

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): **May 13, 2016**

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)

Telephone: +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))
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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 May 13, 2016, VolitionRx Limited hosted a conference call discussing its financial results for the quarter ended March 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of VolitionRx Limited, dated May 13, 2016.
99.2	Transcript of Conference Call held on May 13, 2016.

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: May 19, 2016

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of VolitionRx Limited, dated May 13, 2016.
99.2	Transcript of Conference Call held on May 13, 2016.

VolitionRx Announces First Quarter 2016 Financial Results and Business Update

Namur, Belgium, May 13, 2016 - VolitionRx Limited (NYSE MKT: VNRX), a life sciences company focused on developing blood-based diagnostic tests for a broad range of cancer types and other conditions, today announced financial results for the first quarter ended March 31, 2016.

First Quarter 2016 and Recent Company Highlights:

Clinical:

- Announced results from a 430 patient study in pre-cancerous colorectal adenomas, in which a panel of five NuQ® biomarker assays in an age adjusted algorithm accurately detected 75% of high-risk colorectal adenomas and 86% of stage 1 colorectal cancers, the best adenoma detection rates to-date by VolitionRx.
- Released results from a prostate cancer study that demonstrated a single NuQ® biomarker assay detected 71% of early stage I prostate cancer cases at 93% specificity, significantly higher detection rates compared to the current standard of care, the PSA test
- Reported results from a NuQ® trial in Idiopathic Pulmonary Fibrosis (IPF), the Company's first study for a non-cancer indication; NuQ® detected IPF in 86% of trial subjects

Regulatory:

- Received CE Marks for two NuQ® biomarker assays, NuQ®V001 and NuQ®T003, to detect the presence of colorectal cancer signatures
- Received ISO Certification EN ISO 13485:2012 for quality management system for design, development, production and distribution of NuQ® blood tests

Operational:

- Strengthened leadership team with appointment of Dr. Jason Terrell as full-time Chief Medical Officer and Head of U.S. Operations, and Louise Day as Chief Marketing and Communications Officer
- Completed secondary offering of approximately 4.3 million shares of common stock, generating net proceeds after fees and expenses of approximately \$12.8 million

“We had an extremely productive first quarter, as we significantly advanced our clinical programs and achieved a number of important regulatory and operational milestones. CE marking of NuQ®V001 and NuQ®T003 represented a key step in our path to European commercialization of the NuQ® blood test for colorectal cancer, whose launch we plan for later this year,” said Cameron Reynolds, President and Chief Executive Officer of VolitionRx. “We are excited about our progress in Europe, and we are continuing to advance our U.S. clinical and regulatory strategy as well. Later this year, we intend to initiate an FDA-endorsed clinical trial of NuQ®. Importantly, we expect to submit a 510(k) application to the FDA, which, if approved, would give NuQ® marketing clearance for use as an adjunct test for colorectal cancer. Our strategy positions NuQ® for potential FDA clearance and commercial launch as early as 2017. VolitionRx continues to generate the data necessary to submit a PMA for the potential FDA approval of our NuQ® test for the early detection of colorectal cancer.”

Mr. Reynolds added, “In addition to the continued execution of our commercial strategy, we have had several important clinical accomplishments thus far in 2016. In a targeted clinical trial of 430 pre-cancerous colorectal adenoma patients with Hvidovre Hospital and the University of Copenhagen, a panel of five NuQ® biomarker assays in an age adjusted algorithm detected 75% of high-risk colorectal adenomas and 86% of stage I colorectal cancers. These are our highest adenoma detection rates yet, and they demonstrate the power of NuQ®, not only for the detection colorectal cancer, but also for pre-cancerous polyps. Furthermore, at the AACR Annual Meeting in New Orleans, we presented the results of a prostate cancer study conducted in collaboration with the Surrey Cancer Research Institute at the University of Surrey in the UK. In this study, a single NuQ® biomarker assay detected 71% of early stage I prostate cancer cases with 93% specificity, significantly higher than the Prostate Specific Antigen (PSA) test, which is the current standard for prostate cancer detection. We are continuing to explore the potential of NuQ® to diagnose diseases other than cancer. We released data from our first non-cancer clinical trial with Liège University Hospital in Belgium, in which NuQ® detected 86% of subjects with Idiopathic Pulmonary Fibrosis, a deadly lung disease. We believe that NuQ® has broad potential across a variety of indications beyond cancer and plan to assess these applications further.”

