# Volition ())

# NYSE:VNRX Corporate Deck

February 2025

# Forward Looking Statements and Disclaimer Volition

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# Volition 🕥

# Our mission is to save lives and improve outcomes for millions of people and animals worldwide.

## **At-a-Glance**

# Volition

#### <u>VolitionRx</u>

- (NYSE: VNRX)
- Diagnostics (epigenetics)
- ✓ Commercial
- 9M Rev: \$1M ('24)
- Plus, licensing related payments of \$23M (22-24)
- Total revenue derived from milestone payments and ongoing sales

### **Our Focus**

- Advancing low-cost, early detection and treatment monitoring tests
- Revenue expansion beyond animal assays with strong focus into human health

**Disease Areas** 

- Cancer
- Sepsis
  Licensing Data Room
  LIVE

#### Commercial Validation

- Commercial launches worldwide in animal health (2022-2024)
- Further IP licensing and partnering opportunities beyond animal health in active discussions
   9M Rev: \$1M ('24)

### **Multi-National**

- 85 employees
- 27,000 square foot lab and production spaces in Gembloux, Belgium
- Innovation Lab in California
- Other Offices in:
  - London
  - Nevada (HQ)

Several clinical papers demonstrating clinical utility submitted / due shortly to help advance human licensing deal(s).

## **Investment Highlights**

# Volition 📢

#### Vet Commercial Progress

- Nu.Q<sup>®</sup> Vet Cancer test now available in 20 countries
- Sold >110,000 tests and test components Q1-Q3 2024
- Received \$23 million in upfront and milestone payments to-date
  - Additional \$5 million milestone payment (feline) anticipated 2025
  - Simple, low cost, recurring revenue generating tests performed on standard lab equipment
- Multiple international partnerships launching

#### Expansion into Human Diagnostics

- Same business model as Nu.Q® Vet low capex/low opex, leveraging glocal base of established diagnostic and liquid biopsy companies
- Clinical Partnering: multiple near-term licensing opportunities progressing
- Direct and Indirect sales of CE marked product(s) in Europe as hospitals evaluate for routine clinical use

#### Large Unmet Needs

- Lung Cancer Screening screening, prognostics and MRD represent a \$1.8B opportunity
- Sepsis testing and monitoring ICU patients alone is a ~\$1B+ opportunity
- Other addressable markets include Acute Kidney Injury (AKI), Acute Respiratory Distress Syndrome (ARDS) and use in the Emergency Department >\$10B opportunity

### Strong IP

- 81 patents granted
- 129 pending internationally
- Patent coverage up to 2044

### Derisked R&D and Commercial Strategy: Reported First \$1 million Revenue 2024

## Nu.Q<sup>®</sup> Vet

# Volition 📢

- Licensed to two of the largest veterinary service companies world-wide
  - Available via reference labs and at point-of-care in-clinic exclusively with Antech
  - <u>Nu Q<sup>®</sup> Vet Cancer Test</u> developed with the goal of providing an accessible and affordable screening test to aid in early cancer detection.
- This test can be easily integrated into preventive care programs and used alongside other routine bloodwork during regular wellness visits.
- It's a simple, easy to use screening blood test recommended for older dogs (7 years and older) and those breeds at increased risk of developing cancer in their lifetimes (from 4 years).
- The Nu.Q<sup>®</sup> Vet Cancer Test is now available in the United States, Europe and many countries throughout Asia.
- Revenue ramping-up as Antech rollout globally and FujiFilm Vet System (in 90% of all vet clinics in Japan) came online

# Licensing Portfolio: Platform stable, reproducible Volition

Application	Proof of Concept	Viability	Validation	Licensed
Animal				•
Canine Cancer Screening				Launched
Canine Cancer Monitoring			$\rightarrow$	
Feline Cancer				$\checkmark$
Automated test			$\rangle$	In negotiation
Human				
Sepsis				Data room available
Cancer				Data room available
Lung Cancer Screening				Data room available
Minimal Residual Disease & Disease Management			$\Rightarrow$	Data room available
Multi-Cancer Early Detection				Data room available
Capture-PCR™				Data room available

#### **Executive Team**

# Volition 📢



## What sets us apart?

# Volition 🚺

- Our tests are *simple, low-cost* <u>accessible</u> routine blood tests
  - Platform agnostic, can be adapted to any diagnostic workflow
    - Manual, Reference Lab, Specialist Lab and Point of Care



