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PALVELLA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 11/05/26 for the Period Ending 11/05/26

Address	353 W. LANCASTER AVENUE SUITE 200 WAYNE, PA, 19087
Telephone	(484) 253-1461
CIK	0001583648
Symbol	PVLA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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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): November 5, 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		**19087**
(Address of principal executive offices)		**(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 2.02 Results of Operations and Financial Condition.

On November 5, 2026, Palvella Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2026. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On November 5, 2026, the Company will hold its earnings call and use a slide presentation in conjunction with the earnings call. A copy of the presentation is furnished herewith as Exhibit 99.2, and incorporated herein by reference.

The information furnished pursuant to Item 7.01, including Exhibit 99.2, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Palvella Therapeutics, Inc., dated November 5, 2026*
99.2	Earnings Call Presentation of Palvella Therapeutics, Inc., dated November 5, 2026*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished 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: November 5, 2026

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

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

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., November 5, 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 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.

Contact Information

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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

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First-in-disease therapies for patients with rare diseases



Q3 2026 Financial Results & Corporate Update
November 5, 2026

Forward Looking Statements

This presentation contains forward-looking statements of Palvella Therapeutics, Inc. ("the Company") within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts, and in some cases, can be identified by terms such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements contained in this presentation include, but are not limited to, statements regarding the Company's future financial or business performance, conditions, plans, prospects, trends or strategies and other financial and business matters, the Company's current and prospective product candidates and any additional indications or platform candidates, the Company's planned research and development activities, the Company's planned clinical trials, including timing of receipt of data from the same, the planned regulatory framework for the Company's product candidates, the Company'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, the Company'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, the Company's commercial preparedness and the timing and execution of a potential launch following regulatory approval, the Company's ability and the ability of third-party manufacturers the Company engages to optimize and scale manufacturing, the strength of the Company's intellectual property portfolio, and projections of the Company's future financial results and other metrics. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward looking statements.

These forward-looking statements are based upon current estimates and assumptions of the Company and its management and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: competition, the ability of the Company to grow and manage growth, maintain relationships with suppliers and retain its management and key employees; the success, cost and timing of the Company's product development activities, studies and clinical trials; changes in applicable laws or regulations; the possibility that the Company may be adversely affected by other economic, business or competitive factors; the Company's estimates of expenses and profitability; the evolution of the markets in which the Company competes; the ability of the Company to implement its strategic initiatives and continue to innovate its existing products; and the ability of the Company to defend its intellectual property.

Nothing in this Presentation should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. The Company undertakes no duty to update these forward-looking statements.

Industry and Market Data

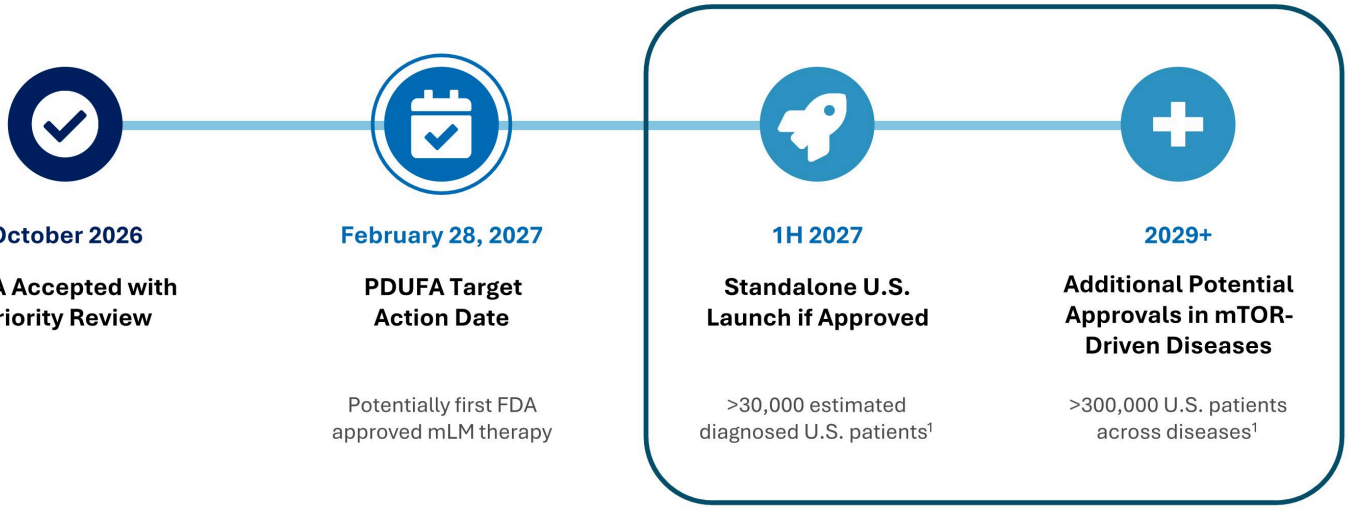
The Company may from time to time provide estimates, projections and other information concerning its industry, the general business environment, and the markets for certain conditions, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this presentation. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

