March 22, 2021

# VolitionRx Limited Announces Full Fiscal Year 2020 Financial Results and Business Update

## Conference call to discuss financial and operational results scheduled for Tuesday, March 23 at 8:00 a.m. U.S. Eastern Time

- Launched first product, the Nu.Q® Vet Cancer Screening Test and recorded first revenue from sales of a commercial product
- Engaged Diagnostic Oncology CRO LLC to conduct U.S. regulatory clinical trial for Non-Hodgkin's Lymphoma
- Expanded research program for the use of Nu.Q® technology in NETosis (COVID-19 and sepsis)
- Strengthened intellectual property portfolio
- Purchased and opened first production facility
- Strongest-ever cash position following a public offering in February 2021

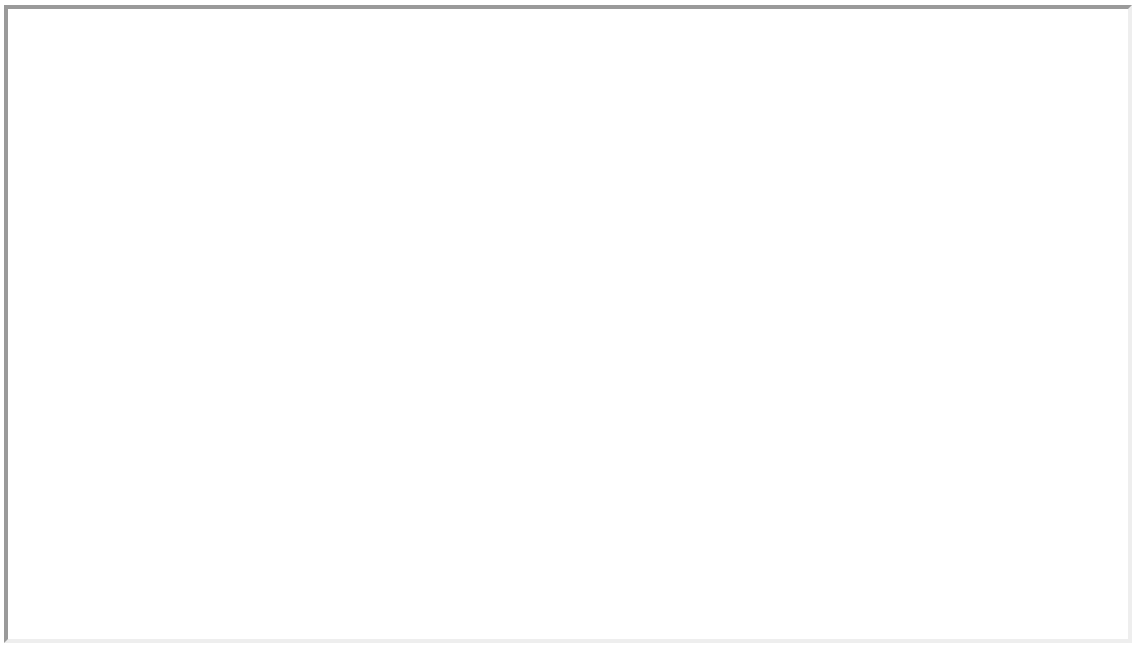
AUSTIN, Texas, March 22, 2021 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the full fiscal year ended December 31, 2020. Volition management will host a conference call tomorrow, March 23 at 8:00 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

"We made significant progress on many fronts throughout 2020, culminating in the launch of our first product, the Nu.Q® Vet Cancer Screening Test in the fourth quarter. This was a pivotal moment for Volition, demonstrating that our platform has the reliability and reproducibility to launch in an independent laboratory," commented Cameron Reynolds, President and Chief Executive Officer of Volition. "Despite the persistence of the COVID-19 pandemic, we kept our laboratory operational throughout the year and completed the fit out and opening of our new Silver One production facility in Namur, Belgium. I am proud of the way our team has adapted to the different world we find ourselves in and has kept working at full speed. It is their efforts and tenacity that have made possible these milestones and the many others that we achieved during 2020."

https://youtu.be/el-7H7SWULA

**An interview with Cameron Reynolds, President and Chief Executive Officer, Terig**

**Hughes, Chief Financial Officer and Jake Micallef, Chief Scientific Officer.**



Mr. Reynolds continued, "We added to our already extensive intellectual property portfolio and at year end held 64 patents with a further 90 patents pending. We have made considerable progress in our human studies with data released in blood cancer, lung cancer, Nu.Q® Capture, COVID-19 and most recently sepsis. Currently we are in our strongest-ever financial position to support the pursuit of our many milestones and look forward to providing updates throughout the year."