- Our expanding Intellectual Property portfolio
  - 81 patents granted, 129 pending, across 54 patent families<sup>1</sup>

## **Go-to-Market Strategy**

## R&D

- **R&D conducted** by Volition and its research partners
- **Monetize IP** through licensing agreements with upfront payments, milestone payments, royalties and sales of key components

## Non-exclusive licensing and partnering criteria:

- Broad geographic reach
- Large installed base
- ✓ Experience of tech transfer
- Regulatory and clinical affairs
- Patient focused

#### Two underlying principles:

- Low CapEx for partners / Low OpEx for Volition
- Low-cost and routine = **accessible** tests worldwide

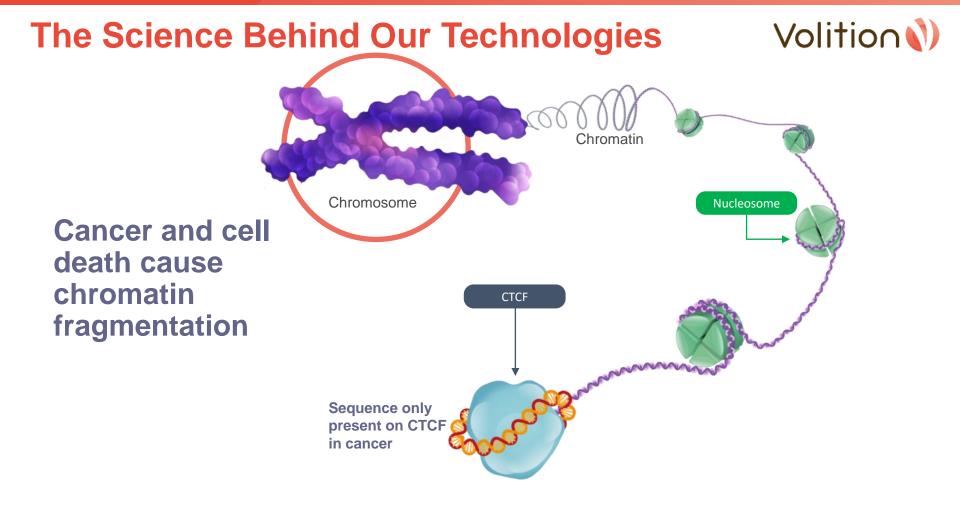


# Volition 📢

**Great Track** 

**Record with** 

Nu.Q<sup>®</sup> Vet





# Nu.Q<sup>®</sup> Vet Cancer Test



Now available in **20** countries and growing! Sold > **110,000** Nu.Q<sup>®</sup> Vet Cancer Tests & Test Components YTD 2024

Revenue

+**307%** Q3 2024 vs Q3 PY

# Licensing & Supply Agreements to-date



 Launched with IDEXX in the U.S Jan '23



 Launched in U.S. / Aus /HK/Singapore/ some EU countries April '24



Volition 锁

Veterinary

Launched in UK & Ireland Nov '23

# FUJIFILM

• Launched July '24



- Launched in Portugal Nov '22
- Vit &
- Launched in Taiwan Nov '23



 Launched in Singapore Nov '23



• Launched in Poland July '24

# Nu.Q<sup>®</sup> exclusively available in-house with Antech.





- Exclusive Element i+ in-house analyzer licensing partnership with Antech
- \$10M upfront and \$13M milestone payments received to-date. \$5M milestone payment linked to use in felines remaining
- Ongoing <u>revenue</u> from the purchase of kits and key components

# Nu.Q<sup>®</sup> Vet Cancer Test on the Element i+ AnalyzerVeterioary Antech

- Immediate Results (<10 mins)</li>
- Accurate (detects 76% of systemic cancers at 97% specificity)
- ₲ Cost effective (\$35 to the vet)
- Allowing veterinarian to make informed clinical decisions quickly in-house whilst the patient is still in clinic



