

**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 12, 2020**

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:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock	VNRX	NYSE American

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 12, 2020, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended September 30, 2020. The Company also confirmed its conference call to be held on November 13, 2020 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of VolitionRx Limited, dated November 12, 2020.

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 12, 2020

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

EXHIBIT INDEX

**Exhibit
Number**
[99.1](#)

Description
Press Release of VolitionRx Limited, dated November 12, 2020.

VolitionRx Limited Announces Third Quarter 2020 Financial Results and Business Update

Conference call to discuss financial and operational results scheduled for Friday, November 13 at 8:30 a.m. U.S. Eastern Time

- Launch of first product, the Nu.Q™ Vet Cancer Screening Test planned for November 30, 2020
- Engaged Diagnostic Oncology CRO LLC to conduct U.S. clinical trial for Non-Hodgkin's Lymphoma
- Expanded research program for the use of Nu.Q™ technology in NETosis

AUSTIN, Texas, November 12, 2020 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the third quarter ended September 30, 2020. Volition management will host a conference call tomorrow, November 13 at 8:30 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

Cameron Reynolds, President and Chief Executive Officer of Volition commented: "During the third quarter, despite the persistence of the COVID-19 pandemic, we have made significant progress on many fronts and are on track to launch our first product, the Nu.Q™ Vet Cancer Screening Test, on November 30. This is a pivotal moment for Volition, demonstrating that our platform has the reliability and reproducibility to launch in an independent laboratory."

An interview with Cameron Reynolds, President and Chief Executive Officer.

<https://youtu.be/JF8bnqhGABY>

Mr. Reynolds added, "We have also made considerable progress in our human cancer program and, in particular, in blood cancer where we have obtained similar results in both humans and dogs using the same assay. Based on these promising results, we have engaged Diagnostic Oncology CRO LLC as a contract research organization to conduct a U.S. clinical trial for Non-Hodgkin's Lymphoma. I am proud of the way our team has adapted to the different world we find ourselves in and has kept working at full speed. It is their efforts and tenacity that have made possible these milestones and the many others that we have achieved this quarter and year to date."

Company Highlights

Financial

- Cash and cash equivalents as of September 30, 2020 totalled approximately \$21 million compared with \$17 million as of December 31, 2019.
- We continue to manage our expenditures carefully, and as we approach launch and commercialization our burn rate is approximately \$1.6 – \$1.7 million per month.

Nu.Q™ Vet Cancer Screening Test Commercial Launch

- Launch date of Nu.Q™ Vet Cancer Screening Test planned for November 30, 2020.
- This test will initially be positioned for use in the annual health check of older dogs (those that are seven years and older) and for cases where there is a high suspicion of cancer.
- The test will be available from the GI Lab at Texas A&M University to potentially thousands of veterinarians across Texas and the rest of the U.S.
- Significant potential market opportunity into the millions of tests per year as there are approximately 77 million dogs in the U.S.
- Revenue to Volition is expected to be \$45 per test and generate a greater than 85% gross margin.
- Pre-launch marketing efforts are underway, including a report entitled "A Look to the Future of Cancer Diagnostics" which compiles contributions from some of the key opinion leaders in the veterinary oncology space. A downloadable copy is available here.

https://volition.com/resources/downloads/1142848-VOL-Volition_Roundtable-Report_USLetter_DIGITAL_V1.pdf

Nu.Q™ Vet Cancer Screening Test: Clinical Data

- The Nu.Q™ Vet Cancer Screening Test is a simple, low-cost, easy to use ELISA based screening blood test which will help streamline the screening process for up to 1/3 of cancers in dogs including common malignancies such as lymphoma and hemangiosarcoma.
- Two abstracts were presented at the Veterinary Cancer Society Virtual Annual Conference in October 2020.
<https://volition.com/press-room/press-releases/volition-veterinary-diagnostics-development-llc-announces-product-data-regarding-its-nu-q-vet-cancer-screening-test-in-lymphoma-and-hemangiosarcoma-to-be-presented-at-the-2020-vcs-virtual-annual-conference>
- In a study of over 330 dogs conducted by Texas A&M University, the Nu.Q™ Vet Cancer Screening Test gave good clinical discrimination with an AUC of 87.3% for lymphoma and 97.6% for hemangiosarcoma.
- At 100% Specificity the Nu.Q™ Vet Cancer Screening Test demonstrated detection rates of 74% of lymphoma and 89% of hemangiosarcoma.

