

March 15, 2023

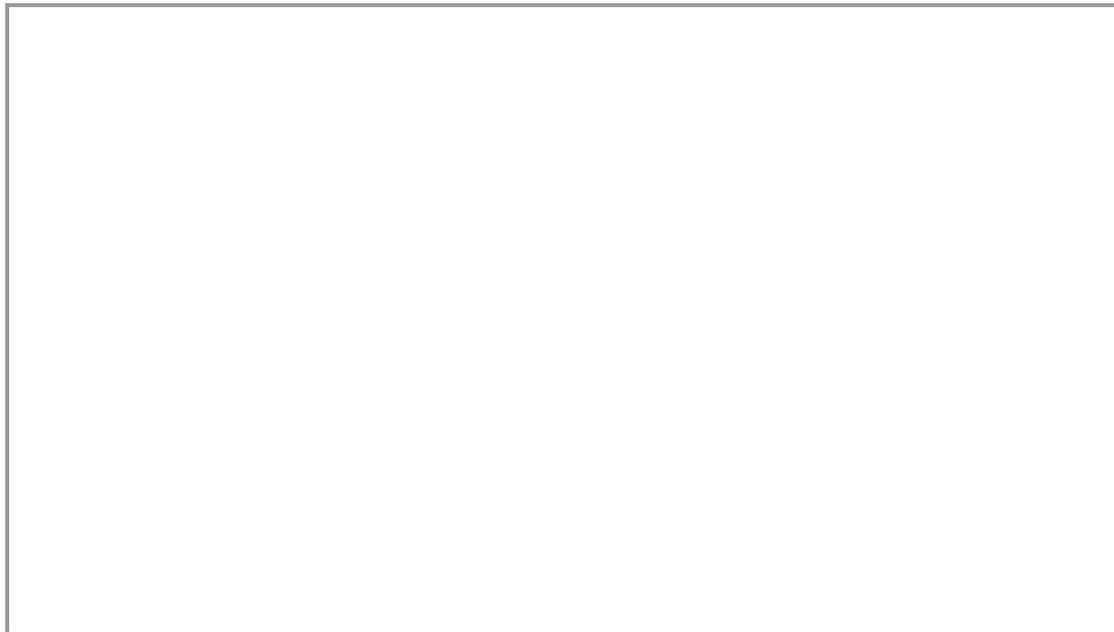


# VolitionRx Limited Announces Full Fiscal Year 2022 Financial Results and Business Update

**Conference call to discuss financial and operational results scheduled for Thursday, March 16, at 8:30 a.m. U.S. Eastern Time**

- Executed global licensing and supply agreement with Heska Corporation ("Heska") to distribute Nu.Q® Vet Cancer Test at the Point of Care with a \$10 million upfront payment and up to \$18 million based upon the achievement of near/mid-term milestones. Volition will also receive ongoing additional revenue from the use by Heska of Volition's key components and reference laboratory kits.
- Executed a global supply agreement with IDEXX Laboratories, Inc. ("IDEXX"), a global leader in pet healthcare innovation, as a provider of the Nu.Q® Vet Cancer Test through its reference laboratory network for cancer indications in animal health. Volition will receive ongoing revenue from the use by IDEXX of Volition's reference laboratory kits.
- Expanded its large intellectual property portfolio.
- Made significant progress with the development of its Nu.Q® NETs product pillar including the receipt of a CE Mark for the test and the engagement of Diagnostic Oncology CRO, LLC ("DXOCRO") to spearhead Volition's clinical product development and its FDA regulatory programs in the United States.

HENDERSON, Nev., March 15, 2023 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition"), a multi-national epigenetics company, today announced financial results and a business update for the full fiscal year ended December 31, 2022. Volition management will host a conference call tomorrow, March 16 at 8:30 a.m. U.S. Eastern Time to discuss these results. Conference call details can be found below.



