Corporate Update

November 11, 2025

Palvella's recently expanded rare disease pipeline now comprises QTORIN™-derived product candidates advancing in four serious, rare skin diseases that currently have no FDA-approved therapies

Top-line results for fully enrolled Phase 2 TOIVA trial evaluating QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for cutaneous venous malformations remain on track for mid-December 2025

Top-line results for fully enrolled Phase 3 SELVA trial evaluating QTORIN™ rapamycin for microcystic lymphatic malformations remain on track for the first quarter of 2026

Expanded QTORIN™ rapamycin's development into clinically significant angiokeratomas, a rare and debilitating lymphatic disease with no FDA-approved therapies, with Phase 2 study initiation anticipated in second half of 2026

Announced new QTORIN™ product candidate, QTORIN™ pitavastatin, for the treatment of disseminated superficial actinic porokeratosis, a rare, chronic, and pre-cancerous genetic skin disease with no FDA-approved therapies, with Phase 2 study initiation anticipated in second half of 2026

Cash and cash equivalents of $63.6 million as of September 30, 2025, expected to fund operations into the second half of 2027

Company to host conference call at 8:30 a.m. ET on November 11, 2025

WAYNE, Pa., Nov. 11, 2025 (GLOBE NEWSWIRE) -- (Nasdaq: PVLA) Palvella Therapeutics, Inc. (Palvella or "the Company"), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare skin diseases for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, reported financial results for the third quarter ending September 30, 2025 and provided a corporate update.

"As we enter year-end 2025, Palvella is now advancing innovative QTORIN™-derived therapies for four serious, rare skin diseases, each lacking a single FDA-approved therapy, giving us the opportunity to potentially be first for each of these deserving rare disease communities," said Wes Kaupinen, Founder and CEO of Palvella Therapeutics. "Our lead product candidate, QTORIN™ rapamycin, continues to demonstrate its potential as a pipeline-in-a-product for mTOR-driven skin diseases, with a planned Phase 2 top-line readout in cutaneous venous malformations expected in mid-December. This will be followed by a Phase 3 topline readout in microcystic lymphatic malformations which we anticipate in the first quarter of 2026. Overall, we anticipate the next 18 months will be a catalyst-rich period highlighted by our objective to advance QTORIN™ rapamycin toward its first potential regulatory approval, with a steady flow of clinical, pre-commercialization, regulatory, and indication expansion milestones for QTORIN™ rapamycin and our additional QTORIN™ pipeline programs expected. Achievement of these milestones will advance our vision of becoming the leading biopharmaceutical company addressing serious, rare skin diseases with no FDA-approved therapies."

Recent Corporate Highlights

- Appointed David W. Osborne, Ph.D., as Chief Innovation Officer to provide leadership across Palvella's early-stage R&D pipeline, including maximizing the potential of the Company's proprietary QTORIN™ platform. Dr. Osborne brings extensive topical product development experience and a track record of translating science into commercially available therapies, including contributing to the development of ZORYVE® (roflumilast) cream and foam while serving as Co-Founder and Chief Technical Officer of Arcutis Biotherapeutics.
- Jeffrey Martini, Ph.D., Chief Scientific Officer, presented at the Center for Dermal Research's *Innovations in Dermatological Sciences Conference* at Rutgers University, showcasing the QTORIN™ platform and its lead product candidate, QTORIN™ rapamycin, in his presentation entitled *"Unlocking the Potential of Topical Therapy in Rare Skin Diseases*."

Recent Research and Development Highlights

QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations (microcystic LMs)

- Following FDA's review of an annual performance progress report submitted by Palvella, FDA awarded the year two proceeds from the FDA Orphan Products Grant program to support the ongoing SELVA trial, a single arm, baseline-

controlled Phase 3 study of QTORIN™ rapamycin for microcystic lymphatic malformations.
- Top-line results from SELVA remain on track for the first quarter of 2026.

QTORIN™ rapamycin for the treatment of cutaneous venous malformations (cutaneous VMs)

- The Company completed enrollment in the Phase 2 TOIVA trial of QTORIN™ rapamycin for cutaneous VMs, meeting its recruitment target of 16 subjects enrolled at leading vascular anomaly centers.
- A peer-reviewed publication in *Lymphatic Research and Biology* highlighted 26 published studies evaluating the real-world use of off-label rapamycin in treating venous malformations, supporting rapamycin's potential as a targeted therapy for the disease. The authors also noted the continued unmet need for a topical treatment option, reinforcing the scientific rationale for the development of Palvella's QTORIN™ rapamycin for cutaneous VMs.
- A nationally representative, retrospective, real-world, subject-blinded, physician-observational probability study published in *Orphanet Journal of Rare Diseases* estimated an annual U.S. treatment prevalence of more than 190,000 diagnosed patients with cutaneous VMs. The findings further underscored the need for the development of targeted therapies for this understudied, debilitating condition.
- Top-line results from TOIVA are on track for mid-December 2025.

