VolitionRx Limited First Quarter 2015 Financial Earnings and Business Update Conference Call Transcript
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CONFERENCE CALL PARTICIPANTS

Brian Marckx, Zacks Investment Research

Jan Wald, Benchmark Company

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Jack Lasday, Morgan Stanley

Menachem Kranz, Ahava Investment Partners

PRESENTATION

Operator:

Good day and welcome to the VolitionRx Limited First Quarter 2015 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, Director of Investor Relations. Please go ahead, sir.

Scott Powell:

Thank you, and welcome everyone to today's earnings conference call for VolitionRx Limited. This call will cover Volition's financial and operating results for the three months ended March 31, 2015, along with a discussion of our key 2015 milestones to date. Following our prepared remarks, we will open up the conference call to a question-and-answer session.

On our call today are Mr. Cameron Reynolds, Chief Executive Officer of VolitionRx; and Scott Powell, Director of Investor Relations.

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, 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 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 on the Company's most recent annual report on form 10-K, and quarterly report 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 first 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 first earnings conference call. I'd like to thank you all for taking an interest in Volition at this very exciting time for us, and I really appreciate you taking an interest in our Company.

The first quarter of 2015 was very significant for the Company. On the capital market side, we listed our shares on the New York Stock Exchange MKT market on February 6, simultaneously closing a $10.6 million financing and a fully registered offering of our common shares, through which we added many new retail shareholders and several key institutional investors.

VolitionRx now has sufficient cash to take us well into the second half of 2016, by which time we should have released substantial amounts of clinical data from several—several of our ongoing clinical trials, and have European regulatory approval CE marks. We ended the quarter Q1 with about $11 million in the bank.

Being listed on a senior US exchange also broadens the universe of investors able to purchase our shares, and further increases our visibility and credibility in the capital markets. This listing also provides us with a stronger platform through which to access the capital markets and should continue to increase the liquidity of our shares in the marketplace.

Turning to our clinical developments in Q1, it was an extremely important one for us. In January, we announced a pilot study in collaboration with the Singapore General Hospital to provide initial evidence of our nucleosome assays' ability to detect early stage ovarian cancer. (Inaudible), we released results from our pilot study in pancreatic cancer. In this 60-patient study, conducted in collaboration with the Lund University in Sweden, which comprised 25 early-stage, treatable IIA and IIB stage pancreatic cancer subjects, 25 healthy subjects, and 10 subjects with competing conditions of the pancreas, our nucleosome blood assay-based diagnostic platform accurately detected 84% of these early stage pancreatic cancers, with only a low, 8% false positive rate. These are extremely exciting results, as there is currently no commonly used, accurate screen available to detect early stage pancreatic cancer.

This is now the fourth cancer in which our blood based screening technology has accurately detected early stage cancer and provides (inaudible) conducting larger trials in the pancreas—pancreatic cancer to further prove out our technology, similar to what we've done in colorectal cancer. We expect to announce one or more large clinical trials in pancreatic cancer in the near future, which we hope will confirm these promising early initial results.

In addition, we are pleased with the (inaudible) acquisition of the only non-core patent family that VolitionRx did not own outright, but which we did have exclusive worldwide rights to. The patent family WO 2005/019826 was acquired from UK based Chroma Therapeutics. This further strengthens our IP position in the detection of cancer, which is based on the detection and measurement of chemically altered nucleosome structures in circulation. This acquisition brings our portfolio of pending and granted patents to 10, and further increases shareholder value by bringing in-house royalty-free access to this patent, and it's the only key patent related to our nucleosome technology that we did not own outright.

In April, we also announced a new 800-subject clinical trial with the Hvidovre Hospital in Copenhagen, Denmark, to establish whether our nucleosome test can detect precancerous colorectal polyps, which are also known as adenoma. We have shown in one of our colorectal studies that we were able to detect up to 60% of precancerous polyps, but this will be our first trial specifically looking at precancers by themselves. These will also be processed on one of our new Tecan robots.

Finally, using a portion of the proceeds from our offering and the February financing, we announced the purchase of three further Tecan machines, or laboratory automated systems, which will significantly expediate the rate at which we process samples for—from our ongoing clinical trials. Once these three Tecan machines are fully operational, by the end of May, and in conjunction with our existing Tecan machine, which is hard at work at the moment, our processing capacity is expected to reach 30,000 samples per month, which for order of magnitude, is approximately the total number of samples that VolitionRx has processed in the entire five-year history of our Company manually. The rapid processing of samples should ensure that we release a significant amount of capital data in the second half of this year, 2015, in several of our ongoing trials, and should allow us to more quickly move our products through the regulatory process and into commercialization, which is of course our ultimate gain—goal.