"I could not be prouder of the team's achievement in securing global supply agreements for our Nu.Q® Vet Cancer Test with two industry-leading companies, Heska and IDEXX," commented Cameron Reynolds, President and Group Chief Executive Officer of Volition. "Volition Veterinary is an exciting, fast-moving part of our business with clear potential to generate significant revenue for the company, through both upcoming milestone payments and ongoing sales of kits and key components. We have also made good progress in other key areas especially our Nu.Q® NETs product pillar with the achievement of a CE Mark and the appointment of DXOCRO to spearhead our product development and regulatory programs in the U.S. through the FDA, as we shift gears towards our goal of becoming a commercial company with products."

## **Company Highlights**

### **Financial**

- Cash and cash equivalents as of December 31, 2022 totaled approximately \$10.9 million.
- In February 2023, received approximately \$8.0 million in net cash (before deducting offering expenses payable by Volition) through an underwritten public offering of its common stock.
- Recorded approximately \$300,000 in revenue in 2022, up 240% over the prior year.
- Received a \$10 million upfront payment on signing the Heska Licensing and Supply Agreement.
- During 2022, strengthened its balance sheet by adding approximately \$6.4 million in net cash (before deducting offering expenses payable by Volition) through an underwritten public offering of its common stock in August.
- In August 2022, announced the award of approximately \$1.5 million in non-dilutive funding from Namur Invest Capital Risk in Belgium to fund an early access program for Volition's Nu.Q® product portfolio at key sites across the EU, the UK, and the U.S.
- Net cash used in operating activities was \$15.3 million for the full year, or a monthly average of approximately \$1.3 million.

## **Commercial Strategy**

- Volition is guided by three underlying principles to its commercialization strategy with the goal of ensuring that its products:
  - Result in low capital expenditures for licensors and end users, and low operating expenses for Volition;
  - Are affordable; and
  - Are accessible worldwide.
- Volition believes, given the global prevalence of cancer and diseases associated with NETosis, and the low-cost, accessible and routine nature of its tests, Nu.Q® could potentially be used throughout the world in both animals and humans, in multiple diseases.
- Volition estimates its annual total addressable market to be approximately \$70 billion worldwide including Nu.Q® Vet, Nu.Q® Discover, Nu.Q® NETs and Nu.Q® Cancer.

## **Personnel/ Operational**

- Strengthened its corporate functions of Human Resources, Legal, Information Technology and Commercial and expanded its manufacturing capabilities to lay foundations for the anticipated growth in a range of product areas.

## **Intellectual Property**

- 34 patent families (plus three in-licensed families) covering both human and animal use of Volition's Nucleosomics™ platform.
- 97 granted patents (12 in the U.S., 15 in Europe, and 70 rest of world).
- 122 patents pending worldwide.

## **Nu.Q® Vet**

- Executed global licensing and supply agreements for the Nu.Q® Vet Cancer Test with two of the industry's leading companies, Heska and IDEXX, as well as with several other providers. Volition continues to advance negotiations with other potential licensing partners with the goal of making Nu.Q® Vet as accessible as possible worldwide and anticipates further announcements in 2023.

## **Heska**

- In exchange for granting Heska exclusive worldwide rights to sell the Nu.Q® Vet Cancer Test for companion animals at the point of care, Volition:
  - received a \$10 million upfront payment on signing;
  - may receive up to \$18 million based upon the achievement of near/mid-term milestones; and
  - ongoing additional revenue from the sales of key components.
- In addition, Volition has granted Heska non-exclusive rights to sell the Nu.Q® Vet Cancer Test in kit format for companion animals, through Heska's network of central reference laboratories for which Volition will receive ongoing additional revenue for such kit sales.
- In February 2023, Heska commenced pre-orders of the Nu.Q® Canine Cancer Screen and Monitor Test to veterinarians at the point of care.

