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

May 7, 2026

FDA Pre-New Drug Application (NDA) meeting granted for QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations, with meeting expected in second quarter of 2026; NDA submission on track for second half of 2026

Accelerating U.S. launch readiness for QTORIN™ rapamycin for microcystic lymphatic malformations; BEYONDmLM.com disease awareness campaign launched to educate, engage, and empower patients, caregivers, and healthcare professionals

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™ pitavastatin for the treatment of disseminated superficial actinic porokeratosis planned for second half of 2026

Phase 2 LOTU trial of QTORIN™ rapamycin for clinically significant angiokeratomas initiated with topline results expected in second half of 2027

Completed upsized, oversubscribed equity financing of $230.0 million in February 2026; cash, cash equivalents and short-term investments of $261.9 million as of March 31, 2026

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

WAYNE, Pa., May 07, 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 first quarter ending March 31, 2026 and provided a corporate update.

"Following the positive Phase 3 SELVA topline results, we believe Palvella is on a clear path toward near-term NDA submission for QTORIN™ rapamycin in microcystic lymphatic malformations, with the potential for approval and U.S. commercial launch in the first half of 2027," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "Our $230.0 million financing with participation from high-quality new and existing investors meaningfully strengthens our balance sheet, which supports our plan for U.S. commercialization, and enables us to attract key talent as we prepare for a potential first-in-disease launch. At the same time, we continue to rapidly advance our pipeline beyond microcystic LMs, with the goal of expanding our QTORIN™-derived programs across six serious, rare skin diseases and vascular malformations by year-end."

Recent Research and Development Highlights

QTORIN™ rapamycin for microcystic lymphatic malformations (microcystic LMs)

- Reported positive topline data from the Phase 3 SELVA study demonstrating statistically significant results across the primary and all pre-specified secondary endpoints.
- In collaboration with leading nonprofit and advocacy organizations, launched the "BEYOND mLM" disease awareness campaign and BEYONDmLM.com to educate and engage patients, caregivers, and healthcare professionals on microcystic lymphatic malformations.
- Announced publication in the *Journal of Vascular Anomalies* highlighting the distinct biology and significant unmet need in microcystic lymphatic malformations, supporting early intervention and reinforcing the scientific rationale for QTORIN™ rapamycin as a targeted therapeutic approach.
- Strengthened global intellectual property for QTORIN™ rapamycin with issuance of a European patent covering anhydrous topical compositions and methods of use, providing protection through 2038.
- Phase 3 SELVA study results to be presented at the International Society for the Study of Vascular Anomalies World Congress 2026 on May 20, 2026, marking the first presentation of these data at a major medical meeting.
- Pre-New Drug Application (NDA) meeting with the FDA granted; meeting expected in the second quarter of 2026.
- NDA submission remains on track for the second half of 2026.

QTORIN™ rapamycin for cutaneous venous malformations (cutaneous VMs)

- Phase 2 TOIVA study results to be presented at the International Society for the Study of Vascular Anomalies World Congress 2026 on May 20, 2026; additional data presentation planned at the 83rd Annual Meeting of the Society for Investigative Dermatology on May 12, 2026.
- Submitted application for FDA Breakthrough Therapy Designation in the second quarter of 2026.
- Phase 3 study initiation anticipated in the second half of 2026.

QTORIN™ rapamycin for clinically significant angiokeratomas

- Dosed first patients in the Phase 2 LOTU trial, a single-arm, baseline-controlled clinical trial of QTORIN™ rapamycin administered topically once daily for the treatment of clinically significant angiokeratomas.
- Topline results from LOTU are expected in the second half of 2027.

QTORIN™ pitavastatin for disseminated superficial actinic porokeratosis (DSAP)

- Presented qualitative insights at the 2026 American Academy of Dermatology Annual Meeting from ten in-depth interviews highlighting the significant burden of porokeratosis, a rare genetic skin disease with no FDA-approved therapies. These insights underscore its pre-cancerous nature and substantial physical, functional, and psychosocial impact, reinforcing the need for pathogenesis-directed therapies.
- Phase 2 trial initiation expected in the second half of 2026.

QTORIN™ rapamycin and QTORIN™ platform expansion

- 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.
- 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.

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 appointments of Jennifer McDonough, Senior Vice President of Market Access & Patient Services, who previously contributed to the successful launch of VYJUVEK® at Krystal Biotech, and Kent Taylor as Senior Vice President of Sales, who previously led U.S. commercialization efforts for ZORYVE® at Arcutis Biotherapeutics and supported the launch of OPZELURA® at Incyte.
- Expanded Palvella's Board of Directors with the appointment of John D. Doux, M.D., M.B.A., a board-certified dermatologist and seasoned life sciences investor with deep expertise in rare skin diseases and biotechnology investing.

First Quarter 2026 Financial Results

- Cash, cash equivalents, and short-term investments as of March 31, 2026 were $261.9 million, which reflects net proceeds of $215.8 million from a February 2026 equity financing.
- Research and development expenses for the three months ended March 31, 2026 were $9.3 million, as compared to $4.1 million for the three months ended March 31, 2025. The increase was primarily due to increased spending for manufacturing activities and costs resulting from increased headcount and consulting services in 2026.
- General and administrative expenses for the three months ended March 31, 2026 were $5.5 million, as compared to $3.8 million for the three months ended March 31, 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 $15.8 million, or $1.20 per basic and diluted share, for the three months ended March 31, 2026, as compared to net loss of $8.2 million, or $0.74 per basic and diluted share, for the three months ended March 31, 2025.
- Shares outstanding were 15,738,543 as of May 1, 2026, including 14,342,844 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, including slides, please click here or visit the "Events & Presentations" section of Palvella's website. To join the conference call by phone, dial 800-715-9871 (domestic) or +1 646-307-1963 (international) and provide Conference ID 9970701. Participants are encouraged to dial in approximately 15 minutes prior to the start of the call.

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 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 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 March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 9,334	$ 4,074
General and administrative	5,521	3,797
Total operating expenses	14,855	7,871
Loss from operations	(14,855)	(7,871)
Total other income (expense), net	(912)	(314)
Net loss	$ (15,767)	$ (8,185)
Net loss per share of Common Stock — basic and diluted	$ (1.20)	$ (0.74)
Weighted-average shares used in computing net loss per share of Common Stock — basic and diluted	13,085,271	11,013,697

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

	March 31, 2026	**December 31, 2025**
Assets		
Cash and cash equivalents	$ 206,394	$ 57,982
Short-term investments	55,459	—
Other current assets	1,378	1,005
Total current assets	263,231	58,987
Non-current assets	528	572
Total assets	$ 263,759	$ 59,559
Liabilities and Stockholders' Equity		
Current liabilities	$ 9,115	$ 11,344
Non-current liabilities	22,331	20,232
Total liabilities	31,446	31,576
Total stockholders' equity	232,313	27,983
Total liabilities and stockholders’ equity	$ 263,759	$ 59,559