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VolitionRx Announces Full Year 2015 Financial Results and Business Update

NAMUR, Belgium, March 11, 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 full year ended December 31, 2015.

Full Year 2015 Company Highlights:

Clinical

- Colorectal cancer and adenomas:
 - Released interim data from first large-scale clinical trial, a 4,800-subject retrospective colorectal cancer study at Hvidovre Hospital, University of Copenhagen, Denmark. A panel of NuQ[®] biomarker assays detected 81% of colorectal cancers at 78% specificity equally well for both for early- and late-stage cancers and 67% of high-risk adenomas (polyps most likely to become cancerous).
 - Announced results from first completed prospective clinical trial in colorectal cancer. In the 121-patient study at CHU Dinant Godinne – UCL Namur in Belgium, a panel of 4 NuQ[®] biomarker assays, adjusted for age, detected 91% of colorectal cancers at 90% specificity. The study also detected 67% of high risk adenomas.
- Pancreatic cancer:
 - Achieved first peer-reviewed validation of NuQ[®] test for pancreatic cancer published in journal [Clinical Epigenetics](#). Results from a 59-patient retrospective study at Lund University, Sweden, showed a panel of four NuQ[®] biomarker assays plus CA 19-9 classical biomarker detected 92% of pancreatic cancers at 100% specificity.
 - Announced results from second preliminary study in pancreatic cancer based on the 4,800 patient clinical trial in Denmark, which included 20 subjects with pancreatic cancer. A 2-assay NuQ[®] panel plus classical cancer biomarker CEA achieved 95% sensitivity at 84% specificity.
- Lung cancer:
 - Announced interim results from ongoing 240 patient trial evaluating NuQ[®] for the detection of lung cancer; when combined with smoking history, a 4-assay NuQ[®]

panel accurately detected 93% of lung cancer cases at 91% specificity, and differentiated lung cancer from the common lung disease, COPD.

Regulatory

- Announced first CE Mark for blood-based diagnostic assay, NuQ[®]X001S, for detection of colorectal cancer.

Operational

- Listed the company on the New York Stock Exchange- MKT market and raised approximately \$9.7 million in net proceeds in public offering of common stock.
- Awarded two key U.S. patents: first (Number 9128086), relating to the detection of epigenetic changes that affect chromosome structure in cancer, by means of a simple test using a single drop of blood; and second (Number 9187780), relating to the measurement of nucleosome adducts (cancer-related proteins bound to nucleosomes).
- Appointed David Kratochvil as Chief Financial Officer to lead the financial strategy in preparation for increased activity related to initial market entry of NuQ[®] tests in the U.S. and several markets worldwide.

Cameron Reynolds, President and Chief Executive Officer of VolitionRx, said, "2015 was a year of significant clinical and operational achievements for VolitionRx that we believe set the Company on a path to long-term growth and success. Notably, we announced our first CE Mark (allowing European clinical sale) for the NuQ[®]X001S biomarker assay for detection of colorectal cancer. We are currently in the process of CE Marking the full panel of NuQ[®] biomarker assays that will comprise VolitionRx's colorectal cancer blood test, and are on track for the commercial launch of the test this year for clinical use in Europe, with meaningful sales expected to begin in 2017."

"In the fourth quarter, we released data from separate clinical trials showing that our NuQ[®] tests detect colorectal, pancreatic and lung cancers at early and late-stages with over 90% accuracy. In particular, we released highly promising results from the first completed prospective study in colorectal cancer patients. The study of 121-patients conducted at CHU Dinant Godinne - UCL Namur in Belgium included 23 cases of colorectal cancer. The study accurately detected 21 out of 23 of the colorectal cancer cases, achieving 91% sensitivity at 90% specificity based on a panel of 4 NuQ[®] biomarker assays. Moreover, the study demonstrated detection of 67% of high-risk adenomas, or pre-cancerous polyps that are most likely to become cancerous. These results highlight the potential of our NuQ[®] tests to accurately detect the entire range of cancer development from pre-cancerous polyps through early-stage to late-stage colorectal cancer. Last month, these results were followed up by encouraging results obtained from a 430 patient study, conducted at the Hvidovre Hospital and the University of Copenhagen in Denmark, which showed NuQ[®] biomarker assays detected 75% of high-risk colorectal adenomas."

