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): **January 13, 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** (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 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 7.01 Regulation FD Disclosure.

On January 13, 2025, Palvella Therapeutics, Inc. (the "***Company***") posted a corporate presentation to its website, which representatives of the Company will use in various meetings with investors from time to time. A copy of the presentation is attached hereto as Exhibit 99.1, and incorporated herein by reference.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, 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, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, 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.	Document
99.1	Corporate Presentation of Palvella Therapeutics, Inc., dated January 13, 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: January 13, 2025

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

Exhibit 99.1


palvella
THERAPEUTICS
First-in-disease therapies for patients with rare genetic skin diseases
Corporate Presentation
January 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 customers and 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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Building the leading therapeutics company focused on
rare genetic skin diseases
Palvella debuted as a publicly listed company (NASDAQ:PVLA) in December 2024
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What Sets Palvella Apart: Building The Leader in Rare Genetic Skin Diseases

Late-stage Rare Disease Pipeline and QTORIN™ Platform

QTORIN™ rapamycin in two ongoing studies: Phase 3 (microcystic lymphatic malformations) and Phase 2 (cutaneous venous malformations), with additional QTORIN™ product candidates planned

QTORIN™ rapamycin: potential to be first approved therapy and standard of care in U.S. for microcystic LMs and cutaneous VMs

Both are serious, rare mTOR-driven genetic diseases currently with no FDA-approved therapies

Phase 3 designed for success & expedited regulatory pathway

Highly statistically significant Phase 2 results in microcystic LMs contributed to Breakthrough Therapy Designation, single arm baseline-controlled Phase 3 study, and FDA Orphan Product Grant

U.S. peak sales potential > $1bn in two uncontested indications

Microcystic LMs (estimated > 30k U.S. diagnosed patients) & Cutaneous Venous Malformations (estimated > 75k U.S. diagnosed patients), with orphan pricing anticipated

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Striving to be first for rare disease patients

Sources: Primary prospective research conducted by Clarity Pharma and Sentero Pharma, claims data, Gallagher et. al. (2022).

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Well-Capitalized Through Multiple Inflection Points with Funding from Syndicate of Leading Healthcare-Dedicated Investors

Palvella closed reverse merger in December 2024 and **debuted as publicly listed company** (NASDAQ:PVLA)

Funded with approximately **$78.9 million of cash** at close of reverse merger and concurrent PIPE financing

Cash expected to **fund through multiple key value driving events and into second half of 2027**, including through:

- Phase 2 TOIVA clinical trial in cutaneous VMs (Q4:25)
- Phase 3 SELVA clinical trial in microcystic LMs (Q1:26)
- Planned Rolling NDA Submission in microcystic LMs (Mid-2026)

Fully diluted **market cap of ~$200 million**[1]

Private Investors

BVF Partners L.P.
CAMCapital
Ligand
Petrichor Healthcare Capital Management
SAMSARA BIOCAPITAL

Select New PIPE Investors

FRAZIER LIFE SCIENCES
ADAR1 Capital Management
BLUE OWL
DAFNA Capital Management, LLC
NANTAHALA CAPITAL MANAGEMENT, LLC

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1. Based on closing price of $13.97 as of 1/10/25, 11.2 million of common shares outstanding, 2.5mm shares issuable upon exercise of pre-funded warrants, and dilutive impact utilizing treasury stock method from 1.7 million options outstanding with a weighted average exercise price of $11.60.

Building On Milestones Achieved in Q4:2024

to Drive Sustained Momentum in 2025 and Beyond

Notable Q4:24 Developments

- ☑ Initiated dosing in Phase 3 SELVA trial in microcystic LMs and Phase 2 TOIVA trial in cutaneous VMs
- ☑ Awarded FDA Orphan Products Grant up to $2.6mm to fund Phase 3 SELVA trial
- ☑ Phase 2 clinical trial results in microcystic LMs published in *Journal of Vascular Anomalies (JoVA)*
- ☑ Research analyst initiations including Cantor (Josh Schimmer) and H.C. Wainwright (Andrew Fein)

→

Potential 2025+ Catalysts

- ▷ Complete enrollment in Phase 3 SELVA and Phase 2 TOIVA trials
- ▷ Anticipated topline data readout from Phase 2 TOIVA trial in cutaneous VMs in Q4:25
- ▷ Anticipated data readout from Phase 3 SELVA trial in microcystic LMs in Q1:26
- ▷ Addition of potential new rare disease programs to development pipeline

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OUR LEAD PRODUCT CANDIDATE
QTORIN™ 3.9%
RAPAMYCIN
ANHYDROUS GEL
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Our Breakthrough Innovation:
QTORIN™ Platform

Reproducible platform for generation of novel topical product candidates for **rare diseases**...

