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VolitionRx Limited

First Quarter 2017 Earnings and Business Update Conference Call

May 11, 2017

CORPORATE PARTICIPANTS

Scott Powell, *Executive Vice President*

Cameron Reynolds, *President and Chief Executive Officer*

David Vanston, *Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Bruce Jackson, *Lake Street Capital Markets*

Raymond Meyers, *Benchmark*

Assistant to Yi Chen, *Rodman & Renshaw*

PRESENTATION

Operator:

Good morning, ladies and gentlemen. Thank you for standing by. Welcome to the VolitionRx Limited's First Quarter 2017 Earnings Conference Call. During today's presentation, all parties will be in a listen-only mode. Following the presentation, the conference call will be opened for questions. If you have a question, please press the star key, followed by the number one on your touchtone phone. If you would like to withdraw your question, please press the star key, followed by the number two. If you're using speaker equipment, please lift the handset before making your selections. This conference is being recorded today, May 11th, 2017.

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

Scott Powell:

Thank you, and welcome everyone to today's earnings conference call for VolitionRx Limited. This call will cover Volition's financial and operating results for the first quarter of 2017 which ended March 31, 2017, along with a discussion of our recent activities and key upcoming 2017 milestones.

Following our prepared remarks, we will open up the conference call to a question-and-answer session. Also on our call today are Mr. Cameron Reynolds, President and Chief Executive Officer, and Mr. David Vanston, our recently appointed 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, upcoming milestones, including results and completion of clinical studies as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer.

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

Other risks and uncertainties include the Company's failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical IVD market; a failure by the marketplace to accept the products in the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company's intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; and other risks identified in the Company's most recent Annual Report on Form 10-K and quarterly reports on Form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission.

These statements are based on current expectations, estimates and projections about the Company's business based, in part, on assumptions made by Management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict.

Forward-looking statements are made as of the date of this conference call and, except as required by law, the Company does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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

Cameron Reynolds:

Thank you, Scott and thank you everyone for joining Volition's first quarter 2017 earnings conference call. I would like to thank you all again for taking an interest in Volition at this key time for us. As you know, we held our end of year results earning call in March of this year. In addition, I saw many of you in New York around the same time. As it has not been a long time since then, we will keep this update to the key events that have occurred in 2017.

I'm delighted with the progress we are making on many fronts. As I've always said, our team is extremely important to us and we continue to grow stronger. We have welcomed some key hires into the business this year. In January we appointed Dr. Jasmine Kway as Vice President of Asia. We expect to see a lot of activity this year in Asia from a very dynamic new hire. We are optimistic that our blood-based tests will uniquely get some strong traction in the very large and growing Asian markets, as a result of their affordability. In April, we also named David Vanston as our Chief Financial Officer. David is a very dynamic and experienced new hire who will work with us to implement and comply with the requirements under the Sarbanes-Oxley Act of 2002, as well as to help us transition from research to revenue. Both of these we expect to be very important over the next 12 months. David joins me on the call today to answer your questions.

We've also added several other important members to our research and development team and to our marketing team as we continue to develop new products and market them. We believe the U.S. healthcare market to be the most important market in healthcare in the world. Our long-term plan which we have stuck is to develop our products in Europe and then transition back to the U.S. market. The U.S. side of our organization moved forward strongly this quarter with the formation of Volition America, Inc. headed up by Chief Medical Officer Dr. Jason Terrell and based out of Austin, Texas. We formed this subsidiary to have a dedicated team in the U.S. whose sole purpose will be FDA trial work and the launching of a range of products in the U.S. over the coming years. Expect to see a lot of progress on this front soon.