“As of today, we have more than 50 antibody programs in development. A majority of the early programs have been successful and are now used in our Clinical Validation Studies. The goal is to continue investing resources into this strategy in order to build our own proprietary antibody banks. Moreover, this will secure the supply of highly performant antibodies, which we believe will lead to more reliable clinical results and products further down the line.”

“In March, we completed a successful secondary offering of common stock in which we issued approximately 4.3 million shares and generated net proceeds of approximately \$12.8 million after deducting underwriting discounts, commissions and expenses payable by us. We completed the first quarter with a strong cash position of \$17.0 million, providing us with the financial resources needed to fund our ongoing trials and initiate new ones, as well as to support our commercialization initiatives in Europe, the U.S. and other markets. Our solid leadership team was enhanced by Dr. Jason Terrell’s transition to full-time status as Chief Medical Officer and Head of U.S. Operations and Louise Day’s appointment as Chief Marketing and Communications Officer. Overall, we believe we are ideally positioned to meet our key clinical, operational and strategic objectives, and we look forward to the opportunities that lie ahead,” Mr. Reynolds concluded.

First Quarter 2016 Financial Results

For the three months ended March 31, 2016, VolitionRx reported a net loss of \$2.5 million, or \$0.13 per share. This compares to a net loss of \$2.0 million, or \$0.12 per share in the first quarter of 2015.

Cash and cash equivalents as of March 31, 2016 totaled \$17.0 million, compared with \$5.9 million as of December 31, 2015.

-End-

About VolitionRx

VolitionRx is a life sciences company focused on developing blood-based diagnostic tests for different types of cancer. The NuQ® tests are based on the science of Nucleosomics® which is the practice of identifying and measuring nucleosomes in the bloodstream – an indication that cancer is present.

VolitionRx’s goal is to make the tests as common and simple to use, for both patients and doctors, as existing diabetic and cholesterol blood tests. VolitionRx’s research and development activities are currently centered in Belgium as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

Visit VolitionRx’s website (www.volitionrx.com) or connect with us on Twitter, LinkedIn, Facebook or YouTube.

An animation introducing VolitionRx’s Nucleosomics® technology can be found at:
<https://www.youtube.com/watch?v=38dodCpyXf0>.

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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 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

First Quarter 2016 Earnings and Business Update Conference Call

May 13, 2016

CORPORATE PARTICIPANTS

Scott Powell, *Vice President of Investor Relations*

Cameron Reynolds, *President and Chief Executive Officer*

David Kratochvil, *Chief Financial Officer and Treasurer*

CONFERENCE CALL PARTICIPANTS

Bruce Jackson, *Lake Street Capital Markets*

Brian Marckx, *Zacks Investment Research*

Yi Chen, *H.C. Wainwright*

PRESENTATION

Operator:

Good day and welcome to the VolitionRx Limited First Quarter 2016 Earnings and Business Update Conference Call. Today's conference is being recorded.

At this time, I would like to turn the conference over to Scott Powell, Vice President of Investor Relations. Please go ahead.

Scott Powell:

Thank you, Vicky, and welcome everyone to today's earnings conference call for VolitionRx Limited. This call will cover Volition's financial and operating results for the first quarter ended March 31, 2016, along with a discussion of our key upcoming 2016 and 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 of VolitionRx, and Mr. David Kratochvil, Chief Financial Officer.

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 identify forward-looking statements. These forward-looking statements relate to the effectiveness of the Company's bodily-fluid-based diagnostic tests, as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer.

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

Cameron Reynolds:

Thank you, Scott, and thank you, everyone for joining VolitionRx's first quarter 2016 earnings conference call. I would like to thank you all for taking an interest in Volition at this very exciting time for us. Firstly, I will start with a review of important Q1 events from this year. We continue to make excellent progress with our clinical trials. As a summary, we made good progress in colorectal cancer where we announced our best adenoma detection rates to-date in a targeted clinical trial of 430 patients conducted with Hvidovre Hospital and with the University of Copenhagen in Denmark. Our panel of five NuQ® biomarker assays in age-adjusted algorithm accurately detected 75% of high-risk colorectal adenomas, those most likely to become cancer, and 86% of stage 1 colorectal cancers.