## **IDEXX**

- In exchange for granting IDEXX the rights to sell the Nu.Q® Vet Cancer Test worldwide through its global reference laboratory network, Volition will receive ongoing revenue from the sales of its reference laboratory kits.
- In January 2023, IDEXX launched the IDEXX Nu.Q® Canine Cancer Screen through its U.S. reference lab network.

## **Nu.Q® Vet Product Updates**

- In August 2022, a peer-reviewed and published clinical study reported that Volition's Nu.Q® Vet Cancer Test detected 76% of systemic cancers (including lymphoma, hemangiosarcoma, and histiocytic sarcoma) at 97% specificity versus control.
- Data presented at the European Society of Veterinary Oncology Congress in May 2022 suggests that Nu.Q® Vet may also serve as a more sensitive measurement of both minimal residual disease and remission than current methods and could be a useful monitoring test for dogs with cancer.

## **Nu.Q® NETs**

- In May 2022, the Nu.Q® NETs product was CE marked for the detection and evaluation of diseases associated with NETosis on two platforms (ELISA plates and i-10), enabling clinical use in more than 27 countries across Europe.
- Volition believes Nu.Q® NETs will have wide applicability for diseases with a NETs component (such as sepsis, COVID-19, influenza, thrombosis etc.) and potentially could enable the stratification of patients with a high level of NETs, allowing physicians to rapidly triage these patients, and monitor their disease progression and response to treatment.
- In 2022, Volition published a peer reviewed paper and two posters; the key finding reported is that levels of NETosis as measured by Volition's Nu.Q® NETs test are highly elevated in sepsis and moreover that the test results correlate very well with the severity of disease (Sequential Organ Failure Assessment) score.
- In August 2022, Volition appointed DXOCRO, a contract research organization specializing in the commercialization of diagnostic biomarker technologies, to spearhead Volition's clinical product development and FDA regulatory programs in the United States.
- DXOCRO is undertaking large-scale finding studies across multiple sites using Volition's Nu.Q® platform to determine clinical utility in sepsis and cancer with a goal that one or more of such studies will support an application to the FDA's Breakthrough Device Program.
- The first phase of the study focused on sepsis has been completed and an application to the FDA's Breakthrough Device Program is expected to be submitted in the first half of 2023.

## **Nu.Q® Cancer**

- Announced Volition's participation in a government-backed prospective study to evaluate the performance of blood biomarkers in the early detection of lung cancer with Hospices Civils de Lyon ("HCL"), France's second largest university hospital.
  - The Lyonnaise Initiative for the Initiation of Lung Cancer Screening ("ILYAD") is a

wide-ranging clinical study assessing the feasibility of a lung cancer screening program and the effectiveness of screening.

- The ILYAD study will evaluate the performance of Volition's Nu.Q® test as a blood biomarker for the early detection of lung cancer, when used alone and in conjunction with CT scan, with the ultimate goal of developing a national screening program in France.
- Volition has conducted a retrospective proof of concept with HCL in lung cancer, the results of which will be presented at an upcoming conference.
- Completed the National Taiwan University Lung study, analysis is underway with publication expected thereafter.

### **Nu.Q® Capture**

- Nu.Q® Capture, when used in combination with either sequencing, mass spectrometry and/or Volition's Nu.Q® assays could potentially aid diagnosis, treatment selection, and both treatment and disease monitoring in addition to aiding biomarker discovery. The aim is to provide accurate, lower cost and easier-to-use tests than those currently available.
- The Nu.Q® Capture program now has several strands of technology which:
  - essentially remove background noise, thereby amplifying the cancer signal,
  - look to identify the signal in a novel way including through mass spectrometry, or
  - isolate various chromatin fragments, including nucleosomes and transcription factors.

