
# VolitionRx Ltd.

## Fourth Quarter and Full Year 2015 Earnings and Business Update

## March 11, 2016

## CORPORATE PARTICIPANTS

**Cameron Reynolds,** *Chief Executive Officer*

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**Jan Wald,** *Benchmark Company*

**Brian Marckx,** *Zacks Investment Research*

**Yi Chen,** *H.C. Wainwright*

**Bruce Jackson,** *Lake Street Capital Markets*

## PRESENTATION

**Operator:**

Good day and welcome to the VolitionRx Limited Fourth Quarter and Full Year 2015 Earnings and Business Update conference call. Today's call 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, 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 full year ended December 31, 2015, 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. 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.

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I'd now like to turn the call over to our Chief Executive Officer, Mr. Cameron Reynolds, who will discuss the fourth quarter and full year 2015 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 full-year 2015 earnings conference call. I'd like to thank you all for taking an interest in Volition at this very exciting time for us.

2015 was a tremendous year for VolitionRx. We significantly advanced our clinical programs in colorectal, pancreatic and lung cancers, with four trials showing over 90% sensitivity in these cancers. We released interim results from our first large-scale clinical trial, the 4,800 subject retrospective colorectal cancer study at Hvidovre Hospital in Denmark from the University of Copenhagen; we set the stage for the expected commercialization of our products, first products for clinical use in Europe in 2016, with our first CE mark on a single biomarker assay last year; we released numerous data sets that further validate the robustness and accuracy of NuQ® technology and Nucleosomics® platform; we bolstered our intellectual property portfolio with the addition of a number of key patents in the U.S. and around the world; cash and cash equivalents as of December 31, 2015 totaled $5.9 million, compared with $2.1 million as at December 31, 2014, and $6.9 million as at September 30, 2015; and, of course, we listed on the New York Stock Exchange's MKT market last year, as well.

Review of important Q4 events: Granting of our second U.S. patent, entitled *Method for Detecting Nucleosome Adducts,* this is a core technology patent covering the methods for measuring nucleosome protein complexes known as adducts. This is a wholly owned and royalty-free patent that expires in December 2032. It covers the management of estrogen receptor adducts and androgen receptor adducts, which should be pivotal for the detection of breast and prostate disease, respectively. We have

come across no competing or even similar IP. We believe this lack of competing IP gives us very large freedom to operate. Together, with our first U.S. patent, the *Detection of Histone Modifications in Cell-Free Nucleosomes,* this second patent reinforces VolitionRx's exclusive market position with its unique Nucleosomics® technology. It was further supported by a third patent, our U.S. patent, announced in the first quarter of 2016 for the detection of nucleosomes, which will also support the first two patents that we had granted.

We continue to make excellent progress with our clinical trials. Starting with colorectal cancer, we announced results from our first completed prospective study in colorectal cancer at CHU Dinant Godinne Hospital in Belgium. It was a 121-patient symptomatic study, which included 23 colorectal cancer patients. A panel of four NuQ® biomarker assays, adjusted for age, accurately detected 21 of 23 cancers, which is a 91% sensitivity at 90% specificity, and the results were not stage dependent. The study also detected 67% of high-risk adenomas, or pre-cancerous polyps, that were most likely to become cancerous, demonstrating the potential for NuQ® tests to accurately detect the complete spectrum of cancer development from pre-cancer polyps through early to late-stage colorectal cancer.

Last month, we followed these results for adenoma by announcing even higher sensitivity in a targeted clinical trial of 430 patients in adenoma conducted with Hvidovre Hospital with the University of Copenhagen in Denmark, in which we detected 75% of high-risk colorectal adenomas and 86% of stage-one cancers.

For pancreatic cancer, the first peer-reviewed validation of our NuQ® tests was published in the Journal of Clinical Epigenetics. A pilot study with Lund University in pancreatic cancer demonstrated a four-assay NuQ® panel, together with the classical biomarker CA 19-9, gave results with a sensitivity of 92%. We also announced results from our second preliminary study in pancreatic cancer based on the 4,800-patient study in Denmark, which happened to include 20 pancreatic patients. Results from a two-assay NuQ® panel, plus the classical biomarker CEA, reached 95% sensitivity at 84% specificity. Results from these two preliminary studies are very encouraging and are the basis for pursuing large clinical trials in pancreatic cancer. It is likely that our second product will be blood test in pancreatic cancer, right behind that of colorectal.

