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 10, 2017**

VolitionRx Limited

(Exact name of registrant as specified in its charter)

Delaware	**001-36833**	**91-1949078**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(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))

VOLITIONRX LIMITED
Form 8-K
Current Report

Item 2.02. Results of Operations and Financial Condition.

The following information, including Exhibits 99.1 and 99.2, 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing:

As previously announced, on March 10, 2017, VolitionRx Limited hosted a conference call discussing its financial results for its quarter and fiscal year ended December 31, 2016. The conference call was announced by a widely disseminated press release and was made available to the public via audio webcast. Furnished herewith as Exhibits 99.1 and 99.2 and incorporated by reference herein are copies of the press release and a transcript of the conference call, respectively.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of VolitionRx Limited, dated March 10, 2017.
99.2	Transcript of Conference Call held on March 10, 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: March 16, 2017

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

EXHIBIT INDEX

Exhibit Number	**Description**
99.1	Press Release of VolitionRx Limited, dated March 10, 2017.
99.2	Transcript of Conference Call held on March 10, 2017.

VolitionRx Limited Announces Full Fiscal Year 2016 Financial Results and Business Update

NAMUR, Belgium, March 10, 2017 /PRNewswire/ -- VolitionRx Limited (NYSE MKT: VNRX) today announced financial results for the full fiscal year ended December 31, 2016.

Full Fiscal Year 2016 Company Highlights:

Clinical

- Pancreatic Cancer
  - Initiated a study with the German Cancer Research Center (DKFZ) to evaluate Nu.Q™'s ability to detect pancreatic cancer. The study follows encouraging data from two previous pilot studies.

- Colorectal Cancer (CRC)
  - Presented research demonstrating our Nu.Q™ Colorectal Cancer Screening Triage Test's potential to reduce colonoscopies by 25% while maintaining almost 97% detection of colorectal cancer when combined with the Fecal Immunochemical Test (FIT) score.
  - Announced collaboration with Hvidore Hospital at the University of Copenhagen in Denmark in a prospective clinical study under which an initial 30,000 blood samples will be collected from 30,000 patients who have tested negative in a national FIT CRC screening test, with an option to collect a further 60,000 blood samples (two blood samples from each of the same 30,000 patients at two year intervals).
  - More recently in March 2017, we initiated a two-phase logistical study of our Nu.Q™ CRC Triage Test. The study is in collaboration with The Danish Research Group on Early Detection of Colorectal Cancer and is a pathway design study to help the Danish government understand the logistics of launching our Nu.Q™ Colorectal Cancer Screening Triage Test prior to rolling out the test nationwide.

Operational

- Strengthened leadership team with the appointments of Jason Terrell, M.D., as full-time Chief Medical Officer and Head of U.S. Operations; Louise Day as Chief Marketing and Communications Officer; and Philippe Willemsen, Ph.D., as Chief Operating Officer of Volition's wholly-owned subsidiary, Belgian Volition SPRL. Additionally, in January 2017 we appointed Jasmine Kway, Ph.D., as Vice President of Asia.

- Acquired a new, 19,000 square foot custom-designed office building and research and development facility in the Crealys Science Park, Les Isnes in the Wallonia region of Belgium. The footprint of the new facility is an almost five-fold increase on our current space and will allow us to expand our research significantly. Volition plans to move into the new facility this month and celebrate with a Grand Opening event in April.

Regulatory

- Received CE Marking on its Nu.Q™ Colorectal Cancer Screening Triage Test and multiple Nu.Q™ biomarker assays, allowing their clinical use in all 28 European Union countries.

- Granted a fourth key U.S. patent for the Nucleosomics® platform's ability to detect nucleosomes in blood circulation.

- Raised $24.9 million in net cash proceeds through public offerings in 2016, $13.1 million in March and a further $11.8 million in October.

Cameron Reynolds, President and Chief Executive Officer of Volition, said, "Volition had a year of remarkable success. We reached a series of significant clinical and operational milestones, enabling the Company's transition into its commercial phase. Most notably, we received CE Marking on our Nu.Q™ Colorectal Cancer Screening Triage Test in December 2016, allowing our commercial expansion into the European Union. Currently, FIT tests are the most frequently used front line tests for colorectal cancer screening across the European Union where 14 of the 28 member states have government-sponsored FIT screening programs. However, approximately 94.8% of people who test FIT-positive do not have colorectal cancer. With CE Marking in hand, we have the potential to reduce a significant number of unnecessary, expensive and invasive colonoscopies while also alleviating a substantially over-burdened healthcare system."