Last month, we also released results from a prostate cancer study conducted in collaboration with the Surrey Cancer Research Institute at the University of Surrey in the United Kingdom. A single NuQ® biomarker assay detected 71% of early stage 1 prostate cancers at 73% specificity. This is significantly higher than the most common blood tests currently used to detect prostate cancer, the PSA, the Prostate Specific Antigen, and which is reported to detect only 53% of prostate cancers at a 73% specificity.

In addition, we also released data from our first non-cancer clinical trial in Q1. Our NuQ® blood test detected 86% of subjects with a deadly lung disease called IPF or Idiopathic Pulmonary Fibrosis. This is the first set of results from a non-cancer trial of VolitionRx's NuQ® assays, which demonstrated the technology's potential as a diagnostic test for other diseases, which was very exciting for us. Also, as of today, we have more than 50 antibody programs in development. These are monoclonal antibodies, which are a key component in our assays and our tests. A majority of the early programs have been successful and are now used in our clinical validation studies. The goal is to continue investing resources into this strategy in order to build our own proprietary antibody banks. Moreover, this will secure the supply of highly performant antibodies, which we believe will lead to more reliable clinical results and produce products further down the line.

We also made significant progress in Q1 towards the commercialization of our blood tests for colorectal and other cancers in both the U.S. and Europe.

We have made several key expansions to our team, including, in January, we announced the transition of Dr. Jason Terrell who is an MD, to be our full-time, U.S.-based Chief Medical Officer and Head of U.S. Operations. Dr. Terrell will lead our U.S. commercialization strategy for our NuQ® blood tests, including spearheading our FDA approval process and efforts.

Last month, we also announced the appointment of Louise Day as Chief Marketing and Communications Officer. Louise will lead VolitionRx's communications and develop the Company's branding and global marketing strategy in preparation for the initial market entry of our NuQ® blood tests for cancer. The Company expects to commence the European launch of our NuQ® tests in colorectal cancer in 2016, to be followed by the U.S., and the rest of the world. Both Jason and Louise are a great fit for the Company and bring tremendous experience and knowledge to our team.

On the regulatory side, VolitionRx has also received the ISO Certification EN ISO 13485:2012 for our Quality Management system for the design, development, production, and distribution of our NuQ® blood tests for a broad range of cancers. This is a significant accomplishment and a key milestone for VolitionRx, demonstrating the Company meets the international regulatory standards and strict requirements for risk management and effective processes to design, manufacture and distribute our NuQ® blood tests. This certification allows VolitionRx to continue our focused efforts for the commercialization of NuQ® cancer tests in Europe and the other major markets worldwide.

We also announced in Q1, the CE Marking of two additional NuQ® biomarker assays for the detection of colorectal cancer. NuQ®V001 and NuQ®T003, which we expect, when combined with other CE Marked biomarker assays, will comprise our first commercial blood test for colorectal cancer that will require only a single drop of blood from the patient.

Finally and also very excitingly, we completed the secondary offering of our common stock in March, issuing approximately 4.3 million new shares at \$3.25 a share, raising net cash proceeds of approximately \$12.8 million after deducting underwriting discounts, commissions, and expenses payable by us. Raymond James & Associates, Inc. acted as the sole book-running manager for the offering. This gave us a cash position of \$17 million at the end of the first quarter of 2016. This is by far the largest cash position we've ever had. We expect to use this cash primarily towards the completion of existing clinical trials, the commencement of new clinical trials, and our commercialization efforts in Europe, the U.S., and elsewhere. We are delighted to report on the current state of our finances, which include no debt and puts us in a strong position as we prepare for commercial launch of our first products.

So looking forward, the milestones for 2016 and 2017; we expect to achieve many important clinical and commercial milestones, as we have had in the last several years. Firstly, we expect CE Marks in additional colorectal assays with a full panel CE Marked and planned European launch for our blood tests at the end of this year. We expect more IP to be generated and granted in several countries as we continue to protect our proprietary technology and the shareholder value that it has the potential to generate.

Also, as announced yesterday, we are initiating a study with DKFZ, the German Cancer Research Center, to evaluate NuQ®'s blood test for the detection of pancreatic cancer. This follows the two very successful pilot studies, which showed very good detection rates using our biomarkers in pancreatic cancer. This 750-patient study has been previously collected and we expect to finish that this year. We also expect in the future, this year, to announce one or more large clinical trials in one of the cancers we've had very successful pilot studies in, and possibly perhaps add more pancreatic, lung, prostate and ovarian to support our regulatory package development following initial pilot studies.

