

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 10, 2021**

**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)

**13215 Bee Cave Parkway  
Suite 125, Galleria Oaks B  
Austin, Texas 78738**  
(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 10, 2021, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended September 30, 2021. The Company also confirmed its conference call to be held on November 11, 2021 at 8:00 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.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release of VolitionRx Limited, dated November 10, 2021.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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 10, 2021

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

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release of VolitionRx Limited, dated November 10, 2021.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**VolitionRx Limited Announces Third Quarter 2021 Financial Results and Business Update**

**Conference call to discuss financial and operational results scheduled for  
Thursday, November 11, at 8:00 a.m. U.S. Eastern Time**

- Healthy balance sheet with approximately \$22.9 million in cash and cash equivalents
- In advanced term sheet negotiations with three large multi-national veterinary companies on potential worldwide licensing/distribution arrangements
- Expanded the Company's intellectual property portfolio
- Made significant progress with the Company's Nu.Q® NETs development
- Continued focus on, and made strong progress towards additional new product launches and licensing in both the human and veterinary spaces worldwide

**AUSTIN, Texas, November 10, 2021 /PRNewswire/** -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the third quarter ended September 30, 2021. Volition management will host a conference call tomorrow, November 11 at 8:00 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

"We have enjoyed an exciting quarter navigating the due diligence process and negotiations with three multi-national companies to advance term sheets for Nu.Q® Vet licensing and distribution arrangements and anticipate signing a term sheet with one of those parties before the end of 2021," commented Cameron Reynolds, President and Chief Executive Officer of Volition. "We have also made progress in other key areas including our Nu.Q® NETs and Nu.Q® Capture programs as we shift gears towards our goal of becoming a commercial company with products."

**An interview with Dr. Tom Butera, Chief Executive Officer of Volition Veterinary Diagnostics Development LLC, Cameron Reynolds, President and Chief Executive Officer of Volition, and Terig Hughes, Chief Financial Officer of Volition.**

<https://youtu.be/-ASwi40hFPY>

**Company Highlights**

**Volition Veterinary**

- In advanced term sheet negotiations with three top global veterinary companies and anticipate signing a term sheet with one of those parties before the end of 2021.
- Published two abstracts at the Veterinary Cancer Society Annual Conference including:
  - o the first data published in relation to what will likely be the second Nu.Q® Vet product, a disease monitoring tool, on track for a planned launch in 2022; and
  - o the first study using Nu.Q® Capture as an enrichment tool in the plasma of dogs with lymphoma.

### **Financial**

- Cash and cash equivalents as of September 30, 2021, totalled approximately \$22.9 million compared with \$19.4 million as of December 31, 2020.
- Cash burn rate averaged approximately \$1.7 million per month, lower than the rate during the previous two quarters and also below the Company's expectations.
- Net loss for the third quarter of 2021 was \$7.2 million versus \$5.6 million the prior quarter with this increase primarily due to non-cash items.

### **Personnel/Operational**

- Dr. Gaetan Michel, Chief Operating Officer, has relocated to the U.S. and is tasked with expanding the team with roles expected to be filled in the quality, regulatory and manufacturing functions.
- On November 1, Mr. Nick Plummer joined the Company as Group General Counsel.

### **Intellectual Property**

- 27 patent families (plus three in-licensed families) covering both human and animal use of Volition's Nucleosomics™ platform.
- 82 granted patents (12 in the U.S., 14 in Europe and 56 rest of world).
- 82 patents pending.
- Continued focus on filings during the third quarter of 2021 and expect portfolio to grow in the quarters and years ahead.

### **Publications**

- Volition's list of publications and abstracts continues to grow.
- Year to date data for Nu.Q® has been presented at four international conferences and Volition has collaborated on four clinical papers.
- These publications are another very important step forward for the Company.