We also announced interim results from the 240-patient lung cancer trial at Liège University Hospital. The interim results included 73 patients, including 29 with non-small cell lung cancer, 20 with COPD, and 22 healthy subjects. COPD is a common competing condition with lung cancer. When combined with smoking history, a four-assay NuQ® biomarker panel accurately detected 93% of the cancers, 27 of the 29, and only two false positives among the healthy subjects, which is a 91% specificity, and it differentiated lung cancer from the other lung disease, COPD. Blood tests could be a valuable tool, as the best current test for lung cancer is a low-dose computed tomography scan that does not distinguish well between cancerous and non-cancerous fibrous nodules in the lung.

Looking forward, the milestones for 2016 and 2017: we expect to achieve many important clinical and commercial milestones. Firstly, CE marks on additional colorectal assays with a full panel to be CE marked and European launch this year, 2016. We expect more IP to be granted in several countries as we continue to protect our technology and, in turn, shareholder value. We expect to announce one or more large clinical trials in both lung and pancreatic cancer to back up the very exciting preliminary data, and release more results from ongoing lung and prostate cancer trials, including the 27-cancer trial at Bonn University, and in the MD Anderson and Surrey Cancer Research Institute prostate cancer trials. We also expect final results from the 4,800-patient retrospective colorectal symptomatic population trial, which we announced the first data last year, and we anticipate this in the second half of this year. We also anticipate the first tranche of the 14,000-prospective colorectal trial during the second half of this year. We also expect further results from non-cancer pilot studies, following the success of the study for the detection of the fatal lung disease, IPF, announced this week, to investigate additional potential lucrative markets for a line of NuQ® products in the longer term.

Our EU commercialization strategy, including upcoming milestones and timelines for European market access and sales for NuQ® and CRC throughout this year. Our U.S. commercialization strategy for NuQ® blood tests and for colorectal, including FDA strategy and for CLIA strategy: we aim to have a pre-submission meeting with the FDA this year regarding our intent to file a 510(k) application focused on symptomatic high-risk CRC patients' intended use of NuQ® as an adjunct diagnostic. We are planning for the FDA 510(k) application submission next year in 2017. We plan to commence a 510(k) trial for symptomatic high-risk CRC patients, the actual trial for the 510(k) application, and we plan to initiate a U.S. FDA-endorsed trial alongside our ongoing large trials in Europe, which will be designed to provide the clinical data to support a PMA submission for the potential FDA approval of our NuQ® tests for the early detection of colorectal cancer as a screening product. In parallel, we aim to license our Nucleosomics® biomarker panels in the U.S. to CLIA labs for development as an LDT.

Early 2017 milestones include: CE mark for pancreatic cancer and lung cancer during the second quarter of 2017; beginning the U.S. PMA pivotal trial for CRC in late 2016, early 2017; and data from the 4,700-prospective Bonn 27-cancer trial during the first half of 2017.

We absolutely believe that blood offers the best platform with which to test cancer, because the tests are non-invasive, convenient, and have the opportunity for higher compliance versus other complicated, unpleasant and/or invasive tests, which often require separate doctor visits and advanced preparatory work, such as a colonoscopy, X-ray or biopsy. Blood tests also tend to be quick and often require just a fraction of a drop of blood, which would allow our NuQ® test to be administered during regularly scheduled blood draws and tested on a commonly used ELISA platform. Our blood tests for a variety of cancers are proving to be highly accurate, cost-effective, convenient and rapid, with the ability to detect pre-cancers in the early stage, which is unusual, and yet so important for cancer tests and the outcome for patients, this early detection.

We are very excited about VolitionRx' s clinical and commercial accomplishments and we look forward to completing these numerous aforementioned milestones throughout 2016 and early 2017. We are particularly enthusiastic about our upcoming commercialization plans for our blood test for colorectal cancer, which we plan to launch in Europe this year with a CE mark and the U.S. next year with a 510(k) clearance from the FDA as an adjunct 510(k).