Mr. Reynolds concluded, “2016 was a year of significant growth and advancement for Volition. The CE Mark signaled the initiation of Nu.Q™'s commercialization in the European Union and we continue to bolster our product pipeline through numerous ongoing trials. In the coming months we expect to present the results of the full 8,000 subject data set for our Nu.Q™ Colorectal Cancer Screening Triage Test as well as results from our other ongoing trials. We also expect to announce additional trial commitments over the course of the year. I thank the dedicated Volition team for their tireless efforts and to whom I owe this remarkably successful year. We look forward to another year of continued success ahead.”

Full Fiscal Year 2016 Financial Results

For the year ended December 31, 2016, VolitionRx reported a net loss of $11.9 million, or $0.52 per share. This compares to a net loss of $9.5 million, or $0.54 per share for the year ended December 31, 2015.

Cash and cash equivalents as of December 31, 2016 totaled $21.7 million, compared with $5.9 million as of December 31, 2015 and $12.5 million as of September 30, 2016.

Conference Call

VolitionRx Limited will host a conference call today, March 10, 2017 at 8:30 a.m. ET to discuss its full fiscal year 2016 financial results and to provide an update on recent developments. To participate in the call, please dial 1-877-407-0789 (toll-free) in the U.S. and Canada, 0 800 756 3429 (toll-free) in the U.K., and 1-201-689-8562 (toll) internationally. A live audio webcast of the conference call will also be available via link from the investor relations page of Volition's corporate website at http://ir.volitionrx.com/. The conference ID is 13656572.

After the live audio webcast, the event will remain archived on Volition's website for one year. In addition, a telephone replay of the call will be available until March 24th, 2017. 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 13656572.

Please dial in at least 10 minutes prior to the scheduled conference call time to ensure timely participation.

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, 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

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 effectiveness of the Company's bodily-fluid-based diagnostic tests, the results and developments of clinical studies, as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include the Company'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 the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company'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 the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about the Company'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, the Company does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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VolitionRx Limited

Fourth Quarter & Full Year 2016 Earnings and Business Update Conference Call

March 10, 2017

CORPORATE PARTICIPANTS

Scott Powell, *Executive Vice President*

Cameron Reynolds, *President & Chief Executive Officer*

David Kratochvil, *Chief Financial Officer & Treasurer*

CONFERENCEC ALL PARTICIPANTS

Bruce Jackson, *Lake Street Capital Markets*

Yi Chen, *H.C. Wainwright & Co., LLC.*

Brian Marckx, *Zacks Investment Research*

PRESENTATION

Operator:

Good morning, ladies and gentlemen, and thank you for standing by, and welcome to the VolitionRx Limited Fourth Quarter and Full Fiscal Year 2016 Earnings Conference Call. During today's presentation, all parties will be in a listen-only mode. Following the presentation, the conference call will be opened for questions.

If you have a question please press the star key followed by the number one on your touchtone keypad. If you would like to withdraw your question please press star, two. If you're using speaker equipment please lift the handset before making your selections. This conference is being recorded today, Friday, March 10, 2017.

I'd like to turn the conference call over to Mr. Scott Powell, Executive Vice President of VolitionRx Limited. Please go ahead, sir.

Scott Powell:

Thank you, and welcome everyone to today's earnings conference call for VolitionRx Limited. This call will cover Volition's financial and operating results for the fourth quarter and full fiscal year ended December 31, 2016, along with a discussion of our key upcoming 2017 milestones.

Following our prepared remarks, we will open up the conference call to a question-and-answer session. Also on our call today are Mr. Cameron Reynolds, Chief Executive Officer; and Mr. David Kratochvil, Chief Financial Officer of Volition.

Before we begin our formal remarks, I'd like to remind everyone that some of the statements on this conference call may be considered 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, and similar expressions identified forward-looking statements. These forward-looking statements relate to the effectiveness of the Company's bodily-fluid-based diagnostic tests, results and completion of clinical studies as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer.

The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations.

Other risks and uncertainties include the Company'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 the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company'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 the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q as well as other documents that the Company files with the Securities and Exchange Commission.

These statements are based on current expectations, estimates and projections about the Company'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 conference call and, except as required by law, the Company does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

Nucleosomics®, 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 on this conference call are the property of their respective owners.

I'd now like to turn the call over to our Chief Executive Officer, Mr. Cameron Reynolds, who will discuss our fourth quarter and full fiscal year 2016 financial results and our clinical and operational results for 2016 and objectives for 2017. Cameron?

