UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **November 4, 2015**

VolitionRx Limited

(Exact name of registrant as specified in its charter)

Delaware	**000-30402**	**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)

Telephone: +1 (646) 650-1351
Facsimile: +32 8172 5651
(Registrant's Telephone and Facsimile Number)

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 Exhibit 99.1, is being "furnished" in accordance with General Instruction B.2. of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing:

As previously announced, on November 4, 2015, VolitionRx Limited hosted a conference call discussing its financial results for the quarter ended September 30, 2015. The conference call was announced by a widely disseminated press release and was made available to the public via audio webcast. Furnished herewith as Exhibit 99.1 and incorporated by reference herein is a copy of the transcript of the conference call.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Transcript of Conference Call held on November 4, 2015.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VOLITIONRX LIMITED

Date: November 10, 2015

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

EXHIBIT INDEX

Exhibit Number	**Description**
99.1	Transcript of Conference Call held on November 4, 2015.

VolitionRx Limited

Third Quarter 2015 Financial Earnings and Business Update Conference Call

November 4, 2015

CORPORATE PARTICIPANTS

Scott Powell, *Director of Investor Relations*

Cameron Reynolds, *President and Chief Executive Officer*

CONFERENCE CALL PARTICIPANTS

Bruce Jackson, *Lake Street Capital Markets*

Brian Marckx, *Zacks Investment Research*

Jan Wald, *The Benchmark Company*

PRESENTATION

Operator:

Good day everyone and welcome to the VolitionRx Limited's Third Quarter 2015 Earnings and Business Update Conference Call. Today's conference is being recorded.

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

Scott Powell:

Thank you, Operator and welcome everyone to today's earnings conference call for VolitionRx Limited. This call will cover Volition's financial and operating results for the three months ended September 30, 2015, along with a discussion of our key upcoming 2015 and 2016 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 VolitionRx.

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 27-A of the Securities Act of 1933 as amended, and Section 21-E 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, speaks, 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.

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 on 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.

I'd now like to turn the call over to our Chief Executive Officer, Mr. Cameron Reynolds, who will discuss the third quarter of 2015 and our clinical and operational objectives for the remainder of the year. Cameron?

Cameron Reynolds:

Thank you, Scott and thank you everyone for joining VolitionRx's Third Quarter Earnings Conference Call for 2015. I'd like to thank you all very much for taking an interest in the Company at this very exciting time for us. I would like to start just with a brief review of the accounts. They obviously have been published so you can follow (phon), so you can get the full details online.

But the key details; we ended the quarter with $6.85 million in cash as opposed to $2.14 million as at December 31, 2014 and you'll also notice there were two exercising the warrants post-balance sheets which was not included in the cash of $880,000 which further strengthens our balance sheet.

As you can see from the accounts, we've stayed on target. We've kept the finances very tight and focused particularly considering all the list of things I am about to go through, we've achieved. I can assure you we value every dollar and we spend them as carefully as possible to deliver the results which will hopefully drive the Company forward.

So I'll next move to review of the important events of Q3 and I think we've been making great progress and I think it really occurred to me at our Science Advisory Board meeting last week which had 17 attendees including the key Team Members from Volition and several new members we announced a few months ago; including Dr. Reis-Filho, who is a pathologist, experimental pathologist, at the Memorial Sloan Kettering Cancer Center, who is a breast cancer specialist; Dr. Ronald Anderson from Lund University who we worked with very closely, who is a pancreatic specialist; and Stuart Blincko who now works for Immucor but in his previous role was a Senior Principle Research Scientist at Abbot Laboratories.

They joined our existing SAB Members and Team to go through the opportunities forward in different cancers as well as go through our clinical achievements and it was extremely encouraging to see such an eminent group together discussing our technology in the best ways forwards for a very, very full day last week.