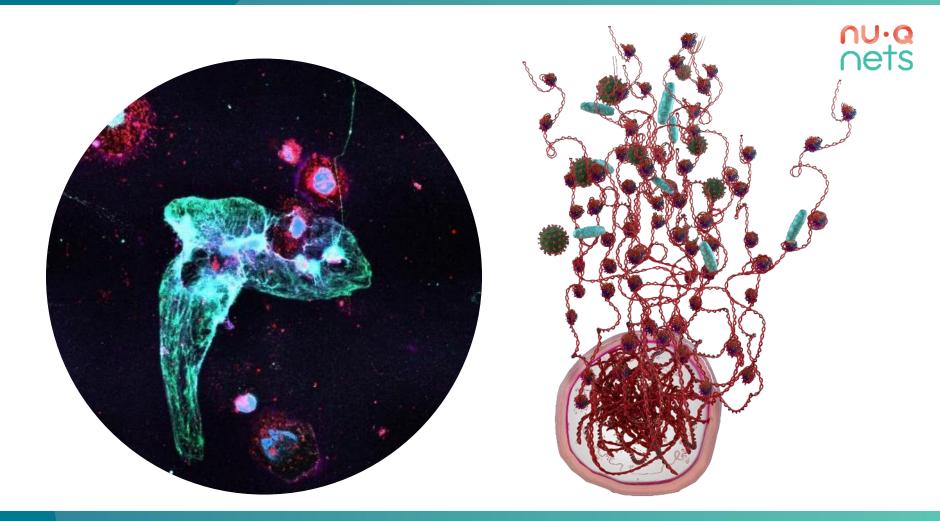


# **Licensing Portfolio**

# nu-a nets

Sepsis & Thrombosis

Property of Volition<sup>®</sup> 2025



# **Neutrophil Extracellular Traps (NETs)**

## **NETs:**

- are produced by ejecting chromosomal material out of the cell
- catch and kill bacteria and viruses
- can sterilize blood in minutes



• first reported in 2004<sup>1</sup> now the subject of > 5000 publications

NEW review article published February 2025 (Dr. Retter, Profs Singer & Annane)

1. Brinkmann V, Reichard U, Goosmann C, Fauler B, Uhlemann Y, Weiss DS, Weinrauch Y, Zychlinsky A. Neutrophil extracellular traps kill bacteria. Science. 2004 Mar 5;303(5663):1532-5. DOI: 10.1126/science.1092385

## 1 in 5 deaths worldwide are associated with sepsis

Almost **50 million** cases resulting in **11 million** deaths

Over 40% of cases are children under 5 years of age

## It's the number 1...

Cause of death in hospitals

Cause for hospital readmissions

Healthcare cost (\$62bn in USA pa alone) Over **40%** of survivors suffer from long-term physical or psychological effects

## **Unmet Needs**



- Current diagnosis is empirical, multi-factorial and subjective.
- CURRENT methods of assessment (SOFA and APACHE II) are both complex & slow.
- Accepted need for **improved diagnostics**<sup>1.</sup>

# Studies at Centers of Excellence: >3000 patients

Study	Country	Description	Cohort Size	Status
SISPCT	Germany	Retrospective analysis of prospectively collected cohort	971 intensive care patients Multiple timepoints	Completed. <u>Manuscript</u> <u>under review</u>
Amsterdam UMC	Netherlands	Retrospective analysis of prospectively collected cohort	1,713 intensive care patients Multiple timepoints	Completed. Manuscript submitted
RHU RECORDS	France	Prospective, multi-center, placebo controlled, bio- marker-guided, adaptive Bayesian design basket trial	1,500 intensive care patients Interim analysis of 416 patients	Ongoing

# **Executive Summary: consolidated conclusions**

nu•a ∩ets

Results from three independent studies totalling over 3,000 patients These findings are consistent across cohorts<sup>1-3</sup>

An elevated H3.1 level reflects a dysregulated immune response and is associated with:

- a risk of **increased mortality**
- an increased risk of **septic shock**
- an increased risk of (multi-) organ failure
- an increased risk of ARDS
- an increased risk of renal failure

...could be thought of as a **Treatable Trait** in sepsis management

1. German Data Set, manuscript submitted; 2. Amsterdam UMC Data Set, manuscript submitted; 3. RHU Records Data Set, data on file

# NETs: Casting a new light on sepsis management $\bigcap_{n \in TS} O(n)$

#### Satellite Symposium at ESICM LIVES 2024



**Prof. Djillali Annane** Professor of Medicine, University Paris Saclay-UVSQ, France



"As a Critical Care Consultant, I see the devastating effects of this disease each day. I believe Nu.Q<sup>®</sup> NETs, as a diagnostic tool, has the potential to bring about a paradigm shift in sepsis management. I hope that Nu.Q<sup>®</sup> NETs becomes widely available - in every intensive care unit, in every hospital setting - to help ensure we detect, treat, and monitor sepsis earlier and save lives."

