

# VolitionRx Adds Three New Laboratory Automation Systems to Expedite Sample Analysis for its Large Ongoing Clinical Trials

# Strategic investment to accelerate development of NuQ® colorectal cancer detection test

NAMUR, Belgium, April 9, 2015 /PRNewswire/ --VolitionRx Limited (NYSE MKT: VNRX), a life sciences company focused on developing blood-based diagnostic tests for a broad range of cancer types and other conditions, today announced that it has procured three additional Tecan EVO200 automated liquid handling systems (automated laboratory robots) to expedite analysis of samples for the ongoing large clinical trials evaluating its NuQ® cancer detection platform. By increasing capacity to four automated systems, throughput and rate of sample analysis will be greatly increased, enabling faster development of the Company's NuQ® tests.

Cameron Reynolds, Chief Executive Officer of VolitionRx, remarked, "This budgeted investment greatly supports our Company's strategic decision to maximize the speed and efficiency of our ongoing large clinical trials. The use of four automated systems will support the generation of extensive amounts of data and allow for faster study timelines to full data readouts. We expect that this increased data generation capacity will result in more scientific publications, quicker access to CE mark in Europe and an overall accelerated approach to regulatory pathways worldwide."

Using its first installed robot, VolitionRx has recently completed the analysis of a first NuQ<sup>®</sup> assay on the complete set of 4,800 blood samples for its large retrospective, symptomatic population colorectal cancer study in collaboration with Hvidovre Hospital, University of Copenhagen, Denmark. Procuring three new Tecans allows the Company to dedicate one robot to this study, and VolitionRx now hopes to complete one NuQ<sup>®</sup> assay per month on the full data set for the 4,800-patient cohort. At this capacity, the Company expects to finalize its analysis and determine an initial NuQ<sup>®</sup> colorectal cancer panel during the second half of 2015.

Gaetan Michel, PhD, Chief Operations Officer of Belgian Volition, commented, "The fully-dedicated Tecan platform currently allows us to run analysis of approximately 5,000 samples per month per robot. The reproducibility and robustness of these automated assays is extremely encouraging and will allow for optimal output of reliable large scale results. We are currently further optimizing the platform process to reach a 50 percent capacity increase to 7,500 samples per month per robot."

VolitionRx Chief Scientific Officer Dr. Jake Micallef added, "Over the past five years, since VolitionRx was established, we have manually processed approximately 30,000 samples across all our studies, in multiple cancers. Due to the significant increase in the number of clinical studies we now have underway, and our constant development of new biomarkers for new assays, we determined that it was essential to make a step change in our processing capabilities through additional automated platforms. This investment will allow us to reach an impressive capacity of 30,000 assays per month, approximately the same amount as we have completed in total. The first robot is fully up and running and all four are due to be delivered by the end of April and should be fully operational by the end of May."

The NuQ<sup>®</sup> tests utilize the Company's proprietary Nucleosomics<sup>®</sup> technology platform, which identifies and measures circulating nucleosome structures for the presence of epigenetic cancer and signals within the blood.

VolitionRx has developed a suite of NuQ<sup>®</sup> assays for more than 20 different epigenetic structures on nucleosomes. These assays use two antibodies. The first antibody is attached to a plastic surface and binds to nucleosomes. The second antibody is chemically detectable and binds to the epigenetic structure of interest contained within the nucleosome. When blood is added to the antibody-coated plastic plate, nucleosomes in the blood bind to the first antibody. The second antibody is then added and can only be chemically detected if nucleosomes containing the epigenetic structure of interest are present. The NuQ<sup>®</sup> assay uses less than a single drop of blood to measure nucleosomes that contain the epigenetic structure of interest and the level of these nucleosomes is different in the blood of cancer patients than in healthy people. Each NuQ<sup>®</sup> cancer test uses a combination of 4-5 of these proprietary assays to form a "panel" test.

Clinical trials assessing the effectiveness of VolitionRx's assays include:

### Colorectal cancer:

- A 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark)
- A 14,000 patient prospective screening study (Hvidovre Hospital, University of Copenhagen, Denmark)
- A 250 patient prospective study (CHU-UCL Mont Godinne Hospital, Belgium)

#### Lung cancer:

• A 600 patient prospective confirmatory study (University Hospital, Bonn, Germany)

#### Prostate cancer:

- A retrospective study to establish the efficacy of VolitionRx's NuQ® tests to distinguish anaplastic prostate cancer, a particularly aggressive form of the disease, from typical castration resistant prostate cancer (CRPC), the less aggressive form (MD Anderson, Texas)
- A 120-patient prospective feasibility study (ImmuneHealth, Belgium)

# Ovarian cancer:

• A 40-patient prospective feasibility study (Singapore General Hospital, Singapore)

# 20 most prevalent cancers

 A 4,000 patient prospective study that involves patients with the 20 most prevalent cancers at University Hospital in Bonn, Germany

#### Endometriosis

 A prospective study to assess VolitionRx's NuQ® tests for the diagnosis of endometriosis (the University of Oxford, United Kingdom)

For more information about Tecan's liquid handling system (robot) please see <a href="http://www.tecan.com/platform/apps/product/index.asp?">http://www.tecan.com/platform/apps/product/index.asp?</a>
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### About VolitionRx

VolitionRx is a life sciences company focused on developing diagnostic tests for cancer and other conditions. 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.

VolitionRx's goal is to make the tests as common and simple to use, for both patients and doctors, as existing diabetic and cholesterol blood tests. VolitionRx'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 US and ultimately, worldwide.

Visit VolitionRx's website (<a href="http://www.volitionrx.com">http://www.volitionrx.com</a>) or connect with us via <a href="mailto:Twitter">Twitter</a>, <a href="LinkedIn">LinkedIn</a>, <a href="Facebook">Facebook</a> or YouTube.

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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," "believes," "seeks," "estimates," "optimizing," "potential," "goal," "suggests" 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 Report 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.

To view the original version on PR Newswire, visit <a href="http://www.prnewswire.com/news-releases/volitionrx-adds-three-new-laboratory-automation-systems-to-expedite-sample-analysis-for-its-large-ongoing-clinical-trials-300063483.html">http://www.prnewswire.com/news-releases/volitionrx-adds-three-new-laboratory-automation-systems-to-expedite-sample-analysis-for-its-large-ongoing-clinical-trials-300063483.html</a>

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