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## **Volition Appoints DXOCRO to Spearhead U.S. FDA Strategy**

HENDERSON, Nev., Aug. 8, 2022 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition"), a multi-national epigenetics company, has appointed Diagnostic Oncology CRO, LLC ("DXOCRO") to undertake development and clinical validation studies for its Nu.Q® product portfolio in the United States.

DXOCRO will conduct large-scale finding studies across multiple sites in the U.S. using Volition's Nu.Q® NETs and Nu.Q® Cancer tests to determine clinical utility in sepsis and cancer. Volition anticipates that subsequent studies will investigate the chosen intended use claims of the tests, with the objective to gain clearance, authorization, or approval from the United States Food and Drug Administration (the "FDA") and allow the tests to be marketed in the U.S.

Sharon Ballesteros, U.S. Head of Quality and Development Process at Volition, said: "DXOCRO is a leading contract research organization specializing in the commercialization of diagnostic biomarker technologies. They are an ideal partner for us as we develop our FDA strategy in the United States.

"DXOCRO will spearhead both our clinical product development and our regulatory program in the United States, and seek to establish clinical utility for our Nu.Q® products. Through multi-site development studies, they will help us demonstrate how our Nucleosomics™ technology can directly benefit patients and support our application to the FDA's Breakthrough Devices Program and a Pre-submission anticipated in 2023."

Thomas Soriano, President and Chief Executive of DXOCRO, said: "We're delighted to be working with Volition, providing support and acting as the company's regulatory and clinical affairs team in the U.S. Volition's technology has the potential to significantly improve patient outcomes in those diagnosed with sepsis or cancer. Through the conduct of Volition's clinical validation studies, we hope to validate a broad range of potential Nu.Q® products and support Volition's U.S. commercialization strategy."

Volition is developing simple, easy-to-use, cost-effective blood tests to help diagnose and monitor a range of life-altering diseases including cancer in both humans and animals. For more information about Volition's Nu.Q® technology go to: [www.volition.com](http://www.volition.com)

### **About Volition**

Volition is a multi-national epigenetics company that applies its Nucleosomics™ platform through its subsidiaries to develop simple, easy to use, cost effective blood tests to help diagnose and monitor a range of life-altering diseases including some cancers and diseases associated with NETosis such as sepsis and COVID-19. Early diagnosis and monitoring have the potential to not only prolong the life of patients but also 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 and monitoring but also has a subsidiary focused on animal diagnostics and monitoring.

Volition's research and development activities are centered in Belgium, with an innovation laboratory and office in the U.S. and additional offices in London and Singapore.

The contents found at Volition's website address are not incorporated by reference into this document and should not be considered part of this document. The address for Volition's website is included in this document as an inactive textual reference only.

### **About DXOCRO**

Diagnostic Oncology CRO, LLC ("DXOCRO") has been engaged in providing professional services to biotechnology, therapeutic, medical device, and *in vitro* diagnostic ("IVD") medical device developers and manufacturers, as well as users of such devices such as laboratories since 1997. DXOCRO provides assistance with tactical and strategic issues related to marketing claims, reimbursement, and regulatory requirements, including the design and conduct of clinical studies and trials to developers, manufacturers and users of medical diagnostic devices. DXOCRO's laboratory also provides testing services for novel and existing IVD's. DXOCRO has participated in more than 150 successful 510(k) clearances, *de novo* authorizations, pre-market approvals, and emergency use authorizations granted by the United States Food and Drug Administration ("FDA"). DXOCRO is located in Oxford, Connecticut – United States.

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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, among other topics, Volition's expectations related to the timing, conduct and completion of clinical studies, potential uses, benefits and effectiveness of its Nucleosomics™ technology platform, including the Nu.Q® NETs test, and the timing and execution of Volition's strategy with the FDA. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including a failure by the marketplace to accept Volition's Nu.Q® NETs test or other products based on its Nucleosomics™ platform; Volition's failure to secure adequate intellectual property protection; Volition will face fierce competition and its intended products may become obsolete due to the highly competitive nature of the diagnostics and disease monitoring markets and their rapid technological change; downturns in domestic and foreign economies; 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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