

Volition 

**Corporate  
Presentation**

October 2020

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Statements in this document may be “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. Words such as “expects,” “anticipates,” “intends,” “plans,” “aims,” “targets,” “believes,” “seeks,” “estimates,” “optimizing,” “potential,” “goal,” “suggests,” “could,” “would,” “should,” “may,” “will” and similar expressions identify forward-looking statements. These forward-looking statements relate to the timing, completion and delivery of data from clinical studies, the effectiveness of Volition’s blood-based diagnostic and prognostic tests as well as Volition’s ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases as well as serving as a diagnostic or prognostic tool for COVID-19. Volition’s actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including, without limitation, results of studies testing the efficacy of its tests. For instance, if Volition fails to develop and commercialize diagnostic or prognostic products, it may be unable to execute its plan of operations. Other risks and uncertainties include Volition’s failure to obtain necessary regulatory clearances or approvals to distribute and market future products; a failure by the marketplace to accept the products in Volition’s development pipeline or any other diagnostic or prognostic products Volition might develop; Volition’s failure to secure adequate intellectual property protection; Volition will face fierce competition and Volition’s intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; downturns in domestic and foreign economies; and other risks identified in Volition’s most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that Volition files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about Volition’s business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are made as of the date of this release, and, except as required by law, Volition does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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# COVID-19 Pandemic Operational Update

## Current status

- ✓ Non-Laboratory staff working from home
- ✓ Lab remains open and is operating near capacity
- ✓ Small and medium size studies already collected and samples available in our biobank.
- ✓ On-going sample collection (CRC and Lung) in Taiwan still on track
- ✓ Work commenced on developing a COVID-19 Triage product utilizing Nu.Q™ technology
- ✓ Strengthened balance sheet
- ✓ Increased the flexibility of our supply chain of key components and are moving towards producing our key components in house

## Currently identified risks

- Consumables and antibody supply chain has slowed, so additional suppliers sought and plans to bring production in-house in hand.
- Service contractors affected by the crisis
- U.S. EDRN study recruitment has been put on hold so potentially delayed. Timing impact currently unknown
- Lab would need to close if any lab techs have the disease.

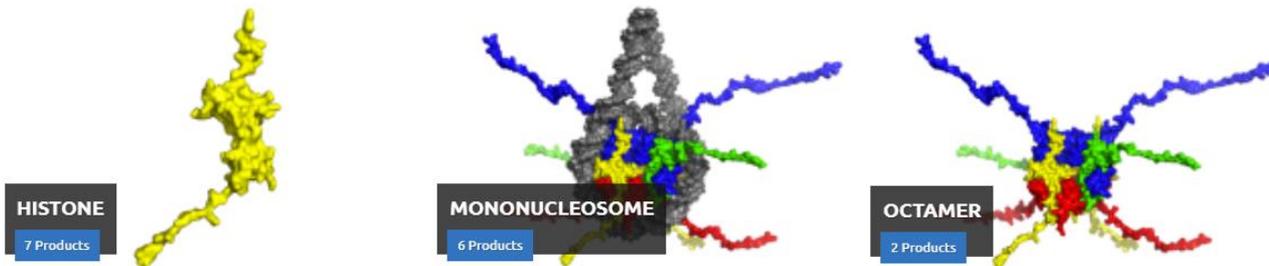
# COVID-19 Product Development



- Our goal is to develop a clinically useful product to help in the battle against the COVID-19 global pandemic and potentially other diseases such as influenza and pneumonia.
- The preliminary study results reported in May demonstrated the Area Under the Curve (AUC) for a single Nu.Q™ assay was 98.7% PCR positive versus control subjects, with 100% sensitivity at 94% specificity. A second Nu.Q™ assay also showed promising results with an AUC of 86.2%.
- To date we have now tested two independent cohorts of COVID-19 positive patients with quantitative nucleosome immunoassays and found that
  - nucleosomes were **highly elevated** in plasma of severe COVID-19 patients relative to healthy control subjects
  - importantly, that both histone 3.1 variant and citrullinated nucleosomes **increased with disease severity**.
- Given that the highest levels of nucleosomes were found in patients requiring artificial ventilation or extracorporeal oxygenation, these data imply that Nu.Q could serve as a guiding biomarker for disease severity in COVID-19 positive patients.
- We are now focused on the completion of larger **longitudinal** studies that would be needed to support a potential COVID-19 product launch.
- We have filed a novel patent for the utilization of our Nu.Q™ epigenetic platform in this area

