

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **November 14, 2022**

VolitionRx Limited

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of Incorporation)

001-36833
(Commission
File Number)

91-1949078
(IRS Employer
Identification Number)

1489 West Warm Springs Road, Suite 110
Henderson, Nevada 89014
(Address of principal executive offices and Zip Code)

+1 (646) 650-1351
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on which Registered</u>
Common Stock, par value \$0.001 per share	VNRX	NYSE American, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

VOLITIONRX LIMITED
Form 8-K
Current Report

Item 2.02. Results of Operations and Financial Condition.

The following information, including Exhibit 99.1, is being “furnished” in accordance with General Instruction B.2. of Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

On November 14, 2022, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended September 30, 2022. The Company also confirmed its conference call to be held on November 15, 2022 at 8:30 a.m. U.S. Eastern Time. Furnished herewith as Exhibit 99.1 and incorporated by reference herein is a copy of the press release.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of VolitionRx Limited, dated November 14, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VOLITIONRX LIMITED

Date: November 14, 2022

By: /s/ Cameron Reynolds
Cameron Reynolds
Chief Executive Officer & President

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of VolitionRx Limited, dated November 14, 2022.

VolitionRx Limited Announces Third Quarter 2022 Financial Results and Business Update

**Conference call to discuss financial and operational results scheduled for
Tuesday, November 15, at 8:30 a.m. U.S. Eastern Time**

Henderson, Nevada, November 14, 2022 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) (“Volition”) today announced financial results and a business update for the third quarter ended September 30, 2022. Volition management will host a conference call tomorrow, November 15 at 8:30 a.m. U.S. Eastern Time to discuss these results. Conference call details can be found below.

“I am delighted with the progress we have made across many of our Nu.Q[®] pillars as we move forward from purely a research and development company to a commercial company with a wide range of innovative products. This quarter, and subsequent to quarter end, I am proud we have executed yet another global supply agreement with a market leader in pet healthcare,” commented Cameron Reynolds, President and Group Chief Executive Officer of Volition.

“Our Nu.Q[®] Vet Cancer Test is now available in the U.S., and soon to be available in Europe, through Heska Corporation’s veterinary diagnostic laboratories. This is a significant step forward in achieving our goal of making affordable canine cancer screening accessible worldwide, and we expect to see more companies launching our product soon. We also continued to make strong progress with Nu.Q[®] NETs in terms of data publication, commencement of clinical studies, extending our KOL network and commencing commercial discussions with potential licensing targets. We believe that there is enormous potential for Nu.Q[®] NETs to support clinical decision-making, enabling physicians to act quickly, and improve patient outcomes.”

Company Highlights**Financial**

- Cash and cash equivalents as of September 30, 2022, totaled approximately \$16.4 million compared with \$16.7 million at the quarter ended June 30, 2022.
- Received approximately \$6.4 million net of underwriter’s fees and expenses in cash through an underwritten public offering of its common stock.
- Secured a further \$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, UK, and U.S.
- Continued to manage expenditures carefully with net cash used in operating activities averaging approximately \$2.3 million per month in the quarter.

Nu.Q[®]
Vet

- Subsequent to quarter end, announced the signing of a global supply agreement with a market leader in pet healthcare. Through this supply agreement Volition will provide the Nu.Q[®] Vet Cancer Test through the counterparty's extensive global reference laboratory network for cancer indications in animal health.
- Subsequent to the quarter end, announced the launch of our Nu.Q[®] Vet Cancer Test across the U.S. and the forthcoming launch in Europe by Heska Corporation, also one of the leading global providers of advanced veterinary diagnostics, through Heska's veterinary diagnostic laboratories. Launching via Heska's reference laboratory network is an important achievement in the parties' transformative work together as Volition moves towards the launch of Heska's flagship point of care solution anticipated in early 2023.
- Subsequent to quarter end, announced a clinical research study with Oncovet, a renowned veterinary referral clinic, specializing in medical and radiation oncology led by Dr. Jérôme Benoit.
- Volition anticipates launching with at least one other company before the end of 2022, which would bring the total to five global and in-country company licensees running Volition's test.

