

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 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 August 11, 2021, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended June 30, 2021. The Company also confirmed its conference call to be held on August 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.

**Exhibit**

**Number**

**Description**

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Press Release of VolitionRx Limited, dated August 11, 2021.</a>

**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 11, 2021

By: /s/ Cameron Reynolds

Cameron Reynolds

Chief Executive Officer & President

EXHIBIT INDEX

Exhibit Number	Description
99.1	<a href="#">Press Release of VolitionRx Limited, dated August 11, 2021.</a>

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

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

- Strong balance sheet with approximately \$27.9 million in cash and cash equivalents
- Strengthened the Company's veterinary leadership team to drive commercial focus
- Expanded the Company's intellectual property portfolio
- Published two clinical papers
- Continued focus on, and made strong progress towards, product launches and licensing in both the human and veterinary spaces worldwide

**AUSTIN, Texas, August 11, 2021 /PRNewswire/** -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the second quarter ended June 30, 2021. Volition management will host a conference call tomorrow, August 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 the first half of 2021, in particular on all four of the Company's key pillars: Nu.Q<sup>®</sup>, Nu.Q<sup>®</sup> Vet, Nu.Q<sup>®</sup> NETs and Nu.Q<sup>®</sup> 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 our commercial focus."

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

<https://youtu.be/jEd7i9Sphnc>

Mr. Reynolds continued, "I am delighted that the Nu.Q<sup>®</sup> Vet beta launch has not only been very successful in providing invaluable real-world learnings for our first veterinary product but has also generated a high level of interest in both the licensing and distribution of our veterinary products, and we are actively negotiating potential arrangements on multiple fronts."

**Company Highlights**

***Financial***

- Cash and cash equivalents as of June 30, 2021, totalled approximately \$27.9 million compared with \$19.4 million as of December 31, 2020.
- Net loss for the second quarter of 2021 was \$5.6 million and net cash used in operating activities was \$5.4million for the quarter.
- Grant income earned in the second quarter of 2021 was approximately \$0.4 million.
- Volition received approximately \$0.9 million of net proceeds through its at-the-market equity distribution program during the second quarter of 2021.
- Continued to manage expenditures carefully with a cash burn rate of approximately \$2 million per month.

### **Personnel**

- On May 1, Dr. Tom Butera, a seasoned veterinary executive with an extensive commercial track record, and former Non-Executive Director of Volition, joined the team full time as Chief Executive Officer of Volition's veterinary subsidiary to drive its product launches.

### **Intellectual Property**

- 27 patent families (plus three in-licensed families) covering both human and animal use of Volition's Nucleosomics™ platform.
- 71 granted patents (ten in the U.S., 14 in Europe and 47 rest of world).
- 89 patents pending.
- Continued focus on filings during the second quarter of 2021 and expect portfolio to grow in the quarters and years ahead.

### **Publication**

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

### **Nu.Q® Vet Cancer Screening Test Beta Launch**

- Volition has received strong indications of interest in the whole Nu.Q® Vet platform, from a range of smaller and very large companies, and it is progressing potential licensing negotiations with several well-known major players in the veterinary space around the world.
- The Company aims to have a very meaningful deal signed before the end of 2021.

### **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.
- Volition previously reported preliminary results demonstrating that its Nu.Q® NETs assay correlated well with current COVID-19 disease severity.
- Recently published posters (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.
- 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.
- The Company has additional large studies in progress related to COVID-19, sepsis and other diseases, some due for completion soon, with the publication of further data expected in the coming months.

### Clinical – Cancer

- Volition has also been in active and continuing negotiations in Asia this year on its first human cancer launch in China.
- The Company has completed preliminary analysis of the lung cancer study conducted with the National Taiwan University and looks forward to reviewing the data with Professor Chen and his team ahead of publication either through clinical paper or conference abstract. Collection has also been completed for the colorectal cancer study also conducted with the National Taiwan University. Volition anticipates the data will be analysed this year, with findings to be presented at a conference in 2022.
- After a 15 month pause, EDRN (a large-scale U.S. colorectal cancer study) re-initiated enrolment in June and aims to be enrolling at full capacity in September 2021. The study collection completion date has been extended to the fourth quarter of 2022.
- With regards to Volition’s two 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 For the 1,500 subject NHL diagnostic study, all preliminary protocol development and study preparation has been completed. The Company aims to begin collection in late 2021, protocols and pandemic permitting, and to submit the first data to the FDA in late 2022.
  - o COVID-19 restrictions have also made sequential therapy-matched specimen collections exceptionally difficult in the DLBCL Treatment Monitoring Study. The Company aims to issue interim analysis results later this year.
- 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<sup>®</sup> Discover, has already generated interest and the Company has provided quotes to multiple pharma and biotech companies. Volition anticipates that it will generate revenue from this activity in 2021 with continued growth in the future.

### Upcoming Milestones

Volition expects to achieve the following milestones during 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<sup>®</sup> Vet, with the aim of signing the first deal this year,
  - o Processing samples at Silver One using its Nu.Q<sup>®</sup> Discovery assays, and
  - o Disease monitoring tests (e.g. COVID-19, Sepsis).
- Continue to progress the research program for the use of Nu.Q<sup>®</sup> 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<sup>®</sup> platform.
- Advance the development of Nu.Q<sup>®</sup> Capture.
- Continue to file patents to expand and extend its intellectual property portfolio.

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

**Date:** Thursday, August 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:** 13722250

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 August 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 13722250.

**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 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](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**

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**Cautionary Note Regarding Forward-Looking Statements**

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 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 expectations regarding Volition’s 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 or prognostic products, it may be unable to execute its plan of operations. Other risks and uncertainties include Volition’s ability to obtain necessary regulatory clearances or approvals to distribute and market future products; marketplace acceptance of the products in Volition’s development pipeline or any other diagnostic or prognostic products Volition might develop; Volition’s ability 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.