"We have also made important progress in our pancreatic cancer program. The results of our first pancreatic cancer study with Lund University were published in the peer-reviewed journal, *Clinical Epigenetics*. We announced results of our second preliminary pancreatic cancer study with Hvidovre Hospital, University of Copenhagen in Denmark, which

demonstrated that a 2-assay NuQ[®] panel plus classical cancer biomarker CEA detected 19 out of 20 pancreatic cancer cases (95% sensitivity) within a 4,800-subject trial at 84% specificity. These very encouraging results provide confidence to move forward with a large, dedicated pancreatic cancer study. We believe that pancreatic cancer represents a significant market opportunity, and expect that pancreatic cancer will be our second target indication for the commercialization of NuQ[®], following colorectal cancer."

Mr. Reynolds continued, "Furthermore, the interim data from our 240 patient prospective lung cancer trial conducted at Liege University hospital was extremely promising. In total 73 patients were studied, including 29 with non-small cell lung cancer, 22 with the common lung disease COPD and 22 healthy subjects. A 4-assay NuQ[®] biomarker panel accurately detected 93% of lung cancer cases with only 2 false positives amongst the healthy subjects. Importantly, the test was also able to distinguish between lung cancer and COPD, and between cancerous and non-cancerous fibrous nodules in the lung. The best current lung cancer diagnostic, a low-dose computed tomography scan, does not distinguish well between cancerous and non-cancerous fibrous nodules in the lung, leading to a high false positive rate¹. Our interim data are exciting because they show both high sensitivity and very few false positives, indicating that a simple NuQ[®] blood test, used alone or in conjunction with current standards, may detect lung cancer and distinguish it from other lung diseases."

Mr. Reynolds added, "In the second half of 2015, our company was granted its first two U.S. patents for the detection of histone modification in cell-free nucleosomes and for methods of detection of nucleosomes adducts. These patents cover the core technologies of VolitionRx's Nucleosomics[®] platform: the measurement of cancerous changes to the nucleosomes themselves and the detection of cancer-related proteins bound to nucleosomes. In the first quarter of 2016, we were granted a third U.S. patent, relating to the detection of nucleosomes, which reinforces the Company's market exclusivity with its novel Nucleosomics[®] technology."

He concluded, "Overall, we accomplished a great deal in 2015 and have set in place the foundations for several key milestones in the year ahead. In addition to the European commercial launch of the NuQ[®] colorectal cancer test, we expect to initiate one or more large studies in both pancreatic and lung cancer and we will continue to report data from our ongoing colorectal cancer trials. We are grateful to our shareholders for their continued support and we are very excited about what the future holds."

Full Year 2015 Financial Results

For the full year ended December 31, 2015, VolitionRx reported a net loss of \$9.5 million, or \$0.54 per share. This compares to a net loss of \$8.2 million, or \$0.61 per share in full year of 2014.

Cash and cash equivalents as of December 31, 2015 totaled \$5.9 million, compared with \$2.1 million as of December 31, 2014 and \$6.9 million as of September 30, 2015.

Conference Call

VolitionRx Ltd. will host a conference call on Friday, March 1st at 8:30 am ET to discuss its full year 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 1-888-401-4669 (toll-free) in the U.S. and Canada, and 1-719-325-2448 (toll) internationally. The conference ID number for both is 5016468. 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 <http://ir.volitionrx.com/>.

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 March 25, 2016. 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 5016468.

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

References

- (1) Moyer, VA. "Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement." *Annals of Internal Medicine* Vol.160; page 330 (2014). Accessed 18 November 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[®], 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 (<http://www.volitionrx.com>) or connect with us via [Twitter](#), [LinkedIn](#), [Facebook](#) or [YouTube](#).

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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" 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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