Targeted Anhydrous Formulations

High payload capacity optimizes potential for therapeutic activity

Delivery to dermis with limited systemic absorption

Manufacturing

Applying established QTORIN manufacturing to additional novel product candidates

Potential Long Duration IP and Other Exclusivities

Each QTORIN™ product candidate eligible for composition IP on formulation

...leading to **First-in-Disease** Therapies

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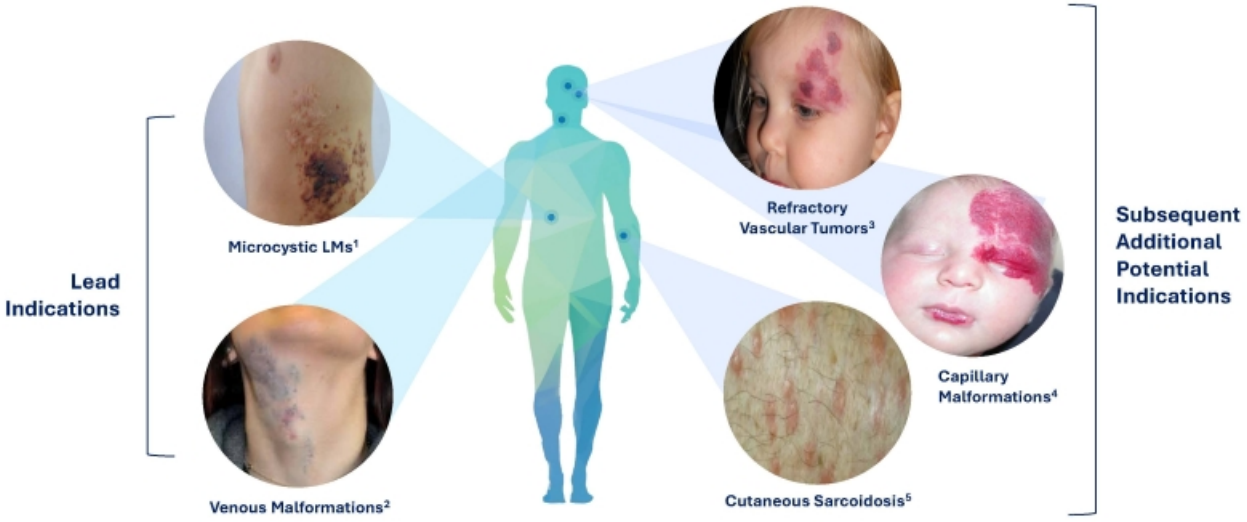
Broad Potential for mTOR Inhibition in Rare Skin Diseases

mTOR is a key driver for genetic skin diseases



1. Adams et. al., Pediatrics. (2016). 2. Seront et. al., JCI Insight. (2023). 3. Greenberger et. al., J Invest Dermatol. (2011). 4. Marqués et. al., J Am Acad Dermatol. (2015). 5. Redl et. al., Lancet Rheumatol. (2024).

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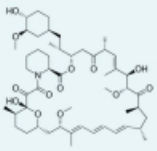
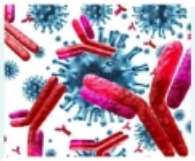
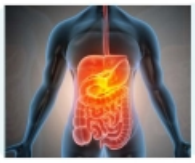
Systemic Rapamycin Limitations Restrict Use in Genetic Skin Diseases

Systemic Rapamycin

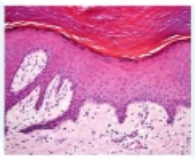




Strong immunosuppressive activity
poses significant risks to patients with localized cutaneous disease[1]



Systemic toxicities
including stomatitis, hypertriglyceridemia, hypercholesterolemia, GI distress, peripheral edema, anemia, urinary tract infection[1]



Poor biodistribution to and within the skin[2]

1. Rapamune package insert. 2. Data on file; Kitayama et al., Journal of Derm. Science (2019)

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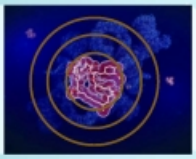
QTORIN™ 3.9% Rapamycin Anhydrous Gel

RAPAMYCIN

Direct mechanistic engagement of causal mTOR pathway

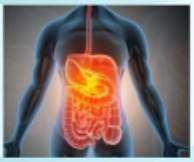


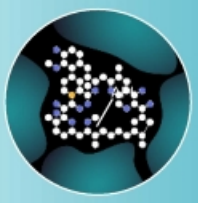
QTORIN™

1000x higher rapamycin levels at site of disease vs. systemic rapamycin[1]

TOPICAL

Limited-to-undetectable systemic absorption[2]





Granted U.S. patents through at least 2038

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.

1.Data on file.
2.Clinical Study Report PALV-0609.


QTORIN™ 3.9% RAPAMYCIN
FOR
Microcystic Lymphatic Malformations
palvella
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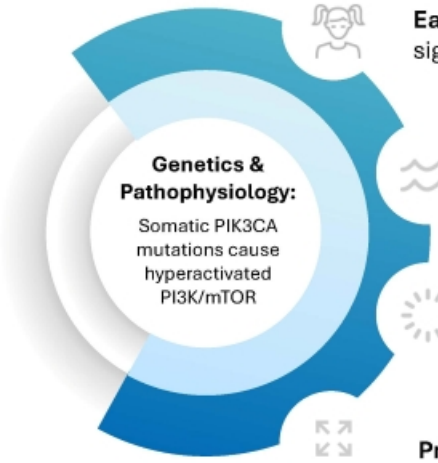
Microcystic Lymphatic Malformations: *Serious, Debilitating, and Lifelong*



Early onset: Present at birth and significant impact to adolescents

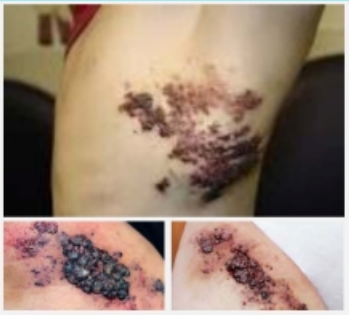
Lymphorrhea: Persistent discharge of lymphatic fluid through skin layers

Deep infections: Cellulitis and other serious infections

Proliferation of infiltrative lesions over time with no spontaneous resolution

> 30k patients

ESTIMATED DIAGNOSED IN THE US[1]



Leads to serious impact to quality of life and hospitalizations, with no FDA approved therapies

Current options: surgeries, sclerotherapy (chemotherapy injections), off label systemic pharmacotherapies limited by toxicities

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1. Gallagher et. al. (2022).