Looking ahead to the remainder of 2015, we have many important clinical and commercial milestones, including the release of results from our large studies in colorectal cancer, in collaboration with Hvidovre Hospital, which we discussed earlier. We expect to release the 4,800-patient retrospective colorectal trial data in the third quarter of this year, utilizing our Tecan robots, using the same assays we used on the smaller sample set (inaudible) manually, to give us as good initial—which gave us the good initial results.

It is important to note that we're now producing our own antibodies analyzing these samples via our Tecan machines. We expect to achieve detection rates and false positive rates at least as good as that under the previous (inaudible) method, but that will be determined by the trials ongoing. Importantly, we continue to optimize our panel, improve quality controls, and now have a streamlined analysis process in place to maximize accuracy. We also expect to release the first results from 2,500 of our 14,000 prospective patient screening study that have now been collected. Having data from a prospective screening population will be another key milestone achieved for Volition.

As a reminder, we released initial results in September of last year, which included a 938-patient sample set as a representative subset of the 4,800 patients, which we are completing now on the Tecan machine. In addition to the detection rate of 84% with cancers, we detected early and late stage cancer, as well as each other, as well as about 60% of polyps, as I discussed before. These results alone, we believe, would be sufficient for us to not only apply for a CE mark, but also begin commercialization in Europe if repeated on a larger sample set, the sample set we're completing now. The 14,000-patient prospective study that we are currently running is being undertaken, as it is large enough to convince insurers to reimburse the nucleosome tests in Europe, once we begin commercial sales based on our early results.

With regard to the FDA approval of our nucleosome tests for colorectal cancer in the United States, we expect to engage in a dialogue with the FDA this year in order to determine what additional trials that will be required by the FDA to complete in order to get their approval. We expect to announce a framework plan and strategy, including potential partners, for commercializing and commencing the FDA trials in the US by the end of this year or early next.

We're also very actively exploring the possibility of partnering with one or more CLIA labs in the United States, whereby nucleosome colorectal tests could be available in the US prior to FDA approval via a CLIA lab waiver. This strategy, if successful, would allow us to commence some sales of the nucleosome test in the United States, generate initial revenue for VolitionRx, and achieving some early market penetration and acceptance, while we simultaneously pursue an FDA approval route for our tests.

With regards to our clinical trials in other cancers, we are pleased to be working very closely with Dr. Stefan Holdenrieder, who has published extensively in the field of nucleosomes and has run two of our clinical trials at the University Hospital Bonn in Germany. Our studies include a 600-patient retrospective trial in lung cancer with him, which follows on

from the very promising pilot study data released late last year in lung cancer, and recently announced the upgrading of a 4,200-subject patient study in the 27 most prevalent cancers.

We should also have initial data from our endometriosis study with Oxford University, and our prostate study with MD Anderson in the coming quarters. Furthermore, we expect to announce one or more large clinical trials in pancreatic cancer, following the stellar results of our 60-patient study, which was released in January—which was released in January, which I discussed earlier.

We've always believed our Nucleosomics® technology platform has very good potential, and we are very pleased to be working with some of the leading research institutions in the world on a variety of clinical trials, including Oxford University here in the United Kingdom, University of Bonn in Germany, Lund University in Sweden, and MD Anderson Cancer Center in Texas, to name a few. We continue to believe that blood is the best platform through which to screen for cancer because it is convenient and has a high compliance, versus other complicated, unpleasant, or invasive tests, which often require separate doctor visits and/or advanced preparatory work, such as the 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 nucleosome test to be administered during regularly scheduled 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, with the ability to detect early stage cancers which are still operable, thereby greatly improving patient outcomes. We are extremely excited about Volition's current status, clinically, commercially, and financially, and we look forward to delivering on these numerous milestones throughout the remainder of 2015 and 2016. We also have a very active upcoming investor relations and market awareness calendar. We are presenting at the Marcum Conference in New York at the end of May and the LD Micro Conference in Los Angeles in early June, and also have a non-deal road show planned throughout—road shows planned throughout May and June in New York, Boston, Philadelphia, San Diego, Los Angeles, and San Francisco, as well as several other European countries, as we continue to build investor awareness of Volition in the United States and Europe. We are also hosting two webinars in May and June, one investor focused and the other scientifically focused.