Cameron Reynolds:

Thank you, Scott, and thank you everyone for joining Volition's fourth quarter and full fiscal year 2016 earnings conference call. I'd like to thank you all for taking an interest in Volition at this pivotal time for us. I'm delighted with the considerable progress we made in 2016 in so many important areas. It really is incredible the amount of work a small dedicated team can accomplish.

Starting with our strong and growing team, which is key to our continued success, we added several key highlights to our business starting last January, with the appointment of Dr. Jason Terrell as our full-time Chief Medical Officer and Head of US Operations. Having previously served in a part-time capacity with us, Dr. Terrell gives us perspective as a US medical doctor, as well as the capability to plan our US clinical work.

Louise Day also joined our team in April as our Chief Marketing and Communications Officer. Ms. Day is responsible for the rebranding of the Company and our website, etc, and of course, the marketing of our products. In June, we expanded the Board of Volition with the appointment of Dr. Ed Futcher, giving further depth to our independent directors, particularly with regards to the Audit, Compensation and Nominations and Governance Committees.

In November, we strengthened our leadership team further with the appointment of Dr. Philippe Willemsen as Chief Operating Officer of our wholly-owned subsidiary in Belgium. He has extensive experience in the biopharmaceutical environment and he's certainly well placed as we ramp up our activities and launch our first product. I personally could not be happier nor more proud of our team we have put together.

We have an extremely talented and experienced team that is dedicated and committed to changing the way cancer is diagnosed. We're also in the process of expanding the research team in Belgium.

Moving on from people but staying in Belgium, we recently acquired a new 19,000 square foot custom designed office building and research development facility located in a Science Park near our current facility in Belgium. This facility is a significant increase in our previous footprint by almost five-fold and comes at a great value, including with loans from the local government and from the local banks.

This new home for our research team will hopefully allow us to greatly increase the amount of research and product we can produce. We intend to move into this new facility next month once the new lab is completely fitted out.

From a product point of view, we made the decision early in the third quarter of 2016 to focus our resources on delivering our first product. This caused us to pause most of our other research, so that we could attain the CE Mark as soon as possible. This focus proved highly successful, as we received our CE Mark on the first product, the Nu.Q™ Colorectal Cancer Screening Triage Test in December of last year, enabling our commercial expansion into EU.

This opportunity was only presented to us in June of 2016, and we had a CE Mark product by the end of December. A truly remarkable accomplishment, which demonstrates our agility as a Company to take advantage of new opportunities and a highly motivated and talented team. The focus we delivered allowed us to meet this crucial milestone in such a short period of time.

Given how important the Triage Test is, I'll give a refresher on what our first product is. Fecal tests are currently the most frequently used frontline screen for colorectal cancer across Europe. These fecal tests look for blood in your stool as a possible sign of cancer. Those who are FIT-positive, which means, they have blood in their stool are then routinely sent on for follow-up colonoscopy.

However, approximately 94.8% of people who test FIT-positive do not have colorectal cancer and have blood in their stool for other reasons, resulting in a very large number of unnecessary colonoscopies each year in these European countries.

With our CRC Triage blood test, which is then added to the FIT, we have the potential to reduce a significant number of unnecessary expensive and invasive colonoscopies, while also alleviating substantially the overburdened healthcare systems.

With approximately 150 million Europeans of screening age and a total addressable market for our Triage Test of approximately 3 to 3.5 million blood tests annually in EU, this is a very exciting market and time for us as we launch this product. This is a market we're initially targeting in Europe and we're also looking at opportunities in Asia for this test.

On the intellectual property front, Volition was granted its fourth US patent for its Nucleosomics® platform and our ability to detect nucleosomes in circulation. This patent will support the first three patents that have already been granted, which collectively cover three of the four core epigenetic components of our Nucleosomics® technology, including nucleosomes containing Histone Modifications, Histone Variants, and Nucleosomes adducts, as well as methods for detecting nucleosomes. We have overall a very broad IP portfolio.

I'm also delighted that we've initiated two very important trials in 2016. First, we initiated the study with the world renowned German Cancer Research Center, also known as DKFZ, to evaluate Volition's Nu.Q™ blood test for the detection of pancreatic cancer. This follows on from our successful early pilot studies in pancreatic cancer.