To assist with the rollout and delivery of products, we plan to move into a much bigger dedicated lab and research facility in Belgium, in late 2016, as our current facilities are becoming far too small for our large expanding team and the large number of clinical trials and antibody programs we have underway. So that's another key milestone we aim to complete.

We also expect more preliminary results from our ongoing lung, prostate and pan-cancer trials. We also expect final results from our 4,800-patient retrospective colorectal symptomatic population by the end of this year; this trial, which we have announced interim data from last year. We also expect the first tranche of results from the prospective 14,000 colorectal screening trial, also with Hvidovre Hospital in Denmark, during the second half of this year.

We also will work a lot on our EU commercialization strategy, including upcoming milestones for the timeline for European market access and sales of NuQ® and colorectal, as it remains on track. We'll also do a lot of work on our U.S. commercialization strategy for our NuQ® blood tests for CRC including the FDA strategy this year. Importantly, we plan to submit a 510(k) application to the FDA, which, if approved, would give NuQ® marketing clearance for use as an adjunct test for colorectal cancer. Our strategy positions NuQ® for potential FDA clearance and commercial launch as early as the end of 2017.

Our 2017 milestones include the following: CE Marks for pancreatic and lung cancer in the second quarter of 2017; also, a U.S. PMA trial underway and likely see an early (inaudible); an FDA 510(k) approval for lung or pancreatic cancer as an adjunct test later in 2017. We are very excited about 2016 and we anticipate this will be the year we transition from a clinical stage Company into a commercialization stage Company with the launch of our best products.

We achieved numerous milestones this quarter, which brings us closer to commercialization, including the two new key hires, two CE Marks, the ISO Certification of our labs, the successful completion of our secondary offering in March. After that successful capitalization, we are very well capitalized, and believe that we are well positioned to execute our commercialization strategy this year.

We are proud of our clinical and commercial accomplishments of the past quarter and look forward to reaching these numerous aforementioned milestones throughout 2016 and 2017. We are particularly enthusiastic about our upcoming commercialization plans for our blood tests for colorectal cancer, which as we said, we plan to launch in Europe this year, with the CE Mark, and then hopefully in the U.S. next year with a 510(k) clearance from the FDA as an adjunct test.

It has been many years of hard work and numerous clinical trials which have now brought us, this Company, to this inflection point. I'm very proud of how our teams and executives and scientists have collaborated in order to bring our blood tests to market, which should lead to the detection of many more early stage cancers and greatly improve patient outcomes.

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

Operator:

If you would like to ask a question, please signal by pressing star, one on your telephone keypad. If you're using a speakerphone, please make sure your mute function is turned off, to allow your signal to reach our equipment. Again, press star, one to ask a question. We'll pause for just a moment to allow everyone an opportunity to signal for questions.

We'll go first to Bruce Jackson with Lake Street Capital Markets.

Bruce Jackson:

Hi, guys. Nice quarter.

Cameron Reynolds:

Thank you.

Cameron Reynolds:

Thank you, Bruce.

Bruce Jackson:

So, if we could just run through the U.S. timelines in a little bit more detail; so, tell us about the 510(k) strategy, so what's your predicate device going to be, and what gives you the confidence that a 510(k) regulatory approval is going to be acceptable to the FDA? Then, just run through the—some of the interim milestones, so when do you plan to set up the U.S. trial? When do you think you're going to be done and how long do you think this submission is going to take?

Cameron Reynolds:

Yes, very good questions Bruce. So, as I am sure you are aware, there is two ways you can get FDA approval with the 510(k), either predicates or as a de novo reclassification. So, the predicates, as I am sure you are aware in this space, possibly Epigenomics, but I think more likely what we'd go for is the de novo reclassification, which I think you are probably also familiar Vermillion has just done on their ovarian cancer test, so that's the path we're going down as an adjunct, initially. I think, obviously, we're in the process of working through the process of a PMA trial, as well. So, I think we would like to get — in colorectal, at least approved, in both aspects, but the quickest way to market would be as an adjunct symptomatic tests which is what that would be.

