



Volition

# Investor Presentation

Cameron Reynolds

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# Forward-Looking Statements and Disclaimer

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Forward-looking statements relate to, among other things, the effectiveness of the Company's bodily fluid based diagnostic tests, as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer. The Company's actual results may differ materially from those indicated by forward-looking statements, due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include, but are not limited to, the Company's failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical IVD market, a failure by the marketplace to accept the products in the Company's development pipeline, or any other diagnostic products the Company might develop. The Company will face fierce competition, and the Company's intended products may become obsolete, due to the highly competitive nature of the diagnostics market and its rapid technological change, and other risks identified on the Company's most recent annual report on form 10-K, and quarterly reports on form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission.

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Team and Company Profile

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Volition

# Our Expert Team

Volition was established in 2010 when we saw a chance to bring together the long-established ELISA diagnostic technology with the cutting-edge nucleosome detection and analysis techniques.

We are a collective force of distinct individuals but our aim is the same – to save lives by revolutionizing the way cancer is diagnosed.



**Cameron Reynolds MBA**  
President & Group CEO



**Dr. Jake Micallef PhD MBA**  
Chief Scientific Officer



**Gaetan Michal PhD**  
CEO, Belgium/Wilson



**Louise Day**  
Chief Marketing &  
Communications Officer



**Jason Tarrell MD**  
Chief Medical Officer &  
Head of US Operations



**Jasmine Kwey PhD**  
Vice President, Asia



**Rod Rootsaert LLB**  
Corporate Secretary



**Volition**

## KEY FINANCIALS\*

TICKER : NYSE MKT:VNRX

SECTOR: Healthcare: Diagnostics  
& Research

Market Cap: \$119.4m

52 week range: \$3.05-\$5.86

Cash-on-hand: \$21.7m



Volition

\* As at 31<sup>st</sup> December 2016

## A Brighter Tomorrow.....

Volition is a multi-national company developing simple, easy to use blood-based cancer tests to accurately diagnose a range of cancers



Volition

The research team based in Namur, Belgium bring together decades of scientific experience with the passion that is commonplace at Volition. The team is dedicated to developing diagnostic tools that will relieve the burden of cancer worldwide



# Early diagnosis is key

“The best way of tackling the disease [cancer] is for patients to receive an early diagnosis, as this improves the chances of beating cancer.”

*National Institute for Health and Care Excellence*

“Cancer screening tests can also improve survival and decrease mortality by detecting cancer at an early stage when treatment is more effective”

*American Cancer Society*

“Early detection of cancer greatly increases the chances for successful treatment”

*World Health Organization*

“Current cancer diagnosis involves expensive, unpleasant and, often, invasive testing. Using our Nu.Q™ technology we aim to make cancer diagnosis as accessible as cholesterol or pregnancy testing”

*Dr. Jake Micallef, PhD, MBA  
CSO*

# Rethinking the approach to cancer

- Nu.Q™ represents a powerful step change in rethinking the approach to cancer.
- It is a simple solution to the challenging problem of early cancer diagnosis.

Nu.Q™ unique technology looks for very early 'nucleosomic' markers of cancer

These tests identify early stage cells before the cancer spreads

Nu.Q™ uses an array of simple, cost-effective, and accurate blood tests

Just a drop of blood

# Nu.Q™ – How it works

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Cancer leads to irregular levels of uniquely structured nucleosomes in the blood. A nucleosome is a section of DNA wrapped around a core of proteins.