If successful, this 750-patient trial could be a revolutionary breakthrough in the diagnosis of the deadly and difficult to detect cancer. Due to our focus on the CRC Triage Test in 2016, we paused this study with the samples banked in our laboratory. However, we currently plan to start again in this year 2017 and hopefully we'll have some more news on this later this year.

Second, in October, we announced the initiation of our largest clinical study to-date, which plays a vital role in expanding our clinical development program. This prospective study, again, in collaboration with Hvidovre Hospital, University of Copenhagen, will ultimately consist of 90,000 blood samples collected from 30,000 patients over seven years, who have tested negative in fecal testing programs of the cancer screening tests.

All blood samples taken will be examined with up to 120 clinical pieces of information or data points, including such things as lifestyle factors and a wide range of other diseases, allowing Volition to use the study in a wider context for other cancers and it will lay the groundwork for our future product pipeline. I could not be prouder of this groundbreaking trial, as it will form part of the basis of much of the work we conduct going forward.

On the financial front, we raised $24.9 million in 2016 through the public offerings, with $13.1 million in March and a further $11.8 million in October. From our investor relations point of view, we're very, very active with Scott Powell and sometimes myself attending over 20 conferences in the calendar year.

We continue to manage cash burn very tightly with an average quarterly burn rate of under $2.5 million per quarter and we finished the year with over $21.5 million in cash and equivalents on the balance sheet, which provides us with a very long runway from the process we're going and it's a record high for the amount of cash we've ever had at the end of the quarter.

Now moving forward to 2017. We have already had a very busy start to this year, as is usual for us. In January, we announced the appointment of Dr. Jasmine Kway as Vice President of Asia. Dr. Kway will lead our clinical and commercialization efforts there. Our products aim to be at a price that can be used in many parts of the world, where expensive and complicated existing and developmental tests will likely never gain any widespread use. We hope to have some further updates on the progress in Asia in the coming quarters.

Like many of you who are listening to the call, we had a very busy week at the JPMorgan Healthcare Conference in San Francisco, meeting existing and potential investors, analysts, and collaborators. We had well over 60 meetings there and continue to follow-up on numerous and varied opportunities created for us during this very busy week.

In February, at the World Congress of GI Endoscopy in Hyderabad in India, we presented the results of our validation study of the Nu.Q™ Triage Test. This data confirms that the role the Nu.Q ™ Triage Test can play in accelerating the diagnosis of colorectal cancer.

Last week, we started a two-phase logistic study of our Nu.Q™ CRC Triage Test. This study is in collaboration with The Danish Research Group on Early Detection of Colorectal Cancer. Both phases are expected to be completed within six months.

The first phase of the study started last week in the capital region of Denmark and involves three centers and up to 250 subjects. The aim of this study is to evaluate the logistics in collecting and processing blood samples at a local screening center and subsequently shipping the samples to a central laboratory to run the analysis within Denmark. This phase is expected to be completed within two months.

The second phase of the study is due to start after ethical approval and will involve five centers and up to 500 subjects. Specifically, this phase will assess the time taken between blood collection analysis and results. When added to the existing clinical data previously announced, this logistic study aims to complete the information needed to add our test to the national screening program in Denmark.

We're delighted to be moving forward so quickly with our first product in Europe and look forward to updating you over the coming months regarding other EU and Asian countries that we enter.

Given the traction we have shown in Europe with this logistic study, I'm delighted to announce that we have formed a new subsidiary, Volition America, Inc., to focus completely on the US market, as well as expand our attention to the all-important market in the US.

Dr. Jason Terrell has been appointed to head up Volition America, and we look forward to updating you in the coming months as to our 510(k) and PMA strategy with regard to the US FDA and also non-diluted funding opportunities of our team trying to attain in the US.

Also, upcoming in the second quarter we look forward to a grand opening of our new facility in Belgium. This move is a significant expansion for us that gives us the ability to carry out additional clinical trials with our four Tecan machines in one place and expedite our sample analysis, and further to expand our scientific team and expedite commercialization of our blood tests.

We expect to present the results of the full 8,000 subject data set for our Nu.Q™ Triage Test and look forward in the coming months to announcing results from our other ongoing trials, in addition to hopefully announcing additional trial commitments over the course of this year.

With the laboratory opening imminently in Belgium, which greatly increases our bandwidth, we will also un-pause the research and product development in a range of cancers beyond colorectal, beginning with pancreatic.

To close, I'm once again extremely proud of our achievements to-date and of our plans for this year. I'm also delighted that Volition is ringing the closing bell at the New York Stock Exchange this Monday, March 13th, at 4:00 PM US Eastern Time. We have numerous colleagues in New York for this very special event. This will also highlight the launch of Volition America and of our Nu.Q™ product the Triage Test.