It has been many years of hard work and numerous clinical trials which have enabled us to come to this major inflection point. I'm very proud of how our team of executives and scientists have collaborated in order to bring a cancer blood test to market which should lead to more individuals being tested for several cancers, allowing for the detection of many more early-stage cancers and greatly improving patient outcomes.

Thank you all very much for your interest in Volition and for joining our 2015 full-year 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. If you would like to ask a question, please signal by pressing star, one on your telephone keypad. If you're using a speaker phone, please make sure your mute function is turned off to allow your signal to reach our equipment. Again, that is star, one for questions.

We will take our first from Jan Wald with Benchmark Company.

**Jan Wald:**

Good morning, Cameron, and congratulations on the quarter. It looks like you're making good progress.

**Cameron Reynolds:**

Thank you.

**Jan Wald:**

I have a couple of— I guess two questions. If I look at the clinical trials you're involved with, I kind of divide them into three different categories: platform extension, like the latest lung trial that you reported on; algorithm or test tuning; and regulatory for commercial. So, those are the three categories. I think the ones I care most about are the commercialization, the regulatory ones so could you describe which of the trials that you're performing are for regulatory submission and where you are in the process?

**Cameron Reynolds:**

Absolutely. Thank you, Jan, and thanks for your interest in the Company. I'll split it into Europe and the rest of the world and the U.S. So far as Europe, the regulatory trials are the CE mark confirmatory trials, which are smaller in population, they tend to be 300 to 500 patients, a little bit like a 510(k) size of trial. So, all of our CE marks involve small trials to justify the CE marks. The larger trials in Europe, the 4,800 and the 14,000 patients are all very good for adoption. So, once you have the CE mark you're allowed to sell the product, but we're doing these massive trials to convince key opinion leaders and convince doctors that they are very good trials. So, if you look at it that way, in Europe, CE mark allows you to sell them and in other places around the world, but the large trials drive people to buy them.

In the U.S., obviously the process we're in now is starting with the FDA along the timelines I outlined, and are outlined in the 10-K, and for those, we're aiming to do smaller 510(k) trials in symptomatic and high-risk populations in colorectal, lung and pancreatic. So, for purely regulatory reasons, those and the PMA trial in colorectal cancer are the ones which are required for the regulatory work.

Now, I think, as I discussed in the 10-K and on the call, we aim to apply for 510(k)s for all the cancers in symptomatic and high-risk, but for the moment the only one which would justify a 10,000 screening trial, we believe, is colorectal in the U.S., and we're very serious about getting that as well. So, basically, for the U.S., the regulatory side are the 510(k) trials and the PMA. Dr. Terrell, we've taken on full time this year, he has been looking at— he's a diagnostics expert— he's been looking at CROs and ways of completing U.S. data for those trials, because he strongly believes the quickest way, potentially, to get them approved is to do a reasonable amount of work in the U.S., so that's what he's working through the plan now, and we'll announce the outcomes of those as they are completed and made public.

**Jan Wald:**

Okay. I guess my second question is— you haven't given guidance for next year in terms of finances, but, notionally, could you talk about what kind of revenues you expect and what SG&A and R&D spends will look like for next year or beyond, just to give us a sense of the spend rates and where revenues will come in?

**Cameron Reynolds:**

Yes, we've been very conservative and— our CFO is on the line. We've been very conservative in the estimates of revenue, just because it's always best to be conservative. The new product which we believe is quite revolutionary, it's often— although we think we will end up probably getting very good revenues, it does take time, so we're being very conservative with minimal revenues in '16 and '17, nothing very meaningful, because ultimately, although we think our products are revolutionary, we want to

make sure that we're not relying on those revenues to fund the trials, so I think minimal in 2016 and '17, and then really taking off through '18, '19, '20. I'm sure our CFO can go through that with you, perhaps his thoughts offline, but ultimately we think '18, '19, '20 will be when it really begins to take off revenue-wise, that's what we'd expect because— although we expect to have a CE mark this year, it certainly takes time to get key opinion leaders and governments in Europe and other places to start buying the product, and typically it does take time. Although I think we have a tremendous advantage in a lot of areas in our product, it does take time, so we're trying to be conservative, but we aim to have the product this year and begin sales next year, but really meaningful sales in the year or two after that.