No Spontaneous Regression Well-Established in Microcystic LMs

PRS ORIGINAL ARTICLE
Reconstructive

Spontaneous Regression of Lymphangiomas in a Single Center Over 34 Years

A 34-year, 28-subject study confirmed no spontaneous regression

Types	Microcystic
Subtotal	28
Sex (F:M)	14:14
Age (y), mean ± SD	0.89±1.4
Maximum diameter (cm), mean ± SD	—
Spontaneous regression	
Positive	0
Negative	28

** Consistent with well-established history of PI3K Related Overgrowth Spectrum, which includes microcystic LM*
***Kato M et al., Plast Reconstr Surg Glob Open. 2017 Sep 25;5(9):e1501.*

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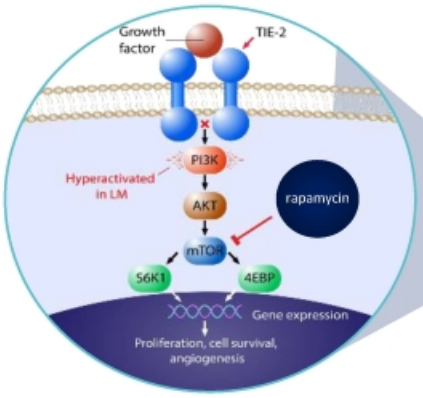
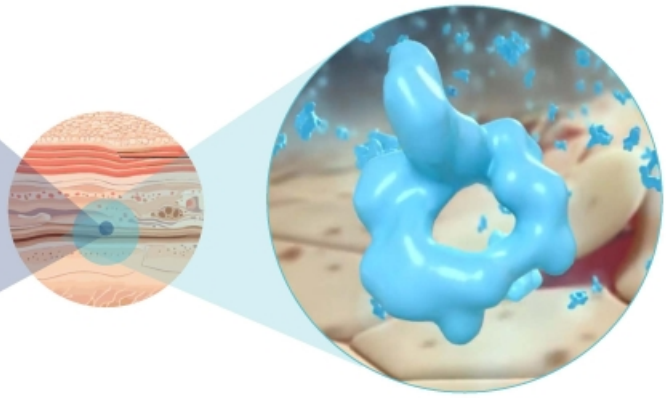
QTORIN™ Rapamycin: On Target, In Tissue

Target: mTOR



Tissue: Dermis



- Monogenic somatic mutations leads to overactivated PI3K/mTOR signaling
- QTORIN™ delivers pharmacologically active levels of rapamycin transepidermally to diseased tissue

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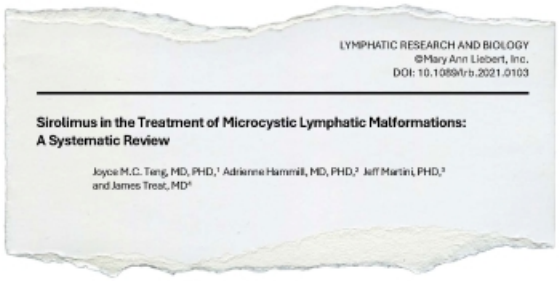
Real World Evidence and OUS Treatment Guidelines

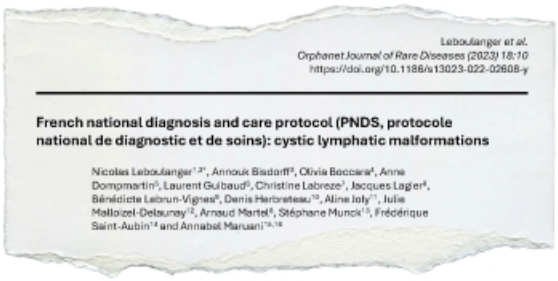


LYMPHATIC RESEARCH AND BIOLOGY
©Mary Ann Liebert, Inc.
DOI: 10.1089/lrb.2021.0103

Sirolimus in the Treatment of Microcystic Lymphatic Malformations: A Systematic Review

Joyce M.C. Teng, MD, PHD,[1] Adrienne Hammill, MD, PHD,[2] Jeff Martini, PHD,[3] and James Treat, MD[4]

"Micro LMs represent therapeutically challenging congenital vascular lesions. There is no universally accepted gold standard of care and there are no FDA approved therapies…this review examines clinical data over the last 10 years on the role of sirolimus [rapamycin]…a total of 16 studies were identified…clinically meaningful, long-term improvement (up to 3 years) was noted…however, developing a commercial topical sirolimus formulation faces important challenges."



Leboulanger et al.
Orphanet Journal of Rare Diseases (2023) 18:10
https://doi.org/10.1186/s13023-022-02608-y

French national diagnosis and care protocol (PNDS, protocole national de diagnostic et de soins): cystic lymphatic malformations

Nicolas Leboulanger[1,2*], Annouk Biadoriff[3], Olivia Boccara[4], Anne Dompmartin[5], Laurent Guibaud[6], Christine Labreze[7], Jacques Lagier[8], Bénédicte Lebrun-Vignes[9], Denis Herbreteau[10], Aline Joly[11], Julie Malloizel-Delaunay[12], Arnaud Martel[13], Stéphane Munck[15], Frédérique Saint-Aubin[14] and Annabel Maruani[16,17]

"Sirolimus [rapamycin] is the disease-modifying treatment of choice. It should be started early in life (early childhood) to prevent the increase in volume of the LM."

