

April 7, 2016



# VolitionRx Announces CE Marks for Two NuQ® Blood Assays for Detection of Colorectal Cancer

## CE Mark Enables European Clinical Use and Sale in 33 Countries to up to 600 million people

NAMUR, Belgium, April 7, 2016 /PRNewswire/ --[VolitionRx Limited](#) (NYSE MKT: VNRX) today announced CE marking for two blood-based diagnostic assays for the detection of colorectal cancer. The biomarker assays, NuQ®V001 and NuQ®T003, identify and analyze fragments of chromosomes, called nucleosomes, circulating within the blood for the presence of cancer signatures.

The two new CE marks follow the announcement last September of VolitionRx's first CE mark, which was for the NuQ®X001S biomarker assay for detecting colorectal cancer. Each of the three biomarker assays now CE marked represent a different family of NuQ® assays that target different features of nucleosomes, which consist of short strands of DNA wrapped around a core of eight histone proteins. The NuQ®T family of biomarker assays target the whole nucleosome. The other family members, NuQ®X and NuQ®V, target epigenetic cancer signals within the nucleosome, which affect gene activity without altering the DNA sequence. These include modifications to the DNA (targeted by the NuQ®X family of biomarker assays) and variations to the histone proteins (targeted by the NuQ®V family).

VolitionRx plans to offer a commercial test for colorectal cancer consisting of a panel of 4-6 individual NuQ® biomarker assays that require only a single drop of blood from patients. The Company is currently conducting ongoing clinical trials and following the CE compliance process for further biomarker assays in order to refine the make-up of the panel and produce the highest accuracy detection rates. VolitionRx anticipates launching a CE marked panel test for the detection of colorectal cancer for clinical use in Europe toward the end of 2016.

The announcement of the two new CE marks also follows the recent release of data from a 430-subject trial, which demonstrated that VolitionRx's NuQ® blood tests accurately detected 86% of early-stage colorectal cancers at 78% specificity, as well as 75% of high-risk colorectal adenomas, or pre-cancerous polyps that were most likely to become cancerous.

"We are delighted to announce CE marking for two new members of our family of NuQ® biomarker assays," commented Gaetan Michel, PhD, Chief Executive Officer of Belgian Volition SA. "In recent months, VolitionRx has achieved consistently excellent results for colorectal cancer detection using a panel test of NuQ® assays and has successfully detected both early- and late-stage cancer, which is critical for improving five-year survival rates.

Since we announced our first CE marked biomarker assay last September, the Company has continued its strategic work toward additional CE marking that will allow us to deliver first-class quality products to physicians and their patients. Through this strategy, we have widened the span of discovery for relevant biomarkers and moreover broadened the potential use of our products. The CE marks mean that these NuQ<sup>®</sup> products are compliant with EU legislation and meet EU in-vitro diagnostic medical device requirements for clinical use in the European market."

"This CE marking is yet another very important milestone for the Company on our path to making our blood tests available to patients," added Cameron Reynolds, President and Chief Executive Officer of VolitionRx. "We are now able to sell three biomarker assays clinically in the 28 member states of the European Union, as well as Switzerland, Turkey, Iceland, Norway and Liechtenstein -- potentially reaching a population of nearly 600 million people including more than 150 million of screening age. We are currently in the process of CE marking other assays to finalise the panel for the anticipated European launch of our tests late this year. We are also progressing toward our goal of making our assays available for clinical use in the U.S. and the rest of the world. Due to the non-invasive, low-cost and patient friendly nature of NuQ<sup>®</sup> blood tests, we believe our technology has the potential to gain market acceptance and save lives in Europe, the U.S. and worldwide."

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 also detected 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 cancers 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 five of 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 the CA 19-9 classical

cancer 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 plus the classical cancer biomarker 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>)

VolitionRx has applied CE marking to its blood-based diagnostic assays, NuQ<sup>®</sup>V001 and NuQ<sup>®</sup>T003, in agreement with the IVD Directive 98/79/EC and the Company has notified the product to the Competent Authorities.

### **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](#).

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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-ce-marks-for-two-nuq-blood-assays-for-detection-of-colorectal-cancer-300247764.html>

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