

November 14, 2013



VolitionRx Expands Sample Size to 11,000 in Pivotal Colorectal Cancer Trial with Hvidovre Hospital, Denmark

NAMUR, Belgium, Nov. 14, 2013 /PRNewswire/ --[VolitionRx Limited](#) (VNRX:OB), a life sciences company focused on developing blood-based diagnostic tests for different types of cancer, today announced an increase of 55% (from 6,000 to 11,000) in the number of prospective blood samples to be included in its forthcoming colorectal cancer clinical trial at no additional cost beyond the \$1.85 million already announced. The randomised, blinded study is designed to evaluate the validity of VolitionRx's proprietary NuQ® panel as a first-step screening tool for colorectal cancer.

Sample collection for this prospective study, which is jointly sponsored by VolitionRx and the University of Copenhagen, is due to commence in April 2014 and be completed by the end of 2015. With the additional blood samples, 8,000 individuals receiving a positive faecal immunological testing (FIT) result and 3,000 individuals receiving a negative FIT result as part of the Danish national screening programme will now be tested using Volition's NuQ assay panel. The results will be verified by colonoscopy. Notably, the Danish team is collecting up to 120 data points for each individual included in the trial (e.g. age, gender, other diseases). This will provide an extremely powerful tool in understanding how different diseases and conditions interrelate with colorectal cancer.

The additional blood samples will be collected by Professor Hans Jorgen Nielsen, Professor of Surgical Oncology at the Department of Surgical Gastroenterology at Hvidovre Hospital, part of the University of Copenhagen, and collaborators at 7 additional Danish hospital departments.

Speaking about the expansion, Professor Nielsen says: "Our decision to provide Volition with these extra samples was driven by the promising interim data from other NuQ trials. This expansion is significant as we will be able to make even stronger conclusions about both the accuracy of VolitionRx's NuQ blood test and the risk factors of colorectal cancer. We also now have the possibility to re-confirm the results of symptom-free individuals who are undergoing screening."

Dr Jake Micallef, Chief Scientific Officer of VolitionRx, adds: "Professor Nielsen and collaborators' collection of extensive blood samples provides the opportunity to identify and validate other molecules and genetic components associated with the growth, invasion and dissemination processes of colorectal cancer. We will now have further data to analyse in relation to colonoscopy findings, to demonstrate the performance of a simple NuQ blood test to diagnose colorectal cancer at an early stage in a non-invasive way. The 11,000 prospective samples are in addition to the already collected 4,800 retrospective symptomatic samples for a combined 16,000 individuals. We have received the first 1,000 samples from the retrospective trial we are carrying out in conjunction with Hvidovre Hospital, and will

begin the analysis this year."

In addition to analysing the 16,000 Danish individuals, Volition is carrying out the following trials:

- 3 ongoing multi-cancer studies at University Hospital in Bonn, Germany, including an 800 patient retrospective study and a 2,000 patient prospective study that involves patients with the 20 most prevalent cancers
- a 250 patient study into colorectal cancer at CHU-UCL Mont Godinne Hospital, Belgium.

Data from these trials will be used to apply for a CE mark for a colorectal cancer test, and will also be submitted to the FDA.

Colorectal cancer is the third most prevalent cancer worldwide, after lung and breast cancers, with approximately 1.24 million new cases diagnosed each year. In the United States alone, 136,717 people were diagnosed with colorectal cancer in 2009, with 51,848 dying from the disease that year.

Safe Harbor Statement

Statements in this press release may be "forward-looking statements". Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates," "optimizing," "potential," "goal," and similar expressions, as they relate to the Company, its business or management, identify forward-looking statements. 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. Actual outcomes and results may, and probably will, differ materially from what is expressed or forecasted in such forward-looking statements due to numerous factors, including those described above and those risks discussed from time to time in the Company's filings with the Securities and Exchange Commission.

Colorectal cancer figures sourced from:

<http://www.cdc.gov/cancer/colorectal/statistics/> and <http://www.cancerresearchuk.org/info/cancerstats/types/bowel/incidence/uk-bowel-cancer-incidence-statistics#geog>.

SOURCE VolitionRx Limited