Volition's Nu.Q Triage Colorectal Cancer Screening Test Expected to Reduce Colonoscopy Referral by 25 Percent

NAMUR, Belgium, Sept. 6, 2016 /PRNewswire/ -- VolitionRx Limited (NYSE MKT: VNRX), a life sciences company focused on developing diagnostic tests for cancer, today announced that it expects to receive CE Marking on its Nu.Q Triage Colorectal Cancer Screening Test (blood test) in late 2016 and aims to begin marketing the test commencing in early 2017. The test, developed at Volition's laboratories in Belgium in conjunction with Hvidovre Hospital, University of Copenhagen, has demonstrated the potential to reduce colonoscopies by 25% while maintaining almost 97% detection of colorectal cancer. Data supporting the test results will be presented at the forthcoming European Society for Medical Oncology Conference in October 2016. Volition plans initially to focus its launch of the test in the EU member states, which have an aggregate screening age population of approximately 148 million persons.

The most frequently used first line screening test for colorectal cancer across Europe is the faecal immunochemical test (FIT). Patients with a positive score following FIT tests are then referred for colonoscopy. However, 94.8% of people who test positive with FIT do not have colorectal cancer. This means there are a significant number of unnecessary expensive and invasive colonoscopies performed, placing a severe burden on both the patient and the healthcare system. For countries utilizing the Nu.Q test, patients with a positive FIT score could subsequently be given the blood-based Nu.Q Triage Colorectal Cancer Screening Test and then only be referred for colonoscopy if the combined test results indicate that it is necessary, thus potentially reducing colonoscopy referrals by 25%.

Speaking about the planned launch, Cameron Reynolds, CEO of Volition said, "Offering European healthcare systems a simple and easy to use blood test which can be used to triage FIT positive populations for colorectal cancer is very exciting as we are coming to market with something that potentially meets a pressing need in many European countries. After much market analysis, we believe that commercializing this product, a single normalized assay, is the quickest way to achieve significant revenue for our proprietary Nucleosomics® platform."

While screening program uptake varies across Europe, European Guidelines for Quality Assurance in Colorectal Cancer Screening and Diagnosis are in place. These guidelines aim to assist Member States in their national screening programs for colorectal cancer and, therefore, provide a target audience for whom colorectal cancer screening is very much on the agenda.

Colorectal cancer is ranked second among all newly-diagnosed cancers and responsible for approximately 215,000 deaths in Europe each year. Early diagnosis is crucial as approximately 97% of bowel cancer patients caught at stage I will have an average five year survival rate and most will be cured, while if caught at stage IV the average survival rates fall to 7%. However, of the 41,500 patients diagnosed with bowel cancer in the U.K. each year, only a very small proportion of these are diagnosed with stage I disease (16% of men and 14% of women). As well as the increased rate of mortality with late diagnosis, there are also significant cost implications as treating late stage disease is often more costly than treating patients with early stage disease.

There are organized colorectal cancer screening programs in 14 of the 28 EU states with a further 10 states offering some form of public or privately accessible screening.

Berkeley Greenwood, Managing Director of Decideum, Volition's market access advisor said: "While colorectal cancer screening programs across Europe have been shown to be successful, they are creating a number of pressure points within healthcare systems, particularly in terms of colonoscopy capacity. In the U.K., for example, colonoscopy referral times can exceed 14 weeks. The introduction of Nu.Q to help physicians decide whether patients need to go on to have a colonoscopy has significant opportunity to alleviate some of these capacity
pressures and to ensure resources are focused on those individuals who really need it.”

Conference Call

Cameron Reynolds, Chief Executive Officer of VolitionRx Ltd, will host a conference call to provide updates on recent developments relating to its NuQ® blood-based diagnostic platform.

An audio webcast of the conference call will be accessible live and archived on the investor relations page of Volition's website, http://ir.volitionrx.com/, for one year.

A telephone replay of the call will be available until September 20, 2016. To access the replay, dial 1-877-870-5176 (U.S. and Canada) or 1-858-384-5517 (international) and use the replay pin number 3832516.

About Volition

Volition is a life sciences company focused on developing diagnostic tests for cancer. 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's goal is to make the tests as easy and simple to use, for both patients and doctors, as existing diabetic and cholesterol blood tests. Volition's research and development activities are currently centered in Belgium as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

Visit Volition’s website (http://www.volitionrx.com) or connect with us via Twitter, LinkedIn, Facebook or YouTube.
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 the Company's bodily-fluid-based diagnostic tests as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include the Company'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 the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company'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 the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about the Company'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, the Company does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

Nucleosomics®, NuQ® and HyperGenomics® 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.


SOURCE VolitionRx Ltd