

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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **October 14, 2025**

PELTHOS THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada (State or other jurisdiction of incorporation)	001-41964 (Commission File Number)	86-3335449 (IRS Employer Identification No.)
4020 Stirrup Creek Drive, Suite 110 Durham, NC (Address of registrant's principal executive office)		27703 (Zip code)

Registrant's telephone number, including area code: **(919) 908-2400**

(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 (see General Instruction A.2. below):

- ☐ 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, par value \$0.0001 per share	PTHS	The NYSE American LLC

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 October 14, 2025, Pelthos Therapeutics Inc. (the “Company”) made available a presentation on its website. A copy of the presentation is attached hereto as Exhibit 99.1. Information contained on the Company’s website is not incorporated by reference into and should not be considered to be part of this Current Report on Form 8-K.

The information contained in this Item 7.01, including Exhibit 99.1 attached hereto, which is incorporated into this Item 7.01 by reference, is being 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. The information set forth in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is required to be disclosed solely to satisfy the requirements of Regulation FD.

Forward-Looking Statements

Exhibit 99.1 attached hereto contains, and may indicate, forward-looking statements within the meaning of Section 27A of the Securities Act, Section 21E of the Exchange Act and as defined in the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements that express the Company’s intentions, beliefs, expectations, strategies, predictions or any other statements related to the Company’s future activities, or future events or conditions, including without limitation, those statements relating to the success of the launch for Zeslumi, timing, progress and results of any preclinical and clinical trials, its estimates regarding the potential market opportunity for Zeslumi, its ability to develop its pipeline, its ability to protect its intellectual property and enforce its intellectual property rights, and its ability to execute its development strategy and sustain its competitive position. Actual future results and trends may differ materially depending on a variety of factors, including, but not limited to, the Company’s limited operating history, the Company’s ability to establish its market development capabilities to commercialize its products and generate any revenue, and the Company’s ability to maintain regulatory approval of Zeslumi, which can be identified by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would” and other similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are not historical facts and are based on current expectations, estimates and projections about the Company’s business based, in part, on assumptions made by its management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict, many of which are beyond the Company’s control. Any forward-looking statements speak only as of the date on which they are made, and the Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date of this Form 8-K, except as required by applicable law.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
<u>99.1</u>	<u>Company Presentation</u>

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, thereunto duly authorized.

Pelthos Therapeutics Inc.

Date: October 14, 2025

By: /s/ Francis Knuettel II

Name: Francis Knuettel II

Title: Chief Financial Officer



Legal Disclaimer

This presentation of Pelthos Therapeutics Inc. ("we", "us", "our" or the "Company") contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act and other securities laws. Words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would" or similar expressions and the negatives of those term are intended to identify forward-looking statements. Forward-looking statements reflect management's current expectations, are based on judgments and assumptions, are inherently uncertain and are subject to risks, uncertainties and other factors, which could cause the Company's actual results, performance or achievements to differ materially from expected future results, performance or achievements expressed or implied in those forward-looking statements. Examples of these forward-looking statements and the related risks, uncertainties and other factors include, but are not limited to, the following: the success of the launch for Zelsuvmi, timing, progress and results of any preclinical and clinical trials, its estimates regarding the potential market opportunity for Zelsuvmi, its ability to develop its pipeline, its ability to protect its intellectual property and enforce its intellectual property rights, and its ability to execute its development strategy and sustain its competitive position. Actual future results and trends may differ materially depending on a variety of factors, including, but not limited to, the Company's limited operating history, the Company's ability to establish its market development capabilities to commercialize its products and generate any revenue, and the Company's ability to maintain regulatory approval of Zelsuvmi.

