

Cameron Reynolds, CEO of Volition, reflects on the company's highlights during 2021 and its plans for 2022.



(Watch video [here](#))

As we embark on a new year with fresh hope and optimism, I must start with a big thank you to our shareholders, collaborators, and particularly our staff for their commitment and dedication to Volition during 2021, which was another difficult year impacted by lockdowns and other restrictions due to the COVID-19 global pandemic. Not only did our team manage to keep our main lab and new 'Silver One' production facility in Namur operational throughout the year, but we also made significant progress across all areas of the business, finishing the year with a commercial licensing agreement which will enable access to our novel Nu.Q[®] Vet Cancer Screening Test across Asia.

Our aim at Volition is to revolutionize the diagnosis and monitoring of life-altering diseases in humans and animals by advancing the science of epigenetics. We have spent over a decade evolving and mastering our understanding of nucleosomes and as a result, have developed a family of simple, easy-to-use, cost-effective blood tests to help diagnose and monitor a range of life-altering diseases such as cancer and sepsis.

Strengthening the executive team

I'm incredibly proud of the expert team we have in place here at Volition.

2021 was a pivotal year for us. We transitioned from solely a research and development company to one with commercial operations, broadening the team with top talent to assist in our commercialization efforts, whilst remaining steadfastly committed to excellence in R&D and driving world-class innovation.

To support our commercial expansion, we welcomed on board Terig Hughes as our Chief Financial Officer, Gael Forterre as our Chief Commercial Officer, and Dr. Tom Butera as the Chief Executive Officer of our veterinary subsidiary. In addition, Gaetan Michel was promoted to Chief Operating Officer. The caliber, experience, and expertise that Terig, Gael, Tom, and Gaetan collectively bring to Volition's leadership team puts the company in a strong position as it enters into this next crucial, income-generating phase.

Meanwhile, within our R&D function, Dr. Mark Eccleston was appointed to the newly created role of Chief Technology Officer, and Dr. Terry Kelly was promoted to Chief Innovation Officer. Terry is leading a team focused on cutting-edge, discovery research at our Innovation Hub at California State University in San Diego.

Rollout of Nu.Q[®] Vet Cancer Screening Test

Undoubtedly, the biggest highlight of the past year has been the successful beta launch of our Nu.Q[®] Vet Cancer Screening Test in the U.S. market. This was a critical milestone for the company, as it demonstrated that our Nucleosomics™ platform had reached the level of reliability and reproducibility to be launched in an independent laboratory.

Cancer is the most common cause of death in dogs over the age of two years in the U.S., with over six million new dog cancer diagnoses each year. As cancer screening is not as commonplace in animal health as it is in human health, blood tests like the Nu.Q[®] Vet Cancer Screening Test have the potential to transform how veterinarians manage cancer in companion animals.

Our simple, cost-effective, and easy-to-use ELISA-based blood screening test is designed to streamline the diagnostic process for older dogs, as part of their annual wellness program and as a complementary test for younger dogs that are “at-risk” breeds.



Our test is now available to U.S. veterinarians through the GI Lab at Texas A&M University and our Volition Veterinary team has spent the past year building our brand awareness and credibility with key opinion leaders, oncology specialists, and general practice veterinarians through studies, publications, and presentations at key veterinary conferences.

We were delighted that our Nu.Q[®] Vet Cancer Screening Test has garnered commercial interest from across the world. In December, we appointed SAGE Healthcare as a non-exclusive licensee and distributor for Volition's Nu.Q[®] Vet Cancer Screening Test in centralized labs in Singapore, with a launch planned for the first quarter of 2022, followed by wider expansion into centralized labs across Asia.

Extensive and wide-ranging negotiations continue to progress with global players in the U.S. and European markets, with the aim of launching our Nu.Q[®] Vet Cancer Screening Test worldwide through both reference labs and point of care testing on an exclusive and non-exclusive basis and we expect to announce further licensing agreements in 2022, starting in this quarter.