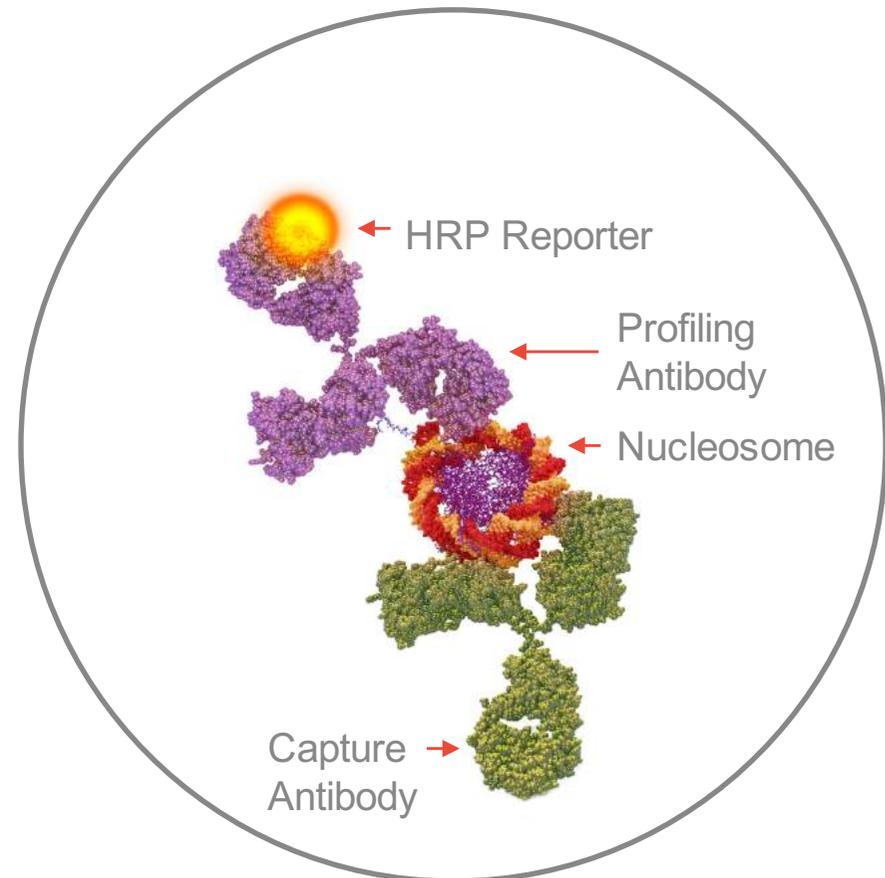
Through a simple test, with less than a drop of blood, we are able to detect those unique nucleosomes; and by measuring and analyzing them, our Nu.Q™ tests can establish whether cancer is present in the patient.

# Nu.Q™ – How it works

The Nu.Q™ family currently consists of 28 Nu.Q™ blood biomarker assays that fall into 5 main families of double antibody ELISA biomarker assays:

1. Nu.Q™ -X specific DNA modifications
2. Nu.Q™ -V histone variants
3. Nu.Q™ -M histone modifications
4. Nu.Q™ -A nucleosome-protein adducts
5. Nu.Q™ -T total nucleosomes

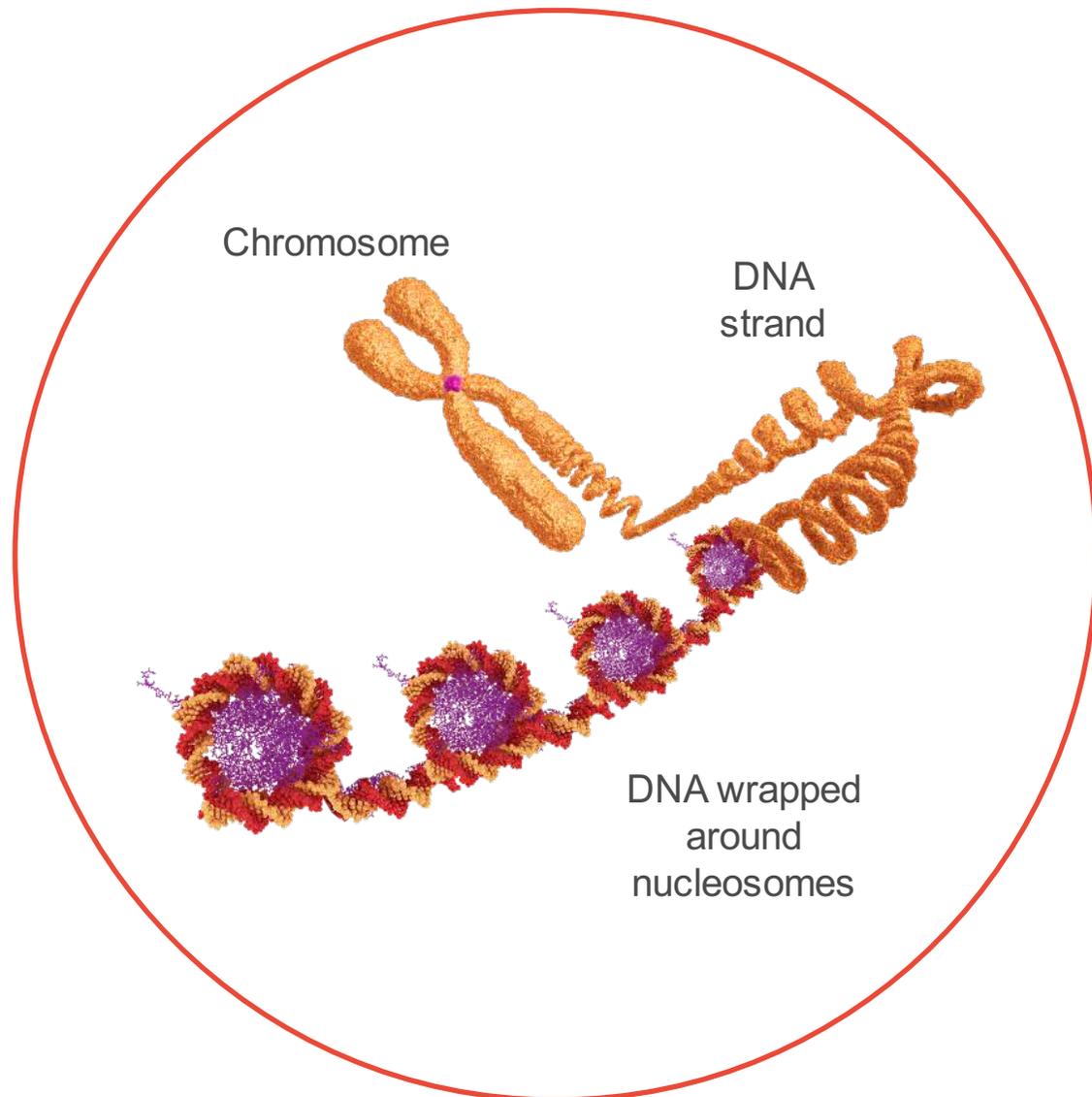
Each captures intact nucleosomes and labels (identifies) a specific structural feature out of thousands of potential biomarkers