Nu.Q[®]
NETs

- Appointed DXOCRO to undertake development and clinical validation studies for Volition's 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.
 - These multi-site studies will help demonstrate how Volition's Nucleosomics™ technology can directly benefit patients and support its application to the FDA's Breakthrough Devices Program and a Pre-submission anticipated in 2023.
- Announced a sponsored research agreement with The University of Texas MD Anderson Cancer Center to evaluate the role of NETs in human cancer patients with sepsis.
- In collaboration with researchers at the University of Namur and QUALiblood in Belgium, published:
 - a clinical paper entitled "NETosis and Nucleosome Biomarkers in Septic Shock and Critical COVID-19 Patients: An Observational Study", and
 - a poster presentation entitled "Evaluation and comparison of NETosis biomarkers in sepsis and COVID-19 patients" at the International Society on Thrombosis and Haemostasis (ISTH) Congress in July.
- Subsequent to the quarter end, presented data at the International Symposium on Infections in the Critically Ill Patient and International Sepsis Forum.
 - The key findings presented are 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, or SOFA score).
- Sponsored a GenomeWeb webinar titled 'The Promise of Neutrophil Extracellular Traps (NETs) as Biomarkers in Inflammatory Disease'. To watch on demand, visit the GenomeWeb [website](#).
- Commenced a Market Access Program with European Key Opinion Leaders and early adopters.

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.
 - o 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.
 - o 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, over the next year with the ultimate goal of developing a national screening program in France.

Upcoming Priorities

- Drive near term revenue in the following key areas:
 - o License the Nu.Q[®] platform, with a particular but not exclusive focus on Nu.Q[®] Vet and Nu.Q[®] NETs.
 - o Work closely with Volition's veterinary licensors to launch the Nu.Q[®] Vet Cancer Test across a number of markets via both reference laboratories and point of care, resulting in:
 - 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.
 - o Achieve the remaining milestones under the Heska Corporation agreement and receive the corresponding substantial milestone payments.
 - o Fulfill ongoing and enter into new Nu.Q[®] Discover agreements.
- Continue to progress the research program for the use of Nu.Q[®] NETs in monitoring disease progression of sepsis and potentially other diseases and as a possible companion diagnostic for the treatment of sepsis.
- Continue to advance Volition's 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 Volition's Nu.Q[®] platform.
- Advance the development of Nu.Q[®] Capture.
- Continue to file patents to expand and extend Volition's intellectual property portfolio.

Event: VolitionRx Limited Third Quarter 2022 Earnings and Business Update Conference Call

Date: Tuesday, November 15, 2022

Time: 08:30 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: 13734304

Cameron Reynolds, President and Group Chief Executive Officer of Volition, will host the call along with Terig Hughes, Group Chief Financial Officer, Dr. Tom Butera, Chief Executive Officer of Volition Veterinary Diagnostics Development LLC, and Scott Powell, Executive Vice President, Investor Relations. The call will provide an update on important events which have taken place in the third quarter of 2022 and upcoming milestones.

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 November 29, 2022. 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 13734304.

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 not only to 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'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.

For more information about Volition's Nu.Q® technology go to: www.volition.com.

The contents found at Volition's and GenomeWeb's website addresses are not incorporated by reference into this document and should not be considered part of this document. Such website addresses are included in this document as inactive textual references only.

Media Enquiries:

Louise Batchelor/Debra Daghli, Volition, mediarelations@volition.com +44 (0)7557 774620

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 launch of product sales with Heska and other counterparties to agreements, 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, success and delivery of data from clinical studies, the potential uses, benefits and effectiveness of its Nucleosomics™ technology platform, including the Nu.Q® NETs test and the Nu.Q® Vet Cancer 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, without limitation, results of studies testing the efficacy of its tests, a failure by the marketplace to accept Volition's Nu.Q® NETs test, Nu.Q® Vet Cancer Test or other products based on its Nucleosomics™ platform; Volition's failure to secure adequate intellectual property protection; Volition's failure to obtain necessary regulatory clearances or approvals to distribute and market future products; 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, including those 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. 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. Forward-looking 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.

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.