Forward-looking statements are provided to allow potential investors the opportunity to understand management's beliefs and opinions in respect of the future so that they may use such beliefs and opinions as one factor in evaluating an investment. These statements are not guarantees of future performance and undue reliance should not be placed on them. Any forward-looking statement in this presentation, in any related presentation supplement and in any related free writing presentation reflects our current view with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our business, results of operations, industry and future growth. You should read this presentation with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Corporate Profile

Pelthos Therapeutics is a bio-pharmaceutical company committed to commercializing innovative, safe, and efficacious therapeutic products to help patients with unmet treatment burdens

- **Commercial launch** of first drug Zelsuvmi, for the treatment of *Molluscum contagiosum* ("MC") in July 2025
- First and only at home treatment for a large, underserved market treating contagious viral disease
 - ❖ 16.7 million affected people
 - ❖ Up to 6 million annual cases in the U.S.
 - ❖ Total addressable market worth in excess of \$20 billion at our WAC
- Experienced management team with over 20 successful prior drug launches and continued growth, including Cosentyx, Otezla, Ohtuvayre, Xifaxan
- Upside option on NaV pain programs from predecessor
- Current peak Net Revenue forecast of \$175M per annum by 2028 and currently meeting or exceeding internal milestones

Key Data Points (as of 10/10/25, except where noted)	
Ticker	PTHS
Stock Price	\$23.26
O/S Shares of Common Stock (on an as converted basis)*	8.8M
Market CAP	~\$205M
Avg. Daily Trading Volume	31,100 shares (NYSE)
Cash at close of merger	\$27.5M
Investment to date	>\$400M

Management Team



Scott Plesha | Chief Executive Officer

- >30 years of experience in the pharmaceutical industry, including two decades building and leading specialty pharma commercial efforts
- President and Chief Commercial Officer at BDSI until it was acquired by Collegium Pharmaceutical in 2022
- Grew BDSI sales from \$5 million to \$160 million
- Previously served as Senior Vice President of Gastrointestinal Sales at Salix Pharmaceuticals. During fifteen-year tenure at Salix, led nationwide salesforce that grew product sales to more than \$1.5 billion annually
- Earned a BA in Pre-Medicine and Pre-Medical Studies at DePauw University and pursued graduate studies in Dentistry at Indiana University Dental School



Frank Knuettel | Chief Financial Officer

- 30 years of management experience in growing early-stage companies
- Raised more than \$400 million via venture, public equity and debt offerings and managed more than 15 mergers and acquisition transactions along with large-scale licensing transactions with fortune 50 companies
- Holds numerous board positions, at both public and private companies, including Ethers Pharmaceuticals
- Earned an MBA from The Wharton School and a BA from Tufts University



Sai Rangarao | Chief Commercial Officer

- >18 years of experience leading, launching, and marketing pharmaceutical products
- VP of Marketing & Head of Neurology Sales at Collegium Pharmaceutical
- VP of Marketing & Commercial Operations at BDSI, until it was acquired by Collegium in 2022
- Head of US Dermatology Marketing for Otezla at Celgene leading to acquisition by Amgen for \$13 Billion
- Member of the commercial and marketing organization at Novartis Pharmaceuticals that launched COSENTYX® in the U.S
- Earned an MS in Bioscience Regulatory Affairs from The Johns Hopkins University, an MBA and MS from the New Jersey Institute of Technology, and a BS in Computer Science from Indiana University of Pennsylvania