So, as far as timelines, we're in the process now of discussing with a range of CROs to be de novo reclassified as a 510(k). We'd need approximately 600 patients, so the amount of time to run those trials aren't very long; that kind of patient population you can collect in six months. So, if you add that on to all the other timings of setting it up and then running it and then go through the FDA process, you'd have to add on at least 12 months to that. So, I think the minimum would be somewhere in the 18 months timescale. So, I think it's something which is very worthwhile doing. I think there is a very much demand for adjunct tests in the initial sense, and certainly in the cancers we're looking at, there's a very big need in lung, pancreatic, colorectal, and prostate because none of them have, by any means, an ideal test for them.

So, whether we do PMAs in the other cancers is questionable. It depends — comes down to incidence in the population and the size of the trial you need to do with general screen so you'd probably stick in the other cancers to high-risk populations, which in lung cancer is obvious, it's higher. People who smoke, who have more than 30-pack years, who are over 55, and in pancreatic, there's a very large list of high-risk groups, but the most obvious would be those who have adult onset diabetes.

So, the strategy with all of it, you look somewhere in the — it depends on the CRO, between \$0.5 million to \$1.5 million for a study of that kind of size, for each of the cancers, and that will be data driven as we go through the trials we're in now, which ones we attempt to do first. But we can certainly do more than one concurrently, given the funding position we have. So, the trials themselves should be able to be completed in the six-month period for that number of patients, but there's at least 12 months more of other work to be done around that, before and after, any combination of before and after. So, it would need to be at least an 18-month process for each of the cancers. As I said, concurrently, we would look to do a PMA in colorectal; the other one's probably not a general screening population, but always to be a high-risk.

We've spoken to people about health economics and given the much lower incidence of cancer in, say pancreatic, we would need to be extremely accurate to do a general population screen, much more in the 97%, 98% range, which is obviously a very, very, very high bar, so I think the 510(k) would be the main push in this — we ever got to that level which is certainly not certain by any means.

Bruce Jackson:

Okay.

Cameron Reynolds:

Does that answer your question, Bruce?

Bruce Jackson:

It does and just one follow-up then. How does this dovetail with what you are doing in Europe with the two Danish studies and then setting up the algorithm? So, how close are we to actually getting the test panel that you guys want to run with in that (inaudible)?

Cameron Reynolds:

Yes, that's a good question, so as you know, we've released data with an algorithm, which gets us around 80%, 80%, which is a very good result and far more accurate than any blood tests out there. We've just been holding on because we're doing more and more assays all the time to see how much better we can get with a different panel. So, we've said we were launching this year so around the next few months, we're going to be picking the best panel we have to launch, so we're going to have it ready by the end of the year. So, we've just been testing more different assays in the symptomatic population.

The algorithm we use in Europe to launch the CE Mark for the symptomatic population would be very similar or the same as what we launch in the U.S. with the CRO trial, to be the 510(k) de novo reclassified test. The 14,000 prospective would be a European self-screening test, meaning we're directly competing with the — or comparing to the fecal tests, the FIT, not with colonoscopies.

So that would be very useful and we'd get a separate CE Mark, certainly the aim is to get a separate CE Mark to be used in that context, in the European screening sense, either — in order to replace or be complementary to a FIT test and that will obviously be data driven. So, that's the process we'll go through, the first CE Mark in symptomatic population in Europe, and then apply, use that same algorithm in the U.S. Then get a screening population in the European sense, and CE Mark that, and then go through the process of the U.S. PMA trial, attempting to get screening population in the US, but obviously that takes — as you've seen from other companies, it needs to take a long time so we start that process with everything else that's going.

Bruce Jackson:

Great, and so it's the prospective 14,000 patient study that you're going to use for the screening dedication in Europe, okay.

Cameron Reynolds:

Yes, in Europe, the screening is — the frontline screening test is very, very rare in colonoscopies so it's the U.S. self-screening population which (inaudible) did and we would need to do if we are going for the same sort of population. We, at the — certainly, at the high water mark, you need about 10,000 patients because the prevalence is about 0.5%. So, to get the 50 cancer range, you need 10,000 patients. Where in Europe, there's not the frontline screening with the colonoscopy, so what you're doing, which is what we're doing in this trial, is going head-to-head with FIT positive and FIT negatives in a very large study.

So that is an ideal study for the European screening market and so that would be a — you know, it remains to be seen how different the panels are. It could be a very similar panel to the symptomatic, it could be exactly the same, or it could be different; that'll be driven by the data.

