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# VolitionRx Demonstrates 75% Accuracy in Detecting Highest-Risk Pre-Cancerous Colorectal Adenomas with NuQ® Blood Test

## Company Announces its Best Detection Rates to Date for Colorectal Adenomas

NAMUR, Belgium, Feb. 17, 2016 /PRNewswire/ --VolitionRx Limited (NYSE MKT: VNRX) today announced results demonstrating that the Company's NuQ® blood test accurately detected 75% of colorectal adenomas, or pre-cancerous polyps, that were most likely to become cancerous. A panel of five of NuQ® biomarker assays also detected 86% of early (stage I) colorectal cancers. The completed clinical trial of 430 patients was conducted with the Hvidovre Hospital and with the University of Copenhagen in Denmark.

The study was specifically designed to assess the effectiveness of VolitionRx's NuQ® blood-based biomarker assays in detecting adenomas before they become cancerous, as well as early stage colorectal cancer. If adenomas are caught early enough and removed, the risk of subsequent cancer is significantly reduced.

The 430 patients, who either presented with symptoms suggesting the presence of colorectal cancer or were high-risk subjects, included 42 subjects with stage I cancer, 46 subjects with stage II cancer and 181 subjects with colorectal adenomas. No later stage cancers were included in the study. The trial was double blinded and age-adjusted; the results were at 78% specificity.

VolitionRx's proprietary NuQ® blood tests are based on biomarker assays that can identify fragments of chromosomes, called nucleosomes, circulating in the blood and analyze them for epigenetic modifications that signal that cancer is present. The final NuQ® test will likely consist of a panel of 4-6 individual biomarker assays that require only a single drop of blood from patients. During this trial, VolitionRx tested a number of new biomarker assays in order to refine the make-up of the panel and produce the highest accuracy detection rates.

Colorectal cancer is one of the most preventable cancers, yet there are still 50,000 deaths and more than 130,000 new cases diagnosed every year in the U.S. alone.[1] Colonoscopy

examinations provide a high percentage of detection, yet due to their invasive and costly nature, more than one third of adults of screening age in the U.S. are not screened with such a procedure.[2] The five-year survival rate for colorectal cancer is 90% when detected at stage I but only 13% if detected at stage IV.

Professor Hans Jorgen Nielsen, Professor of Surgical Oncology at Hvidovre Hospital in Denmark, said, "This study shows extremely good detection of dangerous pre-cancer and early-stage cancer with the non-invasive NuQ® blood test. We are now working with VolitionRx on large retrospective and prospective trials in both screening and symptomatic populations. We expect to release more data from both these studies later this year."

VolitionRx's Chief Scientific Officer, Dr Jake Micallef, said, "Current blood tests and commonly used fecal tests are poor at detecting early stage colorectal cancer or pre-cancer, so we are very excited by these results. NuQ® tests are detecting early stage colorectal cancer and even pre-cancerous polyps that can be removed before cancer can develop. Finding tumors before they spread is a crucial breakthrough that has the potential to significantly improve the outcomes for colorectal cancer patients. In recent months, VolitionRx has identified and manufactured a number of new biomarker assays and now has a greater pool of NuQ® biomarker assay candidates from which to select the panel for the final blood test. These results demonstrate the increased accuracy from this optimization. We are now running these new biomarker assays in all our colorectal cancer trials."

Cameron Reynolds, Chief Executive Officer of VolitionRx, commented, "Not only do these results demonstrate our best detection rates to date for colorectal adenomas, but they further confirm the progress that VolitionRx is making in identifying new NuQ® biomarker assays and optimizing panels to produce the most accurate detection rates of adenomas and colorectal cancers. We are making excellent progress towards an expected launch of a commercial product later this year for clinical use in detecting colorectal cancer. These latest findings, using an increased selection of NuQ® biomarker assays, augur well for VolitionRx's development of blood tests for the detection of other diseases, including lung and pancreatic cancers."

Results from on-going clinical trials assessing the effectiveness of VolitionRx's assays, include:

*Colorectal cancer and pre-cancerous colorectal polyps*

- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released September 9 2015: Panel of four NuQ® biomarker assays detected 81% of colorectal cancers and 67% of high-risk adenomas at 78% specificity
- Results from a prospective study of 121 patient referred for colonoscopy (CHU Dinant Godinne - UCL Namur, in Belgium), released December 8 2015: Panel of four NuQ® biomarker assays detected 91% of colorectal cancer cases at 90% specificity

*Pancreatic cancer*

- Results from a 59-patient retrospective study (Lund University, Sweden) published in Clinical Epigenetics online journal

(http://www.clinicalepigeneticsjournal.com/content/pdf/s13148-015-0139-4.pdf), October 7 2015: Panel of four NuQ® biomarker assays plus CA 19-9 classical biomarker detected 92% of pancreatic cancers at 100% specificity
- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released October 22 2015: Panel of two NuQ® assays and the classical cancer marker CEA (carcino-embryonic antigen) distinguished 95% of pancreatic cancer cases from healthy subjects at 84% specificity

*Lung cancer*

- Interim results (73 of 240 patients collected and assessed) from a prospective study (Liege University Hospital, Belgium), released November 19 2015: Panel of four NuQ® biomarker assays detected 93% of lung cancers at 91% specificity

References

1. National Cancer Institute. "SEER Stat Fact Sheets: Colon and Rectum Cancer." April 2015. Available online at: http://seer.cancer.gov/statfacts/html/colorect.html. Accessed February 16, 2016.

2. American Cancer Society. "Colorectal Cancer Facts & Figures 2014-2016." March 2014. Available online at: http://www.cancer.org/acs/groups/content/documents/document/acspc-042280.pdf. Accessed February 16, 2016.

**About VolitionRx**

VolitionRx is a life sciences company focused on developing blood-based diagnostic tests for different types of cancer. The NuQ® tests are based on the science of Nucleosomics® which is the practice of identifying and measuring nucleosomes in the bloodstream – an indication that cancer 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 U.S. and ultimately, worldwide.

Visit VolitionRx's website (www.volitionrx.com) or connect with us on Twitter, LinkedIn, Facebook or YouTube.

An animation introducing VolitionRx's Nucleosomics® technology can be found at: https://www.youtube.com/watch?v=38dodCpyXf0.

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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," "aims," "targets," "believes," "seeks," "estimates," "optimizing," "potential," "goal," "suggests," "could," "would," "should," "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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/volitionrx-demonstrates-75-accuracy-in-detecting-highest-risk-pre-cancerous-colorectal-adenomas-with-nuq-blood-test-300221339.html

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