

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): **March 30, 2022**

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 March 30, 2022, VolitionRx Limited (the “Company”) issued a press release announcing its financial results and certain business updates for its quarter and fiscal year ended December 31, 2021. The Company also confirmed its conference call to be held on March 31, 2022 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
99.1	Press Release of VolitionRx Limited, dated March 30, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) document)

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: March 30, 2022

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of VolitionRx Limited, dated March 30, 2022.

**VolitionRx Limited Announces Full Fiscal Year 2021 Financial
Results and Business Update**

**Conference call to discuss financial and operational results scheduled for
Thursday, March 31, at 8:00 am U.S. Eastern Time**

- Executed global licensing and supply agreement with Heska Corporation to distribute Nu.Q[®] Vet Cancer Screening Test at the Point of Care with a \$10 million upfront payment and up to \$18 million based upon the achievement of near/mid-term milestones.
- Under said agreement will receive ongoing additional revenue for key components and kits.
- In advanced negotiations with other potential licensing partners in efforts to make Nu.Q[®] Vet as accessible as possible worldwide.
- Expanded its intellectual property portfolio.
- Made significant progress with its Nu.Q[®] NETs development.
- Continued progress towards additional new product launches and licensing in both the human and veterinary spaces worldwide.
- Approximately \$20.6 million in cash and cash equivalents on the balance sheet as of December 31, 2021.

AUSTIN, Texas, March 30, 2022 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition") today announced financial results and a business update for the full fiscal year ended December 31, 2021. Volition management will host a conference call tomorrow, March 31 at 8:00 a.m. U.S. Eastern Time to discuss these results. Conference call details may be found below.

"I could not be prouder of the team's achievement in securing a global licensing and supply agreement for our Nu.Q[®] Vet Cancer Screening Test with Heska Corporation, one of the industry's leading companies," commented Cameron Reynolds, President and Group Chief Executive Officer of Volition. "Volition Veterinary is an exciting, fast-moving part of our business with clear potential to generate significant revenue for the company, initially under our agreements with Heska and SAGE Healthcare, through both milestone payments and ongoing sales of kits and key components. We have also made good progress in other key areas including our Nu.Q[®] NETs and Nu.Q[®] Capture programs as we shift gears towards our goal of becoming a commercial company with products."

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

<https://youtu.be/QH2pMGufmWg>

Company Highlights

Financial

- Cash and cash equivalents as of December 31, 2021, totaled approximately \$20.6 million compared with \$19.4 million as of December 31, 2020.
 - Subsequent to year end, Volition is due to receive a \$10 million upfront payment as a result of the execution of the agreement with Heska Corporation.
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- Cash burn rate averaged approximately \$2 million per month.
- Net loss for the full year of 2021 was \$27 million versus \$20.4 million for 2020 with this increase primarily due to non-cash items in addition to new hire staffing costs.
- Signed our first Nu.Q® Discover agreement in 2021 and subsequent to year end have signed an additional five agreements worth an aggregate of approximately \$200,000 on a full-year basis.
- Made strong progress in improving internal controls and processes and anticipate the remaining weakness regarding segregation of duties in finance will be resolved in 2022.

Commercial Opportunity

- We estimate our annual total addressable market (“TAM”) to be approximately \$70 billion worldwide including Nu.Q® Vet, Nu.Q® Discover, Nu.Q® NETs and Nu.Q® Cancer.
- All estimates are global and on an annualized basis using key assumptions as follows:
 - o We estimate the Nu.Q® Vet TAM to be approximately \$11 billion based on global canine and feline populations that are eligible for screening and monitoring and a price assumption of \$50 per test to the consumer.
 - o For Nu.Q® Discover we estimate the TAM to be over \$200 million using drug pipeline data of registered clinical trial programs for relevant epigenetic targets.
 - o We estimate the Nu.Q® NETs TAM to be approximately \$22 billion calculated using estimated hospital admissions and discharges for sepsis and the associated average length of stay.
 - o We estimate our Nu.Q® Cancer TAM to be approximately \$37 billion calculated based on eligible populations for annual screening, target participation rates and incidence/prevalence of specific cancers, and risk stratification use cases.
 - o Price per test assumptions for Nu.Q® and Nu.Q® NETs range from \$120 for the U.S., \$50 for Europe and \$25 for the rest of the world.