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QTORIN™ Rapamycin: Phase 2 Study in Microcystic LMs

n=12; QD dose

James Treat, M.D.

Joyce Teng, M.D., Ph.D.

Steve Kempers, M.D.

Milton Waner, M.D.

Alison Small, M.D.

Children's Hospital of Philadelphia

Stanford MEDICINE

Associated Skin Care Specialists

vascular birthmark institute

School of MEDICINE OHSU

Baseline (4 weeks) → Single arm, QTORIN™ rapamycin treatment (QD) (12 weeks)

Study Objectives: Safety and efficacy

Results

- Clinically & statistically significant on pre-specified global and individual endpoints
- Patient exit interviews and photographs align with clinical data

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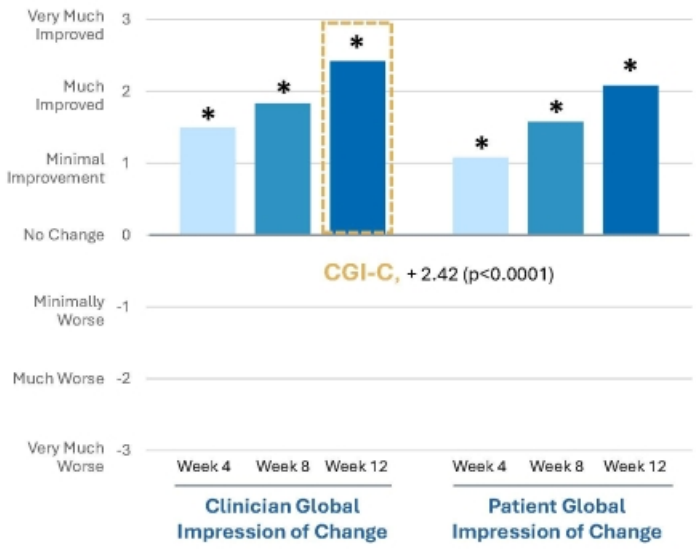
Phase 2: Clinically Meaningful, Statistically Significant Improvements



Individual Clinical Signs: Rapid Onset and Time Dependent Improvements

Statistically significant across key individual signs of microcystic LM at week 12

- Height (p<0.0001)
- Leaking (p<0.005)
- Bleeding (p<0.05)
- Erythema (p<0.005)
- Hyperkeratosis (p<0.005)

* = p-value <0.0001

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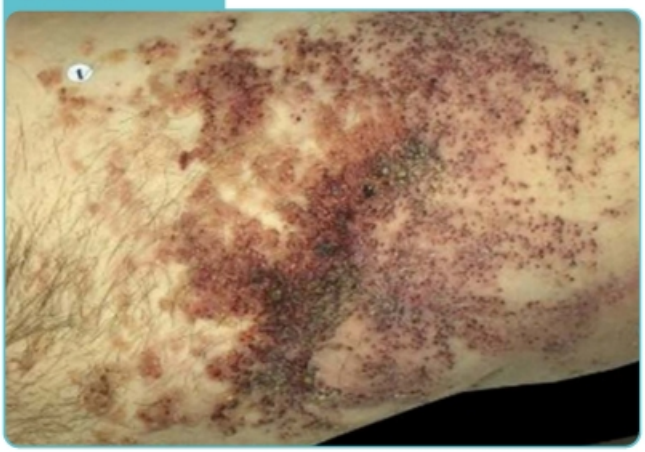
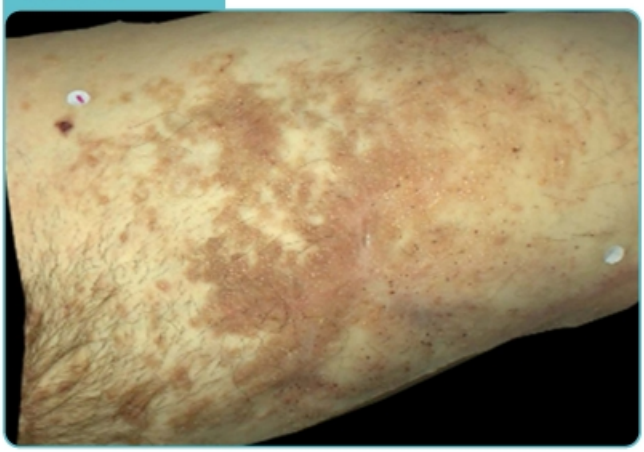
Phase 2 Results: Visible Improvement

