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â??Malignant fungating wounds remain significantly under-recognised and under-treated in Indiaâ?•

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Vyome Holdings, Inc., a Nasdaq-listed clinical-stage biotechnology and healthcare platform company, has recently announced the final results from an investigator-initiated Phase II proof of concept study of VT-1953 topical gel in people with malignant fungating wounds (MFW). With this result, Vyome plans to advance to Phase III pivotal trial, seek US FDA approval, and enter the $1 billion potential addressable market as the only anticipated approved solution for malignant fungating wounds. To find out more about this interesting development, BioSpectrum India had a detailed interaction with Venkat Nelabhotla, Co-Founder, President, and Chief Executive Officer (CEO) of Vyome Holdings, Inc.



What will be the parameters for the Phase III study of VT-1953, including sample size, treatment duration, statistical assumptions, etc., and what will be the clinical milestone that needs to be achieved for a successful registration claim?

The final Phase III or pivotal study design for VT-1953 has not yet been finalised and will be determined in consultation with regulatory consultants and the US FDA. Based on learnings from the Phase 2 study, which showed significant efficacy and safety profile, we are evaluating a couple of clinical designs for the pivotal study focused on clinically meaningful symptom endpoints such as malodor reduction, with appropriate secondary measures related to pain and patient- reported outcomes. Sample size, treatment duration, and statistical assumptions will be finalized following regulatory feedback to ensure the study is adequately powered and aligned with regulatory expectations. A successful registration would be contingent upon achieving the predefined primary endpoint with statistical significance and demonstrating an acceptable safety profile.

What is the planned timeline for conducting Phase III studies, and by when do you expect to complete it?

We are currently preparing for regulatory interactions to discuss the pivotal development pathway. Subject to regulatory alignment and operational readiness, we aim to initiate Phase III activities in the second half of 2026 following these discussions. The overall timeline, including study initiation and completion, will depend on regulatory guidance, site activation, patient enrollment rates, and other execution factors. We anticipate the pivotal study readouts at the end of 2027.

These is an addressable market opportunity of $1 billion for VT-1953 – apart from the US, which will be the other key markets for you, and what is your commercialisation strategy for India?

The US represents our initial focus, given the regulatory clarity and unmet need in malignant fungating wounds. We have employed a recognised third party consulting organisation for further validating the addressable market in the US and sales potential for VT-1953. Over time, we may evaluate opportunities in other major markets such as Europe and select Asia-Pacific regions, subject to regulatory, clinical, and commercial considerations. For India, we recognise the significant unmet

medical need and would expect to evaluate a differentiated access-oriented approach, potentially involving partnerships, to ensure appropriate availability while maintaining sustainability. Specific commercialisation strategies will be determined closer to potential approval. We anticipate a significant partner interest in licensing our product.

Are there any gaps in the Phase II studies that need to be addressed pre-pivotal?

The Phase II study provided important proof-of-concept data and informed our understanding of endpoints, dosing, and clinical execution. As with most development programs, there could be additional points that will be reviewed and refined as part of the pre-pivotal planning process.

These considerations will be addressed through regulatory discussions before finalizing the pivotal study protocol.

In terms of manufacturing and supply, have you identified with whom you want to partner? What will be your pricing strategy for VT-1953?

We are actively evaluating manufacturing and supply options from India in line with our US- India innovation corridor strategy that meet regulatory, quality, and scalability requirements. No final partner decisions have been publicly disclosed at this time. Pricing strategy has not been finalised and will take into account factors such as clinical value, market access considerations, reimbursement dynamics, and patient affordability, while remaining consistent with applicable regulations and ethical standards.

Since you are aiming for orphan drug designation, what kind of market exclusivity are you looking at?

If orphan drug designation is granted and VT-1953 ultimately receives regulatory approval, it may be eligible for the standard statutory exclusivity periods applicable under relevant regulations, such as those in the United States. Any exclusivity would be subject to meeting all regulatory requirements.

What are the current challenges facing the malignant fungating wound market in India?

In India, malignant fungating wounds remain significantly under-recognised and under-treated. Challenges include limited awareness, lack of standardised treatment protocols, constrained access to specialized wound care, and the absence of approved targeted therapies. Additionally, social stigma and delayed presentation further complicate management, highlighting the need for greater clinical awareness and supportive care solutions.

How much funding have you raised so far, and what is your current team size? Are you planning to raise more funds this year?

Vyome has raised capital across multiple stages to support its clinical and operational activities. Specific funding amounts and team size disclosures are provided through appropriate public filings and disclosures. On August 15, 2025, when we were listed on the Nasdaq, we raised approximately $6.5 million. As a public company, we continuously evaluate capital needs in line with our development plans and market conditions; however, any future financing plans would be subject to market conditions, board approval, and regulatory requirements, and cannot be confirmed at this time. As a group, we have approximately 20 employees and retainers.

Dr Manbeena Chawla

(manbeena.chawla@mmactiv.com)