If you notice, the antibody program — when I talk about things like the ISO Certification and the antibody program, I mean you can — it just takes 20 seconds to say it, but it's amazing amount of work the team has done, developing huge banks of monoclonal antibodies, which allow us not only to produce a much lower cost product than bought antibodies, but one which can be used forever. Once you have a monoclonal line, you can produce the antibodies forever and at a much lower cost but also secure to the Company. So, having such a large bank of monoclonal antibodies means we can very quickly adapt new panels with new antibodies, or for different cancers, or for different uses within the same cancer, different antibodies that we've developed ourselves. So, we'd have complete security over those ones we've developed and a much lower cost, and much more adaptability at testing different antibodies and producing them.

So, it's a huge outcome for us and gives us much more flexibility to move overhead (phon) because we've relied in the past on bought antibodies, which, although they can be easy to get, if they're polyclonal, the issue is then that they are not reproducible forever; once that amount is finished, it's finished, because as you probably know, they are made from mice so, we can only get so much out of a mouse.

The second, when you reproduce the polyclonal line, you've got to start from scratch with new mice so it's a whole problem. We've spent a lot of time in developing antibodies and the whole process in the laboratory so that we can be very —much more nimble, and much more broad ranging in what we do going forward.

Bruce Jackson:

All right. Well, congratulations on all the progress.

Cameron Reynolds:

Thank you. Thanks a lot. It's been a great quarter. Thank you.

Bruce Jackson:

Thank you.

Operator:

Again, press star, one to ask a question. We'll go next to Brian Marckx with Zacks Investment Research.

Brian Marckx:

Good morning, Cameron.

Cameron Reynolds:

Good morning, Brian.

Brian Marckx:

Relative to — good morning. Relative to the de novo pathway, it seems that that would certainly be appropriate, given that you're going to seek as an adjunct. But, have you had specific discussions with FDA and has FDA given you the green light that de novo is appropriate?

Cameron Reynolds:

No, we haven't started those discussions. Basically, we wanted to make sure we went to them fully armed because, I mean, there's certainly precedent. As I mentioned, Vermillion is a very good example where exactly this kind of panel has been used in de novo reclassification. But, we want to make sure we go fully armed with all the trial results and the CE Mark process being completed or very close to it. I mean, in every single cancer, I'm sure you are aware there's currently a test or a blood test and using an adjunct forward is a very good way to get into the market very quickly and very successfully.

If you look at something — if you look at each one of the cancers, so colorectal has older existing markers, things like CEA; for pancreatic, there is CA19-9; obviously in colorectal, there's also the fecal tests; in ovarian, there's CA-125. In every cancer, there's some sort of process involved, and this has actually been a big influence of Dr. Terrell, who's actually an MD, not a PhD, like the rest of our doctors. His very strong advice is — doctors are very keen to get more information, and it's a much lower marketing hurdle to be sold with what's currently there, but this is a brand new test. I mean I think our tests are fantastic and incredibly revolutionary, but the safest and easiest way to get to the market is to be an adjunct to whatever's there.

If we can show that ours (inaudible) existing test is more accurate and I think that's exactly what we are doing, if you look at our test trials, then it's a real no-brainer for the doctor. If you're a doctor, Brian, and our tests, say, for example, pancreatic, where we've shown where we add existing biomarker to ours, it's incredibly accurate. I don't see why any doctor wouldn't be prescribing our test in conjunction and I think it's quite a very solid (phon) story to take the FDA. But as you know, there's nothing certain with the FDA, you've also got to go through the process, but I think it makes a tremendous amount of sense why low-cost blood test as an adjunct is certainly almost a no-brainer for physicians. I think that's a process we can get through with the FDA, for all the reasons which they normally approve things; it's more accurate, it's very cost effective, very high compliance. I'd really struggle to see why they'd have any issue with it.

You cannot predict what the FDA is going to do so what we can do is build a very, very strong case and take it to them. We are seeking very good advice. We will be setting up a meeting as soon as the panel has been chosen. We went through that process for each of the cancers, but we wanted to be very certain that we had it all lined up and a very, very strong argument to take to them. I think you can — as they say, you only get one chance to make a first impression. We want to make sure we go in very strong and very hard when we have it all together, rather than sort of an ongoing process, which we have now, but it's something we are putting together, a very strong package for now and we aim to start those meetings this year, obviously, to get the process started for next year. We started the process now of getting quotes from CROs for these trials, for the FDA trials, so it's all coming together.