Trademarks

This Presentation may contain trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, some of the trademarks, service marks, trade names and copyrights referred to in this Presentation may be listed without the TM, SM © or ® symbols, but the Company will assert, to the fullest extent under applicable law, the rights of the applicable owners, if any, to these trademarks, service marks, trade names and copyrights.

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QTORIN™ Rapamycin:
Microcystic LM Opens the Door to Many mTOR-driven Diseases



October 2026

NDA Accepted with Priority Review

February 28, 2027

PDUFA Target Action Date

Potentially first FDA approved mLM therapy

1H 2027

Standalone U.S. Launch if Approved

>30,000 estimated diagnosed U.S. patients[1]

2029+

Additional Potential Approvals in mTOR-Driven Diseases

>300,000 U.S. patients across diseases[1]

1. Clarity Pharma, Trinity Life Sciences, MedaCorp, and ZS Associates.

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What Makes Palvella Stand Apart

Veteran team executing rare disease model designed to reduce time and capital to FDA approval

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Repeatably unlocking multi-billion dollar market opportunities in previously untreated orphan diseases

1. **Zero to One: First-in-Disease Focus**
+
2. **Rare Diseases with Clear Disease Biology**
+
3. **Leveraging Existing Human Proof-of-Concept and Safety Data**
+
4. **Innovative QTORIN™ Platform: Durable IP Generation**

Shaping an Exceptional Launch for mLM Patients

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Proven Orphan Launch Leadership, Applied With Urgency

Significant progress across crucial keys to launch success



Ashley Kline
Chief Commercial Officer

- **Led U.S. launch of Oxervate®** a topical medicine for neurotrophic keratitis, a rare eye disease
- **Oxervate® reached >$1 billion** in U.S. sales seven years after launch
- **Joined Palvella ~18 months ago**; prior roles at Dompé, Genentech, and Bain Consulting

Keys to a Successful Orphan Launch

Strong Prescribing Intent
>70% plan to prescribe within 3 months of approval

Clear Path to Coverage
Payer research has confirmed pricing and access assumptions

Precision Patient-Finding
Multiple patient identification approaches deployed

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New Market Research Reinforces Potential for Strong Orphan Launch

Post-SELVA market research further substantiates previous launch positioning

Physician Survey
(~150 treating U.S. physicians)

>70%

of surveyed physicians expect to begin prescribing within 3 months of approval

>75%

would start several patients at once, then expand

Payer Survey
(10 U.S. payers)

- mLM is recognized as a serious, genetic vascular anomaly
- Product profile supported by compelling clinical evidence package
- Clinical diagnosis with no step-through anticipated
- Favorable coverage anticipated at orphan pricing corridor

Responses weighted by patient volume and adjusted for overstatement. Physicians evaluated a blinded product profile. Source: Palvella-sponsored market research (survey of 150 U.S. physicians; interviews with 14 physicians and 10 payers), April–June 2026.

