UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 28, 2026**

PALVELLA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-37471**	**30-0784346**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

353 W. Lancaster Ave, Suite 200 **Wayne, Pennsylvania** (Address of principal executive offices)	**19087** (Zip Code)

Registrant's telephone number, including area code: (**484) 253-1461**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.001 par value per share	PVLA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 28, 2026, Palvella Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has accepted for filing and granted Priority Review to the Company's New Drug Application for QTORIN™ 3.9% rapamycin anhydrous gel for the treatment of microcystic lymphatic malformations. The FDA has assigned a Prescription Drug User Fee Act target action date of February 28, 2027. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Palvella Therapeutics, Inc. on October 28, 2026*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PALVELLA THERAPEUTICS, INC.

Date: October 28, 2026

By: /s/ Matthew Korenberg
Matthew Korenberg
Chief Financial Officer

Palvella Announces FDA Acceptance and Priority Review of QTORIN™ Rapamycin NDA; February 28, 2027 PDUFA Target Action Date Set

QTORIN™ rapamycin could become the first FDA-approved therapy for microcystic lymphatic malformations, a serious, lifelong rare disease affecting an estimated more than 30,000 diagnosed children and adults in the U.S.

Phase 3 SELVA study achieved highly statistically significant results across all six prespecified efficacy endpoints (all p<0.001), with 95% of participants aged 6 years and older who completed the efficacy evaluation period demonstrating improvement on the mLM-IGA primary endpoint

Palvella preparing for a potential standalone U.S. commercial launch in the first half of 2027, supported by experienced commercial leadership and established medical affairs and patient services capabilities

WAYNE, Pa., October 28, 2026 (GLOBE NEWSWIRE) — Palvella Therapeutics, Inc. (Nasdaq: PVLA) ("Palvella" or the "Company"), 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 announced that the FDA has accepted for filing and granted Priority Review to the Company's New Drug Application (NDA) for QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatment of microcystic lymphatic malformations (microcystic LMs). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of February 28, 2027.

"FDA acceptance of our NDA and granting of Priority Review represent significant milestones in the development of QTORIN™ rapamycin as a potential first FDA-approved therapy for microcystic lymphatic malformations," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella Therapeutics. "Palvella was founded to serve rare disease patients by developing and commercializing first-in-disease therapies that meaningfully improve their lives. With compelling Phase 3 SELVA results and a February 28, 2027 PDUFA target action date, we believe we are closer than ever to delivering on that mission. We have assembled an exceptional team across our medical and commercial organizations as we prepare for a potential U.S. launch and work toward bringing QTORIN™ rapamycin to patients who currently have no FDA-approved therapies."

The NDA is supported by an evidence package that includes results from the Phase 3 SELVA study, which achieved statistical significance across all six prespecified efficacy endpoints (all p<0.001), and Phase 2 clinical results that supported FDA's decision to grant Breakthrough Therapy designation. The application also includes published literature and other evidence regarding the clinical use of off-label rapamycin in microcystic LMs. QTORIN™ rapamycin was well tolerated in SELVA, with no drug-related serious adverse events reported and systemic rapamycin concentrations below 2 ng/mL at all measured timepoints for all participants.

If approved, QTORIN™ rapamycin would become the first FDA-approved therapy for children and adults with microcystic LMs, a serious, lifelong condition associated with persistent leaking, bleeding, recurrent infections, and functional impairment.

QTORIN™ rapamycin has received Breakthrough Therapy, Fast Track, and Orphan Drug designations from the FDA for the treatment of microcystic lymphatic malformations. The development program has also received grant funding from the FDA Office of Orphan Products Development.

Preparing for Potential U.S. Commercial Launch in 2027

Palvella is preparing for a potential standalone U.S. commercial launch of QTORIN™ rapamycin in the first half of 2027, subject to FDA approval. The Company has established key commercial and medical capabilities, including experienced rare disease commercial leadership, a field-based medical science liaison team deployed across the United States, and a dedicated patient services organization. Current launch preparations include disease education, engagement with treating specialists, patient identification, market access planning, and patient support readiness, with the objective of facilitating timely access to QTORIN™ rapamycin following potential FDA approval.
FDA approval of QTORIN™ rapamycin would mark Palvella's transition to a commercial-stage rare disease biopharmaceutical company.

Advancing a Broad Pipeline of Potential First-in-Disease Therapies

Beyond microcystic LMs, Palvella continues to advance QTORIN™ rapamycin for cutaneous venous malformations and clinically significant angiokeratomas, as well as QTORIN™ pitavastatin for disseminated superficial actinic porokeratosis. These programs reflect Palvella's strategy to leverage the repeatability and scalability of its QTORIN™ platform to develop multiple first-in-disease therapies for serious, rare skin diseases and vascular anomalies.

About Microcystic Lymphatic Malformations

Microcystic LMs are a rare, chronically debilitating genetic disease driven by dysregulation of the PI3K/mTOR pathway. Malformed lymphatic vessels can protrude through the skin, persistently leak and bleed, and cause recurrent infections, cellulitis and hospitalization. Published natural history data demonstrate that microcystic LMs are persistent and progressive and do not spontaneously regress. Surgery, sclerotherapy and laser can be limited by recurrence and repeated procedures, while systemic PI3K/mTOR inhibitors may be constrained by chronic safety and tolerability considerations, particularly in children, and by challenges in achieving sufficient exposure in affected skin. Advances in molecular genetics have established dysregulated PI3K/mTOR signaling as a central disease driver, supporting precision, mechanism-based treatment. There are no FDA-approved treatments for the estimated 30,000 or more people diagnosed with microcystic LMs in the United States.

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 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 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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