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# VolitionRx Announces Publication of Results from Pancreatic Cancer Study with Lund University in Clinical Epigenetics

## Non-invasive Blood-based Test Shown to Detect 92% of Pancreatic Cancer Cases in Samples from 59 Individuals

NAMUR, Belgium, Oct. 12, 2015 /PRNewswire/ --[VolitionRx Limited](#) (NYSE MKT: VNRX) today announced that full results from a completed clinical study of its NuQ<sup>®</sup> blood-based test for early stage pancreatic cancers have been published in the online issue of *Clinical Epigenetics*, the official journal of the Clinical Epigenetics Society. The peer-reviewed 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.

The study assessed blood samples from 59 individuals, including 25 patients with stage 2 pancreatic cancer, 10 patients with other pancreatic diseases and 24 healthy individuals, using VolitionRx's Nucleosomics<sup>®</sup> technology platform. Analysis of the blood samples demonstrated that a panel of five NuQ<sup>®</sup> assays distinguished 84% (21 of 25) of the early-stage pancreatic cancer cases from healthy subjects, with only two false positive results among the healthy subjects. The detection rate of the test was improved further to 92% (23 of 25) of cancer cases by inclusion of the classical CA19-9 cancer biomarker with no false positives results among the healthy subjects. Full details are available in the publication: <http://www.clinicalepigeneticsjournal.com/content/pdf/s13148-015-0139-4.pdf>

This is the first peer reviewed validation of VolitionRx's panel approach to diagnostic test development.

Pancreatic cancer is one of the most deadly cancers. There are more than 40,000 deaths and over 50,000 new cases diagnosed each year in the U.S. alone<sup>1</sup>. In addition, pancreatic cancer is projected to become the second leading cause of cancer-related death in the U.S. by 2030<sup>2</sup>. Pancreatic cancer is difficult to detect and diagnose because there aren't any noticeable signs or symptoms in the early stages of pancreatic cancer. The signs and symptoms of pancreatic cancer, when present, are like the signs and symptoms of many other illnesses. The five-year survival rate for pancreatic cancer is currently just 7%<sup>1</sup>. However, these cancers are typically detected at late-stage after the onset of symptoms. VolitionRx believes that there remains a high unmet medical need for tests that detect early-stage cancer and are also non-invasive and easy to use.

VolitionRx Chief Executive Officer Cameron Reynolds, commented, "This is a very important milestone for VolitionRx. To our knowledge, this study is the first to describe the epigenetic profiling of nucleosomes circulating in the blood for the detection of pancreatic cancer, making its publication a significant achievement in the field of blood-based cancer detection.

These results demonstrate that our NuQ<sup>®</sup> tests can accurately and distinctly detect differing levels and epigenetic profiles of nucleosomes in the blood of patients with pancreatic cancer, and differentiate those from healthy populations as well as those with other benign pancreatic diseases. Furthermore, the study confirms nucleosome profiles as distinguished by our NuQ<sup>®</sup> tests represent potential biomarkers for the early detection of cancer with very good accuracy. We are in the process of negotiating large trials to confirm these extremely encouraging results from this pilot study."

Dr. Roland Andersson, MD, PhD, Professor of Surgery Vice Dean, Faculty of Medicine at Lund University, Sweden, added, "Pancreatic cancer has a poor prognosis, with a five-year survival rate of only 6-7 percent, mainly due to the asymptomatic nature of its early stages, aggressive biological behavior, and limitations of current detection technologies. Our pilot study shows that VolitionRx's NuQ<sup>®</sup> blood-based diagnostic tool accurately detects and distinguishes patients with pancreatic cancer from those with benign cases and from healthy patients. On a practical level, these are tests that use a single, small volume of blood and have potential as a valuable screening option, as the test is able to detect with high sensitivity even early stages of disease."

VolitionRx Chief Scientific Officer Dr. Jake Micallef said, "The complete dataset confirms the significant clinical accuracy for our NuQ<sup>®</sup> assays in detecting pancreatic cancer and further validates nucleosomes as biomarkers with their rich variety of available epigenetic features that allow for fine-tuning of sensitivity and specificity. In addition, the study showed that the assays' accuracy could be further improved by combining VolitionRx's nucleosome biomarkers with the well-established CA19-9 biomarker, considered the benchmark to which all new investigational biomarkers are compared, to produce highly specific, clinically-sensitive biomarker panels."

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 published data from the study evaluating NuQ<sup>®</sup> in pancreatic cancer, 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)

#### *Pre-cancerous colorectal adenomas*

- A 800 patient retrospective study (Hvidovre Hospital, University of Copenhagen, Denmark)

#### *27 most prevalent cancers*

- A 4,200 patient prospective study that involves patients with the 27 most prevalent cancers (University Hospital, Bonn, Germany)

#### *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<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 (MD Anderson Cancer Center, Texas)
- A 120-patient prospective feasibility study (ImmuneHealth, Belgium)

#### *Ovarian cancer*

- A 40-patient retrospective feasibility study (Singapore General Hospital, Singapore)

#### *Endometriosis*

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

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

#### **References:**

1. National Cancer Institute. "SEER Stat Fact Sheets: Pancreas Cancer." April 2015. Available online at: <http://seer.cancer.gov/statfacts/html/pancreas.html> . Accessed September 23, 2015.
2. Cancer Research. "Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver, and Pancreas Cancers in the United States." 2014. Available online at: <http://cancerres.aacrjournals.org/content/early/2014/03/25/0008-5472.CAN-14-0155.full.pdf> . Accessed September 25, 2015.

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

## **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" 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.

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## **Media Contacts**

Anita Heward, VolitionRx  
[a.heward@volitionrx.com](mailto:a.heward@volitionrx.com)  
Telephone: +44-0-7756-034-243

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

## **Investor Contacts**

Scott Powell, VolitionRx

[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

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/volitionrx-announces-publication-of-results-from-pancreatic-cancer-study-with-lund-university-in-clinical-epigenetics-300157756.html>

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