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Proven Launch Leaders Recruited to Serve the mLM Community

Anticipated launch in 1H 2027

Leadership team brings deep expertise in both **rare disease** and **dermatology**

>70

field-based team members at launch

Sales
Focused on winners from first-in-indication launches

Field Marketing
HCP education beyond sales call points

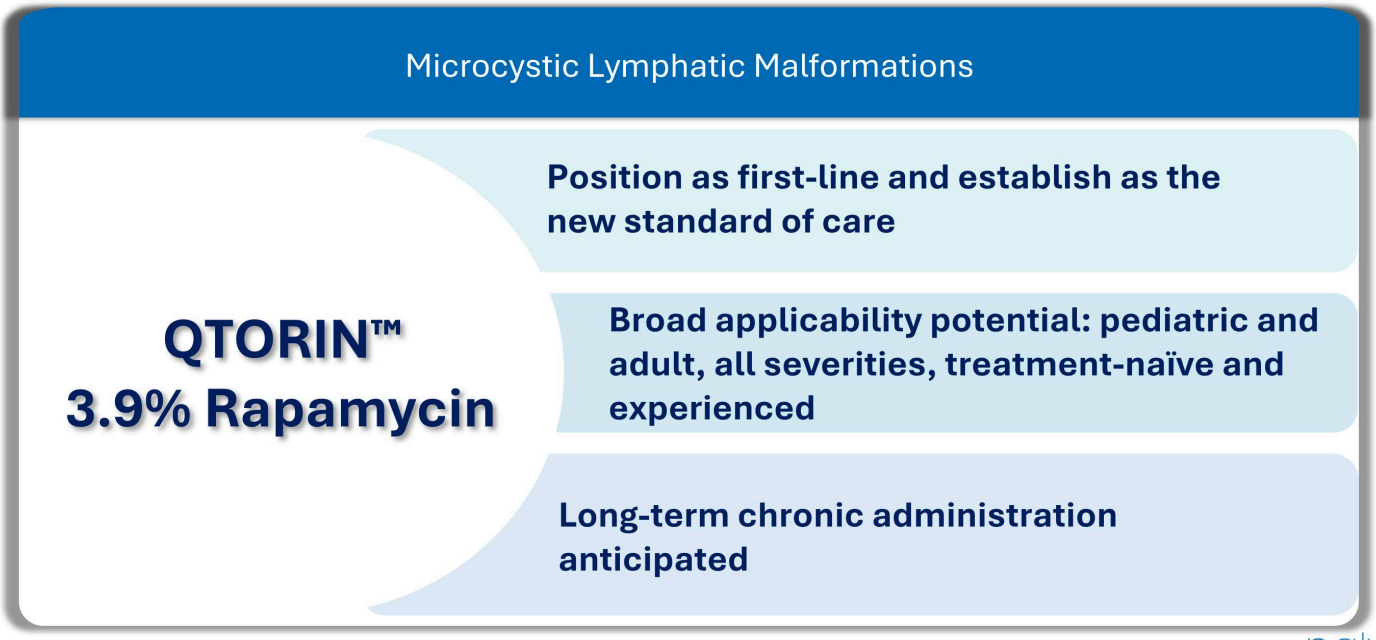
In-House Patient Team
Personalized support for patients

Medical Affairs
Deep discussions with providers on our science

Precision Digital Effort
Physician National Prescriber Identification (NPI)-targeted strategy informed by claims data

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QTORIN™ Rapamycin: Opportunity to be the First FDA-approved Therapy for Estimated >30K Microcystic LM Patients in the U.S.



 QTORIN™ 3.9% rapamycin anhydrous gel is for investigational use only and has not been approved or cleared by the FDA or by any other regulatory agency.

