

**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): **May 7, 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 May 7, 2020, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended March 31, 2020. The Company also confirmed its conference call to be held on May 8, 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>
<u>99.1</u>	Press Release of VolitionRx Limited, dated May 7, 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: May 7, 2020

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

EXHIBIT INDEX

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

Description
Press Release of VolitionRx Limited, dated May 7, 2020.

VolitionRx Limited Announces First Quarter 2020 Financial Results and Business Update

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

AUSTIN, Texas, May 7, 2020 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the first quarter ended March 31, 2020. Volition management will host a conference call tomorrow, May 8 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, upon releasing these results commented, "During the first quarter, we, together with our collaborators, have made very strong progress, particularly in assay and platform development, with our Nu.Q™ Capture program and epigenetic toolkit, Nu.Q™ Vet in collaboration with Texas A&M University and, at the start of the year with the acquisition of the epigenetics reagents company, Octamer GmbH. Our team has done an amazing job completing all these milestones in these difficult times."

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

<https://youtu.be/3AdkLzbRdeA>

Mr. Reynolds added, "We have responded quickly to the COVID-19 pandemic and have a number of clinical trials underway to investigate how Nu.Q™ might be clinically useful as either a diagnostic or prognostic tool for COVID-19. I am delighted to announce exciting preliminary results from our first study today and look forward to providing more details throughout this quarter. This work yet again shows the diverse potential of our Nu.Q™ platform."

Company Highlights

Clinical – COVID-19

- ① A proof of concept study involving 34 polymerase chain reaction (PCR) COVID-19 positive subjects and 50 control subjects revealed that nucleosomes were highly elevated in the PCR positive subjects.
- ① Preliminary study results demonstrated an Area Under the Curve (AUC) for a single Nu.Q™ assay of 98.7% for PCR positive COVID versus control subjects with a sensitivity of 100% at 94% specificity.
- ① A second Nu.Q™ assay also showed promising results with an AUC of 86.2%.
- ① Volition plans to utilise results of this trial and other ongoing studies to further its aim of developing a clinically useful product to help in the battle against the COVID-19 global pandemic and potentially other diseases.

Clinical – Veterinary

- ① In a proof of concept study conducted by Texas A&M University, a single Nu.Q™ Vet assay detected almost 70% of both Canine Hemangiosarcoma and Canine Lymphoma with AUCs of 84.5% and 83.1% cancer versus healthy, respectively, at a specificity of 90%. These two cancers alone represent almost a third of all canine cancers.
- ① Based on the results of this study, Volition plans to move forward with other Nu.Q™ Vet assays in its pipeline, and with the larger range of cohorts and trials that it has collected and planned.

Abstract Publications

- ① Three of Volition's abstracts have been accepted for publication by ASCO (American Society of Clinical Oncology) and are expected to be publicly released on Wednesday, May 13.

Assay Development

- ① Volition has completely re-engineered its Nu.Q™ assays to now use a magnetic particle-based assay format leading to a step-change improvement in analytical performance which Volition expects to translate into improved clinical performance.
 - ① Volition reached its target of eight assays being finalized by the end of the first quarter with respect to its fully-automated magnetic bead-based chemiluminescent format. Studies are now ongoing for colorectal cancer, lung cancer and blood cancer with data read outs expected by the end of the second quarter.
 - ① Volition signed a contract with Shanghai Fosun Long March Medical Science Co., Ltd ("Fosun Long March"), China, to further develop our Nu.Q™ magnetic particle-based assays for use on Fosun's open-access platform LUMIART-II Automated Chemiluminescence Immunoassay System. The agreement also allows for the parties to negotiate an exclusive licensing agreement for Fosun Long March to distribute Volition's Nu.Q™ tests for the LUMIART System in China.
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Epigenetic Toolbox

- ⌚ Volition has developed and is seeking patents on its novel Nu.Q™ Capture-based epigenetic tools. Volition is using these tools to expand diagnostic developments that focus on circulating DNA fragment analysis, leading to a broader and potentially more powerful investigation of the epigenetic status of a patient's circulating chromosome fragments, in addition to its ongoing work with its assay-based format in a range of cancers. Volition expects additional data on this in the coming months.

Organization

- ⌚ Volition completed the acquisition of its epigenetics reagents subsidiary, Octamer GmbH (renamed Volition Germany GmbH), in the first quarter of 2020.
- ⌚ In connection with the acquisition of Octamer, Volition expanded its Scientific Advisory Board to include Dr. Adrian Schomburg, one of the world's leading experts on nucleosomes and founder and CEO of Octamer.

Financial

- ⌚ Cash and cash equivalents as of March 31, 2020 totalled approximately \$12 million.

Upcoming Milestones

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

- ⌚ Release a range of clinical data from COVID-19 studies currently underway.
- ⌚ Release a range of clinical data with its new optimised bead-based assays in colorectal, lung and other cancers.
- ⌚ Advance its previously announced large-scale colorectal and lung cancer trials in Europe, Asia and the U.S.
- ⌚ Advance the development of Nu.Q™ Capture by determining the level of discrimination of tumor associated nucleosomes using mass spectrometry and/or sequencing.
- ⌚ Announce patient data demonstrating the wide utility of its epigenetic toolbox.
- ⌚ Complete further clinical studies for Nu.Q™ Vet with the aim of launching its first product in 2020.
- ⌚ Publish several abstracts and peer reviewed scientific papers with clinical results as well as showing the robustness and utility of its Nu.Q™ platform.

Mr. Reynolds concluded, "We are extremely proud of the accomplishments we have achieved thus far. I thank the dedicated Volition team for their tireless efforts especially given the challenging circumstances we all face during the COVID-19 pandemic. I, along with the rest of the Board and indeed the whole company, look forward to sharing the results of key studies over the coming year."

As a result of the COVID-19 pandemic during the first quarter of 2020, Volition implemented contingency planning to protect the health and well-being of its employees, with most employees working remotely where possible. Its laboratory in Belgium has remained open with the attendance of its dedicated laboratory technicians who have kept its research and development work on track with Volition's expectations. Many of its small and medium sized studies have already been collected and their samples stored at its onsite biobank so the trial work underway and planned for the first half of 2020 is still tracking expectations. Regarding its large-scale studies, both the colorectal cancer and lung cancer studies underway in Taiwan are still ongoing with collection, however the study collection in the U.S. with the EDNR has been paused during the pandemic. The overall timing impact of the EDNR collection pause on the study is unknown at this stage, however, Volition will provide an update once the study re-commences.

For further details please contact mediarelations@volition.com

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

Date: Friday, May 8, 2020
Time: 8:30 a.m. 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: 13703451

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 May 22, 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 13703451.

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 NucleosomicsTM, 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 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>

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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 the timing, completion and delivery of data from clinical studies, the effectiveness of Volition’s blood-based diagnostic and prognostic tests as well as 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. 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.

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