May 13, 2016

VolitionRx Announces First Quarter 2016 Financial Results and Business Update

NAMUR, Belgium, May 13, 2016 /PRNewswire/ --VolitionRx Limited (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 first quarter ended March 31, 2016.

First Quarter 2016 and Recent Company Highlights:

Clinical:

- Announced results from a 430 patient study in pre-cancerous colorectal adenomas, in which a panel of five NuQ® biomarker assays in an age adjusted algorithm accurately detected 75% of high-risk colorectal adenomas and 86% of stage 1 colorectal cancers, the best adenoma detection rates to-date by VolitionRx.
- Released results from a prostate cancer study that demonstrated a single NuQ® biomarker assay detected 71% of early stage I prostate cancer cases at 93% specificity, significantly higher detection rates compared to the current standard of care, the PSA test
- Reported results from a NuQ® trial in Idiopathic Pulmonary Fibrosis (IPF), the Company's first study for a non-cancer indication; NuQ® detected IPF in 86% of trial subjects

Regulatory:

- Received CE Marks for two NuQ® biomarker assays, NuQ®V001 and NuQ®T003, to detect the presence of colorectal cancer signatures
- Received ISO Certification EN ISO 13485:2012 for quality management system for design, development, production and distribution of NuQ® blood tests

Operational:

- Strengthened leadership team with appointment of Dr. Jason Terrell as full-time Chief Medical Officer and Head of U.S. Operations, and Louise Day as Chief Marketing and Communications Officer
- Completed secondary offering of approximately 4.3 million shares of common stock, generating net proceeds after fees and expenses of approximately $12.8 million

"We had an extremely productive first quarter, as we significantly advanced our clinical programs and achieved a number of important regulatory and operational milestones. CE marking of NuQ®V001 and NuQ®T003 represented a key step in our path to European commercialization of the NuQ® blood test for colorectal cancer, whose launch we plan for later this year," said Cameron Reynolds, President and Chief Executive Officer of VolitionRx. "We are excited about our progress in Europe, and we are continuing to advance our U.S. clinical and regulatory strategy as well. Later this year, we intend to initiate an FDA-endorsed clinical trial of NuQ®. Importantly, we expect to submit a 510(k) application to the FDA, which, if approved, would give NuQ® marketing clearance for use as an adjunct test for colorectal cancer. Our strategy positions NuQ® for potential FDA clearance and commercial launch as early as 2017. VolitionRx continues to generate the data necessary to submit a PMA for the potential FDA approval of our NuQ® test for the early detection of colorectal cancer."

Mr. Reynolds added, "In addition to the continued execution of our commercial strategy, we have had several important clinical accomplishments thus far in 2016. In a targeted clinical trial of 430 pre-cancerous colorectal adenoma patients with Hvidovre Hospital and the University of Copenhagen, a panel of five NuQ® biomarker assays in an age adjusted algorithm detected 75% of high-risk colorectal adenomas and 86% of stage I colorectal cancers. These are our highest adenoma detection rates yet, and they demonstrate the power of NuQ®, not only for the

detection colorectal cancer, but also for pre-cancerous polyps. Furthermore, at the AACR Annual Meeting in New Orleans, we presented the results of a prostate cancer study conducted in collaboration with the Surrey Cancer Research Institute at the University of Surrey in the UK. In this study, a single NuQ® biomarker assay detected 71% of early stage I prostate cancer cases with 93% specificity, significantly higher than the Prostate Specific Antigen (PSA) test, which is the current standard for prostate cancer detection. We are continuing to explore the potential of NuQ® to diagnose diseases other than cancer. We released data from our first non-cancer clinical trial with Liège University Hospital in Belgium, in which NuQ® detected 86% of subjects with Idiopathic Pulmonary Fibrosis, a deadly lung disease. We believe that NuQ® has broad potential across a variety of indications beyond cancer and plan to assess these applications further."

"As of today, we have more than 50 antibody programs in development. A majority of the early programs have been successful and are now used in our Clinical Validation Studies. The goal is to continue investing resources into this strategy in order to build our own proprietary antibody banks. Moreover, this will secure the supply of highly performant antibodies, which we believe will lead to more reliable clinical results and products further down the line."

"In March, we completed a successful secondary offering of common stock in which we issued approximately 4.3 million shares and generated net proceeds of approximately $12.8million after deducting underwriting discounts, commissions and expenses payable by us. We completed the first quarter with a strong cash position of $17.0 million, providing us with the financial resources needed to fund our ongoing trials and initiate new ones, as well as to support our commercialization initiatives in Europe, the U.S. and other markets. Our solid leadership team was enhanced by Dr. Jason Terrell's transition to full-time status as Chief Medical Officer and Head of U.S. Operations and Louise Day's appointment as Chief Marketing and Communications Officer. Overall, we believe we are ideally positioned to meet our key clinical, operational and strategic objectives, and we look forward to the opportunities that lie ahead," Mr. Reynolds concluded.

First Quarter 2016 Financial Results

For the three months ended March 31, 2016, VolitionRx reported a net loss of $2.5 million, or $0.13 per share. This compares to a net loss of $2.0 million, or $0.12 per share in the first quarter of 2015.

Cash and cash equivalents as of March 31, 2016 totaled $17.0 million, compared with $5.9 million as of December 31, 2015.

About VolitionRx

VolitionRx is a life sciences company focused on developing blood-based diagnostic tests for different types of cancer. The NuQ® tests are based on the science of Nucleosomics® which is the practice of identifying and measuring nucleosomes in the bloodstream – an indication that cancer 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 (www.volitionrx.com) or connect with us on Twitter, LinkedIn, Facebook or YouTube.

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

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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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