

April 20, 2016



# **VolitionRx Announces Study Results Showing NuQ® Blood Test Detects Prostate Cancer Early with Significantly Higher Accuracy than PSA Test**

## **Results presented today at AACR Annual Meeting**

NAMUR, Belgium, April 20, 2016 /PRNewswire/ --[VolitionRx Limited](#) (NYSE MKT: VNRX) today announced that a single NuQ® biomarker assay detected 71% of early stage I prostate cancer cases at 93% specificity. This is significantly higher than the most common blood test currently used to detect prostate cancer, the Prostate Specific Antigen (PSA), which is reported to detect 53% of prostate cancers at 73% specificity<sup>1</sup>. The study was conducted in collaboration with the Surrey Cancer Research Institute at the University of Surrey in the UK. The results are being presented today at the American Association for Cancer Research (AACR) Annual Meeting in New Orleans, LA.

Approximately 14% of men will be diagnosed with prostate cancer at some point during their lifetime and nearly 3 million men are estimated to be living with prostate cancer in the United States alone<sup>2</sup>. While more than 80% of all prostate cancers are detected at the local stage, and nearly 100% of men diagnosed and treated at this stage will be disease-free after five years, a small percentage of men experience more rapidly growing, aggressive forms of prostate cancer<sup>3</sup>.

Since 2012, the United States Preventative Services Task Force (USPSTF) has recommended against PSA based screening for healthy men and called for research to identify new screening methods<sup>4</sup>. Nonetheless, the PSA test is commonly used for patient monitoring and other purposes because it is a low-cost, non-invasive test that is easy to use for the patient. Like VolitionRx's NuQ® biomarker assays, the PSA test requires a small amount of blood and uses a common screening platform, known as ELISA, that is ubiquitous in healthcare laboratories worldwide. However, sensitivity and specificity of the PSA test remains less than optimal.

VolitionRx has performed a retrospective study on blood samples collected from 537 men, including 266 with prostate cancer and 271 age-matched healthy controls. The samples were analysed with a single NuQ® biomarker assay, which detected 71% of early stage I prostate cancer cases and 86% of late stage IV prostate cancer at 93% specificity (7% false negatives). Details of the data presented at AACR can be found at <http://ow.ly/4mRRRm>.

Prof. Hardev Pandha, Director of the Surrey Cancer Research Institute and Professor of Urological Oncology at the University of Surrey, said, "This NuQ® biomarker study has shown very encouraging results in this patient cohort. Further studies are needed but the

test may potentially have uses in detecting and monitoring men with prostate cancer."

VolitionRx Chief Scientific Officer, Dr. Jake Micallef, commented, "This single NuQ<sup>®</sup> biomarker assay has shown great potential for high accuracy in detecting early stage I prostate cancer. The ability to detect early stage prostate cancer at significantly greater sensitivity than the PSA test with a simple ELISA blood test is a remarkable breakthrough. The accuracy of this single NuQ<sup>®</sup> test may be further improved by use of a combination of NuQ<sup>®</sup> tests in a panel with PSA and this, plus the usefulness of the test for monitoring treatment, will be a focus of future studies by our team. The achievement of high accuracy with a single assay, rather than a panel of assays, is the result of the increasing insight of VolitionRx in predicting and identifying NuQ<sup>®</sup> markers for the detection of specific cancers with high sensitivity and with very few false positives."

Cameron Reynolds, Chief Executive Officer of VolitionRx, added, "VolitionRx's NuQ<sup>®</sup> biomarker assay uses the same ELISA platform as PSA that is ubiquitous in healthcare laboratories worldwide and is a similarly low cost, non-invasive test and also requires very little blood. Over the coming months, we will conduct further clinical studies on this NuQ<sup>®</sup> biomarker assay, in parallel with pursuing CE marking. With the highly-encouraging results from this study, we are currently aiming for VolitionRx to launch a prostate cancer test for clinical use in Europe in 2017 and start U.S. trials following the commercial launch of our blood test for colorectal cancer towards the end of this year."