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Rare Disease Pipeline Updates

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FDA Rare Disease Framework Public Meeting (October 2026)

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

FDA PUBLIC MEETING

Rare Disease Framework Initiative Public Meeting

October 28, 2026

FDA White Oak Campus, Silver Spring, MD
Hosted by the Reagan-Udall Foundation for the FDA

> ***"Dermatology has more rare diseases than any other specialty."***

Dr. Matthew Zirwas, Board-certified dermatologist

Public comment, October 28, 2026

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Deep Pipeline in Serious, Rare Skin Diseases and Vascular Anomalies

PRODUCT CANDIDATE	DISEASE	ESTIMATED U.S. PREVALENCE[1]	CLINICAL STATUS	FDA DESIGNATIONS	UPCOMING MILESTONES
QTORIN™ Rapamycin *3.9% anhydrous gel*	Microcystic Lymphatic Malformations	>30,000	PDUFA: Feb 28, 2027	• Breakthrough Therapy • Fast Track • Orphan	PDUFA: Feb 28, 2027
	Cutaneous Venous Malformations	>75,000	Phase 2 Completed	Fast Track	Phase 3 trial initiation expected Q4 2026
	Clinically Significant Angiokeratomas	>50,000	Phase 2 Ongoing	Fast Track	Phase 2 data expected 2H 2027
	Fourth QTORIN™ rapamycin indication	*TBD*	Phase 2 Ready	Planned	Announcement expected Q4 2026
QTORIN™ Pitavastatin	Disseminated Superficial Actinic Porokeratosis (DSAP)	>50,000	Phase 2 Ready	Planned	Phase 2 trial initiation expected Q4 2026
Third QTORIN™ Program	*Serious, rare disease*	*TBD*		Planned	Announcement expected Q4 2026
Additional New QTORIN™ Programs	*Serious, rare diseases*	*TBD*		Planned	Announcement expected 2027+

1. Clarity Pharma, Trinity Life Sciences, MedaCorp, and ZS Associates.

Why the Microcystic LM Field is Moving Toward Early Intervention

THE BIOLOGY

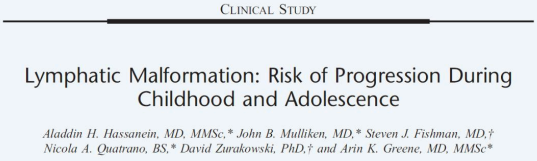
Somatic PIK3CA mutations keep the growth pathway always "on"

LM is proliferative and progressive, not a static lesion

Luks et al., J Pediatr 2015 (Boston Children's)[1]

Boston Children's[2]

85% **of childhood LMs progressed by adulthood**


CLINICAL STUDY

Lymphatic Malformation: Risk of Progression During Childhood and Adolescence

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Stanford[3]

2.8x **higher odds of progression without treatment**


Journal of Clinical & Experimental Dermatology Research

Patel et al., J Clin Exp Dermatol Res 2017, 8:6
DOI: 10.4172/2155-9554.1000424

Research Article | Open Access

Natural History of Lymphatic Malformation Progression in Children: A Retrospective Study

Virat Patel[1], Joanna H. Tu[2,3], and Joyce M. C. Teng[1*]

"Early intervention should be considered…because of their tendency to progress."[2]

1. Luks VL et al. J Pediatr. 2015;166:1048–54. 2. Hassanein AH et al. J Craniofac Surg. 2012;23(1):149–52. 3. Patel V et al. J Clin Exp Dermatol Res. 2017;8(6):424.

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Cutaneous Venous Malformations

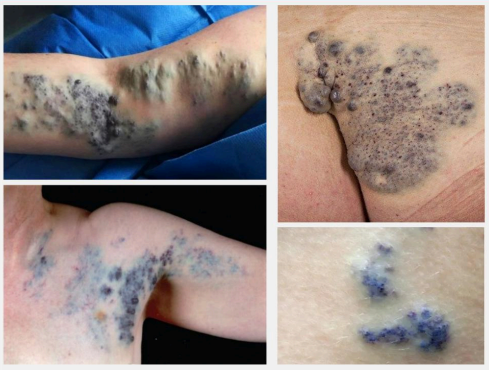
Near-term Phase 3 initiation on track

QTORIN™ RAPAMYCIN HAS POTENTIAL TO BE FIRST APPROVED THERAPY

- **Phase 3 initiation on track for Q4 2026**
- **Significant treater overlap with microcystic lymphatic malformations**
- **Positive Phase 2 TOIVA data with 73% of patients improved on cVM-IGA at Week 12**
  - 24-week data presented at PeDRA October 2026
    - Additional improvement between Week 12 and Week 24 on multiple endpoints
    - Data demonstrated reduction in disease severity and bleeding in pediatric patients after treatment

> 75k patients

ESTIMATED DIAGNOSED IN THE U.S.



