

**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): **August 13, 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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on which Registered</u>
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.

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**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 August 13, 2020, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended June 30, 2020. The Company also confirmed its conference call to be held on August 14, 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>
<a href="#"><u>99.1</u></a>	Press Release of VolitionRx Limited, dated August 13, 2020.

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**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: August 13, 2020

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

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**EXHIBIT INDEX**

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

**Description**  
Press Release of VolitionRx Limited, dated August 13, 2020.

## VolitionRx Limited Announces Second Quarter 2020 Financial Results and Business Update

Conference call to discuss financial and operational results scheduled for  
Friday, August 14 at 8:30 a.m. U.S. Eastern Time

AUSTIN, Texas, August 13, 2020 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) (“Volition”) today announced financial results and a business update for the second quarter ended June 30, 2020. Volition management will host a conference call tomorrow, August 14 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 second quarter, given the persistence of the COVID-19 pandemic, we focused on two key areas to try and mitigate the effects of lockdowns and allow us to keep moving towards our first commercial products utilizing our cutting edge Nu.Q™ platform. Firstly, we significantly strengthened our balance sheet to ensure we have sufficient capital to work on our many programs concurrently, and launch products where possible during the pandemic. Secondly, we have increased the flexibility of our supply chain of key components and are moving towards producing our key components in house. Cancer remains our core disease focus, however, we have discovered that our technology potentially has applications beyond just cancer, for example with COVID-19.”

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

<https://youtu.be/EU0yrbMLgj4>

Mr. Reynolds added, “I am proud of the way our team has adapted to the different world we find ourselves in and kept on working at full speed, their fantastic efforts have put us in an excellent position as we move towards the launch of our first products expected later this year and early next year.”

### **Company Highlights**

#### Financial

- Cash and cash equivalents as of June 30, 2020 totalled approximately \$21.3 million compared with \$12 million the previous quarter.
- Raised \$13.8 million in gross proceeds in an underwritten public offering.
- Periodically sold shares of our common stock pursuant to our previously disclosed “At The Market” equity offering program, or “ATM”, under our existing registration statement along with our Rule 10b5-1 plan. Through the end of the second quarter of 2020 we had raised approximately \$1.7 million in gross proceeds under the ATM.
- During July and the first week of August we raised an additional approximately \$4.7 million in gross proceeds through the ATM.
- Volition was added to both the Russell 3000® and Russell Microcap® Indexes in June.

#### Product Production Facility

- Submitted an offer to purchase a neighboring facility in Belgium known as “Silver One”. We expect this facility to 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.

#### Clinical – COVID-19

- The preliminary study results reported in May demonstrated the Area Under the Curve (AUC) for a single Nu.Q™ assay was 98.7% PCR positive versus control subjects, with 100% sensitivity at 94% specificity. A second Nu.Q™ assay also showed promising results with an AUC of 86.2%.
  - To date we have now tested two independent cohorts of COVID-19 positive patients with quantitative nucleosome immunoassays and found that nucleosomes were highly elevated in plasma of severe COVID-19 patients relative to healthy control subjects and importantly, that both histone 3.1 variant and citrullinated nucleosomes increased with disease severity.
  - Given that the highest levels of nucleosomes were found in patients requiring artificial ventilation or extracorporeal oxygenation, we believe that nucleosomes could serve as a guiding biomarker for disease severity in COVID-19 positive patients.
  - These data imply that Nu.Q™ could have strong prognostic potential, and so we are now focused on the completion of larger longitudinal studies that would be needed to support a potential COVID-19 product launch.
  - Our collaborators have submitted this data for peer-review and we look forward to its publication.
  - We have filed a novel patent for this application and plan to utilise 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 global pandemic and potentially other diseases such as influenza and pneumonia.
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### Clinical – Veterinary

- 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.
- Based on the results of this study, we plan to move forward with other Nu.Q™ Vet assays in our pipeline, and with the larger range of cohorts and trials that we have collected and planned.
- The first Nu.Q™ Vet products expected to be launched late in 2020 are likely to be for blood and lymphoma remission monitoring and we then aim to target additional uses (such as remission monitoring for other cancers and for diagnosis itself) in 2021.

### Assay Development and Clinical Studies (Cancer)

- We exceeded our target of 12 assays being finalized by the end of the second quarter with respect to our fully-automated magnetic bead-based chemiluminescent format. To date, 13 assays have been developed and are being tested in our clinical research programs. We plan to reach a total of 20 by the end of 2020.
- 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 8 assays on subsets of both of our National Taiwan University studies – colorectal and lung cancers - and are working on data analysis. We expect over this coming quarter to run an additional number of assays and to submit the data at upcoming conferences.

### Epigenetic Toolbox

- We have developed and are seeking patents on our novel Nu.Q™ Capture-based epigenetic tools. We are 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. We have made significant progress with this work and will continue to publicise data as it is completed in the coming quarters.

### Publications

- The second quarter was the best quarter ever from a publications point of view.
- We had three abstracts published at ASCO, the American Society for Clinical Oncology, including data in both lung and blood cancers.
- We have received acceptance for oral presentation of two abstracts at the Veterinary Cancer Society Meeting in October this year.
- A Nu.Q™ Vet paper regarding pre-analytics has been submitted for peer review and accepted for publication.
- Three papers have been submitted by collaborators using our Nu.Q™ technology, for lung disease, for complications during pregnancy and for COVID-19, yet again showing the wide adaptability of our platform.
- We have other papers in process, including a pre-analytics paper for humans that we expect to submit over the next couple of months, and two papers from the Nu.Q™ Capture program on mass spectrometry and also sequencing.

### Upcoming Milestones

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

- We will focus on driving revenue in the coming quarters, where possible during the pandemic, in 4 key areas:
    - Our four potential triage tests (3 cancers and COVID-19);
    - Nu.Q™ Vet products;
    - Reagent sales; and
    - 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.
  - Commission and complete longitudinal studies for COVID-19.
  - 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.
  - Complete the purchase and fit out of “Silver One”, to serve as our manufacturing hub and service lab in Belgium.
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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.”

For further details please contact [mediarelations@volition.com](mailto:mediarelations@volition.com)

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

**Date:** Friday, August 14, 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:** 13707978

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 August 28, 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 13707978.

**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<sup>TM</sup>, 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](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.

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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, 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.