

# VolitionRx Initiates Second Prostate Cancer Pilot Study Assessing Nucleosomics(R) Technology

# Study in collaboration with Belgium-based CRO, ImmuneHealth

NAMUR, Belgium, March 5, 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 initiated a pilot study to assess the feasibility of VolitionRx's proprietary NuQ<sup>®</sup> assays in detecting prostate cancer. The study is in collaboration with ImmuneHealth, a global biomarker contract research organization (CRO), and is taking place in Belgium.

In the prospective study, 120 blood samples will be collected from patients across four Belgian hospitals and analyzed by Belgium-based ImmuneHealth using VolitionRx's NuQ<sup>®</sup> assays, which are based on the Company's proprietary Nucleosomics<sup>®</sup> technology. Four groups of patients will be assessed: aggressive prostate cancer, indolent prostate cancer, prostate hyperplasia and negative controls. In addition to determining the test's ability to accurately detect prostate cancer, the study will also assess the tests' ability to distinguish among the different prostate conditions and healthy samples. If the test demonstrates significant accuracy, it could have the potential to become an early-stage screening tool.

VolitionRx Chief Scientific Officer Dr. Jake Micallef commented, "In addition to our anaplastic prostate cancer study in collaboration with MD Anderson, we are now embarking on a pilot diagnostic prostate cancer study with ImmuneHealth of Belgium. While the anaplastic study is aimed at the differential detection of this particularly aggressive form of prostate cancer requiring very aggressive treatment, the ImmuneHealth study will investigate our NuQ<sup>®</sup> assays for more general prostate cancer detection. Both early prostate cancer detection and selection of patients for aggressive treatment are critical for improved outcomes, which is why we are launching a second study with ImmuneHealth to further evaluate our NuQ<sup>®</sup> assays in this indication. In addition, we are grateful to the Walloon region of Belgium which is covering the majority of the costs of the study."

ImmuneHealth Business and Marketing Director Julien Isoard remarked, "As a global CRO specializing in the clinical support for biomarker panels development, we are committed to facilitating the generation of clinically meaningful data and samples through quality patient cohorts that companies like VolitionRx can use to demonstrate their diagnostics' ability to benefit patients and physicians. Based on the analysis we will conduct, it is our hope that VolitionRx's NuQ<sup>®</sup> tests are further evaluated in larger studies that will enable the Company to bring to market a simple, non-invasive and cost-effective blood test to better diagnose patients with prostate cancer."

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

In addition to this prostate cancer study, other clinical trials assessing the effectiveness of VolitionRx's assays include:

- A 4,800 patient retrospective symptomatic population study in colorectal cancer at Hvidovre Hospital, University of Copenhagen, Denmark
- A 14,000 patient prospective screening study in colorectal cancer at Hvidovre Hospital, University of Copenhagen, Denmark
- A 4,000 patient prospective study that involves patients with the 20 most prevalent cancers at University Hospital in Bonn, Germany
- A 600 patient prospective confirmatory study in lung cancer at University Hospital in Bonn, Germany
- A 250 patient prospective study in colorectal cancer at CHU-UCL Mont Godinne Hospital, Belgium
- A retrospective study with MD Anderson, Texas, 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.
- A prospective study with the University of Oxford, United Kingdom, to assess VolitionRx's NuQ® tests for the diagnosis of endometriosis.
- A 40 patient prospective study with Singapore General Hospital (SGH) to establish the feasibility of VolitionRx's proprietary NuQ® assays in detecting ovarian cancer.

### 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 centred 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 (<u>www.volitionrx.com</u>) or connect with us via Twitter, LinkedIn or Facebook.

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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-initiates-second-prostate-cancer-pilot-study-assessing-nucleosomicsr-technology-300046000.html">http://www.prnewswire.com/news-releases/volitionrx-initiates-second-prostate-cancer-pilot-study-assessing-nucleosomicsr-technology-300046000.html</a>

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