Board of Directors



Peter Greenleaf, Chairman



Richard Baxter



Todd Davis



Ezra Friedberg



Richard Malamut, MD



Matt Pauls



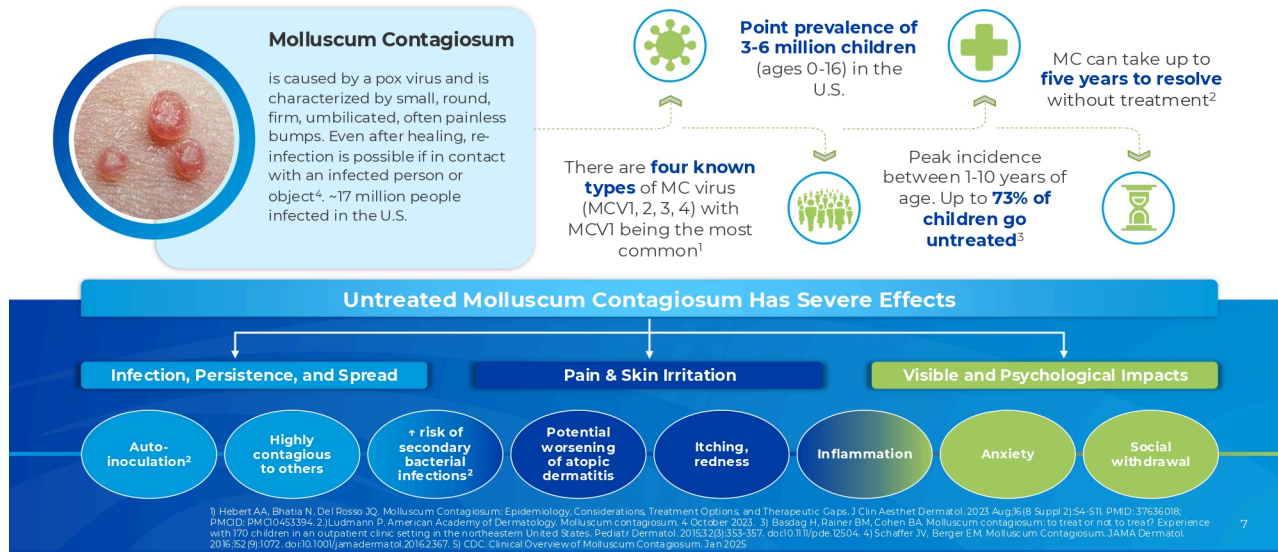
Scott Plesha



Molluscum & Zelsuvmi Overview

Molluscum Contagiosum

A highly infectious viral condition primarily affecting children 1 year of age or older



Zelsuvmi™ Has the Potential to Shift MC Treatment Paradigm

Current Options



- Other available topical treatment **requires in-office visits every 3 weeks²**



- **Painful, destructive** treatments³



- Necessitates travel to HCP offices, adding to the **time burden for MC patients and caregivers²**



- Remaining treatment options such as off-label drugs / natural remedies have **unproven efficacy⁴**

Zelsuvmi™
(berdazimer) topical gel, 10.3%

**Breakthrough Product,
Breakthrough Results**

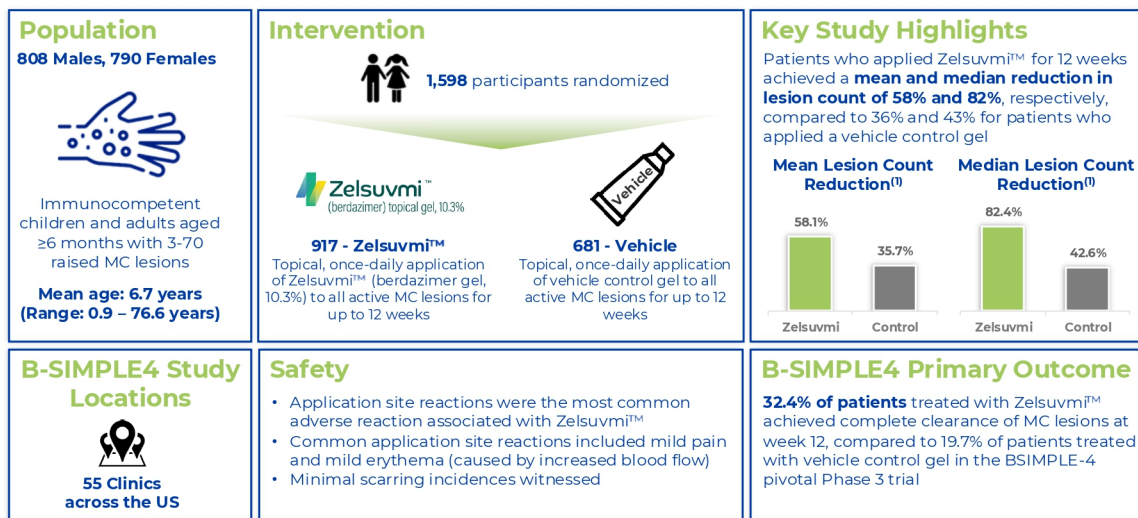
58.1%
Mean MC Lesion
reduction count¹⁾

Zelsuvmi™

- **Daily** application that can be **started immediately**
- **Attractive safety profile** demonstrated in clinical trials with no / minimal scarring^{5,6}
- **First FDA approved medication** for molluscum that can be applied at home by patients or caregivers⁵
- **Demonstrated, proven efficacy** across key primary and secondary endpoints in clinical trials⁶

