

# VolitionRx Limited Announces Interim Results from 680-Subject Clinical Trial in Colorectal Cancer

- **Study demonstrates high detection rates of Stage I cancer and pre-cancerous adenomas in colorectal cancer screening trial for Nu.Q™ blood test**
- **Conference call to discuss interim results scheduled for Tuesday, February 27 at 8:30 a.m. Eastern Time**

ISNES, Belgium, Feb. 26, 2018 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced interim results from its first asymptomatic colorectal cancer (CRC) frontline screening study. This ongoing study is being carried out in collaboration with Hvidovre Hospital, University of Copenhagen, Denmark and involves 680 subjects from the Danish National CRC Screening Program. The interim results demonstrated that a small panel of three ELISA assays, when considered with the subjects' ages and smoking histories, produced an area under the curve (AUC) of 83% and was able to detect 80% of Stage I CRC cases and 66% of High-Risk Adenomas (HRA) at 78% specificity, respectively.

Cameron Reynolds, Chief Executive Officer of Volition, commented, "After seven years of hard work, we are happy to announce these excellent early detection interim results from our ongoing front-line screening trial for colorectal cancer. Using only a small panel of three assays and considering certain limited patient variables, these data demonstrate that we can identify early stage and pre-cancerous adenomas at a high level of accuracy in an asymptomatic screening environment. Our tests use only a small amount of blood and could be added to routine blood screening regimens at a reasonable cost. We believe these are the first data to show high detection rates in a blood test, not only of early Stage I cancer, but also of the extremely important high-risk pre-cancerous adenomas. We believe that with further development, our Nu.Q™ panel could form the basis of new CRC tests with early stage disease detection, and that our tests could become accessible to and usable by a wide section of the screening population around the world."

Hans Jorgen Nielsen, Professor of Surgical Oncology at Hvidovre Hospital in Denmark, commenting on these findings said, "These interim results are encouraging, particularly for detecting early-stage colorectal cancer and potentially pre-cancerous adenomas. Most blood-based cancer biomarkers are more effective at detection of large late-stage cancers than small early-stage cancers, and very poor at detecting pre-cancer. Certainly, these results need to be validated in larger and representative cohorts, which Volition plans to do initially in a 4,300-subject study and subsequently in a 12,000+ double blinded study, using samples collected at 10 collaborating Danish hospitals."

CRC is one of the most preventable cancers, yet it currently remains the least prevented form of cancer. The American Cancer Society Cancer Facts and Figures 2018 report

provides that the five-year survival rate for CRC at all stages is 65%; however, the survival rates differ significantly depending upon the stage at diagnosis: only 14% of patients diagnosed at Stage IV survive more than five years, whereas 90% of those diagnosed at Stage I survive more than five years. This clearly underscores the importance of early detection. Moreover, while not included in the Facts and Figures report, it is widely believed that diagnosis of pre-cancer conditions like HRA and High-Grade Dysplasia can result in cancer-free survival.

In the U.S., Volition is participating in what is believed to be the largest ever CRC screening study in collaboration with the National Cancer Institute's Early Detection Research Network with a cohort of over 13,500 subjects. Collection is underway and is expected to be completed in 2020. The objective is to build upon the European studies to refine test performance and to present final data to the FDA prior to completion of the study. Volition expects to define the final panel for the U.S. front-line test within the next 18 months.

"We have now embarked with confidence on our next stage of assay development to further validate these assays, and ultimately our Nu.Q™ Frontline Asymptomatic Colorectal Cancer Screening Test. This will be run in parallel with ongoing work in our 680-sample set, which still has more Nu.Q™ assays to be tested," said Dr. Jake Micallef, Volition's Chief Scientific Officer. "This next stage of development is a 4,300-subject training study, which will determine the final locked down panel (which we expect to be 5-6 assays), the results of which we hope to report in the second quarter of 2018. We will then conduct a large, 12,000+ subject validation study, which we hope to begin in the second half of 2018, which will form the basis of our EU product claims. In parallel, we are progressing towards obtaining a CE Mark for this panel so that the Nu.Q™ Frontline Asymptomatic Colorectal Cancer Screening Test could be available for sale in the EU later this year."

Professor Stefan Holdenrieder, Director of the Institute of Laboratory Medicine of the German Heart Center at the Technical University of Munich, Germany and a widely published expert in the field of circulating nucleosomes added, "Given these very interesting results in early cancer detection, we are very much looking forward to the upcoming results of the 27-cancer study that will follow the ongoing CRC studies. This study will analyze the performance of the Nu.Q assays in the most prevalent cancers, and it will test the depth of Nucleosomics as a platform technology beyond CRC in other major cancers."

Data is expected from this trial in 2018.

Volition will host a conference call on Tuesday, February 27 at 8:30 a.m. Eastern Time to discuss the interim results from this clinical trial as well as to provide a general business update.

**Event:** VolitionRx Limited Conference Call

**Date:** Tuesday, February 27, 2018

**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:** 13677065

Cameron Reynolds, President and Chief Executive Officer of Volition, will host the call together with Louise Day, Chief Marketing & Communications Officer.

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.volitionrx.com>. In addition, a telephone replay of the call will be available until March 6, 2018. 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 13677065.

### **Notes About the Trial**

In the study, blood samples were taken from 579 asymptomatic subjects, who participated in the Danish National CRC Screening Program. These included: 51 subjects who tested positive in the screening program for FIT and who were subsequently diagnosed with Stage I CRC at colonoscopy, 67 subjects who tested positive with the fecal immunochemical test (FIT) and who were subsequently diagnosed with HRA at colonoscopy, and 461 control subjects who tested negative with FIT.

The blood samples, which were collected according to a validated Standard Operation Procedure, were assayed by ELISA and the results analysed using Logistic Regression. Both age and smoking were included as patient variables. All assay results were highly statistically significant for both Stage I cancer and HRA detection. The panel reported includes two proprietary assays and one non-proprietary assay.

### **About Volition**

Volition is a multi-national life sciences company developing simple, easy to use blood-based cancer tests to accurately diagnose a range of cancers. The tests are based on the science of Nucleosomics<sup>®</sup>, 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 (<http://www.volitionrx.com>) or connect with us via:

Twitter: <https://twitter.com/volitionrx>

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

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## Media / Investor Contacts

Louise Day, Volition <a href="mailto:L.day@volitionrx.com">L.day@volitionrx.com</a> +44 (0)7557 774620	Scott Powell, Volition <a href="mailto:S.powell@volitionrx.com">S.powell@volitionrx.com</a> +1 (646) 650 1351
Joseph Green, Edison Advisors <a href="mailto:jgreen@edisongroup.com">jgreen@edisongroup.com</a> +1 (646) 653 7030	Rachel Carroll, Edison Advisors <a href="mailto:rcarroll@edisongroup.com">rcarroll@edisongroup.com</a> +44 (0)20 3077 5711

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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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