

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): February 13, 2026

VYOME HOLDINGS, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation)

1-37897  
(Commission File Number)

26-1828101  
(I.R.S. Employer  
Identification Number)

Harvard Square, One Mifflin Place, Suite 400  
Cambridge, MA  
(Address of principal executive offices)

02138  
(Zip Code)

(949) 429-6680  
(Registrant's telephone number, including area code)

Not applicable  
(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 Class                            | Trading Symbol | Name of Exchange on which Registered |
|-------------------------------------------|----------------|--------------------------------------|
| Common stock, \$0.001 par value per share | HIND           | 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.**

Representatives of Vyome Holdings, Inc. (the “Company”) intend to make presentations at investor conferences and in other forums, and these presentations may include the information contained in Exhibit 99.1 attached to this Current Report on Form 8-K. A copy of the presentation materials containing such information that may be disclosed by the Company is attached as Exhibit 99.1 to this report, and the information set forth therein is incorporated herein by reference and constitutes a part of this report.

The Company is furnishing the information contained in Exhibit 99.1 pursuant to Regulation FD and Item 7.01 of Form 8-K promulgated by the Securities and Exchange Commission (“SEC”). This information shall not be deemed to be “filed” with the SEC for the 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 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.

The information contained in Exhibit 99.1 is summary information that is intended to be considered in the context of the Company’s SEC filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in Exhibit 99.1, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. By filing this report and furnishing this information, the Company makes no admission as to the materiality of any information contained in this report, including Exhibit 99.1.

## **Forward-Looking Statements**

Certain statements made in this filing are “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words such as “target,” “believe,” “expect,” “will,” “shall,” “may,” “anticipate,” “estimate,” “would,” “positioned,” “future,” “forecast,” “intend,” “plan,” “project,” “outlook”, and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Such statements, include, but are not limited to, statements contained in this filing relating to the Company’s development of its drug candidates, including the timing of its clinical trials and regulatory submissions, the Company’s business strategy, the Company’s future operating results and liquidity and capital resources outlook, the total addressable pharmacologic market in the United States for malignant fungating wounds, and the estimated peak annual net sales for VT-1953. Forward-looking statements are based on the Company’s current expectations and assumptions regarding the Company’s business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. The Company’s actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. The Company cautions you, therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, the Company’s ability to raise capital to fund continuing operations; our ability to protect the Company’s intellectual property rights; the impact of any infringement actions or other litigation brought against the Company; competition from other providers and products; the Company’s ability to develop and commercialize products and services, including VT-1953; changes in government regulation; the Company’s ability to complete capital raising transactions; and other factors relating to the Company’s industry, operations and results of operations. Actual results may differ significantly from those anticipated, believed, estimated, expected, intended, or planned. Factors or events that could cause the Company’s actual results to differ may emerge from time to time, and it is not possible for the Company to predict all of them. the Company cannot guarantee future results, levels of activity, performance, or achievements. The Company assumes no obligation to update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this release, except as may be required under applicable securities law.

## **Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description                                                                 |
|-------------|-----------------------------------------------------------------------------|
| 99.1        | <a href="#">VT-1953 Phase 2 Data Presentation (furnished herewith)</a>      |
| 104         | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

## SIGNATURES

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

### RESHAPE LIFESCIENCES INC.

By: /s/ Venkat Nelabhotla  
Venkat Nelabhotla  
President & Chief Executive Officer

Dated: February 13, 2026



# VT-1953 in Treating Symptoms of Malignant Fungating Wounds (MFW)

PHASE 2 IST STUDY RESULTS & NEXT STEPS

# VYOME HOLDINGS, INC. (“Vyome”)

Any statements contained in this presentation that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Vyome’s current beliefs and expectations. These forward-looking statements include expectations regarding Vyome’s development of its drug candidates, including the timing of its clinical trials and regulatory submissions. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Vyome’s reliance on third parties over which it may not always have full control, public health crises, epidemics and pandemics such as the COVID-19 pandemic, including its impact on the timing of Vyome’s regulatory and research and development activities. Any forward-looking statements speak only as of the date of this presentation and are based on information available to Vyome as of the date of this presentation. **Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. Except as required by law, Vyome assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.**

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. References to any publications, reports, surveys or articles prepared by third parties should not be construed as depicting the complete findings of the entire publication, report, survey or article. The information in any such publication, report, surveys or article is not incorporated by reference in this presentation.