Personnel/ Operational

- To support our commercial expansion, we welcomed Terig Hughes as our Chief Financial Officer, Gael Forterre as our Chief Commercial Officer, Dr. Tom Butera as the Chief Executive Officer of our veterinary subsidiary, and Mr. Nick Plummer as Group General Counsel.
- In addition, Gaetan Michel was promoted to Chief Operating Officer and has relocated to the U.S. to accelerate the development of Volition America.
- Dr. Terry Kelly was promoted to Chief Innovation Officer and is building a team focused on cutting-edge, discovery research at our new innovation hub which opened in California in March 2022.

Volition Veterinary

- Executed a global licensing and supply agreement with one of the industry’s leading companies, Heska Corporation.
- In exchange for granting Heska exclusive worldwide rights to sell the Nu.Q® Vet Cancer Screening Test for companion animals at the Point of Care, Volition will receive:
 - o a \$10 million upfront payment on signing,
 - o up to \$18 million based upon the achievement of near/mid-term milestones, and
 - o ongoing additional revenue for key components.

- In addition, Volition has granted Heska non-exclusive rights to sell the Nu.Q® Vet Cancer Screening Test in kit format for companion animals, through Heska's network of central reference laboratories for which Volition will receive ongoing additional revenue for such kit sales.
- Appointed SAGE Healthcare as a non-exclusive licensee and distributor of our Nu.Q® Vet Cancer Screening Test for the Asian market.
- We remain in advanced negotiations with other potential licensing partners in our efforts to make Nu.Q® Vet as accessible as possible worldwide and anticipate further announcements in 2022.
- Published two peer-reviewed clinical papers and two abstracts at the Veterinary Cancer Society Annual Conference including the first data demonstrating the use of Nu.Q® Vet as a disease monitoring tool.

Clinical – NETosis including COVID-19

- Volition believes the Nu.Q® NETs assay will have wide applicability for monitoring diseases with a NETs component (such as COVID-19, influenza, sepsis, autoimmune diseases, and cancer) and potentially to risk-stratify patients for treatment selection.
- Volition expects to register CE marks on its first NETs product, across multiple platforms including ELISA plate, automated beads, and a proof of concept on a very high throughput platform by the summer of 2022.
- Volition intends to register the Nu.Q® NETs product with a broad almost C-reactive protein (CRP) style claim “for the detection and evaluation of infection, tissue injury, inflammatory disorders and diseases associated with NETosis.”
- Posters published during 2021 (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.
- Further larger studies have been completed in COVID-19 and sepsis which are now awaiting publication, as well as studies in other diseases in progress, with results expected in the coming quarters.

Clinical – Cancer

- Published data at ASCO GI 2022 for two colorectal cancer studies (asymptomatic and symptomatic populations) conducted with the National Taiwan University.
- Results demonstrated that using Nu.Q® assays in conjunction with FIT could potentially reduce unnecessary colonoscopies by up to 28% in patients with gastrointestinal symptoms and that this dual approach could also improve the effectiveness of FIT-based screening programs for asymptomatic patients.
- The Lung Cancer team at the National Taiwan University has completed collection and preliminary analysis and submitted abstracts to upcoming conferences.
- Volition has also undertaken active and continuing negotiations in Asia, in addition to platform development on its first human cancer launch in China.
- Collection for the U.S. Early Detection Research Network (“EDRN”) study restarted in June 2021 and enrollment has been slow but steady. The EDRN has diverted some efforts to drive recruitment and it still anticipates study completion in the fourth quarter of 2022.
- With regards to Volition's 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 Given the pandemic, and resultant delays in the larger Non-Hodgkin Lymphoma (“NHL”) study (of 1500 subjects), the Company has taken the opportunity to upgrade the platform to a high-throughput platform which will help facilitate an FDA compliant product. Consequently, Volition now expects this study to initiate recruitment in the second quarter of 2022 with study completion anticipated in 2023.
 - o A smaller, proof of concept NHL monitoring study is ongoing. However, due to missing serial samples as a result of pandemic collection issues, we are not in a position to publish yet. Collection continues and we anticipate analyzing a more complete data set in 2022.