1) Least-squares mean count reduction. See Figure 9. Browning JC, Hebert A, Enloe C, Cartwright M, Maeda-Chubachi T. Berdazimer Gel 10.3% is a Clinically Meaningful Therapeutic Intervention for Molluscum Contagiosum. Abstract and poster presented at Fall Clinical 2024, Las Vegas, NV, October 24-27, 2024. 2) Eichenfield LF, Kwong P, Gonzalez ME, et al. Safety and Efficacy of VD-102 (Cantharidin, 0.7% w/v) in Molluscum Contagiosum by Body Region: Post hoc Pooled Analyses from Two Phase III Randomized Trials. J Clin Aesthet Dermatol. 2021;4(10):42-47. 3) Hebert AA, Bhatta N, Del Rosso JQ. Molluscum Contagiosum: Epidemiology, Considerations, Treatment Options, and Therapeutic Gaps. J Clin Aesthet Dermatol. 2023;16(8 Suppl 1):S4-S11. 4) Ong SK, Hoff I, Sieghart E. Analysis of over-the-counter products marketed to treat molluscum contagiosum. Pediatr Dermatol. 2021;38(5):1400-1403. doi:10.1111/pde.14776. 5) Zelsuvmi Package Insert. 6) Sugarman JL, Hebert A, Browning JC, et al. Berdazimer gel for molluscum contagiosum: An integrated analysis of 3 randomized controlled trials. J Am Acad Dermatol. 2024;90(2):299-308. doi:10.1016/j.jaad.2023.09.066. Ong

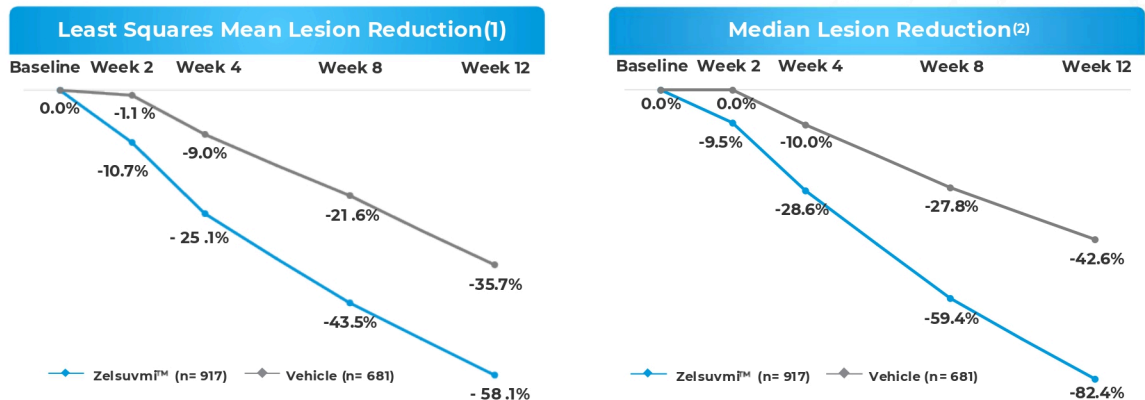
Zelsuvmi™ Efficacy Shown in Phase 3 Clinical Trials Drives Commercial Launch



⁽¹⁾ p-value <0.0001, favoring Zelsuvmi™.
Source: Sugarman JL, Hebert A, Browning JC, Paller AS, Stripling S, Green LJ, Cartwright M, Enloe C, Wells N, Maeda-Chubachi T. Berdazimer gel for molluscum contagiosum: An integrated analysis of 3 randomized controlled trials. J Am Acad Dermatol. 2023 Oct 5;90(9):9622(23):02890-6. doi: 10.1016/j.jaad.2023.09.066.Epub ahead of print. PMID: 37804936.

