

# VolitionRx Initiates Study with Hvidovre Hospital, Denmark, Specifically to Target NuQ(R) Biomarker Panel for Colorectal Polyps

800 patient study will assess VolitionRx's proprietary Nucleosomics® platform for non-invasive detection of pre-cancerous colorectal polyps

NAMUR, Belgium, April 21, 2015 /PRNewswire/ --<u>VolitionRx Limited</u> (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 Hvidovre Hospital, University of Copenhagen, Denmark has initiated a study specifically to identify a NuQ<sup>®</sup> biomarker panel for the identification of patients with precancerous colorectal polyps (also known as precancerous colorectal adenomas, or colorectal adenomatous polyps), particularly those that are at high risk of becoming cancers.

Dr. Jake Micallef, VolitionRx's Chief Scientific Officer, said, "We have had very good detection rates of up to 60% for precancerous polyps as part of our ongoing colorectal cancer trials, though we have never specifically targeted them. This trial will enable us to trial a very large number of NuQ<sup>®</sup> markers specifically targeting precancerous polyps, as they have different epigenetic profiles from the cancers themselves."

Professor Hans Jorgen Nielsen, Professor of Surgical Oncology at Hvidovre Hospital in Denmark, who is leading the study, said, "As a type of pre-cancerous growth, high-risk adenomas or polyps serve as a warning of cancer, but if caught early enough and removed the risk of subsequent cancer is significantly reduced. Precancerous adenomas and polyps can be detected and removed through colonoscopy; however, this is a highly invasive and expensive procedure. A blood-based test would offer a much lower cost and more patient-friendly alternative with higher patient uptake in identifying those who must be offered colonoscopy and those where it's not needed."

In the study, a set of approximately 800 blinded prospectively-collected blood samples will be analyzed, including: 300 patients with single or multiple precancerous polyp(s) (including approximately 100 patients whose polyps subsequently recurred after removal); 400 subjects with no polyps or colorectal cancers (both with and without other diseases); plus 100 early stage (I/II) colorectal cancer patients. The cohort will comprise high and low risk polyps of various histologies. Following collection, the samples will be analyzed by VolitionRx using up to 30 NuQ<sup>®</sup> assavs.

Cameron Reynolds, Chief Executive Officer of VolitionRx, commented, "Our recent IPO and capital raise now allows us to start this exciting new trial and to dedicate one of our three

recently-procured Tecan EVO200 automated laboratory robots to this study of colorectal pre-cancers. In the entire history of the company we have only analyzed 10  $NuQ^{(8)}$  assays in colorectal cancer. We are now in a position to analyze 800 patient samples with 30 different  $NuQ^{(8)}$  assays, five times faster than it would previously have taken us – a hugely increased capacity for our Belgian laboratory."

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.

In addition to this study, additional 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 Cancer Center, 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 (University Hospital, Bonn, Germany)

### Endometriosis

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

### 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<sup>®</sup>, 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="http://www.volitionrx.com">Twitter</a>, <a href="http://www.volitionrx.com">LinkedIn</a>, <a href="https://www.volitionrx.com">Facebook</a> or <a href="https://www.volitionrx.com">YouTube</a>.

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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-study-with-hvidovre-hospital-denmark-specifically-to-target-nuqr-biomarker-panel-for-colorectal-polyps-300069207.html">http://www.prnewswire.com/news-releases/volitionrx-initiates-study-with-hvidovre-hospital-denmark-specifically-to-target-nuqr-biomarker-panel-for-colorectal-polyps-300069207.html</a>

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