

September 9, 2015



VolitionRx Demonstrates NuQ(R) Blood Test Detects 81% of Colorectal Cancers and 67% of High Risk Adenomas in Large Double Blinded Clinical Trial

Interim Data from ~4,800-Subject Retrospective Trial to be Presented at 1:45pm EDT Today during the Rodman & Renshaw 17th Annual Global Investment Conference; webcast at <http://wsw.com/webcast/rrshq25/vnrx>

Results reinforce the Company's decision to proceed with obtaining European and US regulatory approval of its NuQ® tests

NAMUR, Belgium, Sept. 9, 2015 /PRNewswire/ --[VolitionRx Limited](#) (NYSE MKT: VNRX) today announced interim results from its 4,800-subject retrospective colorectal cancer trial at Hvidovre Hospital, University of Copenhagen, and at six collaborating hospitals (Bispebjerg, Herning, Hilleroed, Horsens, Randers and Viborg) in Denmark. The interim data indicates that VolitionRx's NuQ® blood tests detected 81% of colorectal cancers at 78% specificity equally well for both for early- and late-stage cancers. In addition, the tests detected 63% of potentially pre-cancerous adenomas (or polyps) including, most importantly, 67% of high-risk adenomas (the most likely to become cancerous). The preliminary results of this double blinded and independent trial demonstrate the NuQ® test's potential to detect cancers over the complete spectrum of development, from pre-cancerous adenomas through early-stage to late-stage colorectal cancer.

The results will be presented today at 1:45 p.m. EDT during the Rodman & Renshaw 17th Annual Global Investment Conference in New York (webcast live at <http://wsw.com/webcast/rrshq25/vnrx> and archived for at least 90 days at <http://www.volitionrx.com/news/events-calendar>), and will also be presented at the CNAPS (Circulating Nucleic Acids in Plasma and Serum) IX Conference in Berlin on Friday, September 11 at 3:05-3:25 p.m. CEST.

Colorectal cancer is one of the most preventable cancers, yet there are still 50,000 deaths and over 130,000 new cases diagnosed every year in the U.S. alone¹. 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. refuse to be screened with such a procedure². The five-year survival rate for colorectal cancer is 90% when detected at Stage I but only 13% if detected at Stage IV. 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's simple, cost-effective, non-invasive, NuQ[®] colorectal cancer blood test is expected to consist of a panel of 4-6 individual ELISA assays. A function of the 4,800 subject trial is to optimize the composition of this panel; the amount of patient's blood serum available for the trial will allow up to 20 assays to be run per patient. The interim data gives results for the 4,800 samples using a panel of four NuQ[®] assays chosen from the nine candidate assays that VolitionRx has manufactured on a large scale and run in this trial to date. The full study will analyze the sample set with up to 11 additional assays that are currently being finalized, to further refine the choice of assays in the panel to produce the highest accuracy detection rates.

Professor Hans Jorgen Nielsen, Professor of Surgical Oncology at Hvidovre Hospital in Denmark, who is leading the study, commented, "These interim results are compelling, particularly those demonstrating high sensitivity for detecting early-stage colorectal cancer and potentially pre-cancerous adenomas. Most blood-based cancer biomarkers are more effective at detection of large late-stage cancers than small early-stage cancers, and very poor at detecting pre-cancer. The ability to detect both early and late stage cancers, as well as high risk pre-cancer, is critical in demonstrating the value of the NuQ[®] test, as this may enable more cost-effective and successful patient outcomes. We look forward to providing an update on further results from this study, as well as results from an ongoing prospective 14,000 colorectal cancer patient screening study, for which the first 2,500 patient samples have already been collected and are currently being analyzed."

Cameron Reynolds, President and Chief Executive Officer of VolitionRx, added, "We are very excited to report such strong results in our first large clinical trial and will continue to analyze the samples using up to 11 additional assays. We are looking for even better assay candidates and still have two key target assays to scale up for manufacturing for the next round of testing. We believe that this will enable us to develop the best panel of assays with the highest sensitivity and most accurate detection rates for early- and late-stage cancer. We anticipate providing the full data set for the 4,800-subject retrospective study in the first quarter of 2016. Given the strength of this interim data we are also moving forward aggressively with the CE marking of our products to enable them to be sold for clinical use in Europe and to begin the process in the U.S. with the FDA."

Interim sensitivity findings for cancer and the possibly pre-cancerous adenoma in this 4,800-subject population type are outlined as follows:

Cancer	Sensitivity	N=
Colorectal cancer	81%	401 out of 498
Adenomas	63%	415 out of 655
High risk adenomas	67%	256 out of 383
High neoplasia adenomas	68%	76 out of 111
Villous adenomas	73%	8 out of 11
Serrated adenomas	80%	24 out of 30

Importantly, the assays are not stage dependent. All results are age and gender adjusted, measured at 78% specificity against high risk or symptomatic patients who are otherwise healthy subjects referred for colonoscopy but found to have no bowel lesions or other comorbidities.

The NuQ[®] tests utilize the Company's proprietary Nucleosomics[®] technology platform, which identifies and measures circulating nucleosome structures for the presence of epigenetic cancer signals within the blood.

The full list of ongoing clinical trials assessing the effectiveness of VolitionRx's assays, including the 4,800-subject trial discussed here, 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[®] 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[®] tests for the diagnosis of endometriosis (the University of Oxford, United Kingdom)

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 September 8, 2015.

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 September 8, 2015.

Animation:

Animation introducing VolitionRx's Nucleosomics[®] technology. 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[®], 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](#).

Media Contacts

Anita Heward, VolitionRx
a.heward@volitionrx.com
Telephone: +44 (0) 7756 034243

Kirsten Thomas, The Ruth Group
kthomas@theruthgroup.com
Telephone: +1 (508) 280-6592

Investor Contacts

Scott Powell, VolitionRx
S.Powell@volitionrx.com
Telephone: +1 (646) 650-1351

Lee Roth, The Ruth Group
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," "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.

Nucleosomics[®], NuQ[®] and HyperGenomics[®] and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to in this press release are the property of their respective owners.

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/volitionrx-demonstrates-nuqr-blood-test-detects-81-of-colorectal-cancers-and-67-of-high-risk-adenomas-in-large-double-blinded-clinical-trial-300139804.html>

SOURCE VolitionRx Ltd