**Company Highlights**

*Financial*

- Cash and cash equivalents as of December 31, 2020 totaled approximately $19.4 million compared with $17 million as of December 31, 2019.
- Continued to manage our expenditures carefully with a burn rate of approximately $1.5 million per month throughout 2020.
- During the first quarter of 2021 to date added an aggregate of approximately $20.5 million in cash mostly through an underwritten public offering of our common stock that closed in February, as well as through periodic sales of common stock under our at-the-market equity distribution program.
- Secured a further $4 million in non-dilutive funding consisting of a cash grant of $1.3 million and loans totalling $2.7 million from the Walloon Regional Government and associated agencies.
- Following the public offering in February, our cash and cash equivalents totaled approximately $40 million before deducting expenses incurred thus far in 2021, by far our strongest cash position ever.

*Nu.Q® Vet Cancer Screening Test Commercial Launch*

- Launched the Nu.Q® Vet Cancer Screening Test in late November.
- We are very happy with the sales progress to date. We received the first order from

the GI lab at Texas A&M University late last year and have already received three additional orders from them in 2021.
- The test is positioned for use in the annual health check of older dogs (those that are seven years and older). It may also be a complimentary test for younger dogs of breeds at high risk for developing cancer in their lifetimes such as Golden Retrievers.
- This beta launch will facilitate real-world learnings and help shape the marketing mix before our planned launch nationally across the U.S. in the next few months.
- The beta launch also provides us an opportunity to showcase the product to the large multinational companies we are in active discussions with, regarding the distribution and/or sales of our tests in the veterinary market.
- In addition to the Texas beta launch we are finalizing beta launch planning in both Asia and Europe.

*Clinical – New U.S. Regulatory Study*

- Engaged Diagnostic Oncology CRO LLC, the largest U.S. Contract Research Organization specializing in oncology purposed in-vitro diagnostic device clinical trials, to conduct a U.S. regulatory clinical trial for Non-Hodgkin's Lymphoma (NHL).
- The trial is designed to obtain multiple FDA-approved adjunct tests to aid in the diagnosis of the five most common and aggressive forms of NHL.
- The trial will enroll up to 1,500 subjects across 10 major U.S. healthcare institutions over 22 months.
- This extensive program will cost approximately $2.9 million over two years assuming the completion of numerous projects and includes not only the clinical study but also data analysis and regulatory and reimbursement submission preparation.
- Existing data suggests Nu.Q® technology will greatly aid physicians in distinguishing NHL from common conditions, fulfilling what we believe is a critical unmet clinical need and which represents a major market opportunity.
- We expect our first FDA 510(k) submission will be possible approximately 10-12 months into the trial.
- In addition, we are also conducting a proof-of-concept study for the monitoring of treatment response for the most aggressive NHL cancer, diffuse large B-cell lymphoma (DLBCL). We expect the results from this trial in the first half of 2021.

*Clinical – NETosis including COVID-19*

- We have made great progress on a research program for the use of our Nu.Q® technology in NETosis and in particular in monitoring disease progression of COVID-19 and sepsis and, as announced last week, as a potential companion diagnostic for a treatment for sepsis. We are seeking to broaden this further into influenza and potentially other diseases associated with NETosis.
- Several studies have been collected, processed and are now either being analyzed or have been submitted to conferences for publication. This program has taken longer than we expected as the hospitals we are working with have, understandably, been focused on caring for the very high numbers of patients admitted during the 2$^{nd}$ wave of COVID-19.
- We are negotiating a large FDA trial for use of our assays in diseases associated with neutrophil extracellular traps (NETs) such as sepsis, COVID-19 and influenza in the U.S. and will announce the full details once they have been finalized.

- We have filed a novel patent for this application and plan to utilise results of these trials and other ongoing studies to further our aim of developing a clinically useful Nu.Q® NETs product.

*Clinical – Cancer*

- In various ways our "marquee trials" have now been affected by the continued pandemic either by slower or paused collection, or a host of other supply chain or travel and communication issues. We believe we have successfully managed those areas under our direct control (such as assay development and running samples – both of which are on track with our milestones) but many issues are not within our control.
- An abstract regarding Nu.Q® performance in lung cancer detection was presented at the WCLC conference in January 2021. The key message from the presentation is that, based on an interim analysis of a subset of subjects in the ongoing study with the National Taiwan University, Nu.Q® assays could help identify non-cancerous nodules following a scan thereby reducing unnecessary biopsies by as much as 32%.
- We hope to complete this large 1,200 subject lung cancer study and share findings at upcoming conferences later this year.
- If the data continues to be encouraging, we are planning to initiate a 510(k) regulatory study in the U.S. for lung cancer, as we have for NHL.