So I'll go through the list of things that we have achieved. I think it's a very, very impressive list. I'll start with the Danish work. We released the interim data from the 4,800 Retrospective Colorectal Study with Hvidovre Hospital in Copenhagen as well as with six collaborating other hospitals. Just to remind you, this is a double-blinded, randomized and independent trial with a truly world-class collaborator. We very much like Denmark because of their thoroughness, their professionalism, and the collaborator we work with, Dr. Nielsen, who has been a fantastic collaborator and being Denmark, you have a full electronic database of every single citizen. So it's a fantastic trial and one which has been very useful to us.

So the results; as announced, we detected 81% of the cancers and very importantly we detected equally well for both early and late-stage cancers. As I am sure you're all aware, early-stage cancer is the key and we are very encouraged that our assays were detecting very well early cancers, and on that continuum, we also detected 67% of High Risk Adenomas which are the pre-cancers and the most likely to become cancerous. The best way of looking at this is if you can find them and remove them, you get ahead of the curve. Most adenoma, the polyps, do not become cancer but it's almost fair to say, every single cancer starts as a polyp. So to be detecting that many of them is very, very encouraging and we're continuing to doing more work to see how early we can get the cancers even in the pre-cancer.

So these results demonstrate the NuQ® Test's potential to detect cancers over the complete spectrum of development from adenomas or polyp, to early through late-stage cancers. A function of this trial is to best optimize the composition of a panel of four to six of our biomarker assays that will form the basis of the tests that we feel comfortable commercializing.

The interim data was the panel of four of our biomarker assays from the nine assays which we ran in this population of the 4,800 up until the announcements and we are working on 11 more biomarker assays through the same population to be released in the first half of this coming year in 2016. The final results will allow us hopefully to find a final panel to launch in Europe with the most accurate rates we can for detection of early and late-stage cancer as well as polyps. So that was key milestone number one.

Key milestone number two: with the granting of our first US patent which was for the detection of Histone Modifications in Cell-Free Nucleosomes in the US. Patents, as you're probably aware, are very important to protect shareholder value and the large amount of effort everyone has put in. I would like to take this opportunity to congratulate Dr. Micallef on his wonderful job as Chief Scientific Officer, implementing the total suite of patents which he has.

This patent is one of the most important key pieces of IP the Company has. It's a broad-reaching, wholly-owned, and royalty-free patent that expires in mid 2029. It relates to the detection of epigenetic changes that affect chromosome structures in cancer by means of our simple test using a single drop of blood. The patent is already issued in Europe and this was the US patent. We expect more patents to be granted now in the coming quarters as our IP strategy continues to develop and strengthen. We have come across no competing or even similar IP which we believe gives us a very large freedom to operate and patent protection for our Investors and Stakeholders.

The third very, very key milestone this quarter was the granting of our first CE Mark for the detection of colorectal cancer and I would like to thank the entire Belgian (phon) Team and Dr. Micallef for the great work in bringing this key milestone to fruition.

What does this mean practically? It means we can now sell this biomarker assay clinically in Europe which is 28 member states as well as a few smaller ones and bigger ones, Switzerland, Turkey, Iceland, and Norway, and Liechtenstein, with a total population of nearly 600 million people and more importantly, 150 million people of screening age, typically those between 50 and 75. We expect to have additional CE Marks on further assays, biomarker assays, and to launch the panel for the CE Marked assays for clinical use in Europe and the entire panel during 2016.

The next very key milestone this last quarter was our first publication. The publication authored primarily by Lund University, Dr. Anderson's Team, another key collaborator and he'll become more important to us as we continue to expand our pancreatic work into larger and larger trials, and it was published in the journal called Clinical Epigenetics last month.

This is yet another key milestone achieved last quarter and a very big validation of what we do. It was authored by a world class team from Lund University who are experts in pancreatic cancer and it announced that when added to another classical biomarker, CA19-9 to four of our biomarkers, increased our sensitivity, meaning percentage of cancers, from 84% to 92%. So that was even better than we had previously announced about a year ago. This was a first peer-reviewed validation of VolitionRx's panel approach to diagnostic test development

I'd like to thank again the entire Team and Dr. Anderson in particular.

