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): May 15, 2025

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.)**
125 Strafford Ave, Suite 360 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 Capital 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 May 15, 2025, Palvella Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2025. 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 May 15, 2025, 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 May 15, 2025*
99.2	Earnings Call Presentation of Palvella Therapeutics, Inc., dated May 15, 2025*
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: May 15, 2025

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

Exhibit 99.1

palvella
THERAPEUTICS

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

Phase 3 SELVA trial evaluating QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatment of microcystic lymphatic malformations (microcystic LMs) has exceeded enrollment target of 40 patients; enrollment expected to close in June 2025

Phase 3 SELVA trial top-line results anticipated in the first quarter of 2026

Phase 2 TOIVA trial evaluating QTORIN™ rapamycin for the treatment of cutaneous venous malformations top-line results on track for the fourth quarter of 2025

QTORIN™ rapamycin has the potential to be the first approved therapy and standard of care in the U.S. for microcystic LMs and cutaneous venous malformations

Cash and cash equivalents of $75.6 million as of March 31, 2025, expected to fund operations into the second half of 2027

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

WAYNE, PA., May 15, 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 genetic skin diseases for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, reported financial results for the first quarter ending March 31, 2025 and provided a corporate update.

"We are pleased with the strong interest from clinical investigators, clinical trial sites, and study participants in our Phase 3 SELVA study which together has led to exceeding our Phase 3 enrollment target of 40 patients," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "Based on a recently presented epidemiology study estimating diagnosed U.S. prevalence and incidence of lymphatic malformations with cutaneous involvement, the data continue to support a large potential market opportunity for QTORIN™ rapamycin, if approved, as potentially the first targeted therapy for this serious, rare genetic disease which currently has no FDA-approved therapies."

Recent Research and Development Highlights

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

- Announced results from the Phase 2 study of QTORIN™ rapamycin for the treatment of microcystic LMs were published in the *Journal of Vascular Anomalies* (JoVA).

- Expanded SELVA, the Company's Phase 3 clinical trial of QTORIN™ rapamycin for the treatment of microcystic LMs, to include patients ages 3 to 5 years old.
- The SELVA trial has exceeded its enrollment target of 40 patients ages six and older. Enrollment is expected to close in June 2025 and top-line results are anticipated in the first quarter of 2026.
- Presented a poster highlighting the estimated diagnosed U.S. prevalence and U.S. annual incidence of lymphatic malformations with cutaneous involvement at the 82nd Annual Meeting of the Society for Investigative Dermatology.
    - Quantitative analysis of medical claims indicates an estimated 44,553 high probability LM patients with cutaneous involvement are projected based on the methodology developed by the authors that includes having greater than or equal to two diagnosis claims related to LM.
- Reported the United States Patent and Trademark Office granted a patent for QTORIN™ rapamycin for the treatment of microcystic LMs, the Company's fifth patent granted in the U.S. for QTORIN™ rapamycin, with anticipated patent life extending into 2038.

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

- Announced the dosing of the first patients in TOIVA, a Phase 2 single-arm, open-label, baseline-controlled clinical trial of QTORIN™ rapamycin for the treatment of cutaneous VMs. The trial is currently enrolling patients at six sites across the U.S.
- Top-line results from TOIVA are anticipated in the fourth quarter of 2025.

First Quarter 2025 Financial Results

- Cash and cash equivalents as of March 31, 2025 were $75.6 million. Palvella expects such resources will be sufficient to fund its operations into the second half of 2027, and sufficient to accomplish its current strategic agenda.
- Research and development expenses were $4.1 million for the three months ended March 31, 2025, compared to $1.0 million for the three months ended March 31, 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 venous malformations, including conducting our Phase 3 SELVA and Phase 2 TOIVA trials, which were initiated in 2024.
- General and administrative expenses were $3.8 million for the three months ended March 31, 2025, compared to $0.8 million for the three months ended March 31, 2024. The increase in general and administrative expenses was primarily driven by employee compensation expense due to headcount additions, as well as increases in expenses related to operating as a publicly-traded company.