No FDA-approved therapies

Fast Track Designation Granted

Pipeline-in-a-product: sNDA planned

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Clinically Significant Angiokeratomas

Superficial lymphatic malformations

UNDER-RECOGNIZED MARKET OPPORTUNITY

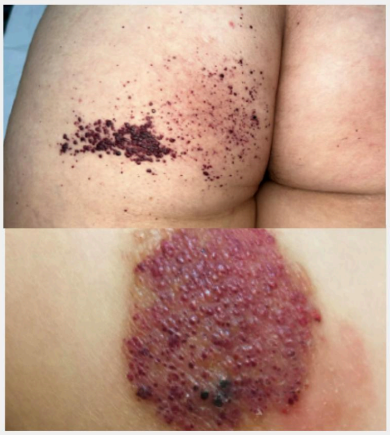
- **Topline results (n=~15) expected in 2H 2027**
  - Phase 2 LOTU study is a 12-week, single-arm, baseline-controlled clinical trial evaluating QTORIN™ rapamycin topically once daily
  - Strong enrollment momentum and site engagement
- **Highly symptomatic with bleeding and painful clots; sensitive location limits destructive interventional treatments**

Market research (n=50 physicians):

96% *would incorporate QTORIN™ rapamycin into their practice*

> 50k patients

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Disseminated Superficial Actinic Porokeratosis

Chronic, pre-cancerous, and progressive

POTENTIAL TO BE FIRST FDA-APPROVED THERAPY AND STANDARD OF CARE

- **QTORIN™ pitavastatin: First pathogenesis-directed therapy**
- **Milestones:**
  - ☑ Yale collaboration: pharmacodynamic proof of principle with pitavastatin reversing hyperproliferation in a human porokeratosis cell model
  - ☑ Formulation development completed
  - ☑ Licensed Yale U.S. patent and filed IP
  - ☑ Multiple IND-enabling tox studies completed
  - ☐ **Q4 2026:** Phase 2 initiation anticipated

FALL CLINICAL DERMATOLOGY CONFERENCE®

New claims analysis October 2026

~155K

diagnosed U.S. DSAP patients

First real-world claims analysis-based characterization of the diagnosed U.S. DSAP population



No FDA-approved therapies

Current options:
Laser, surgery, and off-label topical chemo agents & mevalonate pathway inhibitors

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Finance & Cash Update

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U.S. Launch and Rare Disease Pipeline are Well-Funded with $236.7 Million on Balance Sheet as of 9/30/26

Key strategic priorities accelerating:

- NDA accepted with Priority Review; PDUFA date of February 28, 2027
- Commercial and medical affairs expansion
- Major QTORIN™ pipeline and platform value drivers