Lastly, I'd also like to note that we plan to consistently host quarterly earnings conference calls going forward, so that we may regularly update our shareholders and analysts on the progress, and answer any questions you may have.

Thank you all very much for your interest in Volition and for joining our first earnings conference call today, and I'd be very happy to take any questions from you about any of this or anything else you may have questions on. Kayla, are you there?

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, it's star, one to ask a question at this time, and we'll pause for just a moment.

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

Brian Marckx:

Hey, good morning, Cameron, and congratulations on all the progress and all of the studies that you have ongoing.

Cameron Reynolds:

Thank you very much.

Brian Marckx:

The Q3 announcement that you expect, just for clarity, is that—do you expect all the 4,800-patient data to be included in that from the retrospective study?

Cameron Reynolds:

Yes, the first Tecan we have commissioned now for two months has been doing roughly an assay per month through the entire sample set. So, if it continues at that pace, we'll have the whole—every one we did on the 938 finished in the July/August timeframe. So, you know, Q3 is July, August, September, so sometime probably near the end of the quarter, we'll be able to release the data on all the assays which we did on the 938, but in the 4,800. So yes, it's—we're not doing all eight assays, and a little bit, then a little bit more. We're doing assay by assay, because the roboticized machine works slightly better when you're just doing a single assay through a large number, so it's slightly quicker. So yes, the Tecan, the first one is fully operational and is doing one assay per month, so we aim to have all that done before the end of the quarter and announce it before the end of the quarter.

Brian Marckx:

Okay, and in terms of CE mark filling and support for that, would that include the full data set, then? I think you initially expected that it might just be with about the first 1,000 patients.

Cameron Reynolds:

Yes, very good question, Brian. You actually need a lot smaller number than we're doing to get a CE mark, so—but we're doing confirmatory trials at the University of Bonn. Dr. Holdenrieder is at a clinical setting in a hospital, so it's ideal for that. It will be a smaller number of patients. The actual number we need is about 400 or 450, so now he'll be doing confirmatory trials in his laboratory on those number. We have in place—the things which we needed to be in place included a manufacturer that was CE and FDA compliant, which we now have. We've contracted and those—the first big batch of kits compliant to (inaudible) are being manufactured as we speak. The second thing was to have a quality system throughout our laboratory and in Belgium. That is now complete and operational. The final stage is the final antibodies, which are now being produced. So, once the final antibodies are produced, the final commercial ones, we will ship kits to Dr. Holdenrieder, and he'll perform on these 450 patients. So, it's—the only step we haven't finished is that final step of the confirmatory numbers.

Now, that's not to say—obviously 450 patients gets you a CE mark. It doesn't mean people rush out and buy the tests, because people like to see very large trials. So, that's why we're doing all 18,800 patients in the two Hvidovre Hospital trials in Denmark, so we have very large numbers for reimbursement. But it's a little different, as you may probably know, but in Europe it's a two stage process. Getting the CE mark allows you to sell them, and having very large trials really helps you with reimbursement. So—but we're getting quite advanced on the CE marks, and as you can see from the trials, they're really progressing very smoothly now, so both of those are progressing very, very well.

Brian Marckx:

Okay, great. In terms of the precancerous polyp study, how rapidly do you think that that moves along, and when do you think you might have data? Do you think that that data may be available to support the initial commercialization, I guess, in Europe?

Cameron Reynolds:

Yes, absolutely. We're trying a very wide range of assays. It's not just for adenoma. There's also 100 early stage cancers, so it's a bit of both. It's predominantly focused on adenoma, but we think we may get some new markers at early stage, as well, so—although ours does very well early stage already.

It doesn't take very long, but that will also be done on the Tecan machines. The second one in Bonn will be up and running next month, so we'll be doing the 4,800, the 2,500 prospective, and the adenoma study, so I'd be very surprised if we didn't have a large amount of data by Q1, so certainly ready for commercialization with planning to do 30 assays through all of them. But, it only takes a couple of days. Once you have the antibodies and have prepared them, it's only a couple of days to do 800, so it can be sort of fit in between all the other things we're doing. But I—but we are prioritizing number one, the 4,800, number two, the 2,500 prospectives to get out in Q3, and Q4 perhaps for the prospective 2,500. So, probably look more to Q1 for the 800 adenoma study, but it's certainly in process.