Baseline



Week 12



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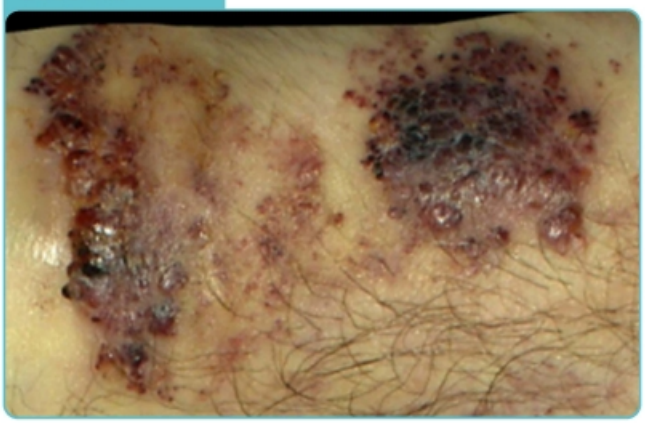
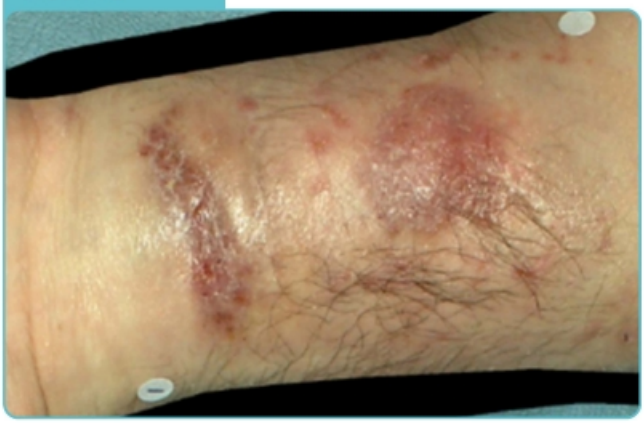
Phase 2 Results: Visible Improvement

Baseline



Week 12



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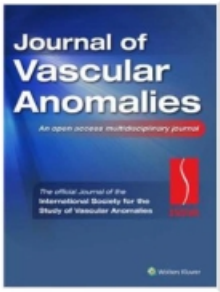
Microcystic Lymphatic Malformation: Phase 2 All Treatment-Related Adverse Events

Low blood levels of rapamycin detected in some patients: 120.98 pg/mL (mean)

TREATMENT RELATED AES	RELATED ANY GRADE EVENTS (%, N=12)
Application site pain	3 (25)
Application site pruritus	3 (25)
Application site discharge	1 (8.3)
Application site erythema	1 (8.3)
Application site paraesthesia	1 (8.3)
Nodule	1 (8.3)
Eczema	1 (8.3)
Skin exfoliation	1 (8.3)
Diarrhea	1 (8.3)
Headache	1 (8.3)

- QTORIN™ rapamycin had favorable safety profile and was well tolerated
- All Treatment Related Adverse Events were moderate or mild (no severe events)
- No discontinuations due to AEs
- No unexpected AEs

Phase 2 Study Results Published in *Journal of Vascular Anomalies (JoVA)*



Clinical Study (Prospective, Retrospective, Case Series)

OPEN

Journal of Vascular Anomalies
An open access multidisciplinary journal ISSVA

Phase 2 study of the safety and efficacy of QTORIN rapamycin in the treatment of microcystic lymphatic malformations

James Treat[a], Jeffrey Martin[b], Jason T. Connor[c], Alison Small[d], Tracy Funk[d], Milton Waner[e], Joyce Teng[f]

*"Efficacy from this phase 2 study showed a **robust clinical response** as measured from **both the clinicians' and patients' perspective**. All 12 patients in the study demonstrated clinical and statistical improvements across a variety of endpoints, including **remarkable visual improvement in disease symptoms** from photographs of microcystic LM lesions. In addition, patient exit interviews that assessed baseline disease severity and changes in disease severity after treatment confirmed the results from this study."*

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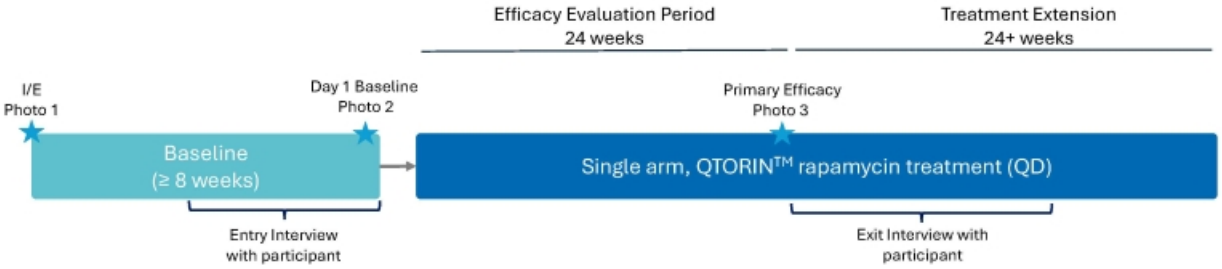
SELVA Phase 3 Study: Single-Arm, Baseline-Controlled

n=40; QD dose



Primary Efficacy

- mLM-IGA, a 7-point clinician change scale

Key Secondary

- Blinded mLM Multi-Component Static Scale (mLM- MCSS)

Data anticipated Q1 2026

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Phase 3 Pivotal Study Design Mimics Phase 2 Study

Phase 3 trial design based on statistical significance with n=12 in Phase 2

	Phase 2	Phase 3
Size	n=12	n=40 (for NDA safety database)
Noteworthy Efficacy Endpoints	CGI-C, a 7-point clinician change scale ($p<0.0001$)[1]	mLM-IGA, a 7-point clinician change scale (primary)[2]
Study duration	12 weeks	24 weeks
Baseline Controlled	✓	✓
QD Dosing	✓	✓
Moderate to severe study population	✓	✓

> 99% powered

1. CGI-C is a 7-point change scale ranging from –3 (very much worse) to +3 (very much improved)
2. mLM-IGA is 7-point change scale ranging from –3 (very much worse) to +3 (very much improved) that uses baseline photos as a required component for live clinician assessment of lesion change

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FDA Orphan Products Grant Recipient: Announced November 2024

Based on scientific and technical merit as determined by rare disease and regulatory experts

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

Hyman, Phelps & McNamara PC

Regulator and Funder? FDA's Orphan Products Grants Program awards significant funding to help move promising treatments through clinical development

By Sarah Wicks & James E. Valentine

- "We would not expect clinical trials to be funded if there was not a meaningful degree of alignment between the FDA review division on the trial design, particularly for later stage trials"
- "Receiving a Clinical Trials Grant provides insight that the FDA review team likely considered the proposed study as being capable of providing acceptable data that could contribute to product approval"
- "Relative to other areas of medicine (e.g., metabolism, neurology, oncology), there has not been the same focus by medical product developers on drugs for rare diseases in dermatology."