**Jan Wald:**

Okay, and then …

**Cameron Reynolds:**

So, as far as burn rate, you saw— you know, we've $9.7 million in February and we still had $5.9 million left at the end of the year, so we don't spend a lot of money, it's just over $2 million a quarter, although— because of some income from warrants, we actually only used just over $1 million this last quarter, which is a remarkably small amount of money for a company our size, I would think. So, we're looking to increase the burn, but not as much as a lot of people would assume. We're doing a bit over $2 million a quarter. I would think we'd probably be getting closer to $3 million a quarter as we go through these trials, but it's not going to be a tripling of spending, we don't expect, for the next period.

**Jan Wald:**

Okay, and my last question is about the 510(k) approach that you described. The 510(k) makes sense, I guess, because it's high-risk patients and late-stage patients. Could you talk a little bit about the rationale for, I guess, assuming that's going to work with the FDA? Have you talked with them about it? Are there other competitors that have done a similar thing?

**Cameron Reynolds:**

Yes, I think if you're looking for a model, you'd probably go for Vermillion for their ovarian test. Ultimately, we think— you know, you don't know what the FDA is going to say until you approach them, and we're in the process of that now, but an adjunct test makes a lot of sense for a very cost-effective, very easy test to administer. It certainly gives the clinician pretty good information. Now, obviously, to make the final decision, you need to go— if it's going to be a full screening test, you need to go through a PMA process most likely, and we are serious about doing that, but we've come to the belief that there is the potential for a very solid market in the meantime being approved as an adjunct. If you think about it, tests which are used currently a lot now, tests like CEA, CA 19-9, have never been through a PMA process in that same manner but are quite widely administered for different reasons. So, we would see ourselves bringing the product to market for those applications while we do the large screening trial, because when you're only— you know, last quarter we spent just over $2 million— not very much revenue becomes very, very meaningful for us, and we think there is a considerable market in the symptomatic population in colorectal, and very much so in lung and pancreatic.

The high-risk groups are reasonably obvious. In lung, it's smokers over 55 years old, and in pancreatic, although it's not as obvious— it is when you think about it— it's anyone who has stress on the pancreas. So, the most obvious people for that would be people who have adult-onset diabetes, you have about an eight times more chance of having pancreatic cancer if you've been diagnosed with adult-onset diabetes. So, I think there's a very solid market testing those people while we do the large trial, the PMA trial in colorectal.

**Jan Wald:**

Okay, thank you very much, and again congratulations on the progress.

**Cameron Reynolds:**

Thank you very much. It has been a very good year. Thank you.

**Operator:**

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

**Brian Marckx:**

Hi, good morning Cameron. A follow-up on the U.S. strategy. I think the latest, prior to the 510(k), strategy was CLIA lab. Is that still in the works? Do you plan on pursuing the CLIA lab route, I guess in parallel with the 510(k) strategy? Then on the 510(k), it's going to be an adjunct, if you could talk about an adjunct to what, I guess.

**Cameron Reynolds:**

Yes, absolutely. So, the CLIA lab, yes, all cards are still on the table until we finalize our strategy and speak to the FDA. I think no one can predict exactly what the FDA will or won't say. I think we have a very solid case, but obviously that's always got to be determined by them. So, the CLIA lab route, I think licensing to become a lab-developed test is an option, or even setting up our own CLIA lab is an option. It's not our preferred option, but it's always an option. So, I think we have several different possible paths to market relatively soon. The CLIA lab is one, the 510(k) is a second in each cancer, and then the longer term route is obviously the PMA.

So, if you look at it as an adjunct, if you take— probably the easiest way to demonstrate it would be in, say, for example, lung cancer, where currently the guidelines are for low-dose CT scanning of people over 55 with— Americans over 55, who are heavy smokers, as defined by 30-pack-years of smoking history or more. So, the CT scan, what I understand, it's quite sensitive, it's not very specific, and our blood tests are proving to be good at both. So, we see ourselves being an adjunct to the current test, the low-dose CT scan, for example, in lung cancer, to provide more information.