- Net loss was $8.2 million or $0.74 per basic and diluted share for the three months ended March 31, 2025, compared to net loss of $2.7 million or $1.54 per basic and diluted share for the three months ended March 31, 2024.
- Shares outstanding were 13,697,114 as of March 31, 2025, including 11,021,389 shares of common stock and 2,675,725 common share equivalents assuming conversion of our outstanding preferred shares and prefunded warrants.

Conference Call Details

Palvella will host a conference call and live audiovisual webcast to discuss the Company's first quarter 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 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 genetic 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 genetic 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 evaluated in the Phase 3 SELVA clinical trial in microcystic lymphatic malformations and the Phase 2 TOIVA clinical trial in cutaneous venous malformations. For more information, please visit www.palvellatx.com or follow Palvella on LinkedIn or X (formerly known as Twitter).

QTORIN™ rapamycin is for investigational use only and has not 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 and financial resources and expected cash runway, and the potential of, and expectations regarding, Palvella's programs, including QTORIN™ rapamycin, 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; 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

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Media
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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 March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 4,074	$ 984
General and administrative	3,797	775
Total operating expenses	7,871	1,759
Loss from operations	(7,871)	(1,759)
Total other income (expense), net	(314)	(777)
Net loss	$ (8,185)	$ (2,536)
Less: Cumulative Series D preferred dividends	—	(194)
Net loss attributable to common stockholders	$ (8,185)	$ (2,730)
Net loss per share — basic and diluted	$ (0.74)	$ (1.54)
Weighted-average number of common shares used in computing net loss per share — basic and diluted	11,013,697	1,770,167

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

	March 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 75,626	$ 83,602
Other current assets	3,813	4,632
Total current assets	79,439	88,234
Total assets	$ 79,439	$ 88,234
Liabilities and Stockholders' Equity		
Current liabilities	$ 8,983	$ 12,038
Non-current liabilities	14,879	13,589
Total liabilities	23,862	25,627
Total stockholders' equity	55,577	62,607
Total liabilities and stockholders’ equity	$ 79,439	$ 88,234

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First-in-disease therapies for patients with rare genetic skin diseases

Q1 2025 Financial Results & Corporate Update
May 15, 2025

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, 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 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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Nasdaq MarketSite
+2.73
$25.50
PVLA
+1,067.87
42,317.25
+165.87
palvella
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Nasdaq
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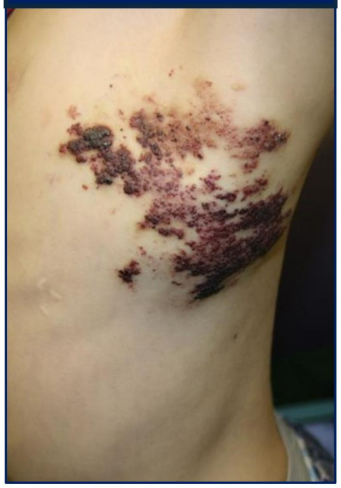
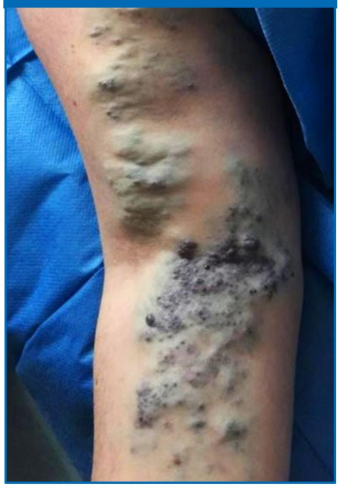
THERAPEUTICS
Photo credit: Nasdaq, Inc./ Vanja Savic.

Multiple High-Impact Milestones Over Next 4 Quarters

Phase 3 SELVA data in microcystic LMs (Q1:26)



Phase 2 TOIVA data in cutaneous VMs (Q4:25)



Additional mTOR-driven indication for QTORIN™ Rapamycin (2H:25)

New QTORIN™ Program (2H:25)

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. The safety or efficacy has not been established for any use.