Thank you all very much for the interest in Volition and for joining our fourth quarter and full fiscal year 2016 earnings conference call today at this very exciting time for our Company. We would now like to open up the call to take your questions. Operator?

Operator:

Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you would like to remove your question from the queue. For participants using speaker equipment it may be necessary to pick up your handset before pressing the star keys. One moment please while we poll for questions.

Our first question comes from the line of Bruce Jackson with Lake Street Capital Markets. Please proceed with your question.

Bruce Jackson:

Hi, everyone, congratulations on all the progress last quarter.

Cameron Reynolds:

Thank you, Bruce. Yes, it was very encouraging.

Bruce Jackson:

So, if we could talk about the progress in Denmark and what is going to happen going forward, so what are the checkpoints in terms of getting to a—the first order? You've got the logistic studies going right now. What happens after those are completed and when are those could be completed?

Cameron Reynolds:

Yes, very good question. So, the clinical data we feel is done. We have 8,000 patients in the FIT-positive trial. So, none of the work currently is—of a clinical nature, it is purely logistics. So, obviously, this test has been run by us. These logistic studies to really show how it's run in a real life situation on real life patients of a few hundred patients in the first phase and then up to 500.

So, the output from that report goes straight to the screening committee. We're very hopeful that they'll make a decision to then implement it in Denmark. The first phase is in three centers in Denmark and the second is in five centers. Then typically, if they do, do and we're very hopeful that they do, they would roll it out nationally as part of the screening program, which we would expect then would be an order in the tens of thousands of kits per year for the national screening program, because they have a very, very immediate problem right now.

If you look at the center, which is in central region, Dr. Lennart Hansen is running that program, and he's on the steering committee. Dr. Morten Rasmussen who was quoted in the press release is the central region of Denmark for the steering committee. So, we're certainly working with the right people to get this putting this up in the national screening program and we're very hopeful.

Bruce Jackson:

Okay, great. Then real quick in the 10-K, there were a note of a material weakness in the internal controls section. Can you just give us a little bit more color on what's going on with that. Have you identified the—what needs to be done? Have you put those fixes in place? What's the road to getting all of that resolved?

Cameron Reynolds:

Yes, absolutely. I'll give you a quick answer, then David can add as a CFO if anything else. We're very aware of all of that. We're a small Company and are growing very fast. We take all of our financial requirements very, very seriously, and we're putting in more and more controls all the time. We anticipate having to comply with Sarbanes-Oxley this year. So, we have a huge amount of work around financial controls and the process going on, and that's something we talk extremely seriously.

But this is typical. I believe of a small company that's in a few places. But we are very, very careful and we're in the process now of fixing all those compliance issues and as well as getting ready to comply with Sarbanes-Oxley. David, anything else?

David Kratochvil:

No, just to reiterate that basically that disclosure notice is, because we are not currently Sarbanes-Oxley compliant, but we are making every effort to be Sarbanes-Oxley compliant as soon as possible and expect to be by the end of the year, and that's when that disclosure should come off at that point.

Cameron Reynolds:

Just—I just finish up on that. We've also added several members to our team in many ways beyond the ones I mentioned. We've also added on a full-time IT person to help with our controls there, and also a part-time HR person to make sure the controls around whistleblowing and a range of other areas are very much taken care of. We're going to be taking on a part-time SOX controller, as well as engaging some companies to help us with that.

So, it's something, which we're very mindful of, but something, which is typical for a Company our size. I think we'll have fixed in a very large part all of those in the coming quarters.

Bruce Jackson:

Okay, good. Last question, on the presentation of the results from the studies in Denmark, this has been a long road and we've been like anxiously awaiting the presentation of the results. Do you have the presentation schedule yet can tell us, which meeting it's going to be presented at?

Cameron Reynolds:

Yes, I can. The full 8,000 FIT-positives for the Triage Tests will be presented at DDW in Chicago, and that will be all 8,000, the final numbers for the clinical data set of this population. The outcome of the Triage studies are presented directly to the screening committee in Denmark.

So, the DDW Conference in Chicago, I believe, is in May. But that data is just about—the assays have been finished being run, we're just waiting for the last of the patient data, so that's just about finished. These are much more for the marketing of the products. The numbers we have currently 2,000 and 4,000, all the positives are very specifically valid, but we'll announcing all 8,000 data at that time.