Now, I do believe our tests have the potential to replace what is currently used in a few different cancers, but I think the easiest path to market is to come into the current system and be complementary to what is currently done while you get some good track record and sales in the process. Every single cancer has some biomarker which people use, so selling your test as an adjunct to that is a very— we think the easiest way to get into the market, get credibility, get sales, and while— don't forget, Brian, there are up to hundreds and hundreds of biomarkers on our intellectual property on the nucleosome, we've only looked at 27, so we think we can continue to get more and more accurate, but we believe the accuracies that we're showing are more than adequate to become this level of testing as adjunct and get to the next level in cancer, like colorectal, for screening populations, so that's what we're working through.

But, I think it's very important for a company our size to get a product out as quickly as it can to generate revenue and start getting a name for itself, rather than waiting. It can take, as I'm sure you're aware, as Exact is aware and Epigenomics is aware, it can take several years to get a PMA finished and approved, or even more, so I think it's a very good corporate strategy to get your test approved for something. As I mentioned, a test like CA 19-9, it's estimated to be up to about 46 million tests sold per year, so you can have a lot of tests sold in this kind of market before you get the PMA process through.

**Brian Marckx:**

So, Cameron, on the 510(k), are you going to— you're going to seek indications for every cancer that you're under clinical trials with today, so colorectal, lung, potentially pancreatic?

**Cameron Reynolds:**

Yes, we have— exactly right, that was our intention. In high-risk population, you're looking— we estimate in the 500- or 600-patient sample size. When it's a symptomatic or high-risk population, those sizes are a bit more, can be enough cancer patients to make it statistically valid, and that's all being determined now. If you look at a few thousand dollars per patient, you're looking in the million dollar range, plus or minus, for the trial. Now, that's still— we're still in negotiations, that's not finalized, but that's the ballpark to what we'd expect to need to pay for those trials, so we think it's an incredibly good investment.

If the FDA are accepting of it and the trials go well, it's a very good way to launch a product quickly, and as I said, other adjunct products could sell very large amounts when they're low-cost, cost-effective blood tests which can be easily administered while we do the process of getting our test better and better and better.

**Brian Marckx:**

Okay, and if you could, just the status of some of the studies that are ongoing. I think you had a pilot study in ovarian cancer, the timing for the data on the 27-cancer study, and then pancreatic, I think you had timing on the size of a bigger pancreatic cancer study, I guess.

**Cameron Reynolds:**

So pancreatic, we're still negotiating larger trials. Lung, we have a trial underway, trials underway. Prostate, we have several trials underway. The 27-cancer trial, we were hoping to get some data later this year, but it took a bit longer in collection on the healthy cancer patients, but it's now all finished collection and he's beginning work on the assays now, so we expect it in the first half of next year. We're expecting to run about 25 assays through that population, so it will be by far the broadest and biggest trial we've done so far as breadth of cancers and number of assays through a population. We're very eagerly awaiting that data. The colorectal trials, as you know, we released the adenoma data in the 430-patient study, and, as it was in the press release, we found some new markers which worked very well in early-stage cancers, particularly in adenomas, so now we're putting that through the 4,800 population to see if those results are borne out in a larger population, as well as in the screening population, so we expect to have data in both those trials this year in the colorectal side with the new and the old markers. As I said, we're negotiating pancreatic, we're working on the 27 cancers, and we're working on a range of different prostate trials. So, yes, it's going to be an exciting year. Sometimes, some come a little faster, you think some go a little slower. We've got three prostate trials coming and we'd expect data from that reasonably soon. As you know, it's a very important cancer. The pan cancer will be fascinating for its own reasons, to see if we can tell between the cancers, and the pancreatic, we'll announce as soon as we've negotiated the trial, assuming we do.

**Brian Marckx:**

Okay, the two big Danish studies, the retrospective and the prospective colon cancer studies, the timelines have slipped a little bit and now it sounds like it's going to be a second-half 2016 event. Do you think that that's a pretty solid timeline where you will have it?

