

January 7, 2015



# Initial Study Demonstrates that VolitionRx NuQ® Blood Test Has 84% Accuracy in Detecting Early Stage Treatable Pancreatic Cancers

## Marks Fourth Cancer Type Detected by VolitionRx's Proprietary Nucleosomics® Platform

### Promising Results are Basis for Further, Larger Studies

NAMUR, Belgium, Jan. 7, 2015 /PRNewswire/ --[VolitionRx Limited](#) (OTCQB: VNRX), a life sciences company focused on developing diagnostic tests for cancer and other conditions, today announced that it has completed a blinded clinical study demonstrating that its NuQ® blood-based diagnostic platform is able to accurately detect 84% of early, surgically-treatable pancreatic cancers at high 92% specificity. The blinded study was conducted in collaboration with Lund University, Sweden and led by Roland Andersson, MD, PhD, Professor of Surgery and Vice-Dean, Faculty of Medicine.

VolitionRx Chief Executive Officer Cameron Reynolds, said, "Pancreatic cancer is the fourth leading cause of cancer deaths in the developed world and its incidence is rising.<sup>[1]</sup> Unfortunately, it is often described as a 'silent killer' with a high mortality rate and 5-year survival rate of approximately 6%,<sup>[1]</sup> which is largely due to a lack of early-stage detection capabilities. With the development of this blood test, we hope to improve the prognosis for pancreatic cancer patients by detecting the disease before it reaches an advanced state."

In the 60-patient study, blood samples were taken from 25 subjects with stage IIa or stage IIb pancreatic cancer as well as 25 healthy subjects and 10 subjects with other pancreatic diseases including chronic pancreatitis, intraductal papillary mucinous neoplasm (IPMN; a pre-cancerous condition which may lead to pancreatic cancer), serous cystadenoma (a benign tumor) and tubular adenoma in papilla vateri (another type of benign tumor).

Analysis of the blood samples demonstrated that a panel of five NuQ® assays distinguished 21 of the 25 pancreatic cancer cases from healthy subjects (84% sensitivity), with only two false positive results among the 25 healthy subjects (92% specificity).

Furthermore, the same panel of NuQ® assays was able to distinguish 19 of the pancreatic cancer cases (76% sensitivity) from all other subjects including healthy subjects and those with other pancreatic diseases with only a single false positive for one healthy subject and two false positives for subjects with other pancreatic diseases, one of which was a subject with pre-cancerous IPMN condition (91% specificity).

Dr. Roland Andersson, MD, PhD, Professor of Surgery Vice Dean, Faculty of Medicine Lund University, Sweden, remarked, "In my opinion there are currently no good diagnostic tests for the early detection of pancreatic cancer, so an 84% rate of detection using a simple blood draw is an exciting result, which, in addition to the further ability to differentiate pancreatic cancer from other pancreatic diseases, demonstrates the potential of a test to save many lives and become a significant medical advancement. VolitionRx appears to have a unique platform technology through its IP in circulating nucleosomes. These results are very encouraging and we look forward to confirming the findings in further, larger studies in collaboration with VolitionRx."

VolitionRx Chief Scientific Officer Dr. Jake Micallef commented, "These early data for NuQ<sup>®</sup> assays in pancreatic cancer show excellent clinical accuracy which may be improved further if used in conjunction with established CA19-9 ELISA tests. Nucleosomics<sup>®</sup> has been found to be effective for the detection of colorectal cancer as well as pre-cancerous colorectal polyps, prostate cancer, lung cancer and now, pancreatic cancer. Moreover, there is evidence that NuQ<sup>®</sup> tests can also distinguish these cancers from each other. We will continue with further clinical studies to demonstrate the clinical utility of our Nucleosomics<sup>®</sup> technology in the detection of cancers and are excited to advance the pancreatic cancer test into larger studies that we hope will confirm these promising results."

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 the pancreatic 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<sup>®</sup> 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<sup>®</sup> tests for the diagnosis of endometriosis.

## **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 ([www.volitionrx.com](http://www.volitionrx.com)) or connect with us via [Twitter](#), [LinkedIn](#) or [Facebook](#).

## **Media Contacts**

Charlotte Reynolds, VolitionRx  
[Charlotte.Reynolds@volitionrx.com](mailto:Charlotte.Reynolds@volitionrx.com)  
Telephone: +44 (0) 795 217 7498

Kirsten Thomas, The Ruth Group  
[kthomas@theruthgroup.com](mailto:kthomas@theruthgroup.com)  
Telephone: +1 (646) 536-7014

## **Investor Contacts**

Scott Powell, Investor Relations  
[S.Powell@volitionrx.com](mailto:S.Powell@volitionrx.com)  
Telephone: +1 (646) 650-1351

Lee Roth, The Ruth Group  
[lroth@theruthgroup.com](mailto:lroth@theruthgroup.com)  
Telephone: +1 (646) 536-7012

## **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.

[i] **American Cancer Society**. Cancer Facts & Figures 2013. Available online at:  
<http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-036845.pdf>

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/initial-study-demonstrates-that-volitionrx-nuq-blood-test-has-84-accuracy-in-detecting-early-stage-treatable-pancreatic-cancers-300016691.html>

SOURCE VolitionRX Ltd