

February 20, 2020



# VolitionRx Limited Announces Full Fiscal Year 2019 Financial Results and Business Update

**Conference call to discuss financial and operational results scheduled for Friday, February 21 at 8:30 a.m. U.S. Eastern Time**

AUSTIN, Texas, Feb. 20, 2020 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the full fiscal year ended December 31, 2019. Volition management will host a conference call tomorrow, February 21, at 8:30 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

Cameron Reynolds, President and Chief Executive Officer of Volition, upon releasing these results commented, "During 2019, we, together with our collaborators, have made very strong progress, particularly in assay and platform development, with our Nu.Q<sup>(TM)</sup> Capture program and epigenetic toolkit, Nu.Q<sup>(TM)</sup> Vet in collaboration with Texas A&M University and, most recently, with the acquisition of the epigenetics reagents company, Octamer GmbH. It is very encouraging that our field of epigenetics is now getting what we believe is long overdue recognition."

<https://youtu.be/Nvt84hfOUEg>

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

Mr. Reynolds added "We strengthened our balance sheet throughout 2019 with existing investors exercising over \$16 million in outstanding warrants to purchase shares of our common stock, receipt of additional non-dilutive funding and maintaining a low cash burn rate and therefore start the new year in a strong position to achieve our key 2020 milestones."

## **Company Highlights**

### *Financial*

- Cash and cash equivalents as of December 31, 2019 totalled \$17 million compared to \$13.4 million as of the end of 2018.
- Existing investors exercised \$16.5 million in aggregate amount of outstanding warrants to purchase shares of our common stock.
- Received additional \$3.3 million in non-dilutive funding taking our total non-dilutive funding (grants and loans) to date to over \$7.5 million.
- Continue to manage cash carefully with a monthly burn (or cash used in operating activities) of approximately \$1.2 million during 2019.

## Assay Development

Volition has completely re-engineered its Nu.Q<sup>(TM)</sup> assays to now use a magnetic particle-based assay format leading to a step-change improvement in analytical performance. Volition expects this enhanced analytical performance to translate into improved clinical performance in the studies to be carried out and reported in the coming months.

Relative to Volition's ELISA plate Nu.Q<sup>(TM)</sup> assay format, the magnetic particle-based assay format demonstrates:

- A 10 to 20-fold improvement in analytical sensitivity of the assays.
- Typical within-day reproducibility of quantitative test results below 3% (previously <10%).
- Decrease in test result turnaround time from 6 hours to approximately 1 hour and 20 minutes, allowing much higher throughput.
- The ability to be developed and processed on fully-automated Random-Access platforms (enabling the use of a wide range of commercial automated platforms).

In terms of clinical accuracy, over the past twelve months as we have been working on the aforementioned assay development, we have completed some proof of concept studies to assess clinical performance. While this work is yet to be completed for the finalized assays, preliminary results were extremely encouraging that for even the development assays we saw our highest ever Area Under the Curve performance in Blood Cancer at 91% and in Lung Cancer at 85% in addition to reporting positive data in colorectal cancer.

## Epigenetic Toolbox

Volition has developed and is seeking patents on its novel Nu.Q<sup>(TM)</sup> Capture based epigenetic tools, in addition to its ongoing efforts regarding its bead-based Nu.Q<sup>(TM)</sup> assay format, to decipher the epigenetic and environmental profiles of cancer nucleosomes with the aim of using:

- Nu.Q<sup>(TM)</sup> Capture methods to enrich cancer nucleosomes and simplify sequencing based "liquid biopsies".
- Nu.Q<sup>(TM)</sup> Capture methods to isolate intact nucleosomes from plasma for mass spectrometry analysis in the framework of both biomarker discovery and clinical diagnostics.
- Nu.Q<sup>(TM)</sup> Capture to measure global methylation patterns in a simple platform.
- Nu.Q<sup>(TM)</sup> Capture to concentrate nucleosomal markers prior to our Nu.Q<sup>(TM)</sup> assays to increase accuracy.
- Nu.Q<sup>(TM)</sup> 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.

Volition is using these tools to expand diagnostic developments that focus on circulating DNA fragment analysis, to a broader and potentially more powerful investigation of the epigenetic status of a patient's circulating chromosome fragments, in addition to its ongoing work with its assay-based format in a range of cancers.

## Organization

- Our laboratory team expanded appreciably to include, among others, the appointment of an Assay Validation Expert who has been instrumental in taking our assays forward.
- We added two new operating subsidiaries with the formation of Volition Veterinary Diagnostics in June 2019 and the acquisition of our epigenetics reagents subsidiary, Octamer GmbH, in the early part of 2020.
- In connection with the formation of Volition Veterinary Diagnostics, we welcomed Nathan Dewsbury as its Chief Executive Officer and, Dr. Heather Wilson-Robles DVM, as its Chief Medical Officer.
- In connection with the acquisition of Octamer we expanded our Scientific Advisory Board to include Dr. Adrian Schomburg, one of the world's leading experts on Nucleosomes and founder and CEO of Octamer.
- We also welcomed Dr. Phillip Barnes to our Board of Directors.

## Upcoming Milestones

We expect to achieve the following milestones during 2020 :

- Release a range of clinical data with our new optimised bead-based assays in colorectal, lung and other cancers.
- Advance our previously announced large-scale colorectal and lung cancer trials in Europe, Asia and the U.S.
- Advance the development of Nu.Q<sup>(TM)</sup> Capture by determining the level of discrimination of tumor associated nucleosomes using mass spectrometry and/or sequencing.
- Announce patient data demonstrating the wide utility of Volition's epigenetic toolbox.
- Complete pre-analytical and clinical studies for Nu.Q<sup>(TM)</sup> Vet with the aim of launching our first product in 2020.
- Publish several abstracts and peer reviewed articles with clinical results as well as showing the robustness and utility of our Nu.Q<sup>(TM)</sup> platform.

Mr. Reynolds concluded, "We are extremely proud of the accomplishments we have achieved thus far. I thank the dedicated Volition team for their tireless efforts. I, along with the rest of the Board and indeed the whole company, look forward to sharing the results of key studies over the coming year."

For further details please contact [mediarelations@volition.com](mailto:mediarelations@volition.com)

### **VolitionRx Limited Fourth Quarter & Full Year 2019 Earnings and Business Update Conference Call**

**Date:** Friday, February 21, 2020

**Time:** 8:30 a.m. 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:** 13699351

Cameron Reynolds, President and Chief Executive Officer of Volition, will host the call along

with David Vanston, Chief Financial 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 March 6, 2020. 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 13699351.

## 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<sup>(TM)</sup>, 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 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 website [volition.com](http://volition.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>

The contents found at Volition's website address, Twitter, LinkedIn, Facebook, and YouTube are not incorporated by reference into this document and should not be considered part of this document. The addresses for Volition's website, Twitter, LinkedIn, Facebook, and YouTube are included in this document as inactive textual references only.

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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 effectiveness of Volition's blood-based diagnostic tests as well as Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if Volition fails to develop and commercialize diagnostic 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 in the clinical IVD or the veterinary market; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic 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; 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, 2019, included in Volition's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 20, 2020, 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, 2019.

Nucleosomics<sup>(TM)</sup> and Nu.Q<sup>(TM)</sup> and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to in this press release are the property of their respective owners. Additionally, unless otherwise specified, all references to "\$" refer to the legal currency of the United States of America.

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