**Cameron Reynolds:**

Absolutely, yes, I think so. Well, it's not so much slipped. For the adenoma study, we finished that and completed the study a little ahead of time and we've identified some very exciting new markers, so we want to— we only have so much sample in the 4,800, we wanted to wait to make sure we were doing the best biomarkers in that population. So, now, given the very good results in the 430-patient study on the old and the new biomarkers, we're very confident to be finishing that now. The team is hard at work on those two large trials, so we decided it was worth waiting to get the best biomarkers we could from the work we finished. That's the reason we accelerated the adenoma study, because I think the key— well, the key to us to the trials is having very good detection in early-stage cancers and in pre-cancers, so we were very, very excited to get such great data. To be getting 75% of the dangerous pre-cancers in a non-invasive test is far better than we could have expected. So, now we have those new biomarkers, we're putting them through the larger population, so it will be this year, and the 4,800, we're processing right now.

**Brian Marckx:**

Okay, great. Thanks, Cameron.

**Cameron Reynolds:**

Thank you. Thank you, Brian.

**Operator:**

We'll take our next question from Yi Chen with H.C. Wainwright.

**Yi Chen:**

Hi, thank you for taking my questions. My first question is between the option of CLIA lab and 510(k), can you provide some comment how— will that potentially affect your pricing of the test, and how will that affect the reimbursement of the test? Thank you.

**Cameron Reynolds:**

Good question, Yi. So, obviously, with the CLIA lab, we have two choices, either we license out to someone to develop their own lab test or we develop our own lab test, and so it would be up to— assuming we license it out to someone developing their own test, it would up to them to decide what the pricing structure is. 510(k), obviously we keep a lot more control over, or we have some control over, where we do have very little if we license it out, so the pricing— our strong bias, though, has always been to keep the test very affordable and make very wide adoption as early as possible. We think that's why there's such a large number of the other biomarker tests which are used, which are very simple tests on the ELISA, like the PSAs, they're very low-cost, very easy to administer tests. So, our strong bias has always been to make it affordable, and given the low cost of production, it's still very, very lucrative for us. But the final pricing structures, we haven't finally determined; that will be determined as the product rolls out, but we see them as both very large markets.

The 510(k) becomes probably a bigger market, because then it can be run in any laboratory in the U.S. We're doing the detail work now, so this is my personal opinion, but I would say the 510(k) market is the bigger one than the CLIA lab market, and we would keep a lot more control over the process than if it's a CLIA lab we're licensing it to. So we're very keen on the 510(k) process, if it's one which is acceptable to the FDA, which we're hopeful for and we'll find out this year.

**Yi Chen:**

If it's a 510(k) test, will it be fully reimbursed, though?

**Cameron Reynolds:**

That's a process we're working through now. We'd certainly— I would expect so, but the exact answer to that question is— and we've got a full review being undertaken by Dr. Terrell, so he will be announcing all the process, but that's certainly my impression.

**Yi Chen:**

Okay. My second question is should we expect to see more lung cancer diagnostic data in the coming quarters?

**Cameron Reynolds:**

Absolutely. We're very, very serious about the lung cancer work, and we have trials underway. We're actually— we've got two ongoing at the moment. So, I expect to see a lot more lung, prostate and pancreatic data.

**Yi Chen:**

Sorry, I meant lung cancer, lung cancer.

**Cameron Reynolds:**

Lung cancer? So, the answer was yes on lung cancer, but probably the next big readout will be in prostate cancer that we expect this year. Yes, we expect lung this year. Thank you.

**Yi Chen:**

Thank you.

**Operator:**

As a reminder, it is star, one for questions, star, one. We will take our next from Bruce Jackson with Lake Street Capital Markets.

**Bruce Jackson:**

Hi guys, good morning.

**Cameron Reynolds:**

Bruce, how are you?

**Bruce Jackson:**

Good. So, if I could just home in on the colon cancer program real quick, so first with the retrospective trial, are there any possible issues with antibody production, anything that could affect the potential timeline for the second half readout?

**Cameron Reynolds:**

Good question, Bruce. Yes, as we've announced before, we've been undertaking large antibody programs, and not only do we control the antibodies ourselves but also it brings the cost down markedly when you have well defined monoclonal lines yourself. So, we've been hard at it now, and we've got a lot under development, so we're very confident in the process, that it will not delay. There's always a possibility when you have several moving parts that one of them slows down, but we're confident in the production of our antibodies and that we've got the process underway and on time to meet our targets.

