

# Volition Issues Business Review 2025

HENDERSON, Nev., Dec. 17, 2025 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition"), a multi-national epigenetics company, issues a Business Review of 2025.

# Review of the Year by Cameron Reynolds, Group Chief Executive Officer

As 2025 draws to a close, I would like to take this opportunity to look back on the year's key milestones and look to the opportunities ahead.

Before diving into the detail, I would like to take a moment to reflect on our founding mission. We set out over fifteen years ago to help save lives and improve outcomes for millions of patients worldwide, and I could not be prouder of the progress we are making towards that goal.

In this fourth quarter we not only received our first order for the Nu.Q® Cancer assays for clinical certification ahead of routine clinical use in lung cancer, but we also announced the inclusion of our Nu.Q® NETs assay in a real-world interventional evaluation of early detection of sepsis, in a government-backed (~\$7.3 million) program in France. Our tests are about to be used in both these devastating diseases to help save lives in real world hospital settings: an extremely proud moment for our entire team.

Cancer and sepsis are leading causes of death, accounting for approximately a<u>third</u> of deaths worldwide<sup>1-3</sup>. With the first clinical use now imminent, we are about to be part of the solution, through simple, easy to use, low-cost tests.

I believe we will look back on 2025, and indeed in time, the next few quarters, as *transformational* for the company.

2025 efforts for Volition have focused on commercializing our groundbreaking Nu.Q® platform in the human diagnostics market. We were excited to start the implementation of our human licencing strategy; with the signing of not one, but two agreements. The first for Antiphospholipid Syndrome ("APS") with **Werfen**, and a Co-Marketing and Services Agreement with **Hologic**. Both are multi-billion-dollar companies, and worldwide leaders in their specialized fields, and we are delighted to report that both have very much hit the ground running.

We have further strengthened our **Intellectual Property** portfolio and are continuing our licensing discussions with around 10 of the world's leading diagnostic and liquid biopsy companies. These discussions are at various stages of the negotiation process across all our different pillars, and we anticipate announcing additional agreements throughout 2026.

Our goal is to secure a wide range of licensing agreements in the human diagnostics space, mirroring our successful strategy in the veterinary market, and we anticipate diverse deal structures, with potential for up-front and milestone payments, and future recurring revenue. We have developed a truly remarkable, versatile platform and now we are working with

governments and some of the biggest diagnostic and liquid biopsy companies to make our technology available worldwide as quickly as possible.

Beyond licensing, we have achieved several significant **commercial milestones**:

- In the first quarter, we recorded our first revenue from sales of our CE-Marked Nu.Q® NETs automated assay, a regulated, clinically approved product.
   NETs, or more specifically NETosis, goes far beyond just sepsis, and is implicated in a very wide range of diseases. Currently more than 20 hospitals in 10 countries are evaluating our Nu.Q® NETs assay across 15 different clinical use cases and indications. We believe NETs testing will become a key part of routine blood testing.
- In February, we announced our first commercial sale of Volition's proprietary High
   <u>Throughput NETs</u> method that measures Neutrophil Extracellular Traps ("NETs")
   activation and inhibition in whole blood in real time, helping companies develop new
   therapeutics to combat sepsis and other NETs-related disease.
- In March, we signed an agreement with a leading pharmaceutical company to utilize Volition's Nu.Q® Discover biomarkers in a longitudinal Phase 1/2b study, the first human clinical study with a pharmaceutical company sponsor that our test supports. Through our Nu.Q® Discover pillar we are now serving over 20 clients worldwide, including many top pharma and diagnostic companies, accelerating disease research and drug development across multiple therapeutic areas.
- The Nu.Q® Vet Cancer Test is the number one canine cancer screening blood test in the world, available in over 20 countries.