### **Clinical – NETosis including COVID-19**

- Volition believes the Nu.Q® NETs assay will have wide applicability for monitoring diseases with a NETs component (such as COVID-19, influenza, sepsis, autoimmune diseases and cancer) and potentially to risk stratify patients for treatment selection.
- Volition expects to register CE marks on its first NETs product, across multiple platforms including ELISA plate, automated beads and a proof of concept on very high throughput platform by the summer of 2022.
- Volition intends to register the Nu.Q® NETs product with a broad almost C-reactive protein (C.R.P.) style claim "for the detection and evaluation of infection, tissue injury, inflammatory disorders and diseases associated with NETosis".
- Posters published this quarter (at the International Society on Thrombosis and Haemostasis Congress) showed that results on admission using the same Nu.Q® NETs assay could predict future COVID-19 disease severity and that serial results correlate with disease progression including 28-day mortality.
- The Company has further large studies completed in COVID-19 and sepsis which are now awaiting the finalization of data and publication, as well as studies in other diseases in progress with results expected in the coming quarters.

### **Clinical – Cancer**

- The Company has completed preliminary analysis of the colorectal cancer studies (both asymptomatic and symptomatic populations) conducted with the National Taiwan University and has submitted these findings for presentation at a conference in early 2022.
- The Company has completed preliminary analysis of the lung cancer study also conducted with the National Taiwan University and looks forward to reviewing the data with Professor Chen and his team ahead of publication either through a clinical paper or conference abstract.
- Volition has also been in active and continuing negotiations in Asia this year in addition to platform development on its first human cancer launch in China.
- Collection for the U.S. EDRN study restarted in June and enrolment has been slow but steady. The EDRN have diverted some efforts to drive recruitment and the Company anticipates study completion in the fourth quarter of 2022.
- With regards to Volition's U.S. blood cancer studies, the timing of expected completion for each has been impacted by the COVID-19 pandemic due to sample collection and protocol issues.
  - o Given the pandemic delays in the larger NHL study (of 1500 subjects) the Company has taken the opportunity to alter the study protocol and are in the process of upgrading the platform to a high-throughput platform which will help facilitate an FDA compliant product. Consequently, Volition now expects this study to initiate recruitment in the first quarter of 2022 with study completion anticipated in 2023.

### **Upcoming Milestones**

Volition expects to achieve the following milestones during the remainder of 2021 and beyond, pandemic permitting:

- Drive revenue in the coming quarters in the following key areas:
  - o Licensing of its technology, with a particular but not exclusive focus on Nu.Q® Vet, with the aim of signing the first term sheet this year,
  - o Processing samples at Silver One using its Nu.Q® Discovery assays, and
  - o Sales of its disease monitoring tests (e.g. COVID-19, sepsis).
- Continue to progress the research program for the use of Nu.Q® in NETosis, in monitoring disease progression of COVID-19, sepsis and potentially other diseases and as a possible companion diagnostic for a treatment for sepsis.
- Continue to advance its 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.
- Continue to file patents to expand and extend its intellectual property portfolio.

**VolitionRx Limited Third Quarter 2021  
Financial Results and Business Update**

**Date:** Thursday, November 11, 2021  
**Time:** 8:00 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:** 13725016

Cameron Reynolds, President and Chief Executive Officer of Volition, will host the call along with Terig Hughes, 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 November 25, 2021. 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 13725016.

**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 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 and monitoring but also has a subsidiary focused on animal diagnostics and monitoring.

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

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

Twitter: <https://twitter.com/volitionrx>

LinkedIn: <https://www.linkedin.com/company/volitionrx>

Facebook: <https://www.facebook.com/VolitionRx/>

YouTube: <https://www.youtube.com/user/VolitionRx>

The contents found at Volition's website address, Twitter, LinkedIn, Facebook, and YouTube are not incorporated by reference into this document and should not be considered part of this document. The addresses for Volition's website, Twitter, LinkedIn, Facebook, and YouTube are included in this document as inactive textual references only.

## Media / Investor Contacts

<b>Louise Batchelor, Volition</b> <a href="mailto:mediarelations@volition.com">mediarelations@volition.com</a> <b>+44 (0)7557 774620</b>	<b>Scott Powell, Volition</b> <a href="mailto:investorrelations@volition.com">investorrelations@volition.com</a> <b>+1 (646) 650 1351</b>
<b>Jen Lewis, Mind&amp;Matter</b> <a href="mailto:Jen.Lewis@ashfieldhealth.com">Jen.Lewis@ashfieldhealth.com</a> <b>+44 (0)7809 867943</b>	<b>Joseph Green, Edison Advisors</b> <a href="mailto:jgreen@edisongroup.com">jgreen@edisongroup.com</a> <b>+1 (646) 653 7030</b>

## 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, 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.

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.