

**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, 2019**

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, 2019, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for the quarter ended September 30, 2019. The Company also confirmed its conference call to be held on November 13, 2019 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 November 12, 2019.

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, 2019

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, 2019.

VolitionRx Limited Announces Third Quarter 2019 Financial Results and Business Update

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

AUSTIN, Texas, November 12, 2019 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the third quarter ended September 30, 2019. 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, upon releasing these results, commented, "I could not be more proud of our dedicated team at Volition, and the ground-breaking work we are doing. I'm happy to say that we have made excellent progress this quarter on our platform development, Nu.Q™ Capture, Nu.Q™ Vet and our colorectal cancer and lung cancer trials, particularly in Asia, and we reported our first revenues from sales of Research Use Only kits and the provision of contract research services.

We are an epigenetics company focused on advancing the science of epigenetics and exploiting these advances in human and animal health. This has been our mission since our founding, and it is coming to fruition with our Nu.Q™ platform at the very heart of epigenetics. We believe the last decade of work and our extensive intellectual property portfolio puts Volition in a strong position to be a significant player in this field by launching multiple products."

Click here to view an interview with Volition's Chief Executive Officer.
<https://volition.com/press-room/video-gallery>

Mr. Reynolds further commented "We aim to strengthen our product pipeline beyond colorectal cancer to cover several cancers, most notably in lung cancer, and so are especially delighted to have commenced two studies in lung cancer this quarter, firstly our large-scale study in lung cancer with the National Taiwan University and secondly our first study in China with Shanghai Fosun Long March Medical Science Co. Ltd. We have also expanded our colorectal cancer work with a first trial in China underway with Fosun.

I am also delighted to announce that subsequent to quarter end we executed a contract with Texas A&M University to collaborate on the research and development of Nu.Q™ Vet products and help drive early revenue in the all-important veterinary market."

Additionally, Mr. Reynolds added "During the third quarter 2019, we further strengthened our balance sheet with an existing investor exercising \$4.8 million in aggregate amount of outstanding warrants to purchase shares of our common stock making a total of \$16.5 million in warrants exercised during the first three quarters of 2019 and ended the quarter with cash and cash equivalents of \$19.7 million. During the third quarter we were awarded a further \$1.4 million in non-dilutive grant-funding from the Walloon Region and, subsequent to quarter end, an additional \$500,000 unsecured loan from SOFINEX was approved. We also recorded our first revenues this quarter from sales of our Research Use Only kits and the provision of services."

Company Highlights

Financial

- ① Cash and cash equivalents as of September 30, 2019 totaled \$19.7 million compared to \$13.4million as of the end of 2018.
- ① Recorded first revenues from the sales of our Research Use Only kits and from the provision of sample processing services to a third party.
- ① Continued to manage cash carefully with an average quarterly cash burnrate over the first three quarters of 2019 of approximately \$3.6 million.

Clinical Trials

- ① Commenced our first large-scale lung cancer study in conjunction with the prestigious National Taiwan University ("NTU"). The study is being conducted under the supervision of Professor Chen Jin-Shing in the Department of Surgery of NTU and will include 1,200 subjects receiving Low-Dose Computed Tomography scans. We expect the first data from this trial in the first half of 2020.
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- ① Commenced our first studies in China for both lung and colorectal cancer with Shanghai Fosun Long March Medical Science Co. Ltd.

Organizational

- ① Completed the formation of a U.S.-based majority-owned subsidiary, Volition Veterinary Diagnostics Development LLC, to drive the development and commercialization of Nu.Q™ Vet products and appointed its Chief Executive Officer, Mr. Nathan Dewsbury.
- ① Executed agreements with Texas A&M University's College of Veterinary Medicine to collaborate on the research and development of Nu.Q™ Vet products.
- ① Made strong progress in platform development, including the appointment of a Clinical Validation Expert with more than 15 years of experience in adapting assays to automated machines to greatly broaden our product platform range.

Intellectual Property

- ① Achieved steady growth in our worldwide patent portfolio. We believe that this is a key differentiator versus many other technologies either under development or available on the market, where the patent position may be poor and/or narrow.
 - 20 patent families related to our diagnostic tests(including both human and veterinary medicine applications).
 - 8 patents granted in the United States.
 - 7 patents granted in the European Union.
 - 25 further patents granted worldwide.
 - 106 patents pending worldwide.

Upcoming Milestones

We expect to achieve the following milestones during 2019 and through 2020:

- ① Announce the results of multiple proof of concept cancer studies, starting in December 2019 and continuing throughout 2020.
- ① Complete the CE Marking of IVD kits for cancer triage tests.
- ① Advance our previously announced large-scale colorectal and lung cancer trials with a significant number of assays on the highly analytically accurate automated platform(s).
- ① Announce preliminary results of Nu.Q™'s performance in other disease conditions.
- ① Advance the development of Nu.Q™ Capture by determining the level of discrimination of tumor associated nucleosomes using immunoassays and sequencing.
- ① Through Volition Veterinary and the collaboration with Texas A&M, complete the pre-analytical and discovery studies to determine and announce the route to revenue for Nu.Q™ Vet products.
- ① Submit abstracts and clinical papers for publication from our Nucleosomics™ work in a wide range of areas.

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. I, along with the rest of the Board and indeed the whole company, look forward to sharing our progress and the results of key studies over the remainder of 2019 and throughout 2020."

For further details please contact mediarelations@volition.com.

**VolitionRx Limited Third Quarter 2019 Earnings
and Business Update Conference Call**

- 🕒 **Date:** Wednesday, November 13, 2019
- 🕒 **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:** 13696533

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. The call will provide an update on recent developments and Volition's activities, including details of new and ongoing clinical trials, important events which have taken place in the third quarter of 2019, and milestones for 2019 and beyond.

About Volition

Volition is a multi-national life sciences 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 majority-owned 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 (<http://www.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 and availability of clinical data, the completion of CE marking for certain products, the effectiveness of Volition's blood-based diagnostic tests as well as Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if Volition fails to develop and commercialize diagnostic 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 in the clinical IVD or the veterinary markets; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic 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; 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.

NucleosomicsTM and Nu.QTM 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.