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Regulatory Overview: NDA Submission Planned for 2026[1]

Phase 3 study in microcystic LMs ongoing; data expected in Q1 2026

Seeking **full FDA approval** based on clinical endpoints utilized in prospective Phase 2 and Phase 3 studies

505(b)(2) pathway leveraging **prior FDA approvals of rapamycin**

Rolling NDA submission with potential for six-month priority review planned for 2026

- Breakthrough Therapy Designation
- Fast Track Designation
- Orphan Drug Designation

1. NDA submission planned if Phase 3 study is successful.

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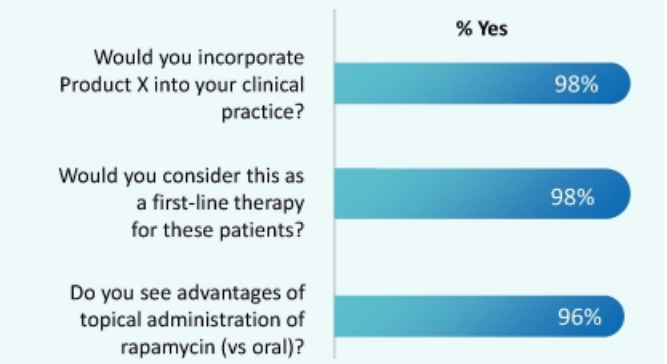
Market Research (May 2024): Strong Uptake in U.S. Anticipated

Product X: topical 3.9% rapamycin gel

Percent of my microcystic LM patients I would prescribe Product X:

75%



”

“It would be a first choice medical therapy”

“I believe patient acceptance would be great”

Survey of 52 high-volume dermatologists and hematologists (average of 11.7 cutaneous microcystic lymphatic malformation patients)

Source: May 2024, Medacorp.

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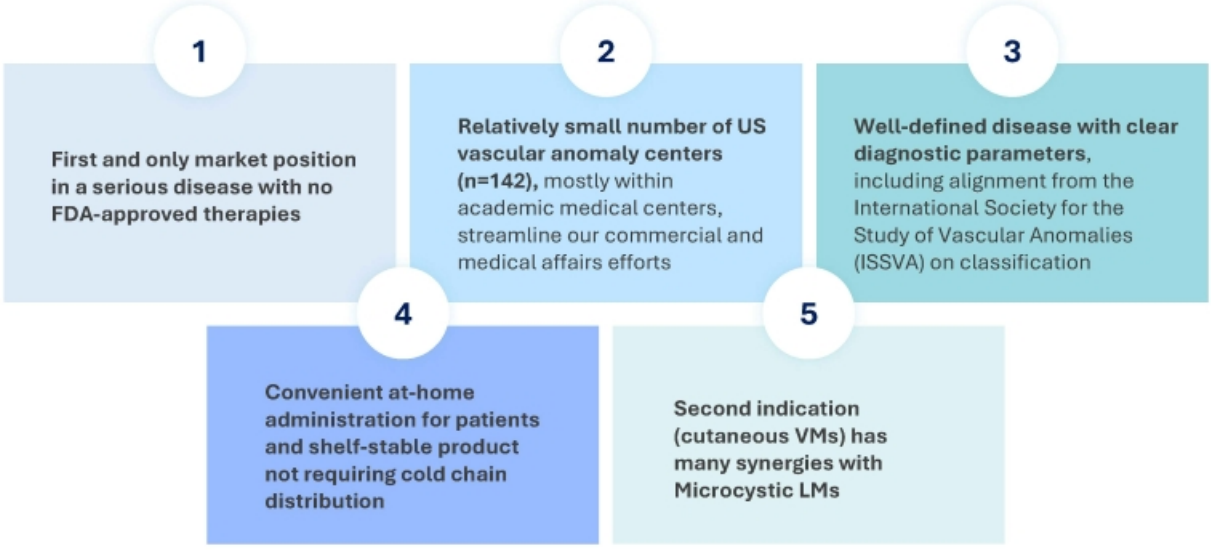
Favorable Market Dynamics Enable Potential for Self-Commercialization