# Key Takeaways From Phase 2 Study

Clear efficacy and safety signals to support further clinical development.



1

**An investigator-initiated Ph2 study to test VT-1953, a topical dual DNA Gyr and MD2/TLR interaction inhibitor, for safety and efficacy in treating the symptoms of MFW**

2

**VT-1953 achieved a significant improvement ( $P=0.002$ ) in the primary endpoint of malodor on Day 14 vs baseline as scored by investigators. The improvement seen with VT-1953 was statistically significant ( $P=0.0015$ ) compared with vehicle-treated patients.**

3

**VT-1953 resulted in a significant improvement ( $P=0.0256$ ) in the secondary endpoint of patient-reported impact of malodor on the quality of life compared to vehicle-treatment by Day 14.**

4

**Patients treated with VT-1953 also reported a clinically significant improvement in lesion pain symptoms (exploratory endpoint) by Day 14 ( $P=0.002$  compared with baseline;  $P=0.0026$  vs vehicle-treated patients).**

5

**VT-1953 was well-tolerated by patients.**

# What is MFW?



An MFW patient from our Phase 2 study

\*The Microbiome, Malignant Fungating Wounds, and Palliative Care. Front. Cell. Infect. Microbiol., November 2019, EASED study (2023).

\*\* BMC Cancer. 2025 Feb 7;25(1):219.

MFW is a rare condition seen in ~10% of advanced cancer patients.\* **Patients suffer from distressing symptoms, including:**

**Malodor (like “rotten meat”\*\*)**

**Pain**

**Extremely poor quality of life  
(social withdrawal,  
depression)**

**~58,000<sup>1</sup>**

New patients/year in US alone

**\$55,000<sup>2</sup>**

Lifetime value per patient

**~\$2.2B<sup>3</sup>/year** US market opportunity

Notes and Sources: (2,3) Report on U.S. Market & Product Assessment and Valuation of VT-1953 for the Treatment of Malignant Fungating Wounds H1 2026 by Destum Partners, Inc.

# Phase 2 IST testing VT-1953 2% gel in MFW

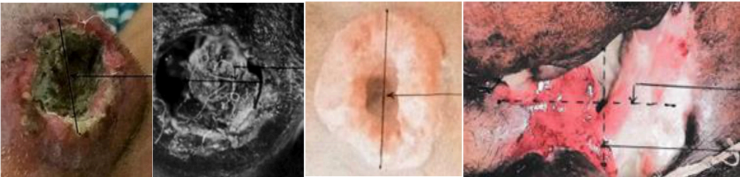
**15 patients with moderate to severe malodorous MFW**  
Sex: 10 male, 5 female. Age: median 50, mean 52.6, range 31–77)  
Diagnosis counts: Oral/Head and Neck cancer: 10; Breast cancer : 4; Vulval cancer: 1

Male or female subjects aged ≥9 years old, with a diagnosis of malodorous malignant fungating wound malodor corresponding to 0,1 and 2 on the TELER odor scale (where 0= Malodor detected upon entering room (>3m or >10ft) with dressing on; 1= Malodor detected at >2m<3m (between 6-10ft) distance from patient with dressing on; and 2= Malodor detected at ~1m or arm's length to the patient with dressing on, as judged by the investigators). ECOG status ≤ 3. Anticipated survival > 3 months.

**Active arm (VT-1953 b.i.d): 10 patients**  
Sex: 7 male, 3 female. Age: median 50.5, mean 56, range 37–77)  
Diagnosis counts: Oral/Head and Neck cancer: 7; Breast cancer : 2; Vulval cancer: 1

**Vehicle arm (5 patients)**  
Sex: 3 male, 2 female. Age: median 47, mean 45.8, range 31–61)  
Diagnosis counts: Oral/Head and Neck cancer: 3; Breast cancer: 2