Brian Marckx:

Okay. One last one on modeling OPEX. What should we think in terms of R&D and SG&A through the remainder of 2015? Do you think it looks like similar to what we were—what you had in Q1?

Cameron Reynolds:

Yes, we've gone through—we've all—I'm just actually in the process now of re-optimizing all of that because it is a little lumpy this—the last—this quarter and the next one. We've obviously bought three Tecans. Although they were leased, there are still upfront payments, and I mean, it's not a hell of a lot of money, but it's—it makes—saves us a lot of time, so it's extremely worth it. But, it's a little lumpy this quarter and next, but I broadly think we're going to meet our targets, and so as capital burn goes, I'll get a very good idea of that by the end of next quarter to see how we're progressing. But as of March 31, we still had $11 million left, so we've got a lot—certainly an awful lot more than we ever have. But we're being extremely careful to keep very tight control on expenses, and the only expenses we do involve speeding things up so the trials happen quicker, so we can get to revenue quicker. But currently, I believe our expectations are very much

along the lines of what they were before. We have sped some things up, but none of that is very expensive, but there may be some slight adjustments. But at the moment, we're on target.

Brian Marckx:

All right. All right, great. Thanks, Cameron.

Cameron Reynolds:

Thank you very much for your time, Mark—Brian.

Operator:

We'll take our next question from Jan Wald with Benchmark Company.

Jan Wald:

Good morning, guys, and congratulations on the quarter. I guess I have a couple of questions. In terms of the pancreatic cancer trial, what's—what do you think the timeline for commercializing that—that—

Cameron Reynolds:

Yes, that's a very good question, something which I can't give an exact answer for because there's a few different opinions. Like a lot of things, clinically, everyone has a different opinion of what's needed to get there. But I can say with some certainty, it would not need to be anywhere near the same size a trial as colorectal, for a couple of reasons. Ultimately, we have to show that we're the best out there, and at the moment, CA19-9 is the standard, and it's not great, as you know. So—and it's very difficult to get the very large patient studies that you could in colorectal, because pancreatic is diagnosed so late, currently. It's not easy to get 10,000 for the cohort. So, we're looking now—as we've discussed, we're looking now, as I discussed in the presentation, for a larger trial. The next trial, we'll be looking at a few hundred patients, and I think we're talking to other groups for larger ones, but it will not get into the 5,000 or 10,000—certainly not cancer patient sizes. I think the next step is a few hundred cancer patients—100 to a few hundred cancer patients—to really show that it works very well. Then that would be a sufficient for a CE mark, because—and it's very similar to the numbers we're doing in colorectal now for the CE mark.

We haven't taken a view on what the FDA would like for that. We've only just obviously got the results earlier this year. But the study we have in the process of attempting to line up, we think would get us to the CE mark stage, but we have not yet taken a view on what the FDA would like to see, because it's—it hasn't really been a (inaudible). The colorectal space has been a good one because there's been a very well-worn path from a few different people, so it's quite definitive what's needed, much more so than in pancreatic.

So, I think the answer for us, we've done the pilot study, which was 60 patients. We're now in the process of getting one

which is three times the size, four times the size, and we may have to get one in the 500 to 1,000 range, patient study wise. But, that's what we're attempting to do now. Then we'll see what happens after that.

Jan Wald:

So (inaudible). Yes, if you were put a crystal ball out there, would you think you would have CE mark sometime in 2016?

Cameron Reynolds:

It's hard to say. I don't think it's going to take as long as it did in colorectal, for a couple of reasons. We now have a quality system. We now have the same plates, the same—well, similar antibodies and some new ones, but a very similar process, so we don't have to recreate a lot of the work we did. I wouldn't want to put a guess on that. Optimistically, perhaps by the end, but I wouldn't want to make too many predictions.

I do think it's going to be—if it continues—if we continue to get anywhere near the results we've got, I think we will get CE mark from the numbers we're looking at. But timing wise, I wouldn't want to put an estimate out right now.

Jan Wald:

Okay, and I guess one last question. You mentioned optimizing the assays during your prepared remarks. Could you talk a little bit about what that means, how you go about it, and what you think you're going to get from it?

