

March 9, 2016



# Preliminary Data Demonstrates 86% Accuracy in Detecting Idiopathic Pulmonary Fibrosis, a Fatal Lung Disease

## Results of First Non-Cancer Trial of NuQ® Blood Test

NAMUR, Belgium, March 9, 2016 /PRNewswire/ --[VolitionRx Limited](#) (NYSE MKT: VNRX) today announced preliminary data from a pilot study demonstrating that the Company's NuQ® blood test detected 86% of subjects with a deadly lung disease, called Idiopathic Pulmonary Fibrosis (IPF). This is the first set of results from a non-cancer trial of VolitionRx's NuQ® blood tests, which demonstrates the technology's potential as a diagnostic for other diseases.

The clinical study was conducted with Liège University Hospital in Liège, Belgium. Of the 78 subjects, 21 were non-treated patients with IPF, 27 patients had been treated for IPF, and 30 were healthy volunteers. Analysis of the preliminary data revealed that a single NuQ® biomarker assay detected 86% of the non-treated IPF patients (18 of 21) from the healthy subjects with only 6 false positives (80% specificity).

IPF is a chronic, progressive and lethal lung disease characterised by scarring and reduction in the lungs' capacity to absorb oxygen. In the United States, around 100,000 people are currently affected by IPF, with approximately 30-40,000 new cases diagnosed each year<sup>1</sup>. The true incidence rate is likely higher given current difficulties in proper diagnosis, classification and reporting.

Diagnosis of IPF is based on a range of clinical, laboratory, radiological and pathological tests, often to exclude other conditions first. The key diagnostic test currently available is High Resolution Computed Tomography (HRCT), a costly procedure to which access is limited in many countries. Current treatments include pulmonary rehabilitation, oxygen therapy, medication, and, in a small number of cases, lung transplants. The disease has a poor prognosis, with many patients surviving only 3-5 years after diagnosis<sup>1</sup>.

VolitionRx's Chief Scientific Officer, Dr. Jake Micallef, said, "Some NuQ® biomarker assays are particularly appropriate for the detection of inflammatory diseases such as IPF. To have achieved such impressive accuracy for detecting IPF using only a single such NuQ® biomarker assay in this pilot study is very encouraging. Our next step will be to work on a larger study sample and to include additional NuQ® biomarker assays to form a panel blood test that could have even greater accuracy."

Dr. Julien Guiot, project coordinator from Liège University Hospital, said, "At present, relatively little is known about this deadly disease. An accurate, cost-effective diagnostic for IPF could have a significant impact in assisting researchers in their efforts to understand the

disease and develop a more viable treatment and potential cure."

Cameron Reynolds, Chief Executive Officer of VolitionRx, commented, "Our recent results show that panels of NuQ<sup>®</sup> biomarker assays can detect colorectal, lung and pancreatic cancers with more than 90% accuracy. The excitement generated by the success of these cancer-related clinical trials has led to interest from clinical partners to investigate the effectiveness of NuQ<sup>®</sup> blood tests in detecting other diseases, starting with IPF. We believe that the success of this pilot study for IPF demonstrates the potential of our Nucleosomics<sup>®</sup> technology as a diagnostic platform for a broad range of diseases and establishes a lucrative potential new market for VolitionRx. Moreover, we are excited that our non-invasive blood tests may assist in creating better outcomes for patients with this deadly disease."

Results from on-going clinical trials assessing the effectiveness of VolitionRx's biomarker assays, include:

#### *Colorectal cancer and pre-cancerous colorectal adenomas*

- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released September 9, 2015: [Panel of four NuQ<sup>®</sup> biomarker assays detected 81% of colorectal cancers and 67% of high-risk adenomas at 78% specificity](#)
- Results from a prospective study of 121 patients referred for colonoscopy (CHU Dinant Godinne - UCL Namur, in Belgium), released December 8, 2015: [Panel of four NuQ<sup>®</sup> biomarker assays detected 91% of colorectal cancer cases at 90% specificity](#)
- Results from a retrospective study of 430 patients referred for colonoscopy (Hvidovre Hospital, University of Copenhagen, Denmark), released February 17, 2016: [VolitionRx Demonstrates 75% Accuracy in Detecting Highest-Risk Pre-Cancerous Colorectal Adenomas with NuQ<sup>®</sup> Blood Test](http://www.volitionrx.com/news/press-releases/detail/542/volitionrx-demonstrates-more-than-90-accuracy-for)<http://www.volitionrx.com/news/press-releases/detail/542/volitionrx-demonstrates-more-than-90-accuracy-for>

#### *Pancreatic cancer*

- Results from a 59-patient retrospective study (Lund University, Sweden) published in Clinical Epigenetics online journal (<http://www.clinicalepigeneticsjournal.com/content/pdf/s13148-015-0139-4.pdf>), October 7, 2015: [Panel of four NuQ<sup>®</sup> biomarker assays plus CA 19-9 classical biomarker detected 92% of pancreatic cancers at 100% specificity](#)
- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released October 22, 2015: [Panel of two NuQ<sup>®</sup> assays and the classical cancer marker CEA \(carcino-embryonic antigen\) distinguished 95% of pancreatic cancer cases from healthy subjects at 84% specificity](#)

#### *Lung cancer*

- Interim results (73 of 240 patients collected and assessed) from a prospective study (Liege University Hospital, Belgium), released November 19, 2015: [Panel of four NuQ<sup>®</sup> biomarker assays detected 93% of lung cancers at 91% specificity](#)

## References

1. National Heart, Lung, and Blood Institute. "What Is Idiopathic Pulmonary Fibrosis?" 20 September 2011. Accessed February 16, 2016.

## About VolitionRx

VolitionRx is a life sciences company focused on developing blood-based diagnostic tests for different types of cancer. The NuQ<sup>®</sup> tests are based on the science of Nucleosomics<sup>®</sup> 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 centred 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](http://www.volitionrx.com)) or connect with us on [Twitter](#), [LinkedIn](#), [Facebook](#) or [YouTube](#).

An animation introducing VolitionRx's Nucleosomics<sup>®</sup> 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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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/preliminary-data-demonstrates-86-accuracy-in-detecting-idiopathic-pulmonary-fibrosis-a-fatal-lung-disease-300233256.html>

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