But, antibodies is something we're very, very serious about, it's a very key part of our business. We spend a lot of capital on developing our own monoclonal line, so there is no slippage in any of the trials from antibodies. So, when we have it developed ourselves and test it ourselves, not only is it much, much cheaper than buying them, up to 80 or 90% cheaper, but also you have complete control and can produce in large quantities, as you say, for the products. So, what we've been very much focusing on is developing our own lines and testing in the trials in every case where we have them, our own antibodies, so that we can roll out a product quickly and seamlessly from those.

So, the short answer is we believe it's under control, and we've spent a lot of time and effort on the antibodies to make that as big a chance as possible.

**Bruce Jackson:**

Okay, great, and then if you could just walk us through the critical path on this project. So, we've got to get the training (inaudible), set up your algorithm, validate the algorithm, then get CE mark on the NuQ® panel that you want to launch with. So, can you tell us what are the (inaudible) factors here, which trials you're going to be getting which pieces of data from and how this whole thing unfolds through 2016?

**Cameron Reynolds:**

So the actual CE mark is on small numbers of patients, the small number of hundreds, so that's not the big trials, but the data which will drive demand are the 4,800-patient study, which will be the first one. The very big readout, as you know, we're around 80% sensitivity and specificity on that at the moment, 78, 81. We have the biomarkers which worked extremely well in the smaller population, but still very meaningful numbers in the 430-patient study, so we're putting them through now. So, we aim to pick the panel, so we'll have— we're running those new assays now. We aim to pick the first panel over the summer and begin the CE marking process as a panel and have it ready with the algorithms and all the things you mentioned this year, and then launch it this year. Although, as we talked about, it will take time to generate revenues as you— but we don't expect the delay to be anything to do with production. We can produce large quantities of our own antibodies in the plates very quickly. It just comes down to getting acceptance from clinicians and key opinion leaders to roll out the product. We've begun that very strongly in several European countries and now, with Dr. Terrell, we're starting that process to really start the U.S. market seriously, with his work in getting the 510(k) process started.

**Bruce Jackson:**

Okay, and then to be clear, the data that's coming, is it coming from the Danish studies or is it coming from any other studies? Which studies are we going to be focused on?

**Cameron Reynolds:**

Yes, good question. The colorectal, the two very large colorectal, the completed one and the adenoma was from Denmark. The two very large studies in colorectal, which we'll have readouts from this year, the 4,800 and the 14,000, are both in Denmark. The other big readouts, I think, in the short term, are in prostate cancer, and they're from a range of different groups in Europe, in England, from Surrey, from the MD Anderson trial, and another one in Europe, so expect data in the short term from them. Then, the pan

cancer trial is with Dr. Holdenrieder in Germany, and he's unique, insofar as he runs the trials himself. We have purchased him two Tecan machines and we send him kits. He collects the samples and runs them. So, in our center and his, the— it's completely in his hands, so— and it's very encouraging, the results we're getting from the two centers, they're very, very similar. So, it works in different centers. Each one of those is a little different in how it all works, but the actual— Dr. Holdenrieder does everything except make the kits. We send him the kits and he collects the blood and does all the testing, because he's an expert in nucleosomes himself.

The rest of the people send us blinded samples, typically. In Denmark, it's double-blinded and we randomize them. Usually, what happens is you have a swap-over of data at a particular day, we send the— when you un-blind it, we send the sample data and they send the patient data, so both sides have the other half of the puzzle at the same time.

**Bruce Jackson:**

Okay, and then to get super-specific here, with the trial for the CE mark, that small sample, where is that going to be drawn from? Is it going to be a separate trial or are you drawing from one of the trials that you're currently running?

**Cameron Reynolds:**

Each one depends on the population and what you're after. The last subset was from a subset from the Danish trials shipped to them, but they run independently, go through a process for the CE mark. The CE mark mainly runs around other tests, there's a whole system for making them accurate, but the trials themselves are not very— are not large. That's why we're doing these massive trials. I mean, 4,800 and 14,000 trials are very, very large trials for marketing purposes, as much as anything else, so that we've shown it works in a very large population, but the actual trials for the CE marks are small numbers of hundreds, and they can be drawn from different locations as long as they're done in a set process which is— proper process, which they were.