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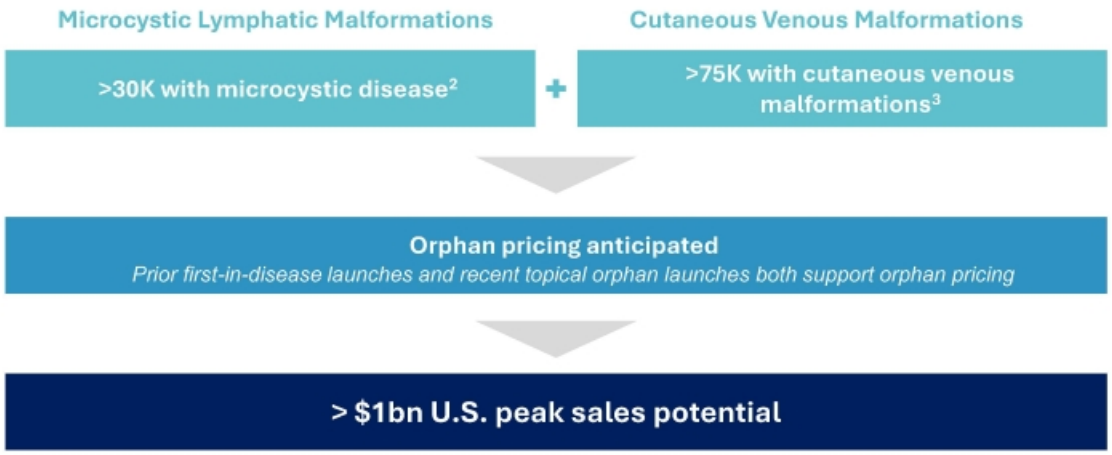
QTORIN™ Rapamycin: >$1bn Sales Potential in Five Years[1]

- **Claims data analysis confirms significant commercial opportunity in both diseases**



1. Primary prospective research conducted by Clarity Pharma and Sentero Pharma, claims analysis conducted by Trinity Research (June 2024).
2. Includes microcystic LM and mixed LM (patients with both microcystic and macrocystic disease).
3. Includes cutaneous only and mixed venous malformations.

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QTORIN™ 3.9% RAPAMYCIN
FOR
Cutaneous Venous Malformations
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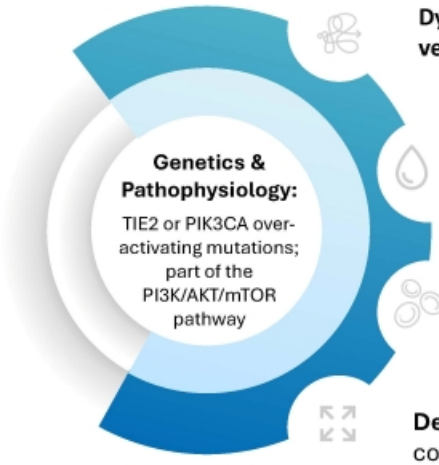
Cutaneous Venous Malformations: *Serious, High Unmet Need*



Dysregulated growth of malformed veins impacting the skin

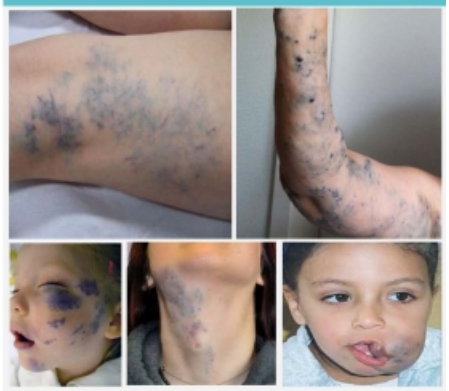
Hemorrhaging

Functional impairment

Deformity as lesions continue to grow

> 75k patients

ESTIMATED DIAGNOSED IN THE US[1]



Leads to physical & functional impairment, psychological distress, with no FDA approved therapies

Current options: laser treatment, off label systemic pharmacotherapies limited by toxicities

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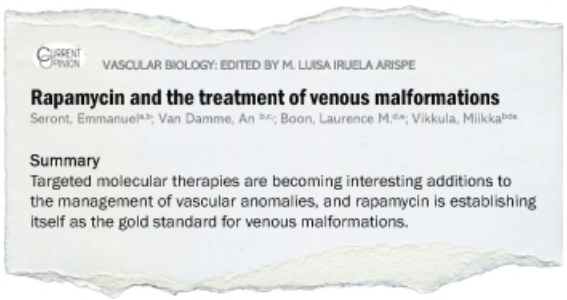
1. Primary prospective research conducted by Clarity Pharma.

Substantial Body of Research Supporting Rapamycin's Potential in VM Led to *FDA Fast Track Designation* for QTORIN™ Rapamycin



CURRENT OPINION VASCULAR BIOLOGY: EDITED BY M. LUISA IRUELA ARISPE

Rapamycin and the treatment of venous malformations

Seront, Emmanuel[a,b]; Van Damme, An [b,c]; Boon, Laurence M.[d,e]; Vikkula, Miikka[b,e]

Summary

Targeted molecular therapies are becoming interesting additions to the management of vascular anomalies, and rapamycin is establishing itself as the gold standard for venous malformations.

Summary Takeaways

1. **High potential of rapamycin**
   "Rapamycin is the first targeted therapy that improves considerably the QoL of these patients"

2. **Need for topical therapies**
   "Topical agents…could abolish the need for systemic treatments that have wider toxicity"

Current unmet need for targeted, localized therapy for Cutaneous Venous Malformations

