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Preliminary Data from Study Demonstrates 94% Accuracy in Detecting Aggressive Prostate Cancer

ISNES, Belgium, Aug. 13, 2018 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced preliminary data from a prospective, multi-centered Proof of Concept Study of 84 men into the utility of Volition's Nu.Q™ assays to diagnose men with high-grade prostate cancer.

Volition panel	PSA alone
94%	33%

At 88% specificity, the Volition panel of five assays (including PSA) identified 94% of high-grade prostate cancers that require treatment (as defined by Gleason Score[1]). This compares with just 33% identified by Prostate-Specific Antigen (PSA) alone.

"This is a very exciting outcome for us as we continue the development of our assays beyond colorectal cancer. The preliminary data from this study showed that Volition's panel of assays identified men with potentially lethal high-grade prostate cancer with much greater accuracy than PSA alone. Based on this data, we believe that this test could assist clinicians in more accurate patient selection for prostate biopsy and treatment and substantially reduce the amount of unnecessary procedures in men with low-grade tumors or no tumor. The next step is to confirm these statistically significant findings in independent larger clinical trials" said Dr. Jake Micallef, Chief Scientific Officer at Volition.

Prostate cancer (PCA) is the second leading cause of cancer death in men in the U.S. after lung cancer[2]. Currently, PCA is diagnosed through medical history, physical examination and by elevated levels of PSA in the blood. Men suspected of PCA are given a prostate biopsy to confirm the presence of cancer. However, most men with elevated PSA levels referred for prostate biopsy either have no cancer or have low-grade cancer which needs monitoring but not treatment.

In the Proof of Concept Study, a blood sample was taken prospectively from men referred for prostate biopsy in three Belgian hospitals. The men were grouped by biopsy findings as having no cancer (most of whom had elevated PSA levels), low-grade cancer or high-grade cancer. The samples were tested with a panel of five assays (PSA, two Nu.Q™ assays and two inflammatory biomarkers).

The assay results correlated with the Gleason Score, which is one of the main predictors for aggressive PCA determined on biopsy. This suggests the assays may provide better risk stratification than that available using PSA tests for men with actual or suspected PCA, leading to better patient management and fewer unnecessary biopsies.

Commenting on the results, Principal Investigator, Professor Thierry Roumeguere, Head of

Urological Services, Erasme Hospital, Brussels, Belgium said "A non-invasive test to help in the risk stratification of men with suspected or actual prostate cancer will be a major step forward in the management of this disease. The correlation of the panel blood test results with Gleason Score shows great promise in this regard. We will further investigate the data in relation to disease stage as well as additional factors used for pre-treatment risk stratification."

Cameron Reynolds, Chief Executive Officer at Volition commented "This small trial is important because it helps demonstrate once more the potential breadth of our technology. If these results are validated in larger trials, they will present a potentially significant new market opportunity. Volition's research team is continuing to develop our Nu.Q™ assays and we aim to launch products in 2019."

Dr. Gaetan Michel, Chief Executive Officer of Volition's wholly-owned subsidiary, Belgian Volition SPRL, commented, "We would like to thank the Walloon Region for their continued support of the company. The funding provided by the region has enabled this study and will support our continued research."

[1]The Gleason Score is a method used to grade prostate cancers based on how normal or abnormal the prostate biopsy cancer tissue appears under the microscope.

[2]https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html

About Volition

Volition is a multi-national life sciences company focused on developing simple, easy to use, cost effective blood tests designed to help diagnose a range of cancers. The tests are based on the technology platform 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 intends to expand the application of its technology beyond cancer by exploring other disease applications. The company's research and development activities are currently centered in Belgium, with additional offices in London, Texas and Singapore, as it 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 websitehttps://volitionrx.com/

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