Nu.Q[®] Capture

- The Nu.Q[®] Capture program now has several strands of technology which:
 - o essentially remove background noise, thereby amplifying the signal,
 - o look to identify the signal in a novel way including through mass spectrometry, or
 - o isolate various chromatin fragments, including nucleosomes and transcription factors.
- Nu.Q[®] Capture, when used in combination with either sequencing, mass spectrometry and/or Volition's Nu.Q[®] assays could potentially aid diagnosis, treatment selection, and both treatment and disease monitoring in addition to aiding biomarker discovery.
- Further to the publication in 2021 of a novel method utilizing Nu.Q[®] Capture and mass spectrometry, Volition is developing a large 1000-plus patient study in lung cancer and colorectal cancer with further announcements expected in 2022.

Intellectual Property

- 29 patent families (plus three in-licensed families) covering both human and animal use of Volition's Nucleosomics™ platform.
- 84 granted patents (12 in the U.S., 14 in Europe, and 58 rest of world).
- 93 patents pending worldwide.
- Continued focus on filings and expect portfolio to grow in the quarters and years ahead.

Publications

- In 2021, data for the Nu.Q[®] platform was presented at five international conferences and Volition has collaborated on four clinical papers.
- In 2022, to date, two posters were presented at the ASCO GI 2022 conference.
- These publications are another very important step forward for the Company.

Upcoming Milestones

- Drive near term revenue in the following key areas:
 - o Licensing of its technology, with a particular but not exclusive focus on Nu.Q[®] Vet.
 - o Complete Heska Corporation agreement milestones in order to receive further milestone payments.
 - o Sales of key components of Point of Care test with Heska.
 - o Sales of kits from non-exclusive agreements for the use of Nu.Q[®] Vet via central reference labs.
 - o Ongoing and new Nu.Q[®] Discover agreements.
 - o Sales of its disease monitoring tests (e.g. COVID-19, sepsis).
- 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.

**VolitionRx Limited Full Fiscal 2021
Financial Results and Business Update**

Date: Thursday, March 31, 2022
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: 13728406

Cameron Reynolds, President and Group Chief Executive Officer of Volition, will host the call along with Terig Hughes, Group 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 April 14, 2022. 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 13728406.

About Volition

Volition is a multi-national epigenetics company that applies its Nucleosomics™ platform through its subsidiaries to develop simple, easy to use, cost effective blood tests to help diagnose and monitor a range of life-altering diseases including some cancers and diseases associated with NETosis such as sepsis and COVID-19. Early diagnosis and monitoring have 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 and monitoring but also has a subsidiary focused on animal diagnostics and monitoring.

Volition's research and development activities are centered in Belgium, with an innovation laboratory in California and additional offices in Texas, London, and Singapore, as the company focuses on bringing its diagnostic and disease monitoring 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.

Media Enquiries:

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+44 (0)7557 774620

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, among other topics, Volition’s expectations related to the potential benefits under the agreements with Heska and SAGE, the size of Volition’s addressable markets, the success of negotiations and the timing, completion and execution of term sheets and/or agreements with third parties regarding the licensing and distribution of Volition’s products, the timing, completion and delivery of data from clinical studies, effectiveness of Volition’s blood-based diagnostic, prognostic and disease monitoring 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, prognostic or disease monitoring tools for such diseases, the timing of product launches and publications, and expectations regarding Volition’s ability to transition to a commercial products company, its 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, prognostic or disease monitoring 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, prognostic or disease monitoring 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 and disease monitoring markets and their 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.

Pursuant to the disclosure requirements of the NYSE American Company Guide Section 610(b), Volition is reporting that its audited consolidated financial statements for the fiscal year ended December 31, 2021, included in Volition’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2021, contains an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to Volition’s ability to continue as a going concern. This announcement does not represent any change or amendment to Volition’s financial statements or to its Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

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.