If you notice, we have the first set with the trial set, and the second set was a validation set. So, we passed both of those. So, we're very confident of those numbers. But we'll be announcing the full 8,000 at DDW in Chicago. That's a very big conference. We wanted to make sure, it was a bigger—as big as conference as we could possibly get for that.

Bruce Jackson:

All right. Thank you for taking my questions. I'll hop back in queue.

Cameron Reynolds:

Thank you, Bruce.

Operator:

Thank you. Our next question comes from the line of Yi Chen with H.C. Wainwright & Co. Please proceed with your question.

Yi Chen:

Hi, thank you for taking my questions. First question, do you have to wait for the logistical study results before launch the test in other European countries?

Cameron Reynolds:

Very good question, Yi. Basically, these will be run in the labs in Denmark, and a lot of other things are similar to other countries, but a few things are different. I think any country has a slightly different healthcare system, so they have slightly different logistical questions as to pertaining to where.

For example, France, if we were to get a country like France, you're talking 200,000 or 300,000 tests per year, but it's much more centralized than Denmark. So, that one or two centers that run a lot of the French capacity would have to have a slightly higher capacity machine run through them.

Now, our platforms,, we can perform manually. We can perform on a small machine, or we can perform on a large machine. So, it's all very much within capabilities. So, the question, I guess, is in several parts. A lot of what we're looking for in the Danish side will be applicable to other countries, but each country, I think, would want some sort of small logistical study to answer the very local questions.

But if you think about it in holistically in the scheme of things signing up tens or hundreds of thousands of tests, which would occur year-on-year, if you have to do a small logistical study, that's a lot better than hiring hundreds of salespeople for millions of dollars, which other companies have had to do.

I think if we do end up signing up Denmark, which again, we're very hopeful for and other countries in Europe in the short to medium term. We've done that with a couple of salespeople. Our current system is run on a very simple platform. The margin, I won't disclose exactly, but it's very high. So, we have a very high margin product with next to no sales costs and laboratories of tens or hundreds of thousands per units, per year recurring year-on-year. Screening programs typically would buy once then buy for many years.

So, this is very, very meaningful revenue and it's something, which—I think when we talk about this earlier, people put into their financial models tens of millions of dollars in sales commissions and massive sales force. All that, we didn't think were necessary and that's certainly proving to be the way it's happening. But—so we're very comfortable with this—the pathway design logistical study in Denmark. I think it's a great way for us to, I mean, I guess, as a CEO, you want to push it out very, very quickly to get it done. But it's very important to get the first country done right.

These are very practical questions, the very things, which we'll need to answer in a very simplistic way. They're not complicated questions. But you don't want to launch nationally and then have a problem. So, I mean, it's going to take a few months, but I think it's a fantastic thing for us to be doing. It's the way we like to do things. It's on real client, so we have to be real patient. We have to make sure, we're doing it exactly correctly.

So, these are the things, which we're very, very happy with this way the study has been designed, the logistic study, and we'd be very happy to do it in other countries as well, because when you're making that kind of order, you want to make sure, you get every single thing exactly right. When you do launch nationally, it goes very smoothly, so other countries will order.

Yi Chen:

Thank you. Second question, I know that you—on your income statement, you currently do not have any sales and marketing expenses. Do you expect to incur any expenses in that category within 2017? Can you give us any color on the amount—potential amount in 2017?

Cameron Reynolds:

Yes. So, what we have currently is, Louise Day, who is heading our Communications and Marketing efforts, along with Gaetan who's our Chief Executive in Belgium, that means spearheading those efforts in the European countries. I think so far you would have to say, they've had a very good success in getting it down the fairway.

So, currently, that—the expenses we have in—for those people and that's what we mentioned earlier that it would be the five countries we're targeting. Those five countries are the ones, which we have been actively targeting picking them off one by one. So, no, I don't expect any other beyond that traveling back and forth. It's very different from the US. You're not going doctor by doctor, you're not going insurance company by insurance company.

The reason we're very attracted to this market is the healthcare systems. The screening systems are quite often separate from the actual. They're all public, so it's government, but separate. But part of the system is separate. So, you need to convince a few key opinion leaders that this is a good product and something they need to buy. So, there's no point having a massive sales force; zero point having a dozen people flying around - they're just bumping into each other. You need to convince some very key people, very smart, very educated, very knowledgeable people.