Representative MFWs from the study

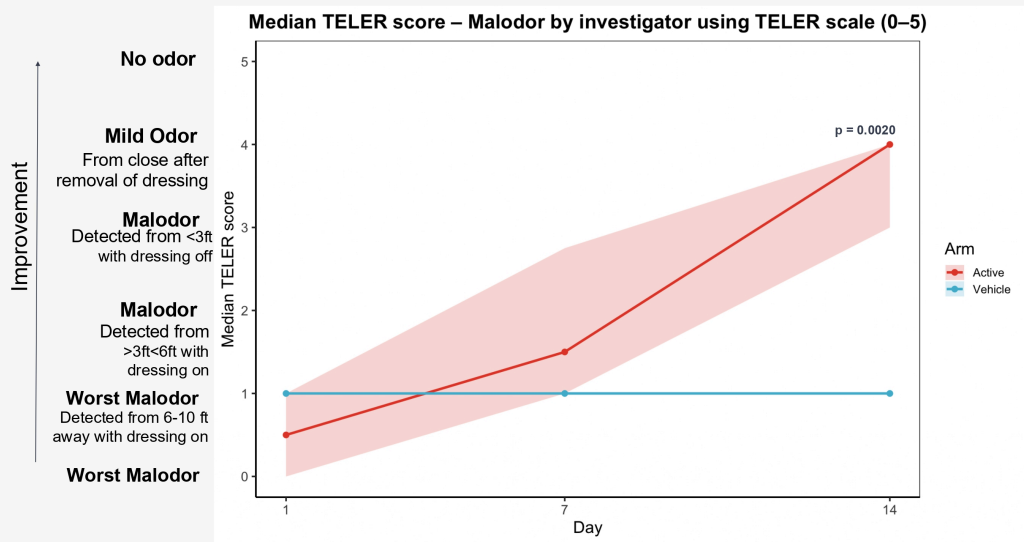


7.5 grams of gel spread evenly twice daily (B.I.D.) across the wound per application

Patients monitored every day over the 14 day study period. Measurements on Day 1 before start of treatment is considered as baseline.

# VT-1953 treatment significantly reduced malodor (scored by investigator on Day 14): primary endpoint

By Day 14, participants treated with VT-1953 Topical Gel showed a marked improvement, achieving a median score of 4.0 (range 3.0-4.0), whereas the Vehicle group remained unchanged at 1.0 (range 1.0-1.0).



P<0.05 is considered as statistically significant.

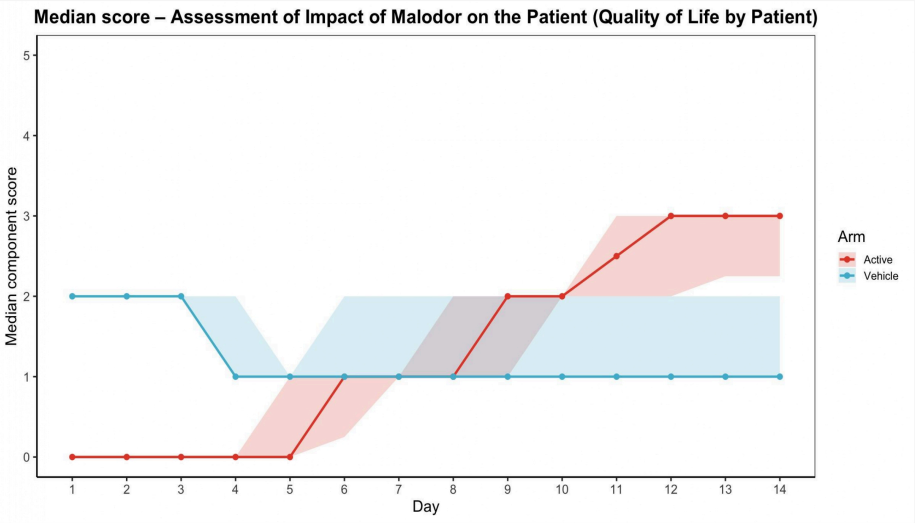
Treatment with VT-1953 2% topical Gel resulted in a **statistically significant improvement in malodor symptom by Day 14** (p = 0.0020, vs baseline. Wilcoxon Signed-Rank Test), while no significant change was observed in the Vehicle arm (p > 0.9999).

**VT-1953 treatment is significantly superior to vehicle treatment** (p = 0.0015, Wilcoxon Rank-Sum Test).

**80% of patients on VT-1953 had a >2 point improvement over 14 Days vs 0% on vehicle arm.**

There was a statistically significant improvement in the VT-1953-treated patients as early as 7 days (P=0.0156 vs baseline).