Also we had more results in pancreatic cancer from our second preliminary study which included 20 pancreatic patients and used a two assay biomarker panel plus another classical biomarker CEA. Just for the background, what trial was this? This was 20 cancers in the 4,800 person trial and there were 20 pancreatic cancers in the colorectal trial just as another coincidence but in 4,800 people, there are obviously going to be some people with pancreatic cancer at that age and there were 20 of them which we detected 19, which is also incredibly encouraging that we have something which perhaps we can, we will trial on larger trials with the aim of launching.

These all makes pancreatic by far the most likely candidate for our second product launch right behind colorectal given the results of over 90% detection in these two smaller trials and leads us to very actively be seeking now larger trials which we hope to announce in the coming quarter or two.

Also another very key milestone we appointed this quarter, we appointed David Kratochvil as a full time US-based CFO for Volition to support our growing Company, enhance our Executive Team, and lead the Company's financial strategy as we move in to commercialization of our NuQ® Tests. David brings more than 28 years of broad financial sector experience and leadership to his role in VolitionRx. I think it was very much time we had a US-based and experienced CFO given our listing on the New York Stock Exchange as well as a need now for a very good ongoing projections as well as at some stage, guidance once we get in to the product ranges so that we can have very, very robust financial statements and forward looking statements so far as income in the coming years, as we roll out products in different companies with the aim of doing all of that. So David will be very key in all of that and I am very happy to have him on our Team.

So as you can see, we had yet another very, very busy quarter and we expect the following quarters to be equally busy if not more. The Teams are working very well together and the process is all gaining speed as we get larger and larger trials completed in different cancers.

Just a brief summary of what we would expect to see in late this year and early 2016. As I discussed, further CE Marks on our additional CRC assays, with a full panel and European launch next year, and additional patents granted in United States and elsewhere.

As we continue to protect shareholder value, we expect to announce one or more large clinical trials in pancreatic cancer, the starting of them and we expect results from ongoing lung and prostate trials soon. That's this quarter or early next quarter, the first and perhaps two or three of these results in the next two quarters.

We've also got a lot of work coming through from other Danish trials. We have the 800 person Adenoma Study which would expect results in the next few quarters as well as the first tranch from the very large prospective population from Denmark of the 14,000 patients, the first batch of 2,500 or 5,000 in the next quarter or two. Also we hope to develop our EU commercialization strategy further, including upcoming milestones and timelines for European live access and sales of NuQ® for CRC as we continue to broaden our strategy and implement the implementation of our tests in Europe. We also aim to make more movement towards US commercialization strategy including with the FDA and a firm CLIA Lab strategy.

For background, we think our Danish trials are very large and world class being about 18,800 patients in total, including the Adenoma Study of about 19,600. But we do expect to need to do some US work as well for the FDA. So we plan to initiate a bridging US FDA endorsed trial with our ongoing large trials in Europe which will be designed to provide the clinical data in a patient population representative of US ethnicity, which means basically similar ethnic diversity to the United States to support a PMA submission for the potential FDA approval of our tests for the early detection of colorectal cancer.

In parallel to the FDA, we aim to license our Nucleosomics® biomarker panels in the United States to CLIA Labs for development as a lab developed test in 2016 and provide VolitionRx with early revenue while proceeding with the FDA process.

In conclusion, we absolutely believe that our blood and other bodily fluids offer the best platform through which to screen for cancer because our tests our non-invasive, convenient, and have the opportunity for high compliance versus other complicated, unpleasant, and/or invasive tests, which often also require separate doctor visits and/or advanced preparatory work such as a colonoscopy, x-ray, or biopsy. Blood tests also tend to be quick and ours require just a fraction of a drop of blood which would allow our NuQ® Test to be administered during regular screened blood draws and tested on the commonly used ELISA platform. Our blood tests for a variety of cancers are proving to be accurate, cost effective, convenient, and rapid throughput, with the ability to detect early-stage cancers which are still operable thereby giving much better patient outcomes.

We are very excited about Volition's current status, clinically, commercially, and financially, and we look forward to delivering on these numerous milestones through the remainder of 2015 and 2016 as I believe we have done very well in the past four years. We also have an active upcoming Investor Relations and market awareness calendar and we'll be announcing our participation at several conferences soon.