So, you have to have a good product, which we're very comfortable with, a very good value products, otherwise they won't buy it, but this is all that's needed. So, and if they do decide to do it, they'll be buying tens or hundreds of thousands of kits, which is—as a massive outcome for a Company. If you look at some of our competitors, I won't mention names, but they've lost hundreds and hundreds and hundreds of millions of dollars before they've got to 10,000 kits, never mind the process where it's continuation.

So, going with the European model, was a little bit different. But it's something, which we had the choice of, because of the low cost of our kits, the low price point, and our European background. It's something, which we're very comfortable with the way we have gone. But that's not to say that we won't be refocusing our efforts, as we are now—now that we're showing a really good traction in Europe.

We feel we've got very, very good responses. Down that pathway, we're pivoting back to the US, because ultimately, referring to your question, we will need more of an effort in the US. We will need to do a lot more of what the other people had to do in the US I think it's always going to be a lot cheaper for us, because we've retained blood test that can be done as a normal clinical procedure. But—so those costs for the market in the US would be at least one to two years out, and we'll be updating a lot more on the US strategy.

Dr. Terrell has been working with some of the team members on working through that and we'll make some announcements in the next few months. But Volition America, Inc. has now been founded. We're now putting a lot of effort into the US strategy, which pertains to the 510(k) for the colorectal simply the symptomatic, and then the PMA, the very large study, which we're hoping to announce a lot of detail on the next quarter or two. We expect it to be a very good value, very good low cost, and have a real pathway to launching our product in the US, where there are more sales and marketing costs, but obviously much—a very, very attractive market and one which are very serious about getting very active in this year.

Yi Chen:

Okay. Thank you very much.

Cameron Reynolds:

Thank you, Yi.

Operator:

Thank you. Our next question comes from the line of Brian Marckx with Zacks Investment Research. Please proceed with your question.

Brian Marckx:

Good morning, Cameron, and congratulations on the results.

Cameron Reynolds:

Thank you, Brian.

Brian Marckx:

Relative to the time and logistics study, is there some sort of, I guess, existing guideline or other benchmarks that you're measured against to help determine whether you're quote unquote successful?

Cameron Reynolds:

Yes. So, this—the clinical data, which the Danish Group we've done it with them, so they're as aware of the data as we are if not more so that we've lined it to us. So, we believe that's been ticked off. So, that these trials have nothing to do with that, it's all about the logistics.

So, the logistics basically come down to, can it fit into the current pathway in Denmark, which currently, as I mentioned in the opening statements, that it comes down to a FIT test, and then if you're positive, you then have a colonoscopy. So, basically, the criteria basically are the people who run the screening program. Do they think this would actually add to the national screening program? I know several things absolutely factual.

I know the FIT tests in Denmark, the whole FIT test program is having severe problems, because although the FIT test does pick up a lot of cancers, it misses a lot, but also it provides a huge stress of colonoscopies on the system. They've just not got the capacity to handle the current screening program at full capacity they'll be about 40,000 FIT-positives per year in Denmark, and they are having trouble with the capacity now 20,000 before they go into the full program in January of next year.

So, the criteria basically comes down to, will it help the screening program meet this demand and if you see from our data, we've cut down the colonoscopies by 25% with keeping very high sensitivity, which we think is a fantastic result. If you look at the quote from Dr. Rasmussen who the central region of Denmark, they're also impressed with results and they're very keen for this product.

So, we're very hopeful. We'll see how it all pans out. But the district study is—should be the final data point they need to make the decision to purchase the product, because I mean, we had great results. But they want to see it just run in the labs in Denmark. We don't see a problem with that. It's an ELISA, it should be able to be run in any lab in the world. But then the very practical questions of who—where the blood is collected going to one center? What's the notification? All those kind of things, which are very simple questions, and we don't anticipate any problems whatsoever.

But you don't want to roll out nationally on several million people and then have a small error, which you have overlooked, bring the whole thing down. So, this is a very good thing for us. I think I thought of everything, which is needed for this. We work very closely with the Danes to design the study, all the suggestions came from them as to what it should look like in the process and they did all the work for It all.

So, I think it will get us to the point, where they can make a decision when it's all finished. As I mentioned before, the output of these logistic studies is report to the national screening committee. So, and—so we're very hopeful, we'll see how it goes.

Brian Marckx:

Cameron, on the second phase, which relates to the time to assess how long it takes, is there a specific number, I guess, or a benchmark that you have to meet that you're—that you have in mind, or is it, I guess, more abstract for lack of a better word?