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Continued Strong Momentum at Palvella

- **QTORIN™ rapamycin for microcystic LMs: Phase 3 SELVA trial**
  - Exceeded enrollment target of 40 patients; enrollment expected to close in June 2025
  - Top-line readout anticipated Q1 2026

- **Phase 2 TOIVA study on track in cutaneous VMs**
  - 6 sites open and enrolling
  - Top-line readout anticipated Q4 2025
- **Insights from SID Meeting and ISSVA Conference: support significant unmet need and attractive commercial opportunity in microcystic LMs**
- **Fortifying leadership team in anticipation of potential U.S. commercialization**
  - Hired Jason Burdette as SVP, CMC & Technical Operations (Jan 2025)
  - Chief Commercial Officer recruitment ongoing; planned hire in 2H 2025
- **Strengthening patent position: 5th U.S. patent issuance with claims into 2038**
  - Patents augmented by trade secrets and anticipated seven-year orphan exclusivity

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LMs: lymphatic malformations. VMs: venous malformations. SID: Society of Investigative Dermatology. ISSVA: International Society for the Study of Vascular Anomalies.

QTORIN™ 3.9% RAPAMYCIN

FOR

Microcystic Lymphatic Malformations

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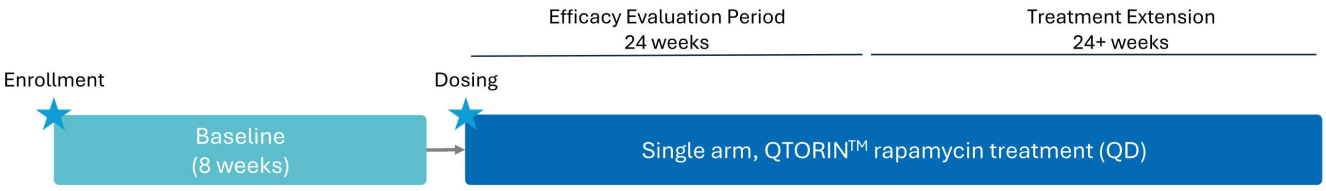
Phase 3 SELVA Enrollment Exceeded Target of 40 Patients

Single-arm, baseline-controlled, QD dose

Enrollment expected to close in June 2025; top-line readout anticipated Q1 2026

Joyce Teng, MD, PhD
Principal Investigator
Stanford MEDICINE

- Children's Hospital of Philadelphia (Sally Cohen-Cutler, MD)
- Cincinnati Children's (Kiersten Ricci, MD)
- Vanderbilt Health (Neeraja Swaminathan, MD)
- UNC Health (Elizabeth Nieman, MD)
- Cleveland Clinic (Mike Kelly, MD, PhD)
- Children's Healthcare of Atlanta (Michael White, MD)
- Mayo Clinic (Megha Tollefson, MD)
- Minnesota Clinical Study Center (Steve Kempers, MD)
- UCI (Maria Buethe, MD, PhD)
- Texas Children's Hospital (Ionela Iacobas, MD)
- Penn State Health (Andrea Zaenglein, MD)
- University of Utah Health (Amy Theos, MD)



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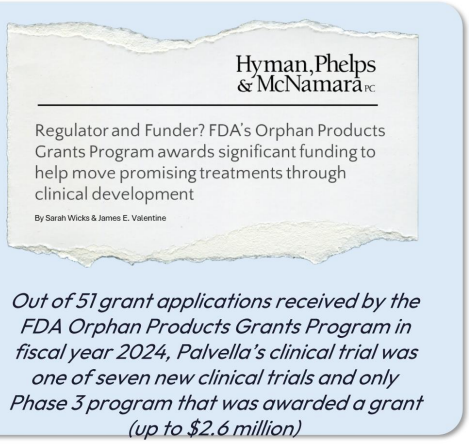
QTORIN™ Rapamycin for Treatment of mLMs: Regulatory Overview

Consistent and productive engagement with FDA on development program

- **FDA Overview:**
  - **Center:** Center for Drug Evaluation Research (CDER)
  - **Division:** Dermatology and Dentistry
  - **Division Leadership:** Dr. Jill Lindstrom remains in Director role
  - **NDA Review and Signature:** Due to planned 505(b)(2) pathway, division leadership is responsible for NDA decision

