

# VolitionRx Announces Third Quarter 2015 Financial Results and Business Update

NAMUR, Belgium, Nov. 4, 2015 /PRNewswire/ --<u>VolitionRx Limited</u> (NYSE MKT: VNRX), a life sciences company focused on developing blood-based diagnostic tests for a broad range of cancer types and other conditions, today announced financial results for the third quarter ended September 30, 2015.

# Third Quarter 2015 and Recent Company Highlights:

- Released interim data from an on-going 4,800-subject double blind clinical trial revealing NuQ<sup>®</sup> blood tests detect 81% of colorectal cancers (CRC) and 67% of high risk adenomas
- Announced first CE Mark for NuQ<sup>®</sup> blood biomarker assay for detection of colorectal cancer (NuQ<sup>®</sup>X001S)
- Awarded first key U.S. patent (Number 9,128,086), relating to the detection of epigenetic changes that affect chromosome structure in cancer, by means of a simple blood test
- Issued full results from a clinical study of NuQ<sup>®</sup> blood test showing detection of 92% of early-stage pancreatic cancers, published in peer-reviewed journal *Clinical Epigenetics*
- Released results from second preliminary pancreatic cancer study demonstrating accurate detection of 95% of pancreatic cancer cases
- Appointed David Kratochvil as Chief Financial Officer.

"In the last several months, we have made a number of substantial clinical and operational advancements, which we believe position the Company optimally for long-term growth and success. We reached an important milestone with the announcement of our first CE Mark for the NuQ® X001S biomarker assay for detection of colorectal cancer. This is the first of several biomarker assays we plan to CE Mark, which together would make up a commercial test for colorectal cancer. This should allow us the opportunity to commercialize the product in any of the 28 European Union member states and several other countries, representing an addressable market of more than 150 million people of screening age (50-75 years). We continue working closely with our market access consultants, DecideumCogentia and MedPass International, to optimize the launch and we expect to commercialize our NuQ® blood test for CRC in Europe in 2016," said Cameron Reynolds, President and Chief Executive Officer of VolitionRx.

"Additionally, in September, we released interim data from our 4,800 patient retrospective CRC study, which demonstrated NuQ<sup>®</sup>'s ability to detect colorectal cancer at all stages of disease progression, from pre-cancerous adenomas to early- and late-stage disease. The test achieved 81% sensitivity at 78% specificity equally well for both early- and late-stage cancers, plus, importantly, 67% of high-risk adenomas, which are defined as those most likely to become cancerous. These results, based on a panel of four NuQ<sup>®</sup> biomarker

assays, are highly promising, and we look forward to the final results in early 2016. The full study results, which will analyze the sample set with an additional nine individual biomarker assays, will help us to optimize the panel for maximum sensitivity and specificity in the detection of colorectal cancer."

Mr. Reynolds added, "In the third quarter, we were also granted our first key U.S. patent, for the detection of histone modification in cell-free nucleosomes, which was previously granted in Europe. This patent, expiring in mid-2029, relates to the use of a simple, single-drop blood test to detect epigenetic changes that affect the chromosome structure in cancer, and is a significant addition to our notable intellectual property estate."

Mr. Reynolds further commented, "We have also made important progress in our pancreatic cancer program, which we expect will be our second marketed product behind colorectal cancer. After the close of the quarter, the results from our pilot study in pancreatic cancer with Lund University were published in the journal *Clinical Epigenetics*. Results demonstrated a panel of five NuQ<sup>®</sup> biomarker assays distinguished 92% of cancer cases with inclusion of the classical CA19-9 cancer biomarker and no false positives results among the healthy subjects. This was the first ever peer-reviewed publication of our panel approach to diagnostic test development and an important validation of our Nucleosomics<sup>®</sup> technology platform. In addition, we announced the results of our second preliminary pancreatic study, which included 20 pancreatic patients as well as healthy patients and those with other conditions, using a two-biomarker assay NuQ<sup>®</sup> panel and the traditional cancer biomarker CEA. The results, which demonstrated 95% sensitivity at 84% specificity, are extremely encouraging, and we expect will lead to larger clinical trials in pancreatic cancer as we move forward."

Mr. Reynolds concluded, "We made a key addition to our executive team with the appointment of David Kratochvil as Chief Financial Officer. With nearly 30 years of finance industry experience, David's leadership and contributions should be instrumental as we continue to advance toward commercialization. We are proud of our accomplishments thus far, are grateful to our shareholders for their continued support and look forward to achieving additional clinical and commercial milestones as we move into 2016."

#### Third Quarter 2015 Financial Results

For the three months ended September 30, 2015, VolitionRx reported a net loss of \$2.96 million, or \$0.16 per share. This compares to a net loss of \$5.89 million, or \$0.44 per share in the third guarter of 2014.

Cash and cash equivalents as of September 30, 2015 totaled \$6.85 million, compared with \$2.14 million as of December 31, 2014.

# **Conference Call**

VolitionRx Ltd. will host a conference call on Wednesday, November 4<sup>th</sup> at 8:30 am ET to discuss its third quarter 2015 financial results and to provide an update on recent developments, including its first U.S. Patent, first CE Mark, and commercialization strategy. To participate in the call, please dial 1-888-452-4030 (toll-free) in the U.S. and Canada, and 1-719-457-2552 (toll) internationally. The conference ID number for both is 994675. A live

audio webcast of the conference call will also be available via link from the investor relations page of VolitionRx's corporate website at <a href="http://ir.volitionrx.com/">http://ir.volitionrx.com/</a>.

After the live audio webcast, the event will remain archived on VolitionRx's website for one year. In addition, a telephone replay of the call will be available until November 18, 2015. The replay dial-in numbers are 1-877-870-5176 (toll-free) in the U.S. and Canada and 1-858-384-5517 (toll) internationally. Please use replay pin number 994675.

Please dial in at least 10 minutes prior to the scheduled conference call time to ensure timely participation.

### 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 U.S. and ultimately, worldwide.

Visit VolitionRx's website (<a href="http://www.volitionrx.com">http://www.volitionrx.com</a>) or connect with us via <a href="http://www.volitionrx.com">Twitter</a>, <a href="http://www.volitionrx.com">LinkedIn</a>, <a href="https://www.volitionrx.com">Facebook</a> or <a href="https://www.volitionrx.com">YouTube</a>.

#### **Media Contacts**

Anita Heward, VolitionRx <u>a.heward@volitionrx.com</u>

Telephone: +44 (0) 77756 034 243

Kirsten Thomas, The Ruth Group <a href="mailto:kthomas@theruthgroup.com">kthomas@theruthgroup.com</a>
Telephone: +1 (508) 280-6592

#### **Investor Contacts**

Scott Powell, VolitionRx S.Powell@volitionrx.com

Telephone: +1 (646) 650-1351

Lee Roth, The Ruth Group <a href="mailto:lroth@theruthgroup.com">lroth@theruthgroup.com</a>

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 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.

Nucleosomics<sup>®</sup>, NuQ<sup>®</sup> and HyperGenomics<sup>®</sup> 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-announces-third-quarter-2015-financial-results-and-business-update-300172088.html

SOURCE VolitionRx Ltd