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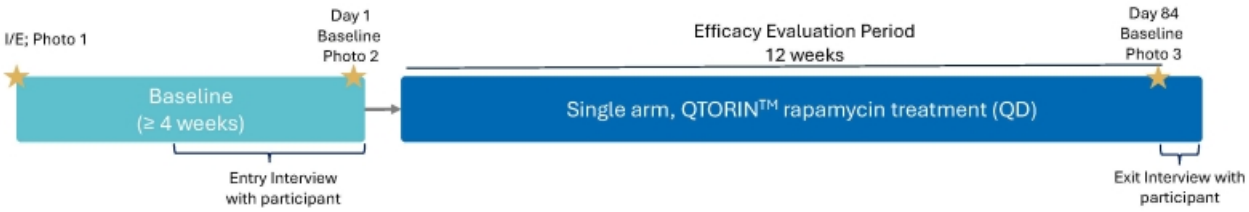
Cutaneous Venous Malformations Phase 2 Study

n=~15; QD dose



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

Data anticipated Q4 2025

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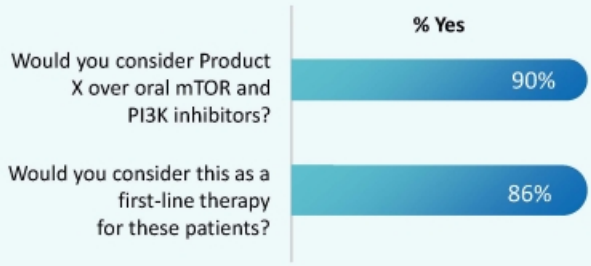
cVM Market Research (Sept 2024): Potential to be First Line Therapy

Product X: Topical 3.9% rapamycin gel

Percent of my cutaneous VM patients I would prescribe Product X:

61%



"This product would be life changing for current patients with limited treatment options"

"Patients deserve this novel treatment"

"Essentially all patients with VMs would be considered for Product X"

Survey of 50 high-volume dermatologists and hematologists with an average of 10.6 cutaneous VM patients seen per month

Source: Sept 2024, Medacorp.

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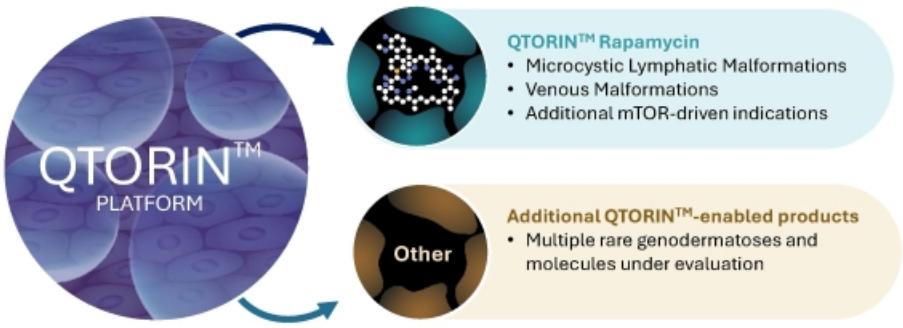
QTORIN™ Platform has Broad Potential Across Rare Dermatological Diseases

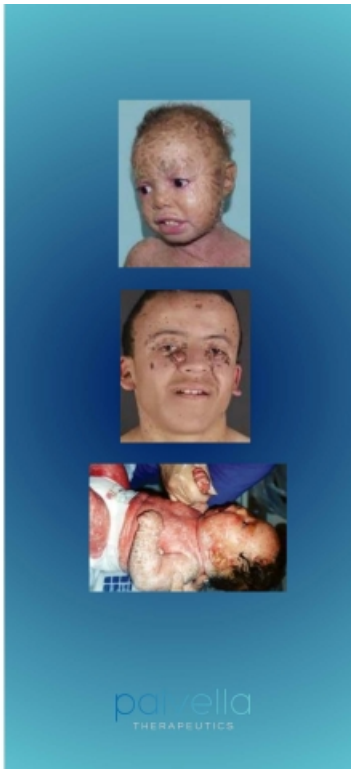


QTORIN™ Rapamycin
- Microcystic Lymphatic Malformations
- Venous Malformations
- Additional mTOR-driven indications

Additional QTORIN™-enabled products
- Multiple rare genodermatoses and molecules under evaluation

"We have begun to see interest from investors and companies in developing treatments for a rare disease such as epidermolysis bullosa, but there are many other diseases within dermatology that remain unaddressed"

John Doux, M.D., Barriers and Opportunities Across the Development Divide, *The Society of Investigative Dermatology*, 2015



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What Sets Palvella Apart: Building The Leader in Rare Genetic Skin Diseases

Late-stage Rare Disease Pipeline and QTORIN™ Platform

QTORIN™ rapamycin in two ongoing studies: Phase 3 (microcystic lymphatic malformations) and Phase 2 (cutaneous venous malformations), with additional QTORIN™ product candidates planned

QTORIN™ rapamycin: potential to be first approved therapy and standard of care in U.S. for microcystic LMs and cutaneous VMs

Both are serious, rare mTOR-driven genetic diseases currently with no FDA-approved therapies

Phase 3 designed for success & expedited regulatory pathway

Highly statistically significant Phase 2 results in microcystic LMs contributed to Breakthrough Therapy Designation, single arm baseline-controlled Phase 3 study, and FDA Orphan Product Grant

U.S. peak sales potential > $1bn in two uncontested indications

Microcystic LMs (estimated > 30k U.S. diagnosed patients) & Cutaneous Venous Malformations (estimated > 75k U.S. diagnosed patients), with orphan pricing anticipated

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Striving to be first for rare disease patients

Sources: Primary prospective research conducted by Clarity Pharma and Sentero Pharma, claims data, Gallagher et. al. (2022).

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Thank You
Striving to be first for rare disease patients
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Palvella Senior Leadership Team

President and CEO
Wes Kaupinen

Chief Financial Officer
Matthew E. Korenberg

Chief Scientific Officer
Jeff Martini, Ph.D.

Chief Operating Officer
Kathy Goin

Chief Technical Officer
Braham Shroot, Ph.D.

SVP of Clinical Operations
Emily Cook

VP of Regulatory Affairs
Christine Kampf

VP of Corporate Development and New Product Planning
Bohan Wei