Cameron Reynolds:

Yes, absolutely. The early work we did, we chose 938 patients as a representative sample from the 4,800 for a couple of reasons. It gave a statistically significant number of cancers, but also, it was about the maximum we could do with the pipetting. So, when we're optimizing, we're doing several things. Everything we do in the lab we're trying to do better. We now manufacture the plates externally from a—they used to be made on a table in our downstairs area. We now manufacture the—we're in the process of manufacturing large batches of our own antibodies, so it's much more consistent, especially between different antibodies in different areas. We now have access to our own capturing antibody, which we use in everything consistently. It's about little things of being better at everything we do through experience, through bigger batches, through using much better external suppliers to do things. We're very lucky that almost everything we do is done by—can be done by external sources, because it's a very standard system, as we talked about. You know, what we do is very unique, but the methods are 30 years old, so a lot of things we can get other people to do better than we did initially.

Then, what we're hoping for is step changes of finding new assays. We've used about eight, nine assays in colorectal, now, target structures of nucleosomes. There are literally hundreds of target structures that we are starting the process of now looking through to see which ones could also help with the firepower that we have already. So, but the assays we've used but were by no means judged by us to be the best eight possible are just slightly opportunistic, did some research that could work. So, we are looking for small, incremental changes in everything we do every day in the lab, and everyone we use for supply and everything—and also, of course, by the Tecan, our staff have had amazing reproducibility, manually, but the robot is a robot, so it is not perfect by any means, but it's certainly very, very good. The company

we use, Tecan, are Swiss made. They're slightly more expensive. They're a couple of hundred thousand dollars per robot, but they are the best ones we could find. Very, very good precision.

So a combination of little things and hopefully big things, which will give us a bump in the actual accuracy. The leading wedge of the new assays is the adenoma and early cancer studies that we have underway from the 800 patients, so we'll be doing 30 assays on those in the next few quarters, as soon as we can, to see if we could find other ones which can fit into the panel, as well. But, I think it was very important for us not to stop everything and stop the commercialization to get the perfect test, because we believe where we are accuracy now is a very sellable product, especially in noncompliant people in the US, especially in Europe, where the fecal test—the cheap fecal test is the main competition, and throughout the world, where we're very, very competitive on cost in places in the developing world, where a few dollars makes a big difference. So, for all those reasons, we're doing a lot of work to make a better product, but we're very serious to making sure that we actually launch a product, rather than spending the next three years just making a perfect product.

Jan Wald:

So (inaudible) in parallel?

Cameron Reynolds:

Sorry?

Jan Wald:

So my—I guess my—I just want to make sure I understand. From what you're saying, you'll probably be—go to get a CE mark at a certain level of specificity and sensitivity, but work's going to continue. So, you very likely will come out with better sensitivity and specificity over time that you would move into the market.

Cameron Reynolds:

That is certainly our hope. But we—you know, we believe that the product we have now is very saleable. We believe everything we do could well lead to some improvements. It's possible that we picked on the best eight in the best way we could day one, but I don't think that's the case. We'll find out. But we are doing a lot of work in the background. Also, we're also using the most basic form of ELISA. There's a lot of multiplexing, chemiluminescence, a whole lot of other ways of actually getting better detection. But we decided to stick to a very simple platform early on to limit the number of variables. We didn't want to be on a dozen different platforms when the test hadn't been fully shown. But yes, we're very comfortable with where we are now, accuracy-wise, and we're doing a tremendous amount in an attempt to push that up, and we've only really just scratched the surface on the—what we feel is the potential of nucleosomes.

Jan Wald:

Well thank you, Cameron, and congratulations. You've made a lot of progress.

Cameron Reynolds:

Thank you. Thank you for your support.

Operator:

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

Bruce Jackson:

Hi, good morning.

Cameron Reynolds:

Good morning.

Bruce Jackson:

Just a couple of questions on the clinical trial timeline. So, with the perspective study at Hvidovre, are we still looking for some preliminary results around the end of 2015, or might those –

Cameron Reynolds:

Yes, we are. Again, this is a lot going on on the Tecan machines, so it's not guaranteed, but I—certainly our aim is to have the 2,500 done in the timeframe of this year. I know that could stretch a little bit into next year. Science and things don't always go in a straight line, but my current expectation was we should see data in the—before the end of the year in the prospective sample set.

Bruce Jackson:

Okay, and then are we still looking to start getting CE mark for some of the individual new (inaudible) starting in Q3?

Cameron Reynolds:

Yes. The only thing we're waiting for is the final production antibodies, and then do the—it will only take Dr. Holdenrieder a small number of weeks to process 400 manually, so we're just waiting for the antibodies. But I think it's—that's our current estimation, would be in the same sort of timeframe of the 4,800 data.

