

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): **July 17, 2017**

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)

1 Scotts Road
#24-05 Shaw Centre
Singapore 228208
(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))

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 1.01. Entry into a Material Definitive Agreement.

On July 17, 2017, Volition America, Inc. (the “Company”), a wholly-owned subsidiary of VolitionRx Limited (“Volition”), entered into a Clinical Study Agreement (the “Agreement”), by and between the Company and the Regents of the University of Michigan (the “Regents”), with regards to the Company’s participation with the Regents and the National Cancer Institute (“NCI”) Early Detection Research Network in a clinical study involving approximately 13,500 asymptomatic screening samples provided by the Regents and/or NCI (including more than 4,600 previously collected samples) from people aged 50 and over who have not previously undergone screening or diagnostic colonoscopy (the “Study”). Pursuant to the terms of the Agreement, the screening samples will be tested by the Company for blood-based, cell-free circulating biomarkers on Volition’s proprietary Nu.Q™ platform to validate Volition’s Nu.Q™ Colorectal Cancer Screening Test for U.S. regulatory purposes. The enrollment period and sample collection is anticipated to take up to 3 years to complete. Either party may terminate the Agreement at will upon at least sixty (60) days’ prior written notice to the other party or upon at least thirty (30) days’ prior notice for an uncured material breach by the other party that remains uncured within such notice period. During the term of the Agreement, the Regents are required to provide periodic reports to the Company concerning the Study. In exchange for participation in the Study and certain rights and obligations under the Agreement, the Company agreed to pay up to \$3 million in twelve (12) equal quarterly installments of \$250,000. The parties have agreed to indemnify each other (and to maintain adequate insurance or self-insurance to cover such obligations) from and against third party claims for personal injury (including death) to any person or damage to property arising out of or in connection with their respective acts or omissions under the Agreement subject to certain limitations. The parties intend to publish the results of the Study and have agreed that the Regents shall provide the Company with a written copy of any proposed publication or disclosure regarding the same for the Company’s review and comment at least sixty (60) days prior to any submission for publication or disclosure. Each party has agreed to mutual confidentiality provisions regarding confidential information of the other party, including certain nondisclosure and nonuse limitations of such information for a period of five (5) years after the term of the Agreement.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by such Agreement, a copy of which will be filed as an Exhibit to Volition’s Form 10-Q for the quarter ended September 30, 2017.

Item 7.01 Regulation FD Disclosure.

On July 18, 2017, the Company issued a press release announcing its entry into the Agreement and participation in the Study and also announcing a conference call to be held on July 20, 2017 discussing the same. The conference call is available to the public via telephone and audio webcast. The Company issued a subsequent press release regarding the Study and the conference call on July 19, 2017. Copies of the press releases are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

The foregoing information, including Exhibits 99.1 and 99.2, is being furnished under Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u> <u>Number</u>	<u>Description</u>
99.1	Press Release of Volition America, Inc., dated July 18, 2017.
99.2	Press Release of Volition America, Inc., dated July 19, 2017.

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: July 19, 2017

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

EXHIBIT INDEX

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99.1	Press Release of Volition America, Inc., dated July 18, 2017.
99.2	Press Release of Volition America, Inc., dated July 19, 2017.

Volition America, Inc. Announces a Colorectal Cancer Screening Trial containing approximately 13,500 Subjects in Collaboration with the Early Detection Research Network of the U.S. National Cancer Institute

AUSTIN, Texas, July 18, 2017 /PRNewswire/ -- Volition America, Inc. (Volition America), a wholly-owned subsidiary of VolitionRx Limited (Volition; NYSE MKT: VNRX), has signed an agreement to participate in a large multi-center clinical study with the Great Lakes New England Clinical Validation Center funded by the U.S. National Cancer Institute's (NCI) Early Detection Research Network (EDRN).

The clinical study will provide approximately 13,500 asymptomatic screening samples of people aged 50 or over who have not previously undergone screening or a diagnostic colonoscopy. Already 4,677 samples have been collected and up to 9,000 will be prospectively collected. The aim of the trial will be to validate a panel of biomarkers that include Volition's Nu.QTM Colorectal Cancer Screening Test in a large asymptomatic population to support U.S. regulatory approval. The study sample collection is expected to take 2 to 3 years. Volition America will contribute up to \$3 million towards this public-private arrangement paid in instalments over a 3-year period.

Volition's Chief Executive Officer, Cameron Reynolds, commented, "This is exciting news for Volition and very much advances our efforts in the U.S. market. We believe this large scale clinical study will be invaluable when we seek FDA approval for Nu.QTM. The public-private arrangement involves joint governmental and private funding and reduces our costs to \$3 million, and we believe that it represents exceptional value for money. We are delighted to work with U.S. institutions and the United States National Cancer Institute with such outstanding reputations who share our aims in improving early diagnosis of cancer."

The NCI is the leading cancer research organization in the U.S. with 69 NCI-Designated Cancer Centers that are at the forefront in supporting cancer research across the U.S. The EDRN is an initiative of the NCI which is focused on early cancer detection. It is the force behind inter-governmental, inter-institutional and public-private collaboration building for the rapid advancement of biomarkers and early detection science.

