

**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 11, 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 May 11, 2021, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended March 31, 2021. The Company also confirmed its conference call to be held on May 12, 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.

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	Press Release of VolitionRx Limited, dated May 11, 2021.

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 11, 2021

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	Press Release of VolitionRx Limited, dated May 11, 2021.

VolitionRx Limited Announces First Quarter 2021 Financial Results and Business Update

Conference call to discuss financial and operational results scheduled for
Wednesday, May 12, at 8:00 a.m. U.S. Eastern Time

- Secured strongest-ever balance sheet with approximately \$33.1 million in cash
- Strengthened the Company's leadership team to drive commercial focus
- Expanded the Company's intellectual property portfolio
- Initiated production of product components at scale at the Company's Silver One facility
- Published three clinical papers
- Continued focus on product launches and licensing in both the human and veterinary spaces

AUSTIN, Texas, May 11, 2021 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the first quarter ended March 31, 2021. Volition management will host a conference call tomorrow, May 12 at 8:00 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

"We have made significant progress on many fronts during 2021 on all four of the Company's key pillars: Nu.Q[®], Nu.Q[®] Vet, Nu.Q[®] NETs and Nu.Q[®] Capture," commented Cameron Reynolds, President and Chief Executive Officer of Volition. "We have also significantly strengthened our balance sheet, our intellectual property portfolio, and our executive team to drive commercial focus."

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

<https://youtu.be/un7YtAecF7o>

Mr. Reynolds continued, "Silver One, our manufacturing facility and service lab, is proving to have been an excellent addition to Volition's commercialization efforts and is now producing finished product and components at commercial scale for our anticipated product launches. I am delighted that the Nu.Q[®] Vet beta launch has not only provided revenue but also invaluable real-world learnings allowing us to move ahead soon with our expected national U.S. and international launches. We are also seeing a high level of interest in both the licensing and distribution of our products and are actively negotiating multiple agreements."

Company Highlights

Financial

- Cash and cash equivalents as of March 31, 2021 totaled approximately \$33.1 million compared with \$19.4 million as of December 31, 2020.
- During the first quarter of 2021, added an aggregate of approximately \$20.3 million in cash mostly through an underwritten public offering of our common stock that closed in February, as well as through periodic sales of common stock under Volition's at-the-market equity distribution program.
- Secured a further \$4 million in non-dilutive funding consisting of a cash grant of \$1.3 million and loans totalling \$2.7 million from the Walloon Regional Government and associated agencies.
- Continued to manage expenditures carefully with a cash burn rate of approximately \$2 million per month.

Personnel

- As Volition transitions from a research and development company to a commercial company, it strengthened the leadership team with the appointment of a new Chief Financial Officer, Mr. Terig Hughes, as well as the appointment of Mr. Gael Forterre as Chief Commercial Officer. In addition, Volition promoted Dr. Gaetan Michel to Chief Operating Officer and Dr. Mark Eccleston to Chief Technology Officer.
 - Volition announced the appointment of two Independent Directors to its main Board – Kim Nguyen, an HR executive with global expertise at Google, and Richard Brudnick, a pharmaceutical business executive with extensive commercial know-how.
 - As of May 1, Dr. Tom Butera, a seasoned veterinary executive with an extensive commercial track record, joined the team as Chief Executive Officer of Volition's Veterinary subsidiary to drive its product launches.
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Intellectual Property

- 28 patent families covering both human and animal use of Volition's Nucleosomics™ platform.
- 64 granted patents (ten in the U.S., 14 in Europe and 42 rest of world).
- 93 patents pending.
- Continued focus on filings during the first quarter and expect portfolio to grow in the quarters and years ahead.

Publications

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

Nu.Q® Vet Cancer Screening Test Beta Launch

- Beta launch of the Nu.Q® Vet Cancer Screening Test in late November 2020 in Texas. This beta launch is facilitating real-world learnings to help shape the marketing mix before Volition's planned launch nationally across the U.S. expected in the next few months.
- Volition has received strong indications of interest in the whole Nu.Q® Vet platform, from a range of small and very large companies, and it is progressing potential licensing discussions with several well-known major players in the veterinary space around the world.
- In addition to the Texas beta launch, Volition is finalizing beta launch planning in both Asia and Europe.

Nu.Q® Capture

- The clinical paper published in Nature's Scientific Reports in March highlighted for the first time that histone H2A1R3 citrulline is, in plasma, upregulated in colorectal cancer patients and so could be a biomarker Volition targets for future Nu.Q® immunoassay development.
- It showed that the use of Nu.Q® Capture may open up the possibility of using mass spectrometry not only for biomarker discovery but also as a high throughput platform for screening and/or diagnostics.
- Volition aims for Nu.Q® Capture to be an important enabling technology in the liquid biopsy space and expects to launch its first product with this technology in 2022.

Clinical – NETosis including COVID-19

- Volition believes that the versatility of the Nu.Q® platform and the range of applications for which these assays can be leveraged may help increase diagnostic power and monitor disease progression and potentially treatment response across a broad range of diseases that involve the over production of NETs, such as COVID-19, pneumonia, influenza and sepsis.
- From a sepsis product development perspective, to date Volition has completed animal studies in the monitoring of disease progress and treatment efficacy which have demonstrated the effective use of Nu.Q® NETs.
- Human studies in the monitoring of disease progress and treatment efficacy in sepsis are now underway at a leading UK hospital.
- From a COVID-19 product development perspective, Volition has conducted studies of serial testing of COVID-19 patients at leading UK hospitals to determine the predictive value of its test, with further data due to be presented at upcoming conferences and potentially additional studies and collaborations as well.

Clinical – Cancer

- As previously reported, due to the pandemic collection for the U.S. EDRN study for colorectal cancer has been paused, and collection for the blood cancer studies in the U.S. have been delayed with an updated timeline expected in the near future.
 - In Asia, Volition has reached its target patient cohorts for both colorectal cancer studies and the lung cancer study, all collected in conjunction with the National Taiwan University, notwithstanding the pandemic. Volition expects to run the assays and finalize the analysis over the coming months with data due to be reported at future conferences.
 - Volition has installed a Service Lab in Silver One, which will undertake sample processing for external parties such as pharmaceutical companies, biotech companies and academic researchers. This service, branded as Nu.Q® Discover, has already generated interest, and Volition expects to see initial revenue from this during 2021.
 - Volition is producing recombinant nucleosomes in-house and at large-scale, building a library for sale through Nu.Q® Discover and also for internal R&D use.
 - Volition is still in active discussions on its first potential licensing deal with a large healthcare company.
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Upcoming Milestones

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

- National launch of the Nu.Q[®] Vet Cancer Screening Test in the U.S.
 - Beta launches of the Nu.Q[®] Vet Cancer Screening Test in Asia and Europe.
 - Continue to focus on driving revenue in the coming quarters in four key areas:
 - Nu.Q[®] Vet products,
 - Disease monitoring tests (e.g. Nu.Q[®] NETs for COVID-19, sepsis),
 - Nu.Q[®] Discover, and
 - Licensing of its technology for others to commercialize in both humans and animals.
 - 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.
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**VolitionRx Limited First Quarter 2021
Financial Results and Business Update**

Date: Wednesday, May 12, 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: 13719633

Cameron Reynolds, President and Chief Executive Officer of Volition, will host the call along with Terig Hughes, 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 26, 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 13719633.

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.

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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, 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, and the timing of product launches and publications. 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.