I think the biggest event so far in 2017 for Volition was the grand opening of our new research and development facility in the Wallonia region of Belgium last month. This is a giant step forward in terms of our capacity to both run large scale clinical trials and allows us to extend our efforts into other cancers, most notably pancreatic, lung and prostate. If you haven't already done so, I'd encourage you to visit our website and watch the video showcasing this fantastic new facility. It certainly helps to bring to life our capacity moving forward. I'm absolutely delighted to say this large new cutting edge facility was completed on time and on budget with the support from the local government. This fantastic new home for our research is a real testament to our Belgium team headed up by Dr. Michel. We also made very strong progress on our CE marked product. We have now successfully completed the training in two large validation sets for this and we presented this data on our CE marked Nu.Q™ CRC Triage test at the European Society for Medical Oncology, also known as ESMO, in October last year, and then at the World Congress of GI Endoscopy also known as ENDO in Hyderabad, India in February of this year.

This last week we have presented the final set of data at the Digestive Disorders Week in Chicago. With a total number of combined data of this set just under 8,000 subjects for this Nu.Q™ Triage test, we identified a reduced need for colonoscopies by 24.5% with a sensitivity for colorectal cancer detection of approximately 95% of cancers. This was a very good outcome. With colonoscopy capacity and indeed healthcare costs under pressure worldwide, the Nu.Q™ triage test has a potential to help alleviate some of these major problems faced by many national screening programs.

We also have recently expanded into Asia with our first clinical evaluation of the Triage test underway in Taiwan. We have also begun the regulatory process in both Taiwan and Singapore, the latter once granted will give us access to nine other Southeast Asian markets. Please see the Volition website for a video interview with Dr. Jasmine Kway in order to hear more about our plans in Asia. For the quarter ended March 31, 2017, we again had a very strong cash position with $18.5 million left in cash and equivalents compared with $21.7 million as of December year-end.

We have kept very close controls of costs despite the high level of research and development and marketing activity in a wide range of areas. Yet again we have completed a large number of milestones on a relatively tight budget to ensure we use our shareholders' equity very carefully. Also on the financial front, I'm delighted to say that our Chairman as well as several other members of the Board and Officers of the Company have recently exercised warrants in the aggregate by over $400,000 in cash providing additional support for our cash position. As always, our insiders have been extremely supportive of the Company.

Milestones for the rest of 2017. Looking ahead for the remainder of this year we are targeting many important clinical and commercial milestones as we kick up a gear with the new lab facility now open. Following the opening of our new lab, I now envisaged a step change in both our discovery and R&D work, not only in colorectal cancer but also in other cancers too. We now have more freezer capacity to store samples, more automates to run samples, a new platform called Gyros to aid quicker biomarker discovery and more bench space for scientists to work. It's tremendously exciting as this will allow us to finalize the frontline screening test for colorectal cancer and get back into other cancers, starting with pancreatic cancer and this will provide us a strong pathway to the U.S. front line product as I mentioned before.

With regards to our CE marked Triage test, I'm hopeful to be able to announce the results of the logistical pathway study we have undertaken in Denmark. This study will hopefully answer the questions required for Danish sales. Also, the results in Asian populations and the publications of the validated product results

in regarded journals. I also anticipate we will file and obtain more key patents in several countries, including the U.S., as we continue to expand our intellectual property portfolio and enhance shareholder value. From a funding point of view, we hope to obtain further grant funding connected to the Wallonia region in Belgium, a very strong ally and supporter of Belgian Volition SPRL. This non-dilutive funding greatly adds to shareholder value.

Lastly, but most importantly, I hope that Dr. Terrell and I can soon update you on a clear and affordable pathway to FDA approval of our colorectal screening cancer product. A large 10,000 plus study in an asymptomatic screening population will put us on the map strongly in the U.S. 2017 is off to a strong start and I'm proud of the team's accomplishments in the first quarter. We look forward to achieving additional milestones in the second quarter of 2017 as we begin to ramp up into a commercial stage Company. With respect to the commercial launch of our first product, our Nu.Q™ Triage test, we have progressed very well.

We plan to accelerate our ability to deliver larger volumes and also to expedite clinical trials following the opening of our new research facility in Belgium. We are proud of our clinical and commercial accomplishments so far and we look forward to achieving these numerous aforementioned milestones throughout the rest of 2017.

Thank you all very much for your interest in Volition and for joining us on this earnings call today at this key time for our Company. We would now like to open up the call to questions. Operator?