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

#### *Colorectal cancer and pre-cancerous colorectal adenomas*

- 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<sup>®</sup> biomarker assays detected 81% of colorectal cancers at 78% specificity and 67% of high-risk adenomas. (<http://www.volitionrx.com/news/press-releases/detail/531/volitionrx-demonstrates-nuqr-blood-test-detects-81-of>)
- Results from a completed prospective study of 121 patients referred for colonoscopy (CHU Dinant Godinne - UCL Namur, in Belgium), released December 8, 2015: Panel of four NuQ<sup>®</sup> biomarker assays detected 91% of colorectal cancer cases at 90% specificity and also detected 67% of high-risk adenomas. (<http://www.volitionrx.com/news/press-releases/detail/542/volitionrx-demonstrates-more-than-90-accuracy-for>)
- Results from a retrospective study of 430 patients referred for colonoscopy (Hvidovre Hospital, University of Copenhagen, Denmark), released February 17, 2016: Panel of four NuQ<sup>®</sup> biomarker assays demonstrated 75% accuracy in detecting highest-risk pre-cancerous colorectal adenomas and also detected 86% of early (stage I) colorectal cancers at 78% specificity. (<http://www.volitionrx.com/news/press-releases/detail/550/volitionrx-demonstrates-75-accuracy-in-detecting>)

#### *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<sup>®</sup> biomarker assays plus CA 19-9 classical biomarker detected 92% of pancreatic cancers at 100% specificity. (<http://www.volitionrx.com/news/press-releases/detail/534/volitionrx-announces-publication-of-results-from-pancreatic>)
- 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<sup>®</sup> biomarker assays and the classical cancer marker CEA (carcino-embryonic antigen) detected 95% of pancreatic cancers at 84% specificity. (<http://www.volitionrx.com/news/press-releases/detail/535/volitionrx-demonstrates-nuq-blood-test-detects-95-of>)

### *Lung cancer*

- Interim results (73 of 240 patients collected and assessed) from a prospective study (Liège University Hospital, Belgium), released November 19, 2015: Panel of four NuQ<sup>®</sup> biomarker assays detected 93% of lung cancers at 91% specificity and differentiated lung cancer from the common lung disease, COPD. (<http://www.volitionrx.com/news/press-releases/detail/540/volitionrx-demonstrates-nuq-blood-test-detects-lung>)

### *Idiopathic Pulmonary Fibrosis*

- Results from a retrospective study of 78 patients referred for colonoscopy (Liège University Hospital, Belgium), released March 9, 2016: Preliminary data demonstrated 86% accuracy in detecting Idiopathic Pulmonary Fibrosis, a fatal lung disease, at 80% specificity. (<http://www.volitionrx.com/news/press-releases/detail/551/preliminary-data-demonstrates-86-accuracy-in-detecting>)

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### **References**

1. Thompson IM, Ankerst DP, Chi C, Lucia MS, Goodman PJ, Crowley JJ, Parnes HL, Coltman CA Jr. "Operating Characteristics of Prostate-Specific Antigen in Men With an Initial PSA Level of 3.0 ng/mL or Lower." *Journal of the American Medical Association (JAMA)*. 2005;294(1):66-70. doi:10.1001/jama.294.1.66. July 6 2005. Accessed March 31, 2016.
2. National Cancer Institute. "SEER Stat Fact Sheets: Prostate Cancer." November 2015. Accessed January 25, 2016.
3. Prostate Cancer Foundation. "What is Prostate Cancer?" Accessed January 25, 2016.
4. U.S. Preventive Services Task Force. "Final Recommendation Statement, Prostate Cancer: Screening." May 2012. Accessed April 8, 2016.

### **Animation:**

Animation showing how VolitionRx's NuQ<sup>®</sup> tests work. Credit: VolitionRx Ltd:  
<https://www.youtube.com/watch?v=38dodCpyXf0>

## **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 centered in the wholly owned subsidiary, Belgian Volition SA, 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 (<http://www.volitionrx.com>) or connect with us via [Twitter](#), [LinkedIn](#), [Facebook](#) or [YouTube](#).

## **About the University of Surrey**

The University of Surrey is one of the UK's leading professional, scientific and technological universities with a world-class research profile and a reputation for excellence in teaching. Ground-breaking research at the University is bringing direct benefit to all spheres of life – helping industry to maintain its competitive edge and creating improvements in the areas of health, medicine, space science, the environment, communications, defence and social policy. Programmes in science and technology have gained widespread recognition and it also boasts flourishing programmes in dance and music, social sciences, management and languages and law.

In addition to the campus on 150 hectares just outside Guildford, Surrey, the University also owns and runs the Surrey Research Park, which provides facilities for 110 companies employing 2,750 staff. The University of Surrey was recently named University of the Year by the Times and Sunday Times, both overall and for 'Student Experience', and has achieved a top-ten ranking in all three major national university league tables.

For more information about the University and its work, visit [www.surrey.ac.uk](http://www.surrey.ac.uk)

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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," "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.

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/volitionrx-announces-study-results-showing-nuq-blood-test-detects-prostate->

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