# Securing supply & developing internal expertise

- Submitted an offer to purchase a 10,000 square ft neighboring facility in Belgium, known as “Silver One”.
- We expect this facility will:
  - Be the production hub for all of our products and components
  - Be a service lab so that we can run samples for other companies
  - Secure supplier at a lower cost
  - Enable us to drive reagent revenue, building on the acquisition of Octamer GmbH Jan 2020



**Our mission is simple.....**



**We want to save lives**





Purpose-built,  
state of the art,  
~20,000 square ft  
Research and  
Development facility  
in Belgium.

  
Volition

  
Volition

# Key Financials

NYSE American: **VNRX**

Market Cap: \$154m\*\*

52-week range: \$2.47-\$5.95\*\*

Monthly Burn: Approx. \$1.7m\*

Cash-on-hand: ~\$21.3m\*

Plus additional funds raised via ATM

\* As of Sept 30, 2020

\*\*As of June 30, 2020



# Key 2020 Milestones.....and beyond

- Multi-well Plate **NU·Q**

✓ Format – LOCKED DOWN 2019

**Q3 2020** First CE Marked Triage Product

Blood

Colorectal

Lung

**H2 2020** Clinical Studies

Colorectal

Lung

- Fully Automated Analyser **NU·Q**

✓ Magnetic bead-based chemiluminescent format LOCKED DOWN Jan 2020

13 assays available, +1/month ongoing

**H2 2020** Medium scale studies

**2021 (Asia) 2022 (U.S)** Large scale studies 7000 subjects +

Colorectal

Lung

- **H2 2020** COVID-19 Longitudinal Study(ies)

**2021** Exploit **NU·Q** licensing opportunities

# Key 2020 Milestones.....and beyond



Toolbox – FINALISED February 2020

4 targets available

**H2 2020** Sequencing results

**H2 2020** Immunoassay results

**H2 2020** Mass Spectrometry results

**2021** Exploit  licensing opportunities



**Q1 2020** Finalize Pre-Analytics – paper now published

**Q2/3 2020** Process Samples

**Q4 2020** Report Clinical Trial Results at VCS, October

**Q4 2020** Launch first  product(s)

**2021** Exploit  licensing opportunities and launch further products

# Investment Highlights

## - Corporate

- Epigenetics healthcare company with a suite of easy to use blood-based cancer tests under development
- We believe that simple to use blood tests are the best way to achieve improved levels of compliance (>80%)
- Broad intellectual property portfolio, including 53 granted patents to date worldwide
- Proof of concept data reported with **plate** based assays in Lung, Colorectal Cancer, Blood Cancer
- Developed a suite of novel epigenetic tools to be used initially in cancer diagnostics
- Texas-based Volition Veterinary subsidiary to develop and commercialise Nu.Q™ Vet
- Acquired epigenetic reagents company Octamer GmbH, now Volition Germany



# Investment Highlights

## - Product

Re-engineered the Nu.Q™ assays in all respects leading to a step-change improvement in analytical performance **PLATFORM LOCKED**

Proof of concept studies with **FINALISED** assays underway in a range of cancers

Large scale Colorectal cancer studies underway globally; Europe, Asia (n=7,000) and the U.S. (N=7,500) **>50% COLLECTED**