A figure of a nucleosome, showing different structures

# Nucleosomics<sup>®</sup> - Technical Overview

- The DNA in every cell is wound around proteins complexes in a “beads on a string” structure.
- Each individual “bead” is called a **nucleosome**
- Nucleosome consist of DNA and histone proteins. Histones and DNA are subjected to a variety of **epigenetic modifications**
- Cell death results in fragmentation and release of nucleosomes into the blood

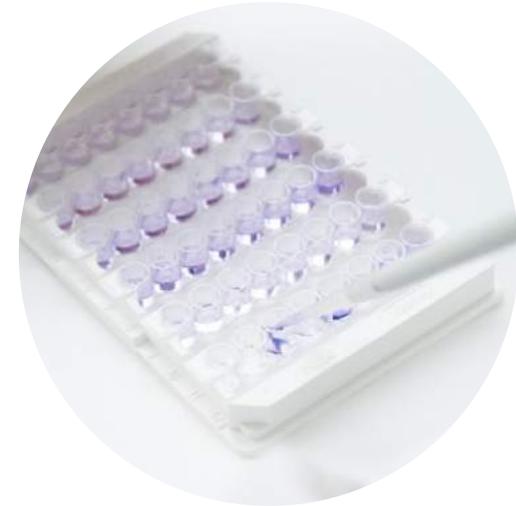


# ELISA-based platform makes it easy and inexpensive

## Cutting-Edge Science that Leverages Robust, Affordable Test Methods

### Test Advantages

1. Ease of use
2. Existing instrumentation already in most labs
3. Established robust methodology allows for low cost per test, and easy to mass produce
4. Flexible to be run in any clinical setting
  - Manual ELISA
  - Automated ELISA
  - Point of Care
5. Small amount of blood required from patient (10ul serum in duplicate)



## Intellectual Property – Nu.Q™ protected by multiple patent coverage

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- Not aware of any other companies working on ELISA measurement of epigenetically modified circulating nucleosomes

- 9 published patent families

### **4 granted US**

- Including 4 core patents protecting the 4 main NuQ ELISA methods
  - Histone modifications (granted US, valid to May 2029)
  - Histone variants (pending US)
  - DNA modifications (pending US)
  - Nucleosomes adducts (granted US, valid to December 2032)
- Further unpublished patents in growing IP portfolio

# Our initial focus is Colorectal Cancer

Patients with bowel cancer caught early (at stage I) have an average 97% five-year survival rate.

Currently, fewer than one in ten people are diagnosed at stage I.

If colorectal cancer is not caught until it has spread (stage IV), the chances of surviving five years or more falls to just 7%.