Launching a second Nu.Q[®] Vet product

Looking ahead, we are planning to launch our second Nu.Q[®] Vet product in 2022. Dr. Heather Wilson-Robles and her team at Texas A&M University have published exciting new data which demonstrates that Nu.Q[®] Vet may serve as a more sensitive measurement of both minimal residual disease and remission and could, therefore, be used as an effective monitoring tool for dogs with cancer. We believe that this additional test has significant potential to improve the treatment and the quality of life for dogs by providing actionable information to support the clinical decision-making process for both veterinarians and pet owners.

In addition, we are looking to broaden the range of cancers detected by Nu.Q[®] Vet, develop a point of care test to provide a timely diagnostic and treatment response, and we are developing additional assays to add to the Nu.Q[®] Vet Cancer Screening Test to effectively differentiate cancer from other inflammatory conditions, immune-mediated disease and endocrinopathies.

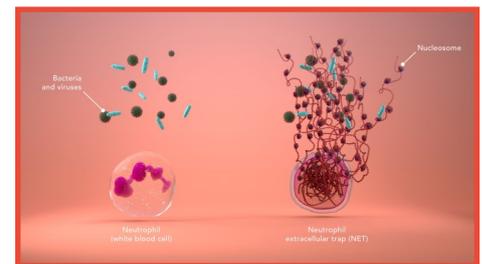
So, all in all, Volition Veterinary is an exciting, fast-moving part of our business with a considerable ability not just to help man's best friend but also with the potential to generate significant revenue for the company.

Detection and monitoring of NETosis

While cancer remains a core disease focus, we have continued, at pace, research and development into the wider application of our proprietary Nucleosomics™ technology. This includes the detection and monitoring of NETosis, an abnormal immune response that can lead to severe complications in COVID-19, sepsis, and other life-altering diseases.

The immune system is comprised of many different types of white blood cells with different functions. The most abundant cells are neutrophils, which serve as the first line of defense. When they detect bacteria or viruses these cells produce Neutrophil Extracellular Traps (NETs) — sticky webs made of long strings of nucleosomes that stop the threat from spreading around the body. Although NETs are an important part of the body's response to infection, the presence of too many of them in the blood can tip the immune system's delicate balance from reaction to overreaction. Excessive production of NETs can damage the tissue and lead to the formation of potentially dangerous minute blood clots called microthrombi.

Elevated levels of NETs are a complicating factor associated with poor patient outcomes in a range of infectious and non-infectious diseases. For example, in sepsis, patients can suffer widespread tissue and organ damage. And, in severe COVID-19, excessive production of NETs in the lungs can lead to significant lung impairment or death.



However, NETs contain nucleosomes, and our proprietary Nu.Q® nucleosome assays have been shown to detect NETs in minute quantities.

We spent a large part of 2021 developing a new product - Nu.Q® NETs - to detect NETosis. Nu.Q® NETs could enable the stratification of patients with a high level of NETs, allowing physicians to rapidly triage these patients and monitor both their disease progression and response to treatment.

Supporting intensive care for COVID-19 and sepsis

We are working with academic researchers and leading hospital clinicians to bring Nu.Q® NETs to the market as quickly as possible. In July 2021, colleagues from Hampshire Hospitals NHS Trust and Kings College Hospitals NHS Trust each presented posters at the International Society on Thrombosis and Haemostasis Congress. Their early-stage data show that the level of circulating NETs, as measured using our Nu.Q® NETs assays, correlates with current disease severity and mortality in COVID-19 patients. In addition, the studies show that our NETs-based tests could be used to predict future disease severity and guide treatment selection in patients, on admission.

Further, we have obtained proof-of-concept for Nu.Q® NETs as an effective test to monitor response to a novel treatment for sepsis. Our collaborators on this project, Santerus AG, are developing a therapy that takes the patient's blood outside of his or her body, removes excess NETs, and recirculates the blood back into the body. Our Nu.Q® NETs test monitors the level of NETs in the blood and is a key part of the ongoing trials of this exciting potential new treatment.