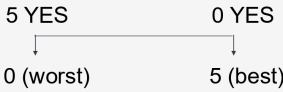
# VT-1953 reduces the negative impact of malodor on quality of life (patient reported): secondary endpoint



|                                                                                                                                      |                                     |                               |
|--------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------|
| Percentage of patients reporting improved Quality of Life (Malodor) composite scores (3–5) on Day 14 *P=0.0256 (Fisher's Exact Test) | VT-1953                             | Vehicle                       |
|                                                                                                                                      | 70%*                                | 0%                            |
|                                                                                                                                      | 95% CI for Proportion ( 41.6, 98.4) | 95% CI for Proportion ( 0, 0) |

Scored on 5 components:

- Awareness of malodor
- Concern about malodor noticed by others
- Reluctance to socialize because of odor
- Nauseated by the odor
- Odor affects appetite





## VT-1953 significantly reduced malodor (scored by patients on VAS Scale): exploratory endpoint

Statistical summary of malodor Visual Analog Scale (VAS) scores, evaluated on a 0–10 scale, at baseline (Day 1) to Day 14 for both treatment groups.

**Patients scored a reduction in malodor with VT-1953**, median scores decreasing to 2.5 (Q1: 2.0, Q3: 3.0) by Day 14 from a baseline median malodor score of 7.5 (Q1: 7.0, Q3: 9.0) ( $p = 0.0020$ , Wilcoxon Signed-Rank Test). A statistically significant reduction was seen as early as Day 6-7 ( $P=0.002$ ).

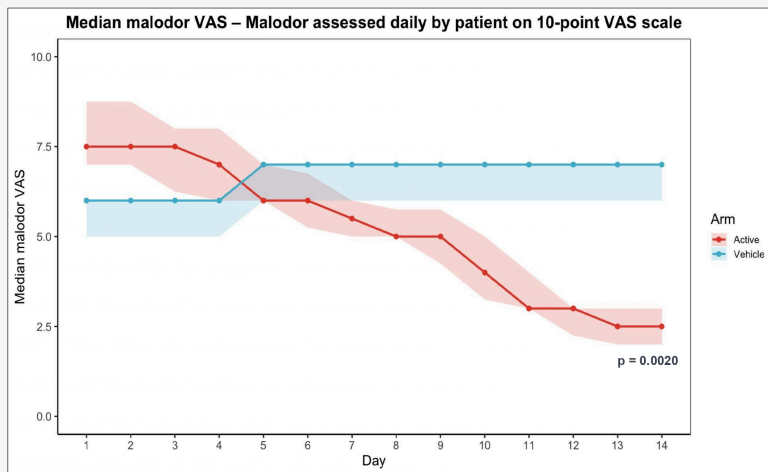
Vehicle Topical Gel group reported no significant improvement, with median scores increasing slightly to 7.0 (Q1: 6.0, Q3: 7.0) from baseline 6.0 (Q1: 5.0, Q3: 6.0).

**VT-1953 was found to be statistically significantly superior to vehicle treatment on Day 14 ( $p = 0.0023$ , Wilcoxon Rank-Sum Test) as well as Day 7 ( $P=0.048$ ).**

Severe malodor

Improvement

No odor



$P < 0.05$  is considered as statistically significant.



## VT-1953 significantly reduced lesion pain (scored by patients on VAS Scale): exploratory endpoint

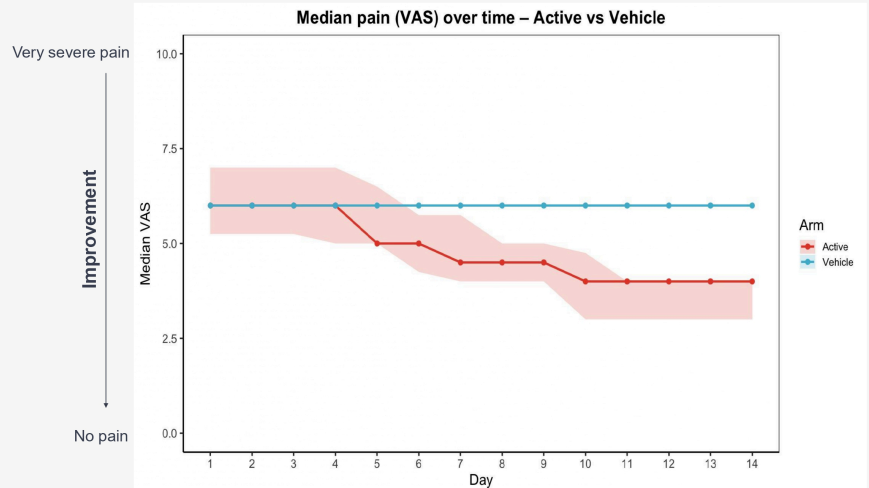
Statistical summary of Malodor Visual Analog Scale (VAS) scores, measured on a 0–10 scale, at Baseline (Day 1) to Day 14 for both treatment groups.