Large scale Lung study underway (n=1,200) **>30% COLLECTED**

Nu.Q™ Capture enriches tumor associated nucleosomes **TOOLBOX FINALIZED**

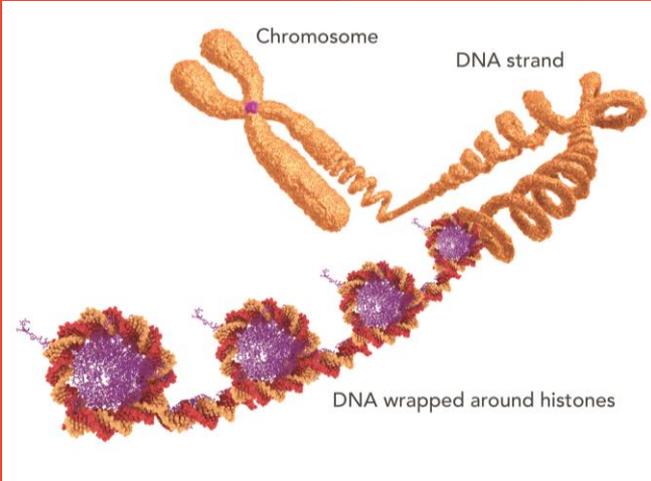
Studies with Nu.Q™ Vet underway with Texas A&M University, product data to be presented at VCS Oct 2020

Initial COVID-19 trials reported, Longitudinal study now underway



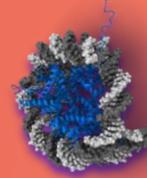
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# Nu.Q™ – The basic concept (across species)



The genome is **3 billion** base pairs. If un-coiled it would measure 5 feet long. Every 150 base pairs of DNA are wrapped around a nucleosome to form a DNA-Nu

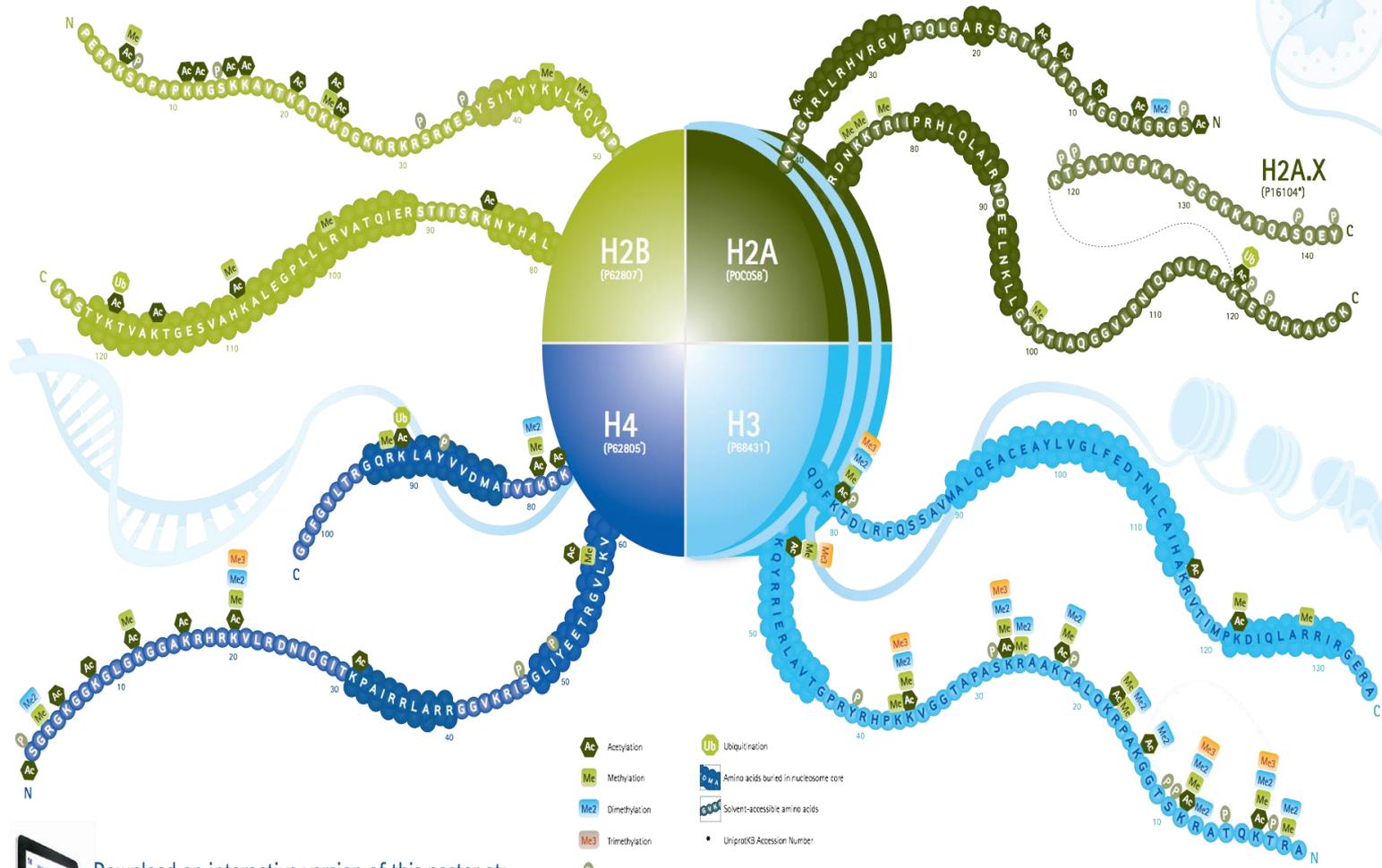
Each individual bead is called a **nucleosome**.