**Bruce Jackson:**

Okay. Then, once you get the panel launched— I believe you said in the press release that you were expecting some meaningful revenue in 2017. Is there any quantification you can provide around "meaningful"?

**Cameron Reynolds:**

We're not providing revenue guidance at this stage. It's tough to know which countries. We're talking to several countries now. We're looking outside Europe, other places where you can sell with a CE mark to the private payer market, but I don't think at this stage it would be accurate, our predictions, until we've really done the numbers ourselves, but we're very active in working with several groups to do distribution in Europe and other places. Basically, where we have home advantage in Europe, which would be United Kingdom, because a lot of the Company are English, have experience with NHS, and we speak English of sorts; Belgium, of course, where our home is, particularly the French region; Denmark, where we work very closely with the Danish screening program; and Holland and France; and they're all a bit different in different models. So, we've done a lot of work on it, but we won't be providing guidance until we've got a lot better idea of what the take-up time in each of the countries is going to be.

I do believe we have a very compelling case. In Europe, almost predominantly the tests are the cheaper, more inaccurate fecal test, there's a lot of FOBT and FIT tests. I think we're much more compliant, much better accuracy early, and we can be very competitive on cost, so I think we've got a very, very good

argument, but timing on those, we need to do a lot of work before we provide guidance as to what the revenues are going to be in those years.

**Bruce Jackson:**

Okay.

**Cameron Reynolds:**

But as we said, the good news is we don't spend very much money, so we don't need to be— you know, a lot of companies spend tens of millions per quarter. We're a very low amount per quarter. So, "meaningful" doesn't have to be a huge amount in that first year to be meaningful, because— you know, we're very hopeful and we're working very hard to get revenue as quickly as we can, but when we're very comfortable with predictions and guidance, we'll provide it; but we're still in the process of developing those models and really actively working on them.

**Bruce Jackson:**

Okay. Last question. You mentioned some warrants exercised last quarter. How many warrants are still outstanding? Is it cash exercise? How much could you potentially get from those if they're exercised?

**Cameron Reynolds:**

It's all in the 10-K. It's several million dollars. It's all exact figures. I don't have it memorized, but all of them are in the 10-K. It's quite large. The average is between $2 and $3.50, depending on whether it's options or warrants, but it's considerable, and we've had considerable income from it this year. That's why we only actually went through just around $1 million in cash this quarter, because there were some warrants exercised. If you look at it, if you take a further step back, the net was around 9.7 at the IPO and we still had 5.9 at the end of the year, so a combination of us not spending much and constantly having some warrant income and other things have really helped us to keep the burn really, really low, still while doing nine ongoing clinical trials and up-listing and being in the process of doing the regulatory work. So, we keep a very, very tight ship.

**Bruce Jackson:**

Okay. Actually, I've got one more question. So, moving over to the US regulatory strategy, specifically, is this going to be a de novo 510(k) or is it one of the newer regulatory pathways?

**Cameron Reynolds:**

There's several options and we'll keep everything open until we've met with the FDA, but the options are predicate or de novo. It depends on, I guess, if you consider some of the tests out there are predicate or not. If not, it'll be a de novo. I believe Dr. Terrell is focusing on de novo just in case there isn't a predicate.

**Bruce Jackson:**

All right, that's it for me. Thank you very much.

**Cameron Reynolds:**

Thank you very much, Bruce. Thank you for your time.

**Operator:**

Another reminder, that's star, one for questions, star, one. We will pause for just a moment.

With no further questions in queue, I'd like to turn it back to our speakers for any additional or closing remarks.

**Cameron Reynolds:**

I'd like to thank you all for your interest in VolitionRx. It's going to be a very exciting 2016, as it was an extremely exciting 2015. I think you see from all our milestones it was a tremendous year for us, and we continue to gain momentum in all the trials we do and with the regulatory work, with the aim of launching our products in '16 and '17. So, thank you very much for your interest, and hopefully we can continue to deliver on the milestones and targets as we have done for the last five years. Thank you very much for your time.

**Operator:**

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