Bruce Jackson:

Okay, and then with—when you have the results—

Cameron Reynolds:

So, just to be clear, once we have one and two, I think—so you answered another question. Apologies, I didn't quite answer it.

Bruce Jackson:

That's okay.

Cameron Reynolds:

The first assay is usually—is going to be the most work, which is what we've done—we're getting close to now. Once we have the first assay CE marked, we would see the other ones coming a lot quicker and easier behind, because it's—once you have the process of a CE mark, it's—the only thing different with each one is the new antibody, and then redoing 400 assays manually, which takes a small number of weeks. So, as soon as we have the antibodies, our own developed antibodies. We could CE mark tomorrow for (inaudible) antibodies, but we thought it's best to wait for our own in-house antibodies, which we can mass produce and do it much cheaper. So we're waiting for those antibodies. As soon as we have them, we'll do the first assay, and then we'd expect them to become reasonably fast behind them, with a view to getting the final panel CE marked in the first half of next year, probably near the end of the first half, so that we can launch a product in Europe.

Now again, that doesn't mean a million people will run out the next day and buy the product, but it means we can start the reimbursement work. We can actually sell it to private clinics and those sort of things, so it's moving ahead very well.

Bruce Jackson:

Okay, great; and then last question: Looking at the prospective trial for the adenomas and the early cancers, is that going to be part of the—is that going to be part of the discussion that you have with the FDA when you go talk to them, in terms of what it is—

Cameron Reynolds:

Yes, I think—yes, we would certainly hope. Our assays currently, as you're aware, do very well early and very well with polyps. But, the polyps were kind of—our assays were not targeted at polyps, so we found a couple of—the percentages we got, the 60% was dependent on a small number of assays. It was a couple of which did the horsepower, where in the cancer it was a lot more to get us that bit higher. So, we're looking to see if we can add to that horsepower, which we're hopeful, but until the trial is done, no one knows the answer. But we would hope that there would be new antibodies we could add to the panel, and we would think if we can get anywhere near over what we are now, that would be very compelling for any regulatory authority to be able to pick up early stage polyps.

The 4,800 data should provide a lot of information on polyps with the existing assays, not the new ones we're looking from the study, but from the existing ones. So, a lot of people obviously want information on how did we detect larger, more high risk polyps, or whether multiple polyps or more high risk polyps. We have that data in a much bigger degree in 4,800 than we did in 938 patients, obviously. So, we would see a key part of the data coming out. In the last quarter would be an analysis of the adenoma in the 4,800 study, and then when we've done enough of the 800-person just adenoma study, perhaps adding to that population, as well. So, there'll be a lot of information coming out about adenoma at the end of Q3, Q4, and early next year, as we add all these different pieces together.

Also, the prospective study will also include a lot of adenoma, so all of these together will give us a very good picture as to—you know, we have good detection rates, but clinically, you really want to separate out the different groups, and we'll certainly have enough information to give us very good information on the different subgroups. Because when you only had the small number we had, and then 938 was still a lot, but a small number, it's very hard to make small subgroups out of that. But there certainly will be enough in this 4,800 to make some judgments on the assays which we've currently been using. Added to the ones from the 800, it should be a very large amount of information.

Bruce Jackson:

Okay, that's great. Congratulations on all the progress.

Cameron Reynolds:

Thank you very much.

Operator:

As a reminder, it's star, one to ask a question. We'll take our next from Jack Lasday with Morgan Stanley.

Jack Lasday:

Good morning, Cameron. I want to clarify something with regard to the CE mark. Once approved, you previously announced that you're going to market in Europe to national health systems, and I believe that—and I'd like you to confirm—that you had said that that will be Q3. Then you had also said that subsequently, in 2016, you may begin then to market to hospitals, labs, large doctor groups, etc. Is that—are those statements correct?

Cameron Reynolds:

Yes, just to clarify, but basically, yes. The system here is different to the US, as I'm sure everyone's aware. You can—in the FDA route, you have to pick a final panel. You have to get a very set clinical trial finished, which is as much a reimbursement trial as it is a regulatory trial. In Europe, it's split off. The first (inaudible) basically says they're produced in the correct manner, and the trial you run just has to be accurate so far as the accuracy of the test. So—and that's what we will have done, assay by assay.