Thank you all very much for your interest in Volition and joining our third quarter earnings call. We would like to now open up for any questions and I would like to thank you all for taking an interest as it is a start. We certainly wouldn't be where we are today date without our Team Members, our Collaborators and all of you for taking an interest in Volition.

Thank you.

Operator:

Thank you. If you would like to signal to ask a question please do so by pressing star, one on your touch tone phone. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again that's star, one for any questions and we'll pause for a moment allowing everybody the opportunity to signal.

We'll take our first question today from Bruce Jackson with Lake Street Capital Markets.

Bruce Jackson:

Hi, guys. Nice quarter.

Cameron Reynolds:

Thank you, Bruce. Yes it was.

Bruce Jackson:

So my, my first question is around the Colorectal Cancer Trial. When you put out the press release about the pancreatic test being done on the colon cancer patient population at Hvidovre, you mentioned that you ran the test with a CEA in addition of some of the Nucleosomic tests, is that something that you're contemplating for the final colorectal cancer testing panel for conclusion?

Cameron Reynolds:

Yes. So I answer one at a time or do you have other questions—or you said you have several questions…

Bruce Jackson:

I have one follow-up.

Cameron Reynolds:

I think our tests have been performing very well but in pretty much every cancer there is an existing biomarker that hasn't quite made it but does provide some good discrimination. I think you're probably familiar with them if you are scientifically minded like yourself, Bruce, but things which are very much off patent and very low cost. So similarly our tests, so far as they are ELISA based, very easy to run, very low cost. Obviously we have very strong IP–we feel we have strong IP, and just the ones which we are now using just because it's very simple to do, ones in different cancers, in pancreatic CA19-9, CEA, the PSA, we're looking in our prostate trials as well.

Because ultimately if another test is low cost and gives us a little extra discrimination then I think it's a very wise thing to use and ultimately I think clinicians are quite naturally quite conservative so they often feel more comfortable if you're doing it in conjunction with the tests which they currently administer now. I am sure you are also aware that there are no blood tests in common screening use except for the PSA for prostate. So none of these are really made it by themselves but they're looking for quite different things to us typically. So we think and we have been advised–actually it was a strong point at the Science Advisory Board meeting last week–they said clinically it's a very good idea to, if you can use some of these very low cost additions to your panels, then certainly use them particularly if it does give you a little–which these both CEA and CA19-9 have done in different trials.

So I think it's a very good strategy and it's one which will be—where there is a very simple low cost biomarker that hasn't quite made it by itself where we can co-opt it without anyone else's IP we're certainly using them.

Bruce Jackson:

Okay, that's great. Next question is can you just kind of tell us a little bit—in a little bit more detail how things might unfold in 2016. So you are going to have publication of your—are you going to have release of your trial results from Hvidovre study. Then you're going to set the panel that you're going to go to market with, how long you think those things might take in and from the time that we get the data to time that you have a commercialized test available.

Cameron Reynolds:

Yes, very good question, Bruce. Basically, we aim to have the panel—certainly this panel finalized by around the middle of the year but as I am sure you remember, there are thousands of potential biomarkers under our IP which is very unique for a Company to have this much—a richness of options but we decided when we have a panel that's good enough to launch we will launch it and while we continue to develop other biomarkers, which we can do very easily on our panel, because we have such a small amount of blood in the trials but we aim to have it ready then and launch next year.

Now that does not mean year one you have 10 million units in sales. Obviously it takes time to ramp up sales and launch in Europe but we aim to launch next year and then spend a good part of 2017 gaining traction. As we discussed before, we're looking to launch in a couple of countries, probably two or three in Europe. There are 29 EU countries now and a lot of them do not have screening programs and they are all supposed to, but we're a small company and any one country is a very important step given our small size of the Company and what we can do. Launching in a couple of countries is an enough work to start with and then we'd roll out continually more countries if it continues to go well in '18, '19 and '20.