## Our focus...



To develop a **low-cost**, **routine** test to **stratify risk** of sepsis particularly those at risk of progressing to multiple organ failure; in addition to **monitoring** the disease progression and response to treatment.

- Data from several large-scale studies presented at ESICM LIVES 2024<sup>1</sup>
- Manuscripts (featuring results from >2,500 patients) now submitted for peer review and publication<sup>2</sup>

Licensing discussions progressing with a number of large diagnostic companies.

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2. Manuscripts submitted
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<sup>1.</sup> Data on file, VNRX

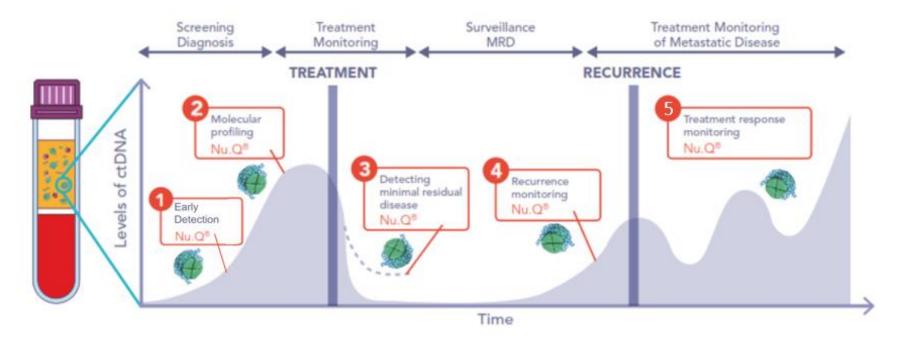
# cancer



Low-cost, routine and accessible tests to help detect and monitor disease
 progression and aid treatment selection

# Potential applications of a blood test in lung cancer: Nu.Q<sup>®</sup> addresses all five





Peng Y, Mei W, Ma K and Zeng C (2021) Circulating Tumor DNA and Minimal Residual Disease (MRD) in Solid Tumors: Current Horizons and Future Perspectives. Front. Oncol. 11:763790. doi: 10.3389/fonc.2021.763790

## **Study Overviews**

- Range of studies from prospective and retrospective, blinded, longitudinal studies of lung cancer.
- Cohort sizes ranging from 70 to 800 patients.
- Covering detection of lung cancer at diagnosis and during treatment
- KEY Outcome measures to demonstrate CLINICAL UTILITY (correlation with):
  - Sensitivity and specificity
  - Positive Predictive Value (PPV) aiding rule-in/rule-out
  - Minimal Residual Disease (MRD)
  - Overall Survival (OS)
  - Recurrence Prediction

## **Our Focus**



## To develop low-cost, routine tests to help:

- detect disease early
- provide tailored treatment
- assess response to treatment
- identify MRD
- support continued treatment decisions

## Many data in the Confidential Data Room

- NTU lung paper available on MedRXIV
- Lyon data presented at AACR and ESMO 2024, manuscript in development
- Next key conference for NEW data release ELCC March 2025

## **Proof of Concept:** Potential <u>Breakthrough</u> Cancer Detection Method<sup>1.</sup>



- Novel wet chemistry pathway for ctDNA analysis
- Discovered a completely new class of biomarkers that are invisible to current methods and demonstrated that they can be isolated as pure ctDNA
- Identified hundreds of potential short cfDNA sequences using samples from six cancer types
- Thus far developed prototype, low-cost, rapid PCR assays to 14 sequences and tested them in a small number of samples
- Performed a small study that demonstrates that the method enriches ctDNA fragment sequences to near 100% purity AND discriminates early-stage cancer

1. Data on file, VNRX



# Summary

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## **Investment Summary**

# Volition

- Listed, commercial stage diagnostics company developing low-cost, early detection and treatment monitoring diagnostics in human and animal health
  - Disease areas global killers: Cancer, Sepsis; significant market opportunities
  - Human and Veterinary use cases:
    - Screening
    - Monitoring (disease progression and response to treatment)
- Revenue focus on veterinary cancer and direct/indirect sales of CE-Marked product(s) in Europe
- Multiple near-term licensing opportunities IN DISCUSSION:
  - for cancer detection and monitoring
  - and sepsis



# **Questions?**

## Thank you for your interest in Volition.

For more details, please visit www.volition.com