Nucleosomes consist of DNA and histone proteins. Histones and DNA are subjected to a variety of **epigenetic modifications**.

Cancer leads to cell death which results in fragmentation and release of nucleosomes into the blood.

Nu.Q™ assays quantifies nucleosomes from different origins e.g. cancer versus healthy using simple immunoassay, mass spectrometry and/or sequencing.



Download an interactive version of this content:

# Intellectual Property (as of June 30<sup>th</sup> 2020)



- Our patent portfolio is growing
  - 24 patent families
  - Nine patents granted in the U.S.
  - 11 patents granted in the Europe
  - 33 additional patents granted worldwide in growing IP portfolio
  - 98 patents pending worldwide
- Protection expected through or least to 2031 for products including **animal** diagnostics

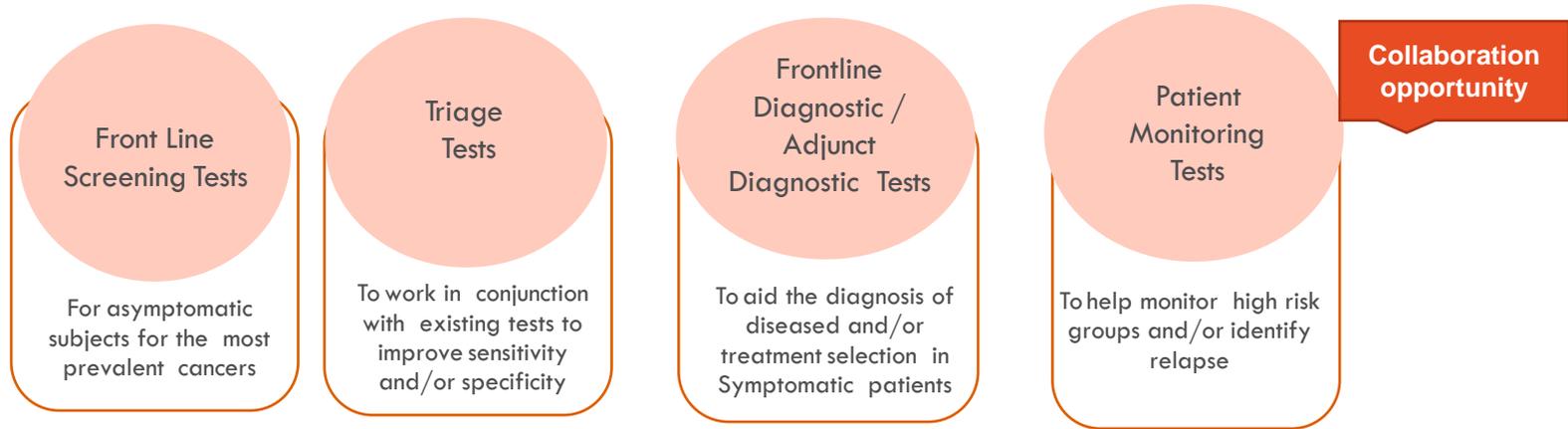
***Further Breakthrough Patents Ongoing***