But the short answer is, the panel is ready for launch, we're CE Marking each individual assay and we'll CE Mark the panel. The volumes of production we're talking now are externally manufactured in a facility that can produce more than that for us. So there is no scaling up issues from that technical side. The main thing is sales and marketing, but in Europe, it's not the same as the US where you're selling to hundreds of thousands of Doctors. You are also (inaudible) on this national screening programs, you'd be selling to the one group, the government programs as the big group. So it's a different marketing operation to what it is in US but we aim to start that process next year and start to get traction in 2017.

Bruce Jackson:

Okay great. Thanks for taking my questions.

Cameron Reynolds:

Thank you Bruce, have a good day.

Operator:

We'll take our next question from Brian Marckx with Zacks Investment Research.

Brian Marckx:

Good morning, guys. Just the first quick one on the financials. It looks like R&D jumped quite a bit based on the purchase of antibodies and other test related supplies and ingredients. Can you give me a little kind of guess sort of a forecast whether R&D will —is expected to stay sort of at these levels or is this kind of just a bulk purchase that will, I guess, be used for the remainder of the big studies that you've got there in Denmark?

Cameron Reynolds:

Yes. Thanks, Brian. Basically we've stuck to our financial projections and there were some big purchases as our IPO was in Q1. We upscaled which I described two quarters ago, I think, to a much larger production facility and as you said many more antibodies. So as lot of those costs are one-offs and a lot of them are—some of them are continuing when we have about ten trials underway including the ones I mentioned. So there are some continuing costs which–while they're a bit lumpy but in a month-by-month—but we've been burning—if you sort of harmonize it over the period about $750,000 a month and it's a little modular. We can spend more or less depending on what trials we want to do.

It's not like a lot of companies where you have to spend a huge amount of money on one trial because it is what it is. Our trials are every cost effective and kind of modular, we can speed up others or do others or slow them down. But I think what we're spending now is expected to be roughly what we are doing for the remainder of this year and the first few quarters. Now as you said we can turn the whip down or turn it up depending on what we want to be doing but I'd expect to see roughly similar amounts of funding over the next few quarters as we have done the last few quarters, spending in the last few quarters.

Brian Marckx:

Okay. Relative to the timing of the release of the full data of the 4800 retro study and then the prospective study, it sounds like maybe though that timing has slipped by a little bit based on your prepared remarks, do you expect the 4800 full data in Q1 now or is that maybe a Q2 and on the prospective study, is that the Q1 still?

Cameron Reynolds:

Yes. Brian, I think we have tried to be conservative. I think if you remember the last earnings call in August, I predicated, maybe October, November for the interim results and actually turned out to be in September. So it's a little dependent on the trial, sometimes we're a little early, sometimes we're a little late. I'd expect both of them to be in the first half.

Now that—we could be surprised on the early side like we were last time. As I said in the August earnings call, I predicted by the end of year, and it was September, early September, and sometimes we've been a little late but it'll be sometime in those two quarters. It's hard to say exactly. It's driven a lot by the process and you have to get some antibodies developed and then other processes, but broadly in Q1 and Q2, both of those will be completed and released we think.

There is a lot other things going on as you saw it. We're expecting some data from some prostate trials, a lung trial, we except to announce a big pancreatic trial and further CE Marks, further patents. All the things are progressing. So there's plenty of news. I couldn't give an exact sort of month or quarter depending on how it goes but we're expecting the first half of the year for both of those.

Brian Marckx:

Okay, so the—I think you said you had nine or ten assays, additional assays that are being used in the retro study. Are all those also being used in the prospective study and do you need the topline data from the prospective study to put together the full panel, the full initial panel?

Cameron Reynolds:

Yes. We're doing all the assays. There is going to be more done in the prospective than the retrospective purely because we have more samples. We've got a lot more sample in the prospective because we got the 4,800, if you remember correctly, for free. So there was enough just under around 20 assays, biomarker assays, or a little under, where we're getting a lot more prospectively so we can do a lot more assays.

