February 18, 2020

Volition Unveils Its Epigenetic Toolbox

AUSTIN, Texas, Feb. 18, 2020 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced that research on its Nu.Q(TM) Capture program has led to the development of a suite of novel epigenetic tools building on the breakthroughs announced last month on its assay platform. This epigenetic toolbox aims to initially be used in cancer diagnostics.

Dr. Mark Eccleston, one of the founding scientists of Volition and its Business Development Director commented, "I believe these exciting new tools will lead to a paradigm shift in epigenetic based blood tests and help us to establish a leadership position in the epigenetics diagnostics field. We are now processing samples and expect to announce patient data demonstrating the wide utility of these methods in the coming months."

Dr. Jake Micallef, Chief Scientific Officer at Volition added, "These Nu.Q(TM) Capture technologies have emanated from years of focused research in clinical epigenetics. We have filed several patents relating to these Nu.Q(TM) methods to add to Volition's already extensive patent portfolio, with the aim of securing broad coverage and protection in this key area of epigenetics."

Volition has developed and has filed patent applications on its novel Nu.Q(TM) Capture based epigenetic tools, in addition to its bead-based Nu.Q(TM) assay format, to decipher the epigenetic and environmental profiles of cancer nucleosomes with the aim of using:

- Nu.Q(TM) Capture methods to enrich cancer nucleosomes and simplify sequencing based "liquid biopsies".
- Nu.Q(TM) Capture methods to isolate intact nucleosomes from plasma for mass spectrometry analysis in the framework of both biomarker discovery and clinical diagnostics.
- Nu.Q(TM) Capture to measure global methylation patterns in a simple platform.
- Nu.Q(TM) Capture to concentrate nucleosomal markers prior to our Nu.Q™ assays to increase accuracy.
- Nu.Q(TM) platform to detect and measure circulating nucleosomes and transcription factors with potential to be tissue specific, and therefore cancer specific. This, if successful could result in a simple blood test for multiple cancers.

Volition is using these tools to expand diagnostic developments that focus on circulating DNA fragment analysis, to a broader and potentially more powerful investigation of the epigenetic status of a patient's circulating chromosome fragments, in addition to its ongoing work with its assay-based format in a range of cancers.

Further Technical Background

Cell free DNA has been widely investigated for liquid biopsy in the previous decade. The cell

free DNA ("cfDNA") in circulation is derived from fragmented chromatin released as cells die. This originates mainly as a result of natural turnover of white blood cells, but also from diseased cells including cancer. The relatively large background of cfDNA from normal cells makes detection of low levels of circulating tumor DNA ("ctDNA") much more difficult, especially in the context of early disease detection and has limited the applications of liquid biopsy to detection of specific mutations in advanced disease which can be used to guide treatment in a precision medicine paradigm.

DNA is relatively unstable and only fragments protected by association with proteins (predominantly histone/DNA complexes or nucleosomes and smaller transcription factor/DNA complexes) survive in circulation. The proteins and various chemical modifications to them control access to the DNA within our chromosomes and therefore the genes that are selectively switched on and off. This epigenetic level of control determines how our genetic code is ultimately expressed and allows the formation of all the cells in our body from the same genetic code. In cancer, dysregulation of this epigenetic code can deactivate tumor suppressor genes or activate tumor promotors.

Most research into new diagnostic methods in oncology has focused on extracting the short cfDNA fragments from their associated proteins circulating in the blood of cancer patients to identify genetic information (mutations for example). This process removes the equally important epigenetic components in those circulating fragments. The discarded nucleosomes and transcription factor complexes contain an immense repository of epigenetic information. At its simplest level this is related to activation/suppression of associated genetic mutations but may also explain tissue of origin of the cfDNA and can explain why ctDNA is subtly shorter than general cfDNA. Combining both the epigenetic features of the DNA/protein complexes and the DNA sequencing can differentiate disease associated and background chromatin fragments and will provide much deeper understanding of how and why these fragments are associated with disease.

About Volition

Volition is a multi-national epigenetics company developing simple, easy to use, cost effective blood tests to help diagnose a range of cancers and other diseases. Early diagnosis has the potential to not only prolong the life of patients, but also to improve their quality of life. 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. Volition is primarily focused on human diagnostics but also has a subsidiary focused on animal diagnostics.

Volition's research and development activities are centered in Belgium, with additional offices in Texas, London and Singapore, as the company focuses on bringing its diagnostic products to market.

For more information about Volition, visit Volition's website (http://www.volitionrx.com) or connect with us via:

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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 Volition's blood-based diagnostic tests as well as Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if Volition fails to develop and commercialize diagnostic products, it may be unable to execute its plan of operations. Other risks and uncertainties include Volition's failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical IVD or the veterinary market; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic products Volition might develop; Volition's failure to secure adequate intellectual property protection; Volition will face fierce competition and Volition'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 Volition's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that Volition files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about Volition'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, Volition does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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