$236.7 million

9/30/26 cash

Cash, cash equivalents and short-term investments

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Closing Remarks

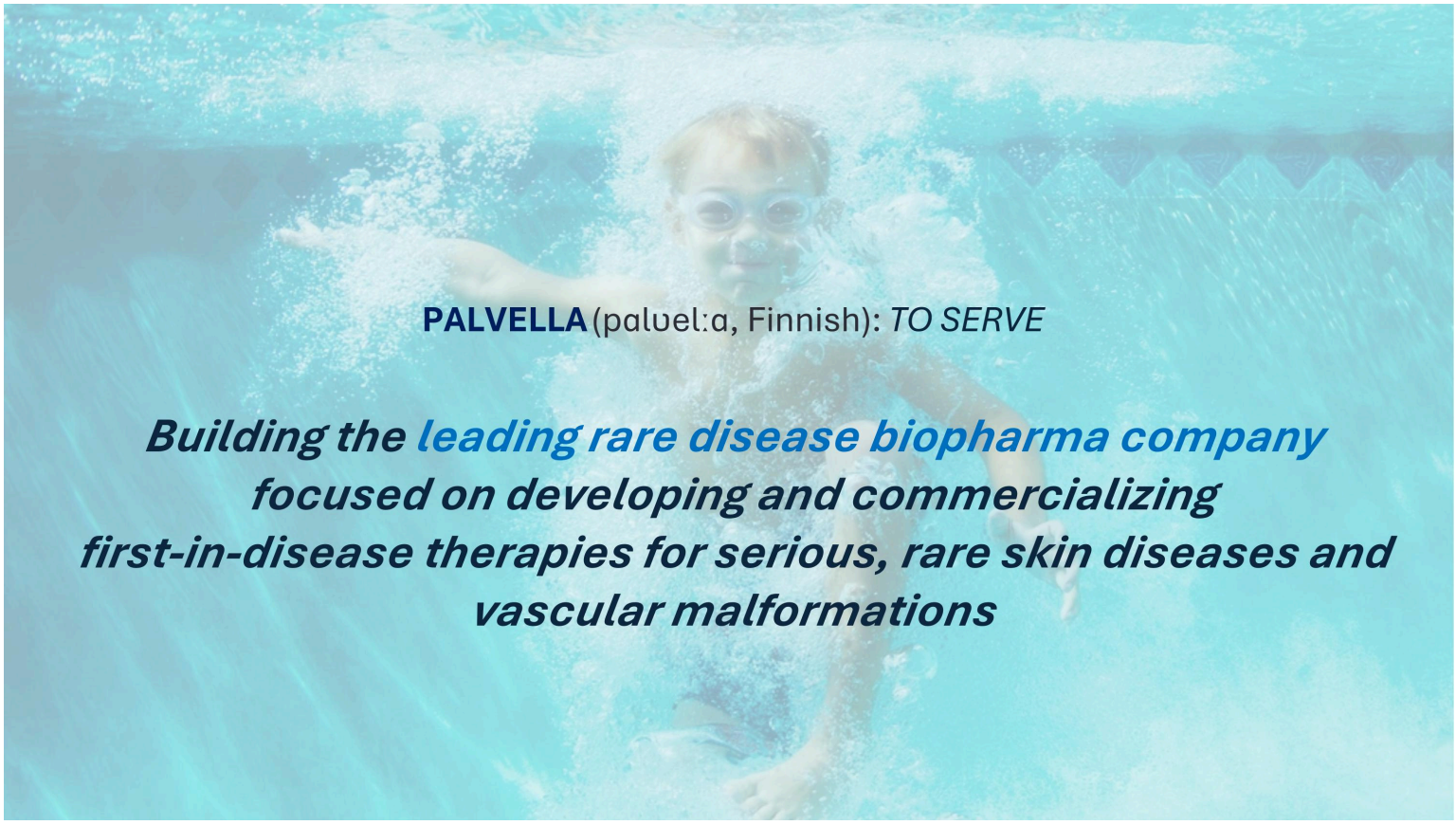
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Palvella: Driving the Next Wave of Innovation in Under-Appreciated Rare Skin Diseases and Vascular Malformations

	Microcystic LMs	Cutaneous VMs	Clinically Significant Angiokeratomas	Disseminated Superficial Actinic Porokeratosis
Diagnosed **US Prevalence** (Estimated)[1]	30k+	75k+	50k+	50k+
Number of **FDA Approved** Therapies	None			
Physicians Who Would Consider QTORIN™ Rapamycin / Pitavastatin as **First-line Therapy**[2]	> 80%			

1. Clarity Pharma, Trinity Life Sciences, MedaCorp, and ZS Associates. 2. MedaCorp market research.

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PALVELLA (palʋelːa, Finnish): *TO SERVE*
Building the leading rare disease biopharma company focused on developing and commercializing first-in-disease therapies for serious, rare skin diseases and vascular malformations

Thank You

Striving to be first for rare disease patients

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