Colorectal Cancer is responsible for nearly 700,000 deaths worldwide each year

# Mandated Screening

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- In response to the findings on the benefits of early diagnosis, the EU and numerous other countries worldwide have mandated colorectal cancer screening programs.
- There are currently organized colorectal cancer screening programs in 14 of the 28 EU states, with a further 10 states offering some form of public or privately accessible screening.

# Mandated Screening

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Volition's first Nu.Q™ test is the Nu.Q™ Colorectal Cancer Screening Triage test.

- This test works in conjunction with the current standard screening test, the fecal immunochemical test (FIT), used in most colorectal cancer screening programs.

# Streamlining the diagnostic process

The **Nu.Q™ Triage Test** identifies patients who have received a false positive result on their FIT test

The **Triage Test** has demonstrated the potential to reduce colonoscopies by up to **25%** while maintaining almost **97%** detection of colorectal cancer.

Approximately **95%** of people who receive a positive FIT score do not have colorectal cancer, just blood in their stool

The **Nu.Q™ Triage Test** aims to streamline the diagnostic process and ensure that fewer patients are referred for unnecessary colonoscopies.







# Ongoing Clinical Trials

Institution	Condition	Sample Collection	Cohort
Hvidovre Hospital, University of Copenhagen	Colorectal cancer	Retrospective	4,800 symptomatic
Hvidovre Hospital, University of Copenhagen	Colorectal cancer	Prospective	14,000 screening population
Hvidovre Hospital, University of Copenhagen	Colorectal cancer and other cancers	Prospective, longitudinal	30,000 screening population to provide 3 samples each (90,000 total)
University of Bonn	27 most prevalent cancers	Prospective	4,700
German Cancer Research Center (DKFZ)	Pancreatic cancer	Retrospective	750

# Innovation Pipeline

Colorectal cancer is responsible for nearly 700,000 deaths worldwide.

## Colorectal Cancer

- Interim results of a panel of 4 Nu.Q™ assays detected **81%** of colorectal cancers at **78%** specificity in a cohort of 4800 symptomatic patients.
- A panel of 4 normalised Nu.Q™ assays detected **67%** of high risk adenoma at **80%** specificity in a cohort of 530 symptomatic patients.

Currently, emergency presentation is the most common route to diagnosis of Pancreatic Cancer and only 21% of patients survive for more than a year.

## Pancreatic Cancer

- A panel of 4 Nu.Q™ assays plus CA19-9 in a pilot study of 59 patients detected **92%** of pancreatic cancers at **100%** specificity
- Interim results of a panel of 2 Nu.Q™ assays plus CEA detected **95%** of pancreatic cancers at **84%** specificity.

Lung cancer is the most common cancer worldwide. Only 10% of lung cancer patients will survive for five years or more.

## Lung Cancer

- A panel of 4 Nu.Q™ assays in a pilot study of 73 patients detected **93%** of lung cancers at **91%** specificity.

# Regulatory Environment

## CE Mark (Europe)

- Conformité Européenne (“CE”) Marking is a rough equivalent of the United States’ Food and Drug Administration (“FDA”) approvals process, although it is a somewhat lighter regime.
- Establishes certain harmonized EU health, safety and environmental standards. Diagnostic device manufacturers are allowed to use retrospective samples to validate their technologies and products.
- CE Marking expedites or eliminates the regulatory process for commercialization on many clinical markets outside the EU.
- Volition has engaged contract manufacturers with regulator approval, with whom it can work in the initial stages of the commercialization.

## FDA Approval (USA)

- Cancer diagnostics are class III IVD products (the highest classification – in Europe, cancer diagnostics are not in the high classification group except for home use). Volition’s products will have to go through either Premarket Approval (PMA) process of the US FDA or receive clearance of a 510(k) pre-market notification from the FDA.
- US FDA approval is a more expensive and usually longer process than obtaining CE Marking.
- Volition will likely be able to initially use the same samples as for CE Marking, adding further prospective studies and likely extra US-gathered samples.

## CLIA Lab Approval (USA)

- The FDA has the authority to regulate Laboratory Developed Tests (LDTs), although historically labs have been regulated through CMS under the 1988 Clinical Laboratory Improvements Amendment. In October 2014, the FDA issued draft guidance to increase oversight of LDTs
- CLIA waivers allow products to be sold in the USA pre-FDA approval

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website and watch our Corporate  
Video at

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[info@volitionrx.com](mailto:info@volitionrx.com)