Phase 3 Trial Results

Zelsuvmi™ showed statistically significant benefit vs. vehicle after 2 weeks of therapy and through out the entire 12-week length of the Phase 3 studies



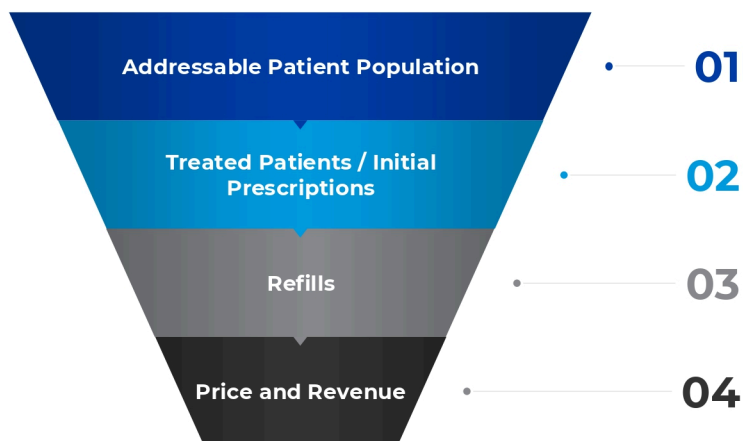
P<0.0001 at all time points, favoring Zelsuvmi™

1) Figure 9: Browning JC, Hebert A, Enloe C, Cartwright M, Maeda-Chubachi T. Berdazimer Gel 10.3% is a Clinically Meaningful Therapeutic Intervention for Molluscum Contagiosum. Abstract and poster presented at Fall Clinical 2024, Las Vegas, NV, October 24-27, 2024. 2) Figure 10: Browning JC, Hebert A, Enloe C, Cartwright M, Maeda-Chubachi T. Berdazimer Gel 10.3% is a Clinically Meaningful Therapeutic Intervention for Molluscum Contagiosum. Abstract and poster presented at Fall Clinical 2024, Las Vegas, NV, October 24-27, 2024.

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Zelsuvmi Commercial Overview

Activating Key Leverage Points Is Essential to Maximize the Commercial Potential of Zelsuvmi™



Key Leverage Points

Up to 6 million new cases each year with an average untreated resolution time of 13 months, during which disease is highly contagious

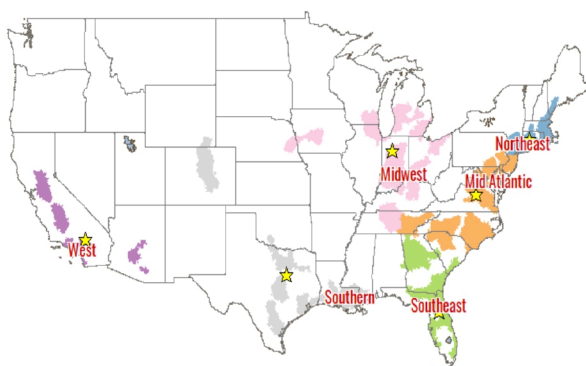
Treated patients respond well to Zelsuvmi and experience dramatic reduction in lesion count and mean time to resolution

FDA approved for 12-week treatment regimen, but internal forecasts assume lower

WAC of \$1,950 per unit. Disclosed peak net revenues of \$175M per annum by 2028

Commercial Launch Overview

Sales Force of 50 Territory Managers Reaching Highest Molluscum Treaters



NORTHEAST		MID ATLANTIC		SOUTHEAST	
1.	Boston North, MA	1.	Toms River, NJ	1.	Atlanta North, GA
2.	Boston South, MA	2.	Philadelphia, PA	2.	Atlanta South, GA
3.	Providence, RI	3.	Baltimore, MD	3.	Jacksonville, FL
4.	Hartford, CT	4.	Washington, D.C	4.	Fort Lauderdale, FL
5.	Long Island, NY	5.	Richmond, VA	5.	Orlando, FL
6.	Brooklyn, NY	6.	Raleigh, NC	6.	West Palm Beach, FL
7.	New York, NY	7.	Charlotte, NC	7.	Tampa, FL
8.	Summit, NJ	8.	Knoxville, TN	8.	Miami, FL
9.	Spring Valley, NY				