*Expansion*

- As we transition from a research and development company to a commercial company, we strengthened the leadership team with the appointment of a new Chief Financial Officer, Mr. Terig Hughes, Mr. Gael Forterre as Chief Commercial Officer, in addition to the promotion of Dr. Gaetan Michel as Chief Operating Officer and Dr. Mark Eccleston as Chief Technology Officer.
- We completed the purchase and fit-out of "Silver One", the production hub for our products and key components located in Namur, Belgium. With this new facility we can provide a service for clinical trial purposes and produce CE-marked products for Europe and beyond.
- We have also opened a small, shared laboratory at California State University in San Marcos, California where we will focus on blue-sky innovation and discovery research.

*Upcoming Milestones*

Volition expects to achieve the following milestones during 2021 and beyond:

- Beta launches of the Nu.Q® Vet Cancer Screening Test in Asia and Europe.
- National launch of the Nu.Q® Vet Cancer Screening Test in the U.S.
- Focus on driving revenue in the coming quarters, where possible during the pandemic, in four key areas:

  - Nu.Q® Vet products,
  - Disease monitoring tests (e.g. Nu.Q® NETs for COVID-19, sepsis and other diseases),
  - Reagent sales, and
  - Licensing of our technology for others to commercialize in both humans and

animals.

- Continue to progress the research program for the use of Nu.Q® in NETosis, in monitoring disease progression of COVID-19, sepsis and potentially other diseases and as a possible companion diagnostic for a treatment for sepsis.
- Continue to advance our previously announced large-scale blood, lung and colorectal cancer trials in Europe, Asia and the U.S.
- Publish several abstracts and peer-reviewed scientific papers with clinical results showing the robustness and utility of our Nu.Q® platform.
- Advance the development of Nu.Q® Capture.
- Continue to file patents to expand and extend our intellectual property portfolio.

**VolitionRx Limited Full Fiscal 2020 Financial Results and Business Update**

**Date:** Tuesday, March 23, 2021
**Time:** 8:00 a.m. U.S. Eastern time
**U.S. & Canada Dial-in:** 1-877-407-9716 (toll free)
**U.K. Dial-in:** 0 800 756 3429 (toll free)
**Toll/International:** 1-201-493-6779
**Conference ID: 13717672**

Cameron Reynolds, President and Chief Executive Officer of Volition, will host the call along with Terig Hughes, Chief Financial Officer, Jake Micallef, Chief Scientific Officer and Scott Powell, Executive Vice President, Investor Relations.

A live audio webcast of the conference call will also be available on the investor relations page of Volition's corporate website at http://ir.volition.com.

In addition, a telephone replay of the call will be available until April 6, 2021. The replay dial-in numbers are 1-844-512-2921 (toll-free) in the U.S. and Canada and 1-412-317-6671 (toll) internationally. Please use replay pin number 13717672.

**About Volition**

Volition is a multi-national epigenetics company developing simple, easy to use, cost effective blood tests to help diagnose a range of cancers and other diseases. Early diagnosis has the potential to not only prolong the life of patients, but also to improve their quality of life. The tests are based on the science of Nucleosomics™, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid - an indication that disease is present. Volition is primarily focused on human diagnostics but also has a subsidiary focused on animal diagnostics.

Volition's research and development activities are centered in Belgium, with a small laboratory in California and additional offices in Texas, London and Singapore, as the company focuses on bringing its diagnostic products to market.

For more information about Volition, visit Volition's websitevolition.com or connect with us via:

Twitter: https://twitter.com/volitionrx

LinkedIn: https://www.linkedin.com/company/volitionrx

Facebook: https://www.facebook.com/VolitionRx/

YouTube: https://www.youtube.com/user/VolitionRx

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**Safe Harbor Statement**

Statements in this press release 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, 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, and the timing of product launches and publications. 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.

Pursuant to the disclosure requirements of the NYSE American Company Guide Section 610(b), Volition is reporting that its audited consolidated financial statements for the fiscal year ended December 31, 2020, included in Volition's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 22, 2021, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to Volition's ability to continue as a going concern. This announcement does not represent any change or amendment to Volition's financial statements or to its Annual Report on Form 10-K for the fiscal year ended December 31, 2020.



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