- **Palvella is anticipating expedited pathway to submission given Breakthrough, Fast Track and Orphan Drug Designations and 505(b)(2) pathway**



Out of 51 grant applications received by the FDA Orphan Products Grants Program in fiscal year 2024, Palvella's clinical trial was one of seven new clinical trials and only Phase 3 program that was awarded a grant (up to $2.6 million)

- **Other FDA dynamics for pipeline programs**
  - New potential accelerated pathway for rare and ultra rare disease drugs based on a "plausible mechanism" announced by Commissioner Makary

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. The safety or efficacy has not been established for any use.

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QTORIN™ Rapamycin for Treatment of mLMs: Commercial Opportunity

Est. Diagnosed U.S. Prevalence	Estimated U.S. Incidence	Concentration
> 44k	~1,500 annually or more	*~1/3 of patients treated at institutions with VACs (~150 centers)*

Orphan pricing anticipated

Prior first-in-disease launches and recent topical orphan launches both support orphan drug pricing

Multi-Billion Dollar Total Addressable Market (TAM) Currently With No FDA-Approved Therapies

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ISSVA Conference 2025: April 23rd-25th in Paris, France

- Treatment paradigm rapidly evolving to **targeted pharmacotherapy** approaches, replacing surgery and sclerotherapy
- **Off-label systemic agents, incl. oral PI3K inhibitors, introduce unacceptable side effects** (e.g., growth retardation) for diseases that locally present on the skin – significant unmet needs exist for targeted, topical therapies

Strong KOL support for QTORIN™ Rapamycin and other potential QTORIN™ programs

- **Identification of additional high unmet need clinical indications** that could be future disease targets for Palvella

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QTORIN™ 3.9% RAPAMYCIN

FOR

Cutaneous Venous Malformations

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Phase 2 TOIVA Study in cVMs: Enrollment Ongoing

Single-arm, baseline-controlled, QD dose, age 6+, 12 weeks, n=~15

6 sites open and enrolling, including 5 sites opened in last two months

Megha Tollefson, MD
Principal Investigator

Stanford MEDICINE (Joyce Teng, MD, PhD)

UNC HEALTH (Elizabeth Nieman, MD)

UCI (Maria Buethe, MD, PhD)

HEALTH UNIVERSITY OF UTAH (Amy Theos, MD)

MINNESOTA CLINICAL STUDY CENTER (Steve Kempers, MD)

Children's Hospital Colorado (Taizo Nakano, MD)

Safety
- Safety and tolerability

Efficacy
- Cutaneous venous malformation – investigators' global assessment (7-point clinician change scale)
- Cutaneous venous malformation - multicomponent static scale
- Other clinician and patient-reported outcomes

Topline data anticipated Q4 2025

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Key Value Drivers from Pipeline Programs in Second Half of 2025

Additional mTOR-driven indication for QTORIN™ Rapamycin (2H:25)

QTORIN™ rapamycin next indication

- Serious, rare, no FDA-approved therapies
- mTOR drives disease pathology
- Commercially attractive

New QTORIN™ program

- Serious, rare, no FDA-approved therapies
- Well-defined genetics
- Clear biology
- Commercially attractive
- Targeting <$10mm and <2.5 years to Phase 2 POC data

New QTORIN™ Program (2H:25)

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. The safety or efficacy has not been established for any use.

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Financial Update

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THERAPEUTICS

Q1 2025 Financial Highlights and 2025 Outlook

Strong Cash Position

2+ years
Runway into 2H 2027

$75.6 million
Cash at 3/31/2025

$7.9 million
R&D + G&A spend in Q1 2025

>$55 million
Projected cash at year end

Oversubscribed PIPE Financing (Dec. 2024)

BVF PARTNERS L.P.
FRAZIER LIFE SCIENCES
BLUE OWL
LIGAND
CAMCapital CAXTON ALTERNATIVE MANAGEMENT
PETRICHOR
SAMSARA BIOCAPITAL

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Q&A

Striving to be first for rare disease patients

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