### **Upcoming Milestones**

- Drive near term revenue in the following key areas:
  - Achieve the remaining milestones under the Heska agreement and receive further milestone payments of potentially \$13 million expected in 2023, and a further \$5 million anticipated in 2024.
  - Sales of key components of point of care test with Heska.
  - Sales of kits from non-exclusive agreements for the use of Nu.Q® Vet via central reference labs to Heska, IDEXX, and others.
  - License of Volition's technology, with a particular but not exclusive focus on Nu.Q® Vet.
  - Fulfill ongoing and enter into new Nu.Q® Discover agreements.
  - Sales of disease monitoring tests (e.g. sepsis and COVID-19).
- Continue to progress the research program for the use of Nu.Q® in NETosis and submit an application to the FDA's Breakthrough Device Program anticipated in the first half of 2023.
- Continue to advance the previously announced large-scale blood, lung, and colorectal cancer trials in Europe, Asia, and the U.S.
- Publish several abstracts and peer-reviewed scientific papers with clinical results showing the robustness and utility of its Nu.Q® platform.
- Advance the development of Nu.Q® Capture products to proof of concept.
- Continued focus on filing patents to expand and extend Volition's intellectual property portfolio, and protect the large number of patents already granted.

**Date:** Thursday, March 16, 2023  
**Time:** 8:30 a.m. U.S. Eastern time  
**U.S. & Canada Dial-in:** 1-877-407-9716 (toll free)  
**U.K. Dial-in:** 0 800 756 3429 (toll free)  
**Toll/International:** 1-201-493-6779  
**Conference ID:** 13736997

Cameron Reynolds, President and Group Chief Executive Officer of Volition, will host the call along with Terig Hughes, Group Chief Financial Officer of Volition, Dr. Tom Butera, Chief Executive Officer of Volition Veterinary Diagnostics Development LLC, and Scott Powell, Executive Vice President, Investor Relations of Volition.

A live audio webcast of the conference call will also be available on the investor relations page of Volition's corporate website at <http://ir.volition.com>.

In addition, a telephone replay of the call will be available until March 30, 2023. The replay dial-in numbers are 1-844-512-2921 (toll-free) in the U.S. and Canada and 1-412-317-6671 (toll) internationally. Please use replay pin number 13736997.

#### **Future Event**

**Volition's Capital Market Day: Thursday, May 11, at 2:30 p.m. U.S. Eastern Time.**  
**To register your interest please contact [investorrelations@volition.com](mailto:investorrelations@volition.com)**

#### **About Volition**

Volition is a multi-national epigenetics company powered by Nu.Q®, its proprietary nucleosome quantification platform. Through its subsidiaries, Volition is developing 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'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. Such website address is included in this document as an inactive textual reference only.

#### **Media Enquiries:**

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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 potential benefits and timing of payments under the agreements with Heska and IDEXX, the size of Volition's addressable markets, the success of negotiations and the timing, completion and execution of term sheets and/or agreements with third parties regarding the licensing and distribution of Volition's products, the timing, completion and delivery of data from clinical studies, effectiveness of Volition's blood-based diagnostic, prognostic and disease monitoring tests, Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases as well as serving as a diagnostic, prognostic or disease monitoring tools for such diseases, the timing of product launches and publications, and expectations regarding Volition's ability to transition to a commercial products company, its future revenue and financial performance. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including, without limitation, results of studies testing the efficacy of its tests. For instance, if Volition fails to develop and commercialize diagnostic, prognostic or disease monitoring 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; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic, prognostic or disease monitoring 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 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.

Pursuant to the disclosure requirements of the NYSE American Company Guide Section 610(b), Volition is reporting that its audited consolidated financial statements for the fiscal year ended December 31, 2022, included in Volition's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2023, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to Volition's ability to continue as a going concern. This announcement does not represent any change or amendment to Volition's financial statements or to its Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Nucleosomics™ and Nu.Q® and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to in this press release are the property of their respective owners. Additionally, unless otherwise specified, all references to "\$" refer to the legal currency of the United States of America.

Video - <https://www.youtube.com/watch?v=-sjOJqmvFBA>

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