So we—a lot of that is data driven. We will launch the panel when we're happy with the results. Now we launched—we announced in September because we were happy with the 81% we had. We're continuing to do more assays in the prospective and the retrospective. So what the final panel looks like could be dependent on a bit of both. It just comes down to that's going to be data driven but we are very keen to launch. So why I am not 100% certain is it comes down to the results if we are getting better results from these new assays, we could launch earlier. If we think there's some really good ones to go that we haven't quite completed, we'll complete them before we launch.

But the prospective one will become the big trial because not only do we have a lot more patients, we also have a lot more sample. So we can do a lot more assays through these. As you remember, there are dozens of biomarkers which have been shown to be different in different diseases including cancer and there hundreds if not thousands of different biomarkers under our IP. So this could be a process which we can continue to optimize for long period of time but I think it's very important when we are very happy with the panel we have and then I think where we are is a very good start. We are very keen to launch.

Brian Marckx:

For the pancreatic cancer, what are your thoughts in terms of—what do you think in terms of studies? Is it one or two big studies which could support an eventual regulatory summation or do you need to do may be one or two smaller studies first to kind of flush out more of the data.

Cameron Reynolds:

Yes, very good question. I think the data we have has been extremely compelling to have two different entirely different populations with over 90% detection, is really good. I think a population, that ones we are seeking out—we don't believe for regulatory purposes you'll need to do anything the size of the ones we're doing in Denmark in the 19,000 to 20,000-patient range, simply not needed in pancreatic because—also because you would not be starting with a population screen unless you're very, very, very accurate which we're accurate but not at the necessary levels to screen every single citizen. So we're looking for trial of about 300 cancer patients and maybe 400 or 500 other controls.

We believe that would be enough to get us the regulatory approval in Europe if it is anywhere near as accurate as we've been getting. I think it would give us a good shot at the US process as well because currently the diagnostics for pancreatic cancers, as I am sure you're aware, are pretty dire and the only blood marker is CA19-9 which we're considerably better than in the trials we've done. So I would see the regulatory process being a considerably easy one to get a product launched but not necessarily as an ultimate screening test because—for everybody, because of the low incidence, but certainly an important test, quite quickly behind the colorectal. And just for the order of magnitude of the size of the market and we've done research and there are about 46 million CA19-9 tests performed every year, 46 million. So it's, even for a biomarker such as that which is far from ideal, it's a large market if you can get it out there as a blood test.

So we are very excited about the pancreatic. We are actively negotiating some larger trials and I think—we estimate you don't know the regulatory authorities till you really got there but I would estimate that they would be big enough for product launch and something we're very excited about and we're putting a lot of our energy into.

Brian Marckx:

Great. Thanks Cameron.

Cameron Reynolds:

Thank you, Brian.

Operator:

Just as a reminder, if you would like to ask a question please press star, one and we'll go next to Jan Wald with Benchmark.

Jan Wald:

Hi. Good morning, Cameron and congratulations on the milestones that you have achieved.

Cameron Reynolds:

Thank you.

Jan Wald:

I guess a bunch of, a bunch of my questions have been asked but I guess maybe a little bit more on the prospective trial for colorectal cancer. That's a large trial, you're going to get a lot of data from that. How are you going to use that data except as a mechanism to improve the assays? Is that going to be part of a clinical–is that going to be part of the submission, perhaps you know part of the FDA submission or what?

Cameron Reynolds:

Yes. That's a very good question. I think the trial that size has to form a part of your submission if you have done 14,000 patients and if the results are as good as we hope, I think it'll form a part of it. Now what the FDA will require exactly we are in the process of working through those thoughts now. As we talked about I think they'll want a US ethnic population mix trial as well. But the 14,000 if you look at what the FDA have discussed in other companies in the recent past, like Preventative Services Task Force. They really are comparing to FIT, the other fecal test and this is essentially what this trial is, there's 8000 FIT positives and 6000 FIT negatives.

This is—FIT is the fecal test used in the majority of the world and what this (inaudible), so we'll have direct results comparing ourselves to the most widely test used in the world by far, the Fecal Immune Test, direct head to head in 14,000 patients. So it'll give us a tremendous guide—well, compared to colonoscopy as well. So it'll be a mountain of data with a very large amount of sample size that we can do a lot of, of our biomarkers in this population and it will give us a direct head to head with colonoscopy and the FIT test which is the overwhelmingly dominant test currently used worldwide, not in the US as much. Colonoscopy is obviously a very important part but worldwide the FIT is the key test.