MIDWEST		SOUTHERN		WEST	
1.	Chicago North, IL	1.	New Orleans, LA	1.	Phoenix North, AZ
2.	Chicago South, IL	2.	Houston North, TX	2.	Phoenix South, AZ
3.	Indianapolis, IN	3.	Houston South, TX	3.	San Bernardino, CA
4.	Grand Rapids, MI	4.	Fort Worth, TX	4.	Santa Ana, CA
5.	Detroit, MI	5.	Dallas, TX	5.	Los Angeles South, CA
6.	Cleveland, OH	6.	Austin, TX	6.	Los Angeles North, CA
7.	Cincinnati, OH	7.	San Antonio, TX	7.	Visalia, CA
8.	Omaha, NE	8.	Denver, CO	8.	Sacramento, CA
9.	Nashville, TN				

Fully built out commercial team:
Territory managers supported by Sales Training, Marketing,
Commercial Operations & Market Access teams

Zelsuvmi Tactical Launch Approach

Driving Awareness and Adoption

Health Care Providers Education



KOL Education



Live & Virtual
Educational Speaker
Development



National & Regional
Conference Presence



Now Available Congress
Booth & Virtual Booth



CRM Platform: Education &
Communication



MD ZELSUVMI
Experience Videos

Consumer/Patient Education & Awareness



How to Start & Use
Infographic Brochure



Banner Ads, Native &
Paid Search



Now Available Website with
Patient-Specific Education



Advocacy & Partnerships



Patient CRM Platform



Social Media



ZELSUVMI GO
Patient Support Program

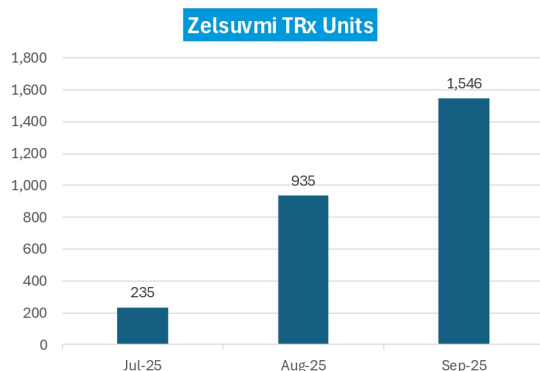


Telehealth

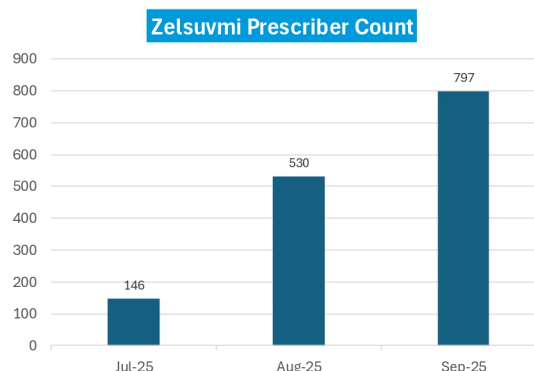


Patient Testimonial Videos

Strong Uptake of Zelsuvmi in Early Launch Phase



**Total of 2,716 Prescribed Units
During Q3 2025**

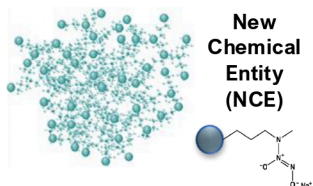


**Total of 1,169 Unique Prescribers
During Q3 2025**

Nitricil™ Platform & NaV1.7 Pipeline Overview

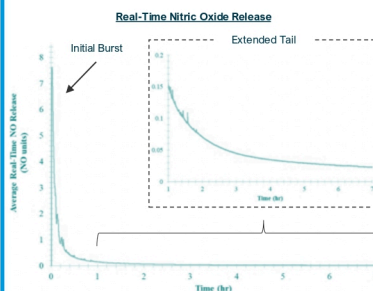
Macromolecular platform to achieve stable, tunable and druggable delivery of nitric oxide

Stable



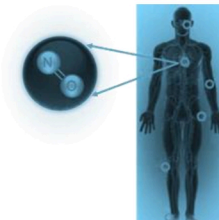
Proprietary platform enabling development of NCEs with sustained delivery of nitric oxide