So, we've done about eight, nine assays in colorectal now, and so to CE mark each one of those assays individually is our aim. So starting, again, with the first one, which we're in the process of doing now, and followed by each one rapidly behind that, with a view to—so we'll have our first CE mark this year, aiming for the end of this quarter, the third quarter. But that doesn't make a panel, because our good results for a panel of four assays, depending on the—between three and five assays, so we need all of those to be CE marked before we launch a panel as a reimbursable product. But what CE marking each one individually allows us to do is we can mix and match different panels in different areas, because four different things, some are better for adenoma, some are better for cancers. We will pick a panel which we'll launch in Europe as soon as we have enough, but it does give us flexibility. Or, to add a new one, which we find from—for example, from the adenoma study—onto the panel, where we don't have that option in the US. The US FDA are very strict about picking something, filing, and running with it. So, that's why we've pushed the FDA to after the CE mark process is started, so once we are certain about the final panel.

So, just to clarify, we will—we have begun CE marking now, and we aim to have the first one end of Q3, early Q4, probably (inaudible) Q3, and then fast behind them the ones to make the panel, finishing up in the first half or next year, probably nearer mid-year now. Then that allows us to commercially sell our products in Europe. But as you correctly point out, that doesn't mean the healthcare system will buy it on the small numbers needed for a CE trial. That's why we're doing these very large trials, as well. So, we aim to have the 4,800 finished by the end of Q3, which we'll announce, so that's a huge study for the European governments. But we also thought it was important to do a prospective one, as well, so that's why we're doing this 14,000-patient study, as well. So, we have 2,500 of that 14,000 in our freezer now from the prospective, and our Danish partners are collecting in the region of 500 per month. So, it will be chunks every quarter, or every three or four months we'll get another few thousand samples we can do. So, that will pretty quickly become a very sizeable study. So, the combination of all of those, we'll get the CE marks while concurrently doing these large trials to encourage reimbursement. Does that answer your question?

Jack Lasday:

But the reimbursements won't begin until you have a panel? Is that the idea?

Cameron Reynolds:

Yes, I don't think—we've sounded out some of the reimbursement people, and we're getting plans. We're in the process of engaging people in Europe and the United Kingdom to do the work for us, but the advice they said was at least get the first few CE marks and have a timetable, a final timetable for when you have the rest before you very strongly engage the actual regulatory organizations. So, we're in the process now of doing all the background work so we can hit the ground running.

Jack Lasday:

That's when you go after the hospitals and the labs and the doctor groups?

Cameron Reynolds:

That's correct. Yes, there's—the European markets are a little different to the US. It's about only—depending on the country, but it's certainly in single digits private payers. So the big, big people—I mean, the private payers are a good early source of revenue, but ultimately the main game has to be the large countries, (inaudible) the countries, because—so basically, you have 28 clients, plus the small—you know, these small ones, but 28 big clients. So, we don't see ourselves being able to target all of them at the same time. Obviously, we're not a big Company, so the plan all along has been doing a hit list of a couple of countries to start with—one big, a couple of small countries. There's a few contenders we're working through now to see which ones are the best ones to start with.

It's not immediately obvious which ones to start with. Sometimes, some countries have screening programs; some don't. You might think it's easy to start one with a program, but they're often funded for two or three years, so you've got to wait for the end of that. There's a lot of choices in Europe where to start because there are 28 countries, so we're just working now—and a lot of them have no screening programs at all, so you start a program. So, we're doing an analysis now of which countries to start, and then wrapping up country by country, because it's way beyond our capabilities to launch in 28 countries concurrently. So, we will start with one large and a couple of small countries as test markets, and then roll out beyond that. That's the aim.

Jack Lasday:

All right, great, great. My second question is the medical and largely the investment communities generally are skeptical until you publish in medical journals, where things are peer reviewed. When can we expect to see that kind of a scenario start to play out?

Cameron Reynolds:

Yes, absolutely, and we're very serious. I guess my—I was involved in a company very early on where we published very early and didn't have a commercial product, (inaudible) focused all of our efforts on getting a commercial product. But I'd say you're absolutely correct; we are in the need of publishing and are in the process now. There's some things underway. It's not all public, so you'll expect to see some publication from us in the not too distant future in a range of different cancers. We're now—we're fully comfortable with our IP; we're fully comfortable with our commercialization. The team is now focusing a lot more on getting some publications, so that's certainly something which now is a priority, and expect to see that in the not too distant future.

Jack Lasday:

All right, great. Thanks, and congratulations, and best of luck, continued success.

Cameron Reynolds:

Thanks for your time, Jack.

Operator:

Once again, it's star, one to ask a question. We'll take our next from Menachem Kranz with Ahava Investment Partners.