# Product Strategy – nu·q

We plan to develop multiple products across a range of cancers falling into the following categories:



**AND:**

nu·q  
capture

nu·q  
vet

**PLUS LICENSING  
Opportunities**

# American Cancer Society

“ Screening increases the chances of finding certain cancers early, when they are most likely to be curable. ”

# Cancer is diagnosed differently to most other diseases

Disease	Frontline Screening / Diagnostic Blood Test	Cancer
Diabetes	✓	<ul style="list-style-type: none"><li>• Chest X-Ray</li><li>• Mammography</li><li>• MRI Scan</li><li>• CT Scan</li><li>• Biopsy</li><li>• Colonoscopy</li><li>• Flexible sigmoidoscopy</li><li>• Fecal test</li><li>• Pap Smear</li></ul>
Cardiovascular function	✓	
Kidney function	✓	
Thyroid function	✓	
Liver function	✓	
Reproductive function	✓	
Infectious disease (HIV/Hepatitis)	✓	
Inflammatory disease	✓	

# The Compliance Problem

1/3<sup>rd</sup>

of eligible  
adults have  
NEVER been  
screened<sup>1</sup>.

USTSPF  
recommendations  
stress that CRC  
Screening can  
help save lives

Offering patients  
different test  
options  
substantially  
**increases**  
adherence

“ We believe the only way to achieve this is  
with a routine blood test.

**Jake Micallef** ”  
Chief Scientific Officer

1. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2017-2019.pdf>



# Proof of concept data: Product grade Nu.Q™ assays (on plates)

nu·q

In a **Lung** cancer cohort (76 subjects), a single Nu.Q assay detected lung cancer, including **stage I** lung cancer.  
The AUC for this single assay was **85% (cancer vs healthy)**

In a second Confirmatory **Lung** cancer cohort (152 subjects), the same single Nu.Q assay also detected lung cancer with an AUC of **79% (cancer vs healthy)**

In a **Colorectal** cancer cohort (123 subjects) the same Nu.Q assay detected colorectal cancer with an AUC of **72%** while a two-assay panel had an AUC of **84% (cancer vs healthy)**

In a **Blood** cancer cohort (54 subjects) the same Nu.Q assay detected blood cancer with an AUC of **91% (cancer vs healthy)**

*AUC is Area Under the Curve. The AUC is an accepted measure of the effectiveness of an assays whereby 100% is the most accurate.*

# Three Abstracts Published at ASCO 2020



***Enrichment of circulating tumor DNA from cell-free DNA of hematopoietic origin***

[abstract e13534](#)

***Circulating nucleosomes in hematological malignancy***

[abstract e20078](#)

***Lung Performance of a Nu.Q<sup>TM</sup> H3.1 assay for lung cancer detection***

[abstract e15542](#)



The background is a solid light purple color. It features three large, semi-transparent purple circles of varying sizes. One large circle is on the left side, another is in the top-left corner, and a smaller one is on the right side. The text 'nu·Q capture' is centered in the upper half of the image.

nu·Q  
capture

**nu·q** - we believe we can *enrich* tumor associated nucleosomes capture

## What's next?

**H2 2020** Determine the level of tumor associated nucleosomes using mass spectrometry and identify NEW biomarker targets