Patients treated with VT-1953 reported a statistically significant decrease in pain intensity by Day 14 to median score of 4.0 (Q1: 3.0, Q3: 4.0) from a baseline median score of 6 (Q1: 5.0, Q3: 7.0) ( $p = 0.0020$ , Wilcoxon Signed-Rank Test).

A statistically significant reduction in pain was seen as early as Day 7 in VT-1953-treated arm ( $p=0.002$ ). Vehicle Topical Gel group showed no change in pain scores, remaining at 6.0 (Q1: 6.0, Q3: 6.0) ( $p > 0.9999$ ).

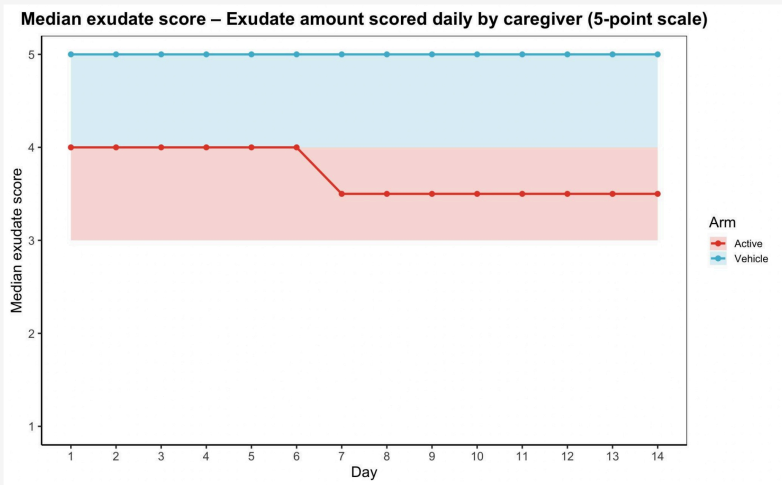
Treatment with VT-1953 was statistically superior in reduction of lesion pain compared to vehicle on Day 14 ( $p = 0.0026$ , Wilcoxon Rank-Sum Test).

90% of patients reported a 2-point reduction in pain intensity in VT-1953-treated arm vs 0% in vehicle-treated arm.



$P < 0.05$  is considered as statistically significant.

# VT-1953 did not significantly reduce exudate: exploratory endpoint

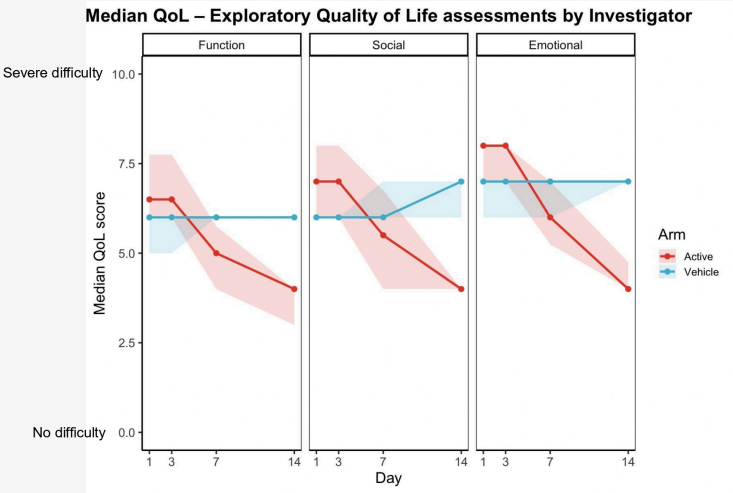


At Day 14, the overall median exudate amount remained unchanged compared to baseline. A statistically significant difference was observed between treatment groups at Day 14 ( $p = 0.0268$ ), favoring the VT-1953 Topical Gel group. Within-group evaluations from baseline to Day 14 showed no statistically significant reduction in exudate scores in the VT-1953 Topical Gel group (Median change from 4.0 to 3.5;  $p = 0.5000$ ).