Menachem Kranz:

Hi, good morning, Cameron.

Cameron Reynolds:

Good morning, Menachem. How are you?

Menachem Kranz:

I'm all right, thanks. Just a couple of questions. Talk about, if you can, the study, the expanded study now in Germany, and sort of what are you—what are you trying to get out of that study? How big can it be, I guess? Then really, what's the downside to that? Meaning if it doesn't work, how does that hurt us? So, take us both ways with that a little. Which way do you want to run with that?

Cameron Reynolds:

Yes, thank you. It's very important so far as I think early on we naively thought we'd have a "test" for cancer, meaning cancers. But, that obviously clinically is a bit of a disaster, because it just scares someone when you can tell them they've got cancer, but you don't know where it is. So, we focused early on on colorectal, because it was a very good cancer to get started in. It's something where the gold standard, although expensive and invasive and low compliant, is very accurate, so our clinical trials we've managed to do incredibly cost effectively and quickly, at a lightning speed compared to most therapeutics or even diagnostics.

But single cancers are incredibly valuable. You will see Exact Sciences, a multi-billion dollar company based on a fecal test in a single cancer. But ultimately, our nucleosome technology is not a single cancer marker. The changes we look for are—been shown to be in every cancer and raised level of nucleosomes as Dr. Holdenrieder, the work he's done, in a very wide range of cancers. So, we always thought it could and should and would be expandable, but we were very focused on getting one product out the door to make sure we had good revenue. As you can see, a company can become a multi-billion dollar company purely on one cancer.

But Dr. Holdenrieder's trial I'm extremely excited about. No company—because we're the only ones doing it but—and have it all the (inaudible)—but no one has ever looked in the same study at a range of different cancers using the same assays. It's—for me personally, it's—I'm really, really energized by this trial because not only is it a pilot study in 27 cancers, and that's every single cancer that really is ever really going to be worked on, it provides in the very high 90s percentage of cancer (inaudible). So, what our dream would be, and this is certainly not—it's—we'll have indication from the trial—is to find a set of assays which can tell the cancers from each other, with the aim of diagnosing multiple cancers with the same blood draw.

Now, we won't have those results until the trial is finished. We don't—it's speculation until that's happened, but that's the purpose of the trial, is to see if we can find assays which could distinguish between the cancers, and therefore, you could have a single test for multiple cancers. Now, as far as humanity and the Company goes, that would be beyond value. But, it's all speculation until we do the trial. But, I think the trial is as good as it could be. Dr. Holdenrieder is, in my opinion, the worldwide expert of anyone on the planet in nucleosomes. He's collected 27 cancers from his hospital, and has very well matched other conditions, other diseases associated with each of those single cancers, as well as healthy. So, it's a good a trial as we could get. We now make a very wide range of different assays, which we can—we'll be sending to him. So, it's blinded to us. He's getting our assays, our plates, and running the trial himself, and he collected the blood, so it's completely independent. So, we'll know by the end of this trial how our assays, the ones we've developed anyway so far—and there's a lot more to go—work in the 27 most prevalent cancers, and we'll know if a single blood test could tell between cancers. To me, it's incredibly exciting. We expect the first flood of data in the first half of next year. I'm extremely excited to see how that goes, because it would be incredibly useful if that was the case.

Menachem Kranz:

Thank you.

Cameron Reynolds:

Did that answer your question? Thank you.

Menachem Kranz:

Yes, no, that's all I have. Thanks.

Cameron Reynolds:

Thank you.

Operator:

There are no further questions at this time. I'd like to turn it back to our speaker for any additional or closing remarks.

Cameron Reynolds:

Thank you everyone.

Scott Powell:

Thank you everyone, and—

Cameron Reynolds:

Scott or me? I'm joking. Thank you for coming on the line, everyone. I very much appreciate your interest in Volition, and our team now are very much hunkered down, implementing our business plan, which is to use the very large capacity we have now to finish off these very large trials which we have lined up, and to commercialize as soon as we possibly can to really derive shareholder value. Thank you for all your faith in us. We will certainly work as hard as we possibly can over the next quarters to implement the plan that we have put forward to make nucleosomes a real important part of health diagnostics. Thank you. Scott, do you have anything else to say?

Scott Powell:

No, just wanted to thank everyone for joining us today for our first Volition earnings conference call, and we appreciate your interest in the Company and look forward to speaking with everyone in the near future.

Operator:

This concludes today's conference. Thank you for your participation.


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