Dr. Terrell has been working extremely hard over the last few months, working on the FDA strategy and the CROs, as we have been working very hard on getting the trials finished in Europe, so that we can pick the panel for those cancers. As you can see, we're starting up bigger trials now. As of yesterday, we've just signed up the large pancreatic trial and 750 patients is a very big trial in pancreatic; it's 300 pancreatic patients in there, cancer patients. So, it's a big one. So, all the time we're gathering more and more data.

But, just as an order of magnitude, I think if you've seen in our presentations, adjunct tests or tests which aren't approved for screening processes can still be a massive seller. If you look at CA19-9, it's predicted there'll be 46 million sold in two years' time, every year in just the top five countries, 46 million tests prescribed. So, it's potentially a massive market as an adjunct test in the meantime while we're in the process of the colorectal PMA, and I think each of those markets is potentially as big as CA19-9 or the other ones. So, it's a strategy we're very happy with and very committed to, but ultimately we'll really (phon) know exactly what the FDA is going to think once we've got everything together and taken to them. We're planning on doing that a bit later this year.

Brian Marckx:

Okay. On the new pancreatic cancer study that you just announced, will that be using any or all of the assays that were in the two pilot studies? Will it be using any more additional assays other than that and will it also be incorporating the CA19-9?

Cameron Reynolds:

Yes, we aim to use the ones which were so successful in the other clinical trials, as well as some new ones. As you have seen from our clinical trials, we're getting better and better at picking the best biomarkers within our IP. I think you probably remember, but there's thought to be around or more than a thousand biomarkers on the nucleosome and we've only tried 28 in clinical trials so far and we're finding actually some very good ones now, in addition to the ones we've been using. So, that's the process, and yes, we aim— there's typically, in any pancreatic study, the pancreatic patients do have CA19-9 performed on them. I guess that's why there's 42 million done every year. So we'll do some ourselves and take some of the existing data.

So, the short answer is yes, we will use CA19-9; yes, we'll use all the ones that worked so well in the pilot studies; and yes, we will look to do some of the new ones, which is why, if you noticed, we've got 50 antibody programs underway and we're adding at least four or five every month now. So, we're going to have a massive bank of antibodies, and we actually aim to get to well into the hundreds in a few years, which will give us a very unique asset and a very unique library.

That, on top of our IP, on top of all the clinical trials, and our knowledge will put us in an incredibly strong position to really dominate this entire field, so that when we look at a new cancer or when something new comes up, we can either use the existing antibodies we have, very well defined monoclonal lines, or we can develop a new one through the processes we have to target that one, whatever the new structure is to add to our panels.

Going forward, the clinical trials, what we do prospectively, we're going to be collecting quite a bit more serum or plasma than we have been, so that when we do get new biomarkers, we can test it on the population very quickly. So, everything is getting a lot quicker and easier in what we do, as we develop a lot of knowledge in this field, a unique knowledge because we're still not aware of anyone who's done any real work in this except us. On top of all the other things we do, it should give us, if we play our cards right, an extremely dominant position in this whole field going forward.

Brian Marckx:

When do you expect you will have at least some preliminary data on the 750 pancreatic study?

Cameron Reynolds:

They're already collected. So, I would be very surprised if it wasn't this year. It's going to be quick. Don't forget, we're also getting the pan cancer study started — the processing. So, we'll have data in 27 cancers by this time next year, in about 20, 25 different biomarkers. So, we're developing a lot of information very, very quickly. So, expect to see pancreatic. Now, if that goes well, there's absolutely no reason we can't launch in Europe next year in pancreatic, and again, it's very hard to tell what the FDA are going to do, but where there's such an unbelievable need as in pancreatic cancer and you have something — if it does continue to go anywhere near as well as the pilot study, than these studies, I think we could do a U.S. trial pretty quickly, given the small number of patients in it and the high risk population, to get to market. I think, I would imagine the FDA would be very helpful with that. If the tests are going as well as they look to be going, it would tremendously help patients. So, I wouldn't expect that much resistance from the FDA.