Dr. Jason Terrell, Chief Medical Officer of Volition and the Chief Executive Officer of Volition America, commented, "We are extremely excited about joining this study and are confident that our relationship with the EDRN will be highly beneficial to both parties. This study is a major milestone for Volition and will provide significant clinical data for us as we move firmly into the U.S. market and commence the process of launching a frontline screening test in the U.S."

An interview with Cameron Reynolds and Jason Terrell on this announcement is available to view at <http://volitionrx.com/news/video-gallery>.

Volition will host a conference call on Thursday July 20 at 8:30 AM U.S. Eastern Time to further discuss the participation in this clinical study in addition to providing a business update. The call will be hosted by Cameron Reynolds along with Jason Terrell. To participate in the call, please dial 1-877-407-9716 (toll-free) in the U.S. and Canada, 0800-756-3429 (toll-free) in the U.K., and 1-201-493-6779 (toll) internationally. The conference ID number is 13666552.

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.volitionrx.com>. In addition, a telephone replay of the call will be available until July 27. 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 13666552.

About Volition

Volition is a multi-national life sciences company developing simple, easy to use blood-based cancer tests to accurately diagnose a range of cancers. 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.

As cancer screening programs become more and more widespread, our products aim to help to diagnose a range of cancers quickly, simply, accurately and cost effectively. Early diagnosis has the potential to not only prolong the life of patients, but also to improve their quality of life.

Volition's research and development activities are currently centered in Belgium, with additional offices in London, New York, Texas and Singapore, as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

For more information about Volition, visit Volition's website (<http://www.volitionrx.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>

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Media / Investor Contacts

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Tirth Patel, Edison Advisors tpatel@edisongroup.com +1 (646) 653 7035	Rachel Carroll, Edison Advisors rcarroll@edisongroup.com +44 (0)20 3077 5711

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 effectiveness of Volition’s bodily-fluid-based diagnostic tests as well as Volition’s ability to develop and successfully commercialize such test platforms for early detection of cancer. 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 market; a failure by the marketplace to accept the products in Volition’s development pipeline or any other diagnostic products Volition might develop; 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.

Nucleosomics[®], NuQ[®], Nu.Q[™] and HyperGenomics[®] 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 the United States of America.

View original content: <http://www.prnewswire.com/news-releases/volition-america-inc-announces-a-colorectal-cancer-screening-trial-containing-approximately-13500-subjects-in-collaboration-with-the-early-detection-research-network-of-the-us-national-cancer-institute-300489731.html>

VolitionRx Limited to host a conference call regarding a 13,500 Subject Colorectal Cancer Screening Trial with the Early Detection Research Network of the U.S. National Cancer Institute

AUSTIN, Texas, July 19, 2017 /PRNewswire/ -- VolitionRx Limited (Volition; NYSE MKT: VNRX), announced it will host a conference call tomorrow, July 20 at 8:30 AM U.S. Eastern Time to discuss its participation in a large multi-center clinical study with the Great Lakes New England Clinical Validation Center funded by the U.S. National Cancer Institute's (NCI) Early Detection Research Network (EDRN) in addition to providing a business update.

Volition will host a conference call on Thursday July 20 at 8:30 AM U.S. Eastern Time to further discuss the participation in this clinical study in addition to providing a business update. The call will be hosted by Cameron Reynolds along with Jason Terrell. To participate in the call, please dial 1-877-407-9716 (toll-free) in the U.S. and Canada, 0800-756-3429 (toll-free) in the U.K., and 1-201-493-6779 (toll) internationally. The conference ID number is 13666552.

The clinical study will provide approximately 13,500 asymptomatic screening samples of people aged 50 or over who have not previously undergone screening or a diagnostic colonoscopy. Already 4,677 samples have been collected and up to 9,000 will be prospectively collected. The aim of the trial will be to validate a panel of biomarkers that include Volition's Nu.Q™ Colorectal Cancer Screening Test in a large asymptomatic population to support U.S. regulatory approval. The study sample collection is expected to take 2 to 3 years. Volition America will contribute up to \$3 million towards this public-private arrangement paid in instalments over a 3-year period.

Volition's Chief Executive Officer, Cameron Reynolds, commented, "This is exciting news for Volition and very much advances our efforts in the U.S. market. We believe this large scale clinical study will be invaluable when we seek FDA approval for Nu.Q™. The public-private arrangement involves joint governmental and private funding and reduces our costs to \$3 million, and we believe that it represents exceptional value for money. We are delighted to work with U.S. institutions and the United States National Cancer Institute with such outstanding reputations who share our aims in improving early diagnosis of cancer."

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Volition's research and development activities are currently centered in Belgium, with additional offices in London, Texas and Singapore, as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

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View original content: <http://www.prnewswire.com/news-releases/volitionrx-limited-to-host-a-conference-call-regarding-a-13500-subject-colorectal-cancer-screening-trial-with-the-early-detection-research-network-of-the-us-national-cancer-institute-300489799.html>