Overall, these findings indicate that although exudate scores did not significantly improve within groups over 14 days, the VT-1953 Topical Gel group demonstrated comparatively better exudate status at Day 14 versus the vehicle control.

# VT-1953 significantly improves QoL (patient-reported outcome measures): exploratory endpoint

Summary of patient-reported QoL outcomes scored using a 10-point Visual Analog Scale (VAS)



Mean of all individual QoL components was computed by visit for each subject, and the median analysis was then performed on these mean composite scores.

Patient-reported Quality of Life (QoL) scores derived from the mean of all QoL components

|          | Median Composite QoL    |                        |
|----------|-------------------------|------------------------|
|          | VT-1953                 | Vehicle                |
|          | 5.5 (Q1: 4.5, Q3: 6.0)  | 4.8 (Q1: 4.3, Q3: 4.8) |
| Baseline |                         |                        |
| Day 14   | 3.0* (Q1: 2.8, Q3: 3.3) | 5.0 (Q1: 4.5, Q3: 5.0) |

\*Statistically significant within-group improvement from Baseline ( $p = 0.0020$ , Wilcoxon Signed-Rank Test).

VT-1953 treatment resulted in a statistically significant improvement vs vehicle-arm ( $p = 0.0032$ , Wilcoxon Rank-Sum Test)

## **VT-1953 did not exhibit any safety signals during the study period at doses used**

- No TEAEs reported
- No changes in vital signs
- No reports of local skin reactions
- \*Consistent with observations from prior clinical trials with VT-1953

\* VT-1953 (2% topical gel) has been studied for safety and efficacy in 5 clinical studies, including chronic use for 90 days

# Summary

**Treatment with VT-1953 for 14 days successfully met its primary endpoint of significantly reducing malodor associated with MFW as scored by investigators. There is consistency between investigator scores (on TELER score) and malodor scored by patients using VAS (exploratory endpoint)**

**Patients treated with VT-1953 for 14 days did not report any adverse effects or safety signals**

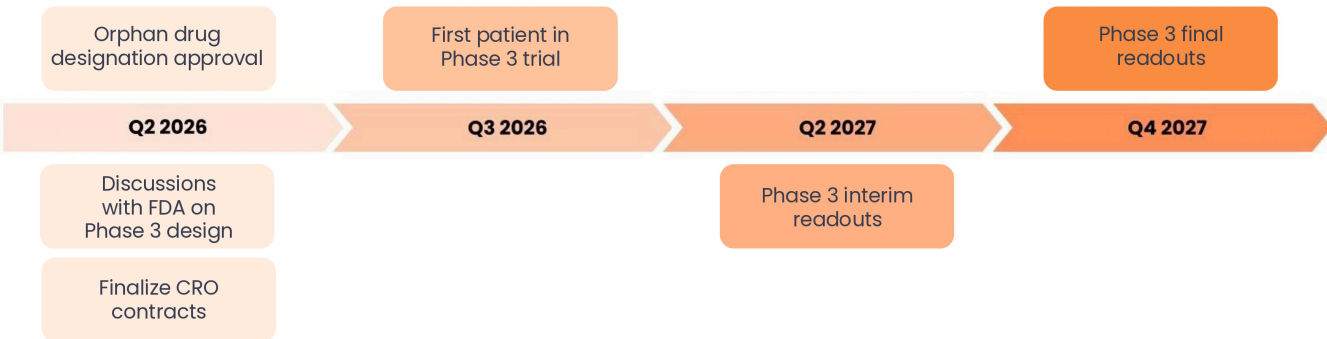
**Treatment with VT-1953 for 14 days achieved its secondary endpoint of significantly reducing impact of malodor associated with MFW as scored by patients, and exploratory endpoints of reducing lesion pain (scored by patients), and improved QoL (patient reported outcome measure). There was no significant change in exudates.**

**These results provide a clear clinical rationale to advance VT-1953 to pivotal studies for the treatment of symptoms associated with MFW. Clear statistical significance in Ph2 and low variance suggests the need for fewer patients in a pivotal study.**



# VT-1953 Anticipated Milestones – Key Focus of Vyome

The orphan drug designation application for VT-1953 has been filed and discussions regarding CRO estimates ongoing



Capitalized to fund until Phase 3 Interim readouts

# Vyome Holdings, Inc. ("Vyome")

Venkat Nelabhotla, CEO & Co-Founder

|                                                                                   |                                                                                 |
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