If you look at a lot of the recommendations from the US groups, they do compare companies to the FIT a lot. So it'll give us very, very good information on that. The 6,000 FIT negatives are about as close to an ideal control group as you'll be able to get. We estimate there will be less than 12 cancers in that 6,000 colorectal cancers. So it'll be a very-very interesting trial not only running all of our biomarkers that we have through a large population and lot more of the biomarkers also, being Denmark, we have a lot of data points on these patients for all the other co-morbidity—the other sicknesses, the other cancers. It's going to be a very, very exciting trial.

As we've talked about before, we have the first large amount of sample, the 250,000 patients worth. We're running assays now. We've run quite few through this population and we'll continue to run them through with the aim of releasing the data in the first half of next year. But I think it's a very exciting trial, the Danes have been fantastic collaborators and we're really eager to see the results. But as I discussed, there's probably other work we need to do for US FDA. I can't say to speak to exactly what they will want but we are preparing a submission and a case to what will be in there. But you would have to think 18,800 patients between the two trials and 19,600 patients if you include the Adenoma trial would have to be at least a strong part of the submission if it is good compelling data.

Jan Wald:

So Cameron, just so I have a clear understanding. The assays you're using, there's no way to compare the two trials, the 4800 patient trial and 14,000 patient trial because you are trying different assays and different things in both trials and you are going to come out with a panel as a result of both of those trials but there is going to be no way to—there is no comparison between those?

Cameron Reynolds:

There is a comparison. We intend—we haven't run the same ones, a lot of the ones we have run are the same, some are not, but the aim is to certainly have run all the biomarkers through the large prospective that we did through the large retrospective. It's just we haven't finished that yet because there were different ones doing at different times. But to be clear the—when we finished the 18, 21 we are doing in this 4,800, we will run them all through the prospective as well.

So we'll be able to see slightly–perhaps similar results, perhaps slightly different, we are not sure between the two populations and the most interesting thing I think from our point of view is the symptomatic population doesn't have any true healthies (phon) because they are all people who've had a colonoscopy for a reason. So they typically have to have something wrong with you either losing weight or bleeding, those kind of things.

So you're not truly healthy. The 6000 of the FIT negatives in the prospective trial will be the first time we've had a really good control of healthies, as heathy as you can in this kind of population. So for all those reasons I think it will be an important part and they will tell us very interesting things if there are any differences between the symptomatic and the screening population, we'll know. So I think there will be something quite a lot to gain from the comparing the data from both those trails.

Jan Wald:

Okay and I guess my last question is, you mentioned the CLIA strategy. Is there any more detail you can give us on where you are in that process?

Cameron Reynolds:

Yes. We've been actively seeking partners. For those listeners who are not familiar with the US system, you can license to a licensed laboratory in the US to market to get their versions of your tests and we are in active discussions with several groups but nothing more I can announce right now. But our aim has been and still is to launch in the United States in a CLIA Lab in 2016 as license to a lab which launches as a lab developed test. There is nothing more to announce just that we are in active discussions with a couple of groups and we think we can stick to that time frame.

Jan Wald:

Okay, well. Thank you very much and again congratulations on the quarter.

Cameron Reynolds:

Thank you for your interest, Jan.

Operator:

Just as a final reminder, it is star, one if you would like to ask a question. Gentlemen it appears we have no further questions, I'll turn the call back to you for any additional or closing remarks.

Cameron Reynolds:

No closing remarks. Thank you all very much for your time and interest and I assure you this quarter as with the other quarters, we'll be working very hard to deliver on the numerous milestones as we have done for the past I guess—how many quarters, past 10 or 15 quarters.

Thank you very much for interest in Volition and I look forward to updating you again at the next quarter.

Operator:

Thank you and that does conclude today's conference call. Thank you for your participation.