Tunable



**Proprietary formulations,
targeted to each indication,
enable tunable dosing**

Druggable



Multiple drug candidates with unique nitric oxide delivery and proven target engagement








Nitricil Platform Pipeline

Asset Description	Asset Description	Approx Time to NDA Filing	Market Potential
SB204 (Acne)	Berdazimer topical gel, 3.4% for treatment of acne vulgaris. Phase 3 Clinical stage.	4.5 years	\$\$\$
SB414 (AD/Psoriasis)	Berdazimer topical cream, dose TBD, for treatment of mild to moderate atopic dermatitis. Phase 1/2 Clinical stage.	7.5 years	\$\$\$ (AD) \$\$ (Psoriasis)
SB208 (Tinea Pedis -> Onychomycosis)	Low alcohol berdazimer topical gel for treatment of athlete's foot with label expansion for onychomycosis following initial approval. Phase 2/3 Clinical stage.	5 years (T. Pedis) 6.5 years (Onychomycosis)	\$\$\$\$
SB208 (Tinea Pedis + Onychomycosis)	Low alcohol berdazimer topical gel for treatment of both athlete's foot and onychomycosis. Phase 2/3 Clinical stage.	6.5 years	\$\$\$\$
SB207 (EGW/PAW)	Berdazimer topical gel, 10.3% for treatment of external genital and perianal warts. Same active gel (Tube A) as Zelsuvmi but different hydrogel (Tube B) formulation. Phase 3 clinical stage.	6.5 years	\$

NaV1.7 Pipeline

Product/ Indication	Asset Description	Approximate Time to NDA Filing	Market Potential
CT2000 Eye Drops Chronic Ocular Pain	CC8464 1%, 1.25% and 1.5% ophthalmic solution Phase 1-2a ready	3-4 years	\$8 billion globally
CT2000 Eye Drops Acute Ocular Pain	CC8464 1%, 1.25% and 1.5% ophthalmic solution Phase 1-2a ready	2-3 years	\$400 million globally
CT3000 depot Nerve Blocks	CC8464 5% and 10% depot injectable Preclinical Stage	5+ years	\$300-570 million globally
CC8464 Oral Erythromelalgia	CC8464 melt-granulation capsules 50mg, 100mg, 400mg Phase 1 stage	5+ years	\$2.4 billion globally
CC8464 Oral Small Fibre Neuropathy	CC8464 melt-granulation capsules 50mg, 100mg, 400mg Preclinical stage	5+ years	\$50 million – 100 million
CC8464 Oral Acute Pain	CC8464 melt-granulation capsules 50mg, 100mg, 400mg Preclinical stage	5+ years	\$20 billion globally

Key Highlights

	Commercially Launched	Zelsuvmi™ was FDA approved in January 2024, and commercially launched in July 2025 as the first and only at-home treatment aimed to revolutionize how MC is treated today for patients ≥ 1 year old
	Significant Unmet Need and Sizeable Market Opportunity	Large market potential, with up to 6M new cases annually. Treatment of new cases alone has a total addressable market potential of over \$20 billion
	Zelsuvmi™ Differentiated Characteristics	Zelsuvmi™ is a topical gel that uses proprietary nitric oxide release technology and is applied once daily at-home with very good safety profile; opportunity to replace and complement current approved treatment options that are painful and require in-person visits
	Strong, Proven Clinical Efficacy	In the combined results from the three Phase 3 clinical trials, patients who applied Zelsuvmi™ for 12 weeks achieved a mean and median reduction in lesion count of 58% and 82%, respectively, compared to 36% and 43% for patients who applied a vehicle control gel
	Barriers to Entry	Pelthos' bespoke manufacturing processes require a dedicated line and manufacturing of API under extremely high pressures with stringent safety protocols and procedures; robust set of FDA Orange Book listed patents
	Biopharmaceutical Platform Poised for Growth	Pelthos is strategically positioned to execute and integrate complex, synergistic acquisitions, serving as a platform for investors seeking a strong foothold in the specialty biopharmaceutical market
	Financial Opportunity	Retained Channel Therapeutics' pipeline of several Nav1.7 programs following business combination, providing further upside optionality. Currently exploring best monetization strategies.



Thank You



Contacts

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