The development of Nu.Q[®] NETs once again underlines the breadth of the Nu.Q[®] platform technology which is supported by our robust intellectual property portfolio.

Given the broad range of potential use case settings for Nu.Q[®] NETs, we are currently driving forward our plans for commercialization. With a product manager now in place, we aim to launch a CE Marked Nu.Q[®] NETs product across multiple platforms in 2022. We are also developing a U.S. clinical study plan geared towards FDA approval of our Nu.Q[®] NETs product, which we expect to start with a pilot study later in 2022.

To sum up, this is an incredibly exciting new area of use for our proprietary Nu.Q[®] platform. We have seen excellent results to date, with a range of different world-class collaborators, with more data to be published in the coming months. We are now shifting gears to focus on regulatory registration and to transform these results into a range of Nu.Q[®] NETs products worldwide.

Our pipeline

Lastly, whilst we made great strides in taking forward our Nu.Q[®] Vet Cancer Screening Test and Nu.Q[®] NETs product development in 2021, I must also shine a light on the incredible work our teams have undertaken within other areas of our product portfolio, namely Nu.Q[®] and Nu.Q[®] Capture.

Nu.Q[®] has been developed for the early detection of blood, lung, colorectal, and other human cancers, as well as for disease and treatment monitoring of blood cancers. Whilst COVID-19 has unfortunately impacted our two U.S. blood cancer studies this year, in Asia, we reached our target patient cohorts for both our colorectal cancer and lung cancer studies, in conjunction with the National Taiwan University. Findings from our colorectal studies will be presented at the ASCO Gastrointestinal Cancers Symposium at the end of January 2022.

Meanwhile, Dr. Terry Kelly has continued to recruit team members for our Innovation Hub in San Diego, where they are developing Nu.Q[®] Capture, an enabling and enrichment technology to capture and concentrate nucleosomes containing particular epigenetic signals for further analysis, more accurate diagnosis, and to guide treatment. The team published two papers on Nu.Q[®] Capture in 2021, in Nature's Scientific Reports, regarding the use of Nu.Q[®] Capture with mass spectrometry and at the Veterinary Cancer Society Conference, outlining the use of our transformational technology in dogs with lymphoma.



We believe that Nu.Q[®] Capture offers enormous potential. Deployed as the first blood sample processing step, we plan to use the technology internally to enhance the sensitivity of our subsequent Nu.Q[®] immunoassays. It could also be used commercially to aid the development of improved diagnostic DNA sequencing methods, serve as a quality control tool, and aid the discovery of new biomarkers. It is an extremely cutting-edge use of our Nu.Q[®] platform and will be a key part of our future product development.

Goals for 2022

Overall, on so many fronts, with our ever-growing team and intellectual property, I am delighted with the progress we are making and am excited by the momentum we have developed in the epigenetics field. Indeed, our whole team is incredibly excited by the company's future opportunities.

Looking ahead to 2022 we want to ensure we remain at the cutting edge of epigenetics. I anticipate more news surrounding the licensing of our Nu.Q[®] Vet Cancer Screening Test in the near term and am excited that we plan to launch our second Nu.Q[®] Vet product later this year.

Underpinned by a robust clinical study and regulatory program, we also aim to launch a Nu.Q[®] NETs product. Other goals [for 2022] include further development of Nu.Q[®] Capture as a transformational technology, achieving ISO 13485 for our Silver One production facility, and continued development of our platforms, antibodies, and controls. Without a doubt, these are ambitious targets, but with the support, dedication, and phenomenal expertise of our team, I'm confident we'll achieve them and 2022 will be a very successful year for Volition.

Thank you to all our shareholders, staff, and collaborators for your continued support and we look forward to keeping you updated on our progress this year.

Wishing you all a prosperous new year,

Cameron

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For more information: Please visit our new website at volition.com or contact mediarelations@volition.com

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