#### We have also achieved significant scientific and clinical progress:

- Pre-print paper showcases both a new method, Capture-Seq<sup>™</sup>, and new biomarkers for the detection of cancer, with the potential for accurate, low-cost tests for a wide range of cancers. The 180-fold (18,000%) enrichment of ultrashort DNA, separating out the massive amounts of background DNA, is, we believe, a world-first breakthrough, and has generated significant interest from potential licensing partners.
- Independent peer-reviewed and <u>published study</u> (1713 patients) clearly demonstrates that Nu.Q® NETs is a clinically meaningful, biologically specific marker of NETosis, with actionable potential in defined patient subgroups. This evidence positions the assay not as a traditional rule-in/rule-out diagnostic, but as a dynamic tool for prognostic enrichment, therapeutic targeting, and clinical monitoring.
- In July, Volition announced the groundbreaking<u>Lateral Flow Test for Point-of-Care</u>
   Quantification of Nucleosomes. This technological breakthrough is the first report of a
   bedside lateral flow test to quantify nucleosomes, a marker of NETosis. It is not simply
   a positive/ negative test but provides a quantitative readout to facilitate clinical
   decision-making.
- In January, we announced the results of a<u>large-scale study</u> which shows that our Nu.Q®NETs H3.1 biomarker is an independent predictor of 28-day mortality and need

for renal replacement therapy (RRT) in sepsis and septic shock patients.

In May, we announced the successful detection of nucleosomes in cats and the
publication of a <u>peer-reviewed pre-analytics paper</u>. We have subsequently completed
our first clinical study to detect lymphoma in cats and look forward to publishing the
results early in 2026, a development which will unlock a \$5 million contractual
milestone payment in due course.

## **Our Commercial Opportunities:**

Our vision is for our tests to be used first by millions, then by tens, then hundreds of millions of people and animals a year, with our platform licensed to a range of large diagnostic and liquid biopsy companies (and governments) worldwide. Combining our groundbreaking technology with their installed base of laboratories, analyzer machines and sales forces around the world will achieve the optimal outcome for us – large companies have the resources to realise the opportunities better than Volition.

The Total Addressable Markets<sup>4</sup> (TAMs) for our technologies, on an annualised basis, are considerable, multi-billion-dollar opportunities, not only for Volition, but for our licensing partners:

- \$2.3 billion Lung Cancer Screening & Management
- \$23 billion Multi-Cancer Early Detection / Liquid Biopsy
- \$2.8 billion Sepsis Early Detection & Management
- \$1 billion Broader NETosis (Trauma, Antiphospholipid Syndrome, Hidradenitis Suppurativa)
- \$128 million Canine and Feline Cancer Screening
- \$991 million Pharma Companion Diagnostic

We have dedicated the last fifteen years to revolutionizing the diagnosis and monitoring of life-altering diseases by advancing the science of epigenetics. When we started, we believed epigenetics would be an important part of oncology diagnostics in humans. Since then, our platform has shown an even broader utility by becoming the biggest selling test in canine cancer, and we are on the way to becoming a leader in NETs detection and monitoring.

While there is no doubt it has been a tough couple of years in the market, Volition has made strong progress, both clinically and commercially, and our technology is now poised to be used very widely in a wide range of clinical utilities.

- 1. <u>UN, World Population Prospects (2024)</u> (accessed on 15<sup>th</sup> December 2025)
- 2. Global Cancer Observatory 2022 (accessed on 15<sup>th</sup> December 2025)
- 3. Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. Rudd, Kristina E et al. The Lancet, 2020.

## https://doi.org/10.1016/S0140-6736(19)32989-7

#### 4. Data on File: Volition TAM

#### **About Volition**

About Volition: Volition is a multi-national company focused on advancing the science of epigenetics. Volition is dedicated to saving lives and improving outcomes for people and animals with life-altering diseases through earlier detection, as well as disease and treatment monitoring.

Through its subsidiaries, Volition is developing and commercializing simple, easy to use, cost-effective blood tests to help detect and monitor a range of diseases, including some cancers and diseases associated with NETosis, such as sepsis. Early detection and monitoring have the potential not only to prolong the life of patients, but also to improve their quality of life.

Volition's research and development activities are centered in Belgium, with an innovation laboratory and office in the U.S. and an office in London.

The contents found at Volition's website address are not incorporated by reference into this document and should not be considered part of this document. Such website address is included in this document as an inactive textual reference only.

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