Clinical – New US Regulatory Study

- Engaged Diagnostic Oncology CRO LLC, the largest U.S. Contract Research Organization specializing in oncology purposed in-vitro diagnostic device clinical trials, to conduct a U.S. clinical trial for Non-Hodgkin's Lymphoma (NHL).
- The trial is designed to obtain multiple FDA-approved adjunct tests to aid in the diagnosis of the five most common and aggressive forms of NHL.
- The trial will enroll up to 1,500 subjects across 10 major U.S. healthcare institutions over 22 months.
- This extensive program will cost approximately \$2.9 million over two years assuming the completion of numerous projects and includes not only the clinical study but also data analysis and regulatory and reimbursement submission preparation.
- Existing data suggests Nu.Q™ technology will greatly aid physicians in distinguishing NHL from common conditions, fulfilling what we feel is a critical unmet clinical need which represents a major market opportunity.
- We expect our first FDA 510K submission will be possible approximately 10-12 months into the trial.

Clinical – NETosis including COVID-19

- We have made great progress on the research program for the use of our Nu.Q™ technology in NETosis and in particular in monitoring disease progression of COVID-19.
- Several studies have either been collected or are being negotiated in Europe and we anticipate the next results will be reported before the end of this year.
- We are also negotiating a large FDA trial for use of our assays in neutrophil extracellular traps (NETs) for COVID-19 and influenza in the U.S. and will announce the full details once they have been finalized.
- We have filed a novel patent for this application and plan to utilize results of these trials and other ongoing studies to further our aim of developing a clinically useful product to help in the battle against the COVID-19 pandemic and potentially other diseases such as influenza and sepsis.

Expansion

- We are in the final paperwork stages for “Silver One” the production hub for our products and components close to our Lab in Belgium.
 - Facility will be the production hub of all of our products and components, to both secure our own supply at a lower cost, and to drive reagent revenue, building on our purchase of Octamer GmbH (now called Volition Germany) earlier this year.
 - We plan to achieve full ISO certification next year.
 - Our plan is to produce, at large scale, raw materials such as recombinant nucleosomes, which act as the calibrant to our Nu.Q™ assays, in addition to antibodies that are key elements to our branded products. We plan to manufacture our full diagnostic kits once finalized.
 - We expect to offer all elements, including a service lab provision, for both commercial sale and for clinical trial purposes and CE-marked products for Europe and beyond.
 - To drive revenue, we have appointed our first Sales Manager who starts in December.
 - We have also opened a small, shared laboratory at California State University in San Marcos, California where we will focus on blue-sky innovation and discovery research.
-

Assay Development and Clinical Studies (Cancer)

- In various ways our “Marquee trials” have now been affected by the continued pandemic either by slower or paused collection, or a host of other supply chain or travel and communication issues. We believe we have successfully managed those areas under our direct control (such as assay development and running samples – both on track with our milestones) but many issues are not within our control.
- We have now successfully completed 12 Nu.Q™ discovery grade assays on subsets of both of our National Taiwan University studies – colorectal and lung cancers - and are working on data analysis.
- An abstract has been accepted regarding Nu.Q™ performance in lung cancer detection for presentation at the upcoming IASLC conference in January 2021. We expect to submit the colorectal cancer data to upcoming conferences.

Upcoming Milestones

Volition expects to achieve the following milestones during 2020 and beyond:

- Launch of the Nu.Q™ Vet Cancer Screening Test in the U.S.
 - Complete the purchase and fit out of “Silver One”, to serve as our manufacturing hub and service lab in Belgium.
 - Focus on driving revenue in the coming quarters, where possible during the pandemic, in four key areas:
 - Nu.Q™ Vet products
 - Disease monitoring tests (e.g. COVID-19)
 - Reagent sales
 - Licensing of our technology for others to commercialize.
 - Continue to advance our previously announced large-scale colorectal and lung cancer trials in Europe, Asia and the U.S.
 - Publish several abstracts and peer-reviewed scientific papers with clinical results as well as showing the robustness and utility of our Nu.Q™ platform.
 - Advance the development of Nu.Q™ Capture.
 - Announce patient data demonstrating the wide utility of our epigenetic toolbox.
 - Continue to file patents to expand and extend our Intellectual Patent portfolio.
-

**VolitionRx Limited Third Quarter 2020 Earnings
and Business Update Conference Call**

Date: Friday, November 13, 2020
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: 13713126

Cameron Reynolds, President and Chief Executive Officer of Volition, will host the call along with David Vanston, Chief Financial Officer and Scott Powell, Executive Vice President, Investor Relations.

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 27, 2020. 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 13713126.

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 a small laboratory in California and 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 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

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

Scott Powell, Volition
investorrelations@volition.com
+1 (646) 650 1351

Jen Lewis, Pegasus
jen.lewis@thisispegasus.co.uk
+44 (0)7809 867943

Joseph Green, Edison Advisors
jgreen@edisongroup.com
+1 (646) 653 7030

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 timing, completion and delivery of data from clinical studies, the effectiveness of Volition’s blood-based diagnostic and prognostic 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 or prognostic tool for COVID-19, the timing of product launches and publications, and the timing and completion of the acquisition of the additional facility in Belgium. 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 or prognostic 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 or prognostic 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; 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.