Cameron Reynolds:

I don't think there is any specific targets. It comes down to just actually, I think, I look at it in this way - sort of a dry run. People give their bloods after the FIT results, and just a notification, all those things. It's not actually any specific targets, or criteria, which would make it fail.

The assays work very well. They definitely can be run in the labs. But if you actually bring yourself in a position of Dr. Hansen and Dr. Rasmussen, they just want to make sure on a few hundred patients that it goes smoothly. There are also people who are very caring and dedicated, to their patients, they just want to make sure, they would never use these tests in public—on the public in actual —in the pathway before. So, they just want to see that all goes smoothly.

So, no it's not a matter of actually missing or hitting criteria, it's more just the whole process works smoothly, because it's an analyzer it takes one day to process, it's not an issue with the timing being more or less or anything like that. It's just—it's never been run in patients in a country before. So, they just want to see that it goes smoothly before they commit to doing any national program.

So, there's always things can go wrong, I just—but it's not set criteria missed by 1% and something doesn't happen, it's just the purely logistics of getting it done.

Brian Marckx:

Okay, okay and have—I assume that other new diagnostics that have come to market through those national screening programs have gone through something similar, is that correct?

Cameron Reynolds:

Yes, typically absolutely. Any country that has a national screening program that wants to do something will go through a process where they work through the actual very practical logistics of getting it implemented because each country is a little different. As I mentioned to one of the questions I think with Yi before, ultimately this hasn't been done before in any country, so they wanted to see the actual specifics.

If it was something very routine that's done like a, if you look at the blood test for cholesterol for example, it's been done before in a lot of different ways. You wouldn't need to do logistics study, but this is something which is helping with their current pathway in the screening programs. So, they just want to see it fits into their pathway before they look at the national rollout, so yes, that's something which is very routine.

Brian Marckx:

Okay and just one on timelines if you would. So, the—both of the first and second—the first and second phase of this time and logistics study should be done within about six months. Then what is kind of after that? So, then you get kind of a yes or no I guess and in a certain timeframe? If you can kind of talk about what your expectations are in terms of when you think you'll hear back?

Cameron Reynolds:

Yes, absolutely. So, it goes from national screening committee, the next round for the national screening program starts in January. If we were, I would be hopeful to be added to that, which would mean that I have to make the orders this year. Obviously, it starts in January, I have to get the whole thing bought and setup.

I've been asked before, we are not 100% certain with that order, three months' worth or six months' worth of the time, but in any situation we'd be expecting tens of thousands of kits per year. If it's done per the whole national screening program, it will be in the 20,000 to 40,000 kits per year range. If it was added to the program in January, which is what we'd be hopeful of, then that have to place the orders this year sometime in Q4. So, it's all coming on us pretty quickly, so that was what we'd expect timing wise.

Brian Marckx:

So, is that a reasonable timeline you think between—so it starts, say, beginning of March and so that puts you ahead…

Cameron Reynolds:

Started, yes.

Brian Marckx:

I'm sorry.

Cameron Reynolds:

Yes, it has started, yes.

Brian Marckx:

It has started, okay so then that would put you at, say, the end of August I think. So, between August or the beginning of September and the end of the year, you would—is that a reasonable timeframe to hear back that yes, you are going to be accepted into the program?

Cameron Reynolds:

Yes, that's what we'd expect.

Brian Marckx:

Okay, okay, great. All right, great, thanks Cameron.

Cameron Reynolds:

Thank you.

Operator:

Thank you. Once again if you would like to ask a question please press star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. For participants using speaker equipment it may be necessary to pick up your handset before pressing the star keys. One moment please while we poll for more questions.

There are no further questions at this time. I would like to turn the call back over to Mr. Reynolds for closing remarks.

Cameron Reynolds:

Thank you everyone who is joining us today for the VolitionRx Limited's fourth quarter and full fiscal year 2016 earnings conference call. We really appreciate your interest in Volition and look forward to speaking to you with again in the near future.

Just as a quick reminder, we also have some interviews that will be on our website from proactive investors EDISONTV and Dr. Terrell will be giving some information on the new Volition America and his vision for how we rollout the product in US.

Of course just a last reminder, we're ringing the closing bell on the New York Stock Exchange this Monday at 4 o'clock Eastern. This is to highlight the product launch of Nu.Q^{TM} tests and the traction we're getting in Europe and also the pivoting back to the US in the forming of Volition America, Inc. So, I believe it's broadcast on a few channels here, if you want to watch us. It's a very good event for us and something we're all very much looking forward to. So, thank you and goodbye.

Operator:

This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.