Colorectal is a little different because it's quite a crowded market; there is a lot of things out there, obviously Exact and Epigenomics and existing biomarkers in colonoscopy, and all the fecal tests; where in lung and pancreatic, there really isn't much. So, I would expect, I guess, we will find out when — once we get through, finished through the process, but I would expect quite a bit of support, especially from key opinion leaders, as well, because they're really quite deadly cancers.

Brian Marckx:

Great. Thanks, Cameron.

Cameron Reynolds:

Thank you, Brian.

Operator:

We'll go next to Yi Chen with H.C. Wainwright.

Yi Chen:

Thank you for taking my — hi, good morning. Thank you for taking my question. My question is: how large a sales team do you think you would need to market the colorectal test in the U.S. versus in putting efforts in Europe?

Cameron Reynolds:

Yes, that's a very good question. So, basically I'll just go through Europe and the U.S. and contrast them. Europe is 28 countries, 31, 32, if you include some of the other ones like Turkey and Lichtenstein and each one's a bit different. So, we're targeting the bigger countries first where we have home advantage, obviously England. Louise Day, our new Communications and Marketing Director is very knowledgeable about the FDA, and as are some of our team because they've been working in England, so there is some really good, strong, local advantage. We've been working with the Decideum consultants now for a long time. We also have — so that would be a very obvious one to start and that's what we are doing a lot of work in now.

We obviously have a good home advantage in Belgium, as well, particularly the French (phon) area. We've been very strongly supported by the government there, and we've been working through that process. We've done large trials in Denmark and Germany now, so those countries. It comes down to more than a sales force; ultimately the government is 80%, 90% of the market in all the European countries. So, it's a matter of convincing the processes of the reimbursement or insurance for the government programs.

So, it's not like exactly you need a large sales force in Europe because you are not selling directly to doctors. You are sort of keeping this, ultimately, the big — it's more of a lobbying role, if you will. There is a private payer market in Europe, but it's typically in single-digits of the entire market in each country. So, it's much more of a few key people are lobbying in the European countries. So, we'll start with those countries and then roll it out, so we do not need a large footprint in Europe.

Also, I think a recalibration of what most people would think, when you are — I'm not exactly sure of the Exact price, but from what I understand \$599 or thereabouts and it's a separate system of analysis. You need a whole separate biosphere for the product where, when you are a blood test which is very easy to run and part of your normal blood work, you don't need that whole separate sales network and supply network for the product. So, I don't see ourselves ever needing anywhere near the kind of sales force; there are a lot of other (inaudible). I think as we get into the normal (inaudible) procedure, (inaudible) quite a lot below \$100, that means you can really be part of the normal biosphere of how tests are provided.

So, for all those reasons—now it's part of this large (phon) fund raise — we've also negotiated with Cosmo Pharmaceuticals who are launching two of their own products in U.S., in the colorectal space, not directly diagnostic, but in the colorectal space where they have a right to negotiate with us, help us launch in the U.S., as well. They're a multibillion dollar company and looking to launch their own product. So, we'll be utilizing them, hopefully, if we can come to good terms with them as per the agreement. We'll always look to license to the bigger diagnostic companies and their auto analyzing machine; Roche, Abbott, Siemens.

So, what we look to do is, in different markets, really approach in different ways; some direct marketing, some through some product sales, some through— for example in France, is one centralized company that's been given the government programs to negotiate with them. So to my mind, in Europe and in some extent, the U.S., it's much more— some key regulatory and key opinion leaders to develop the demand for the product through the key opinion leaders and the doctors, and then making sure it's provided, by getting reimbursed and through the process including the large companies, on their large auto analyzer machines.

So, none of that requires sales forces in the hundreds; it's a matter of hiring key people and key people to negotiate all those agreements, which is what we've been doing in Europe now with, as you've seen, we've added a few key people in this quarter and we'll continue to add key people as we roll out in those markets.

Yi Chen:

Okay, thank you very much.

Cameron Reynolds:

Thank you.

Operator:

Again, press star, one to ask a question. We have no more questions at this time. So, I'll turn the call back over to our speakers for any additional or closing remarks.

Cameron Reynolds:

Okay. Thank you, Vicky, and thank you everyone for joining us today for VolitionRx's first quarter 2016 earnings conference call. We really appreciate your interest in us and look forward to speaking to you again in the near future, and reporting our next results for the second quarter of 2016. Thank you. Good morning. Goodbye.

Operator:

That does conclude today's conference. We thank you for your participation.