**H2 2020** Utilize Nu.Q™ Sequencing to identify tumor of origin and specific mutations

**H2 2020** Utilize in conjunction with Nu.Q™ immunoassay approach to enhance performance

Ultimate aim to provide complete nucleosome analysis and origin of cancer

Potentially a *breakthrough* product

# Our Epigenetic Toolbox

- Nu.Q™ Capture methods to enrich cancer nucleosomes and simplify sequencing based “liquid biopsies”.
- Nu.Q™ Capture methods to isolate intact nucleosomes from plasma for mass spectrometry analysis in the framework of both biomarker discovery and clinical diagnostics.
- Nu.Q™ Capture to measure global methylation patterns in a simple platform.
- Nu.Q™ Capture to concentrate nucleosomal markers prior to our Nu.Q™ assays to increase accuracy.
- Nu.Q™ platform to detect and measure circulating nucleosomes and transcription factors with potential to be tissue specific, and therefore cancer specific. This, if successful could result in a simple blood test for multiple cancers.

**Potentially more *powerful* investigation of a patient’s epigenetic status**



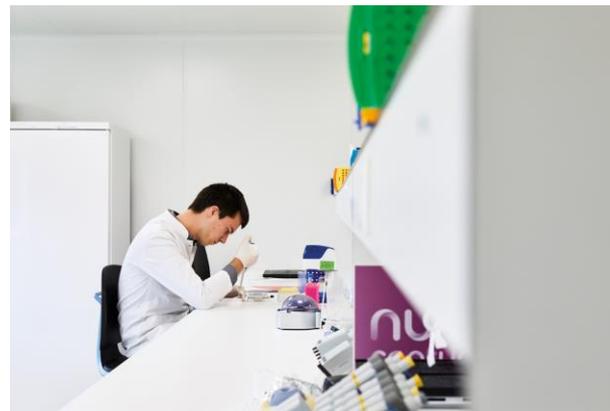
Volition   
Veterinary

# Working together with Texas A&M



- Formed a Texas-based subsidiary “Volition Veterinary Diagnostics Development LLC” and appointed Professor Heather Wilson-Robles as Chief Medical Officer
- **Massive market opportunity; the unmet need is just as great as in human diagnostics**
  - 25% of dogs will develop cancer at some stage of their life
  - In the U.S. alone there are 6 million canine cancer diagnoses per annum compared to 1.7 million human diagnoses
  - Pricing likely to be \$150-\$200 per test
- **Clinical studies underway in collaboration with Texas A&M University College of Veterinary Medicine**
  - **Q1 2020** Finalize Pre-Analytics paper now [published](#)
  - **Q2/3 2020** Process Samples
  - **Q4 2020** Report Clinical Trial Results at VCS, October
  - **Q4 2020** Launch first product(s)
- **Plan to register product with the United States Department of Agriculture (USDA)**

***Potentially faster route to revenue than human diagnostics***



# Becoming a leading epigenetics company



**Significant milestones  
throughout 2020....**

**....Exciting times!!**



## Executive Team



**Dill Faulkes PhD, Executive Chairman** - Dill Faulkes has over 30 years of entrepreneurial and managerial experience as the founder and CEO of several software companies within the United Kingdom and the United States. As the Founder and one of the Benefactors of the Dill Faulkes Educational Trust, a UK registered charity, Dill also focuses on charitable activities.



**Cameron Reynolds MBA, President & Chief Executive Officer** - Cameron has extensive experience in the management, structuring, and strategic planning of start-up companies and has held positions including Chief Executive Officer, Chief Financial Officer, and Non- Executive Director of public and private enterprises. Cameron was educated at the University of Western Australia receiving both a B.Com. and an MBA.



**David Vanston MBA FCCA, Chief Financial Officer** - David has 20 years of financial management experience and recently held the position of Vice President Europe, Finance for Monster Worldwide, Inc.. He is a certified chartered accountant and holds an MBA from Warwick Business School.



**Jake Micallef PhD MBA, Chief Scientific Officer** - Jake is an experienced scientist with expertise in research and development and in the management of biotechnical companies, including manufacturing and establishing operations. He received his BSc and a PhD in Physical Chemistry from King's College London. In addition, he received his MSc in Chemical Pathology, and an MBA from Imperial College Management School.