QTORIN™ rapamycin for the treatment of clinically significant angiokeratomas

- Palvella expanded the development of QTORIN™ rapamycin into clinically significant angiokeratomas, a disease characterized by superficial vascular malformations of lymphatic origin which can cause bleeding, pain, functional impairment, and risk of infection.
- Angiokeratomas were recently classified as an isolated lymphatic malformation in 2025 by the International Society for the Study of Vascular Anomalies (ISSVA).
- There are currently no FDA-approved therapies available for the estimated more than 50,000 patients in the U.S. with clinically significant angiokeratomas.
- Palvella plans to meet with the FDA in the first half of 2026 to discuss the proposed design of a Phase 2 study of approximately 10-20 patients; study initiation is anticipated in the second half of 2026.

QTORIN™ pitavastatin for the treatment of disseminated superficial actinic porokeratosis (DSAP)

- The Company announced a new QTORIN™ product candidate, QTORIN™ pitavastatin, for the topical treatment o disseminated superficial actinic porokeratosis, a rare, chronic, and pre-cancerous genetic skin disease which presents as persistent, often extensive lesions that enlarge and increase in size, number, and extent over time.
- Recent breakthrough discoveries on the genetics and biology of porokeratosis by Keith Choate, M.D, Ph.D., Chair of Dermatology at Yale School of Medicine, enable the development of QTORIN™ pitavastatin as the first potential pathogenesis-directed therapy for DSAP, a subtype of porokeratosis, by locally targeting the causal mevalonate pathway in the pathogenic epidermal and dermal tissue.
- There are currently no FDA-approved therapies available for the estimated more than 50,000 patients in the U.S. with DSAP.
- Palvella plans to meet with the FDA in the first half of 2026 to discuss the proposed design of a Phase 2 study evaluating QTORIN™ pitavastatin in subjects with DSAP; study initiation is anticipated in the second half of 2026.

Third Quarter 2025 Financial Results

- Cash and cash equivalents as of September 30, 2025 were $63.6 million. Palvella expects these resources will be sufficient to fund its operations into the second half of 2027.
- Research and development expenses were $6.5 million for the three months ended September 30, 2025, as compared to $3.2 million for the three months ended September 30, 2024. The increase in research and development expenses was primarily due to increased spending on the clinical development of QTORIN™ rapamycin for the treatment of microcystic LMs and cutaneous VMs, including conducting the Phase 3 SELVA and Phase 2 TOIVA trials, which were initiated in the second half of 2024.
- General and administrative expenses were $3.6 million for the three months ended September 30, 2025, as compared to $1.9 million for the three months ended September 30, 2024. The increase in general and administrative expenses was primarily driven by increased employee compensation expense due to headcount additions, as well as increases in costs related to being a publicly-traded company.
- Net loss attributable to common stockholders was $11.3 million, or $1.03 per basic and diluted share, for the three months ended September 30, 2025, as compared to net loss attributable to common stockholders of $7.0 million, or $3.94 per basic and diluted share, for the three months ended September 30, 2024.
- Shares outstanding were 13,768,036 as of November 7, 2025, including 11,836,490 shares of common stock and 1,931,546 common share equivalents assuming conversion of outstanding preferred shares and prefunded warrants.

Conference Call Details

Palvella will host a conference call and live audiovisual webcast to discuss the Company's third quarter 2025 financial results and provide a corporate update at 8:30 a.m. ET on November 11, 2025. 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 drug development 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 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, 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 topical 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 or cleared by the FDA or 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 ongoing clinical trials, Palvella's clinical development plans and related anticipated development milestones, 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; 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.

Contact Information

Investors
Wesley H. Kaupinen
Founder and CEO, Palvella Therapeutics
wes.kaupinen@palvellatx.com

Media
Marcy Nanus
Managing Partner, Trilon Advisors LLC
mnanus@trilonadvisors.com

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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 6,528	$ 3,182	$ 15,720	$ 5,608
General and administrative	3,649	1,880	11,578	4,121
Total operating expenses	10,177	5,062	27,298	9,729
Loss from operations	(10,177)	(5,062)	(27,298)	(9,729)
Total other income (expense), net	(1,168)	(1,713)	(1,703)	(3,754)
Net loss	$ (11,345)	$ (6,775)	$ (29,001)	$ (13,483)
Less: Cumulative Series D preferred dividends	—	(194)	—	(582)
Net loss attributable to common stockholders	$ (11,345)	$ (6,969)	$ (29,001)	$ (14,065)
Net loss per share — basic and diluted	$ (1.03)	$ (3.94)	$ (2.63)	$ (7.95)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	11,064,282	1,770,167	11,043,758	1,770,167

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

	September 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 63,567	$ 83,602
Other current assets	3,370	4,632
Total current assets	66,937	88,234
Total assets	$ 66,937	$ 88,234
Liabilities and Stockholders' Equity		
Current liabilities	$ 10,312	$ 12,038
Non-current liabilities	17,943	13,589
Total liabilities	28,255	25,627
Total stockholders' equity	38,682	62,607
Total liabilities and stockholders’ equity	$ 66,937	$ 88,234