

VolitionRx Announces its European Colorectal Cancer Strategy

ISNES, Belgium, Sept. 19, 2017 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced its colorectal cancer (CRC) strategy for Europe. As part of its strategy, Volition plans to select a frontline panel to be validated in two large trials (4,300 and 10,000 sample), followed by CE marking, with a goal to launch a European frontline CRC screening product in 2018.

Chief Executive Officer of Volition, Cameron Reynolds, commented, "We believe that the market for the frontline screening test represents the largest near-term opportunity for Volition, as there are 150 million Europeans of screening age. Our strategy for Europe is now in place using patient samples that have already been secured in our very large ongoing Danish trials. Our U.S. strategy includes a 13,500-patient study in collaboration with the Early Detection Research Network (EDRN) of the U.S. National Cancer Institute (NCI). We have also made significant progress in Asia. We look forward to executing on our worldwide strategies and to the anticipated launch of our frontline test in Europe in 2018."

"We are making significant progress with our frontline CRC screening test," said Dr. Gaetan Michel, Chief Executive Officer of Belgian Volition. Dr. Michel added, "We have received considerable support from the local government and agencies which has helped Volition's operations, notably through the large increase in capacity from our purpose-built facility which allows us to conduct more clinical trials effectively. This has also helped us grow our talented team and make key hires, which we will continue to do."

The current 12-month plan:

- Fourth Quarter, 2017 Volition aims to complete its choice of a panel for the Nu. d^M colorectal cancer screening test for Europe.
- First Quarter, 2018 The chosen panel will then be subject to validation in a 4,300subject trial using secured samples from Danish cohorts, already acquired by Volition's subsidiary, Belgian Volition SPRL. Following the completion of the study, the results will be submitted for publication in a peer reviewed journal.
- Second Quarter, 2018 The chosen panel will be subject to further validation in a blinded 10,000-subject trial using secured samples from Danish cohorts, then submitted for peer reviewed publication. This very large trial will include over 100 samples with colorectal cancer and will be representative of an asymptomatic screening population.
- Third Quarter, 2018 CE Marking is expected to be completed on the chosen panel, providing the ability to market the product in 28 European Countries as a frontline colorectal cancer screening test. The completion of the CE Marking also offers a regulatory platform to expedite approval in many of the Asian markets.

Volition was recently informed by its Danish collaborators that the previously announced

Triage Pathway Design Study is likely to be completed at the end of November 2017. Volition also expects that adaptions to the Nu.QTM Colorectal Cancer Triage Test will be completed around the same timeframe.

About Volition

Volition is a multi-national life sciences company developing simple, easy to use bloodbased cancer tests to accurately diagnose a range of cancers. 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.

As cancer screening programs become more widespread, Volition's products aim to help to diagnose a range of cancers quickly, simply, accurately and cost effectively. Early diagnosis has the potential to not only prolong the life of patients, but also to improve their quality of life.

Volition's research and development activities are currently centered in Belgium, with additional offices in London, Texas and Singapore, as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

For more information about Volition, visit Volition's website <u>http://www.volitionrx.com</u>) or connect with us via:

Twitter: <u>https://twitter.com/volitionrx</u> LinkedIn: <u>https://www.linkedin.com/company/volitionrx</u> Facebook: <u>https://www.facebook.com/VolitionRx/</u> YouTube: <u>https://www.youtube.com/user/VolitionRx</u>

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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 bodily-

fluid-based diagnostic tests as well as Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer. 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 market; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic products Volition might develop; 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.

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