**Jason Terrell MD, Chief Medical Officer & Chief Executive Officer of Volition America, Inc.** - Jason has expertise in clinical medicine and in laboratory diagnostics in the areas of business development, clinical trials, regulatory affairs and commercialization strategies. He was educated at Hardin-Simmon University where he graduated Summa Cum Laude, also receiving the Holland Medal of Honor. He received his MD from the University of Texas Medical School an affiliate of the MD Anderson Cancer Center.

## Executive Team



**Jasmine Kway PhD, Chief Executive Officer, Singapore Volition** - Jasmine has a proven track record in achieving positive business results by developing strategic business alliances and identifying new markets. She has successfully commercialised and expanded companies into the Asian markets. Jasmine has a B.Eng and a PhD in Oceanography from the National University of Singapore.



**Louise Batchelor, Chief Marketing and Communications Officer** - Louise has more than 25 years of marketing, sales and leadership experience. Formerly Louise worked in various roles at Reckitt Benckiser including roles in Paris and New York. She holds a BA in Business Studies from Sheffield Hallam University.



**Gaetan Michel PhD, Chief Executive Officer of Belgian Volition SPRL & Volition Veterinary Diagnostics Development LLC** - Gaetan has over 10 years of experience in production management. Previously he has held positions such as project manager and production manager in proteomics at Advanced Array Technology and production and process development manager at KitoZyme. He has a PhD in Biochemistry from the University of Namur.



**Heather Wilson-Robles DVM, Chief Medical Officer of VVDD** – Heather is a well-established veterinary medical oncologist specializing in canine models of human cancer. Her research over the past 12 years has focused on improving canine models of pediatric and adult cancers and translating these findings to the mutual benefit of both species. Her basic research focuses on the identification and targeting the tumor initiating cells in osteosarcoma, melanoma and mammary/breast cancers in both canines and humans.



**Nathan Dewsbury MsC, Chief Commercial Officer, Volition Veterinary** - Nathan has unique global expertise in the animal health industry. Having direct involvement in national testing programs, current health diagnostics platforms and commercializing next generation. He was educated at Texas A&M University where he received both his science and business degrees.

## Executive Team



**Mark Eccleston PhD, MBA Business Development Director** - Mark is an enthusiastic and passionate biotechnology entrepreneur with over 20 years experience in the sector. He holds a PhD in Polymer Chemistry for biomedical applications and gained an MBA (entrepreneurship) from the University of Dundee in 2008.



**Marielle Herzog PhD, Research & Development Director** – Marielle is an epigeneticist with nearly 15 years research experience at the Institute of Genetics and Molecular and Cellular Biology (IGBMC), Strasbourg, the Laboratory of Cancer Epigenetics, Free University of Brussels and as the R&D director at Volition. She manages a team with four project managers and coordinates several external academic collaborations as well as outsourced commercial R&D and clinical programs.



**Theresa Kelly PhD, Chief Scientific Officer of Volition America, Inc.** - Terry has over 10 years of experience in Epigenetics including developing novel technologies and seeing them through to commercialization. She previously was the R&D Director at Active Motif and the Global leader for custom assays and services and Agena Bioscience. She received her PhD from UCLA and did Post-doctoral training at USC's Norris Cancer Center where she studied epigenetic regulation in Cancer.



**Rod Rootsart LLB, Corporate Secretary** - Rod is an experienced legal and corporate secretary with over ten years' experience in providing corporate, legal and administrative services to start-up companies. He previously served as corporate secretary for several junior mining companies in the United Kingdom. Rod received a LLB from the University of Western Australia.



**Scott Powell PhD, EVP, Investor Relations & CFO of Volition America, Inc.** - Scott has over 20 years of experience in the U.S. capital markets and investor relations. Scott worked for several years as an investment banker. He earned his B.S. in Business Administration from Bryant University and his MA and PhD degrees from Brown University.

# Thank you for your interest in Volition

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watch our Corporate Video at [www.volition.com](http://www.volition.com) or email  
[mediarelations@volition.com](mailto:mediarelations@volition.com)