Operator:

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

Our first question today is from Bruce Jackson of Lake Street Capital Markets. Please go ahead.

Bruce Jackson:

Good morning everybody nice quarter.

Cameron Reynolds:

Thank you.

David Vanston:

Thanks, Bruce.

Bruce Jackson:

So, first with you and Dr. Terrell talking about a potentially a 10,000 patients asymptomatic patient study, when can we expect to hear more about that?

Cameron Reynolds:

Very good question, Bruce. We made public for the last few months in the last quarter we've been really looking for a very large affordable trial which would really put us on the map in the U.S. to really show that a very clear timeline. Expect to see that soon. I can't tell you exactly, we're in discussions currently it would be on and I think that would be a massive step change for the Company because our plan all along has been to develop the product in Europe where we can do it very cost effectively on very good populations

with fantastic trials, but our aim has always been to shift back to the U.S., and a key part of that - you can do it several ways, you can try CLIA labs and smaller trials. By being a very serious Company we want to do a very serious trial of 10,000 plus asymptomatic patients. So, expect to see that soon.

Bruce Jackson:

Then moving over to Denmark, you're in the process of doing the final logistics trial I call them, how are those proceeding? When you think those might finish up, and then what's the potential for getting some kind of commitment by the end of the year from the Danish screening program?

Cameron Reynolds:

Yes, it's running as we have said in the press releases. We're through the logistics studies now, we have got our approval for the second phase, that's all progressing. We've had some back and forth with them. It's proceeding very well. I think there's definitely a need for the product there. I think our product, as you've seen we've now confirmed it in a very large population of 8,000 FIT positive. It was well and truly within the specifications of— the minimum criteria we set were 90% of cancers and 20% of colonoscopy, so at 95%, 24.5%, we well and truly met that. So, we're very hopeful. As you know Bruce, you never know until it's all done, but there's a very strong need, we have the product, it's validated in a large set, so we're very hopeful. I think everything we said before is still on track. We very much hope and expect to have something this year, and we're also pushing in other markets, and also as you've noticed, we're also pushing into Asia where we believe there may also be markets in Taiwan in the form of similar products and in some other countries. So yes, it's going very well and we're just continuing— like we always do, we have a plan, we announced the plan and we're just working through that now with the aim of getting that revenue.

Bruce Jackson:

Okay. Last question, you've done a very good job in terms of the expense control. Should we expect— in terms of the operating expense profile going forward, would we expect for the next couple of quarters to be at roughly the same level, or given some of the increased activity would that move up at all?

Cameron Reynolds:

First, this allows me to introduce David, our new CFO who we're very happy has come on board. He has tremendous stock experience and background in accounting to really help us to become fully compliant with all those areas, and of course one of his big areas is helping us to make sure we keep control of our costs. I will give a very top line answer and then he can give some more detail.

This was a slightly exceptional month with the move and some large trial work being paid for. But I think we would— so, I would expect it to go down from this month in the next couple of months, but David would you care to answer?

David Vanston:

Sure. So, hi Bruce. In the quarter you've got a number of one-offs, particularly if you look on the cash flow around about $875,000. That's due to the building fit out and also bringing in the capacity of the machines that we bought in. So, I'd expect the run rate to not be as high, but to be in the region of a quarterly burn rate between $2.5 million to $3 million going forward.

Bruce Jackson:

Okay.

Cameron Reynolds:

So, slightly higher than we were but below where we were this month I think is bottom line Bruce.

Bruce Jackson:

Okay, great. Thank you very much.

Cameron Reynolds:

Thank you. Take care.

Operator:

The next question is from Raymond Meyers of Benchmark. Please go ahead.

Raymond Meyers:

Thanks for taking the questions. Cameron, let me ask you about this 10,000 patient screening study aimed at getting FDA clearance. How is it that you had planned to do this in such an affordable manner, and when you say affordable, can you bracket what the cost of that test might be?

Cameron Reynolds:

Yes. Thank you, Raymond. That's actually a very important question to answer. I think one of the things which people have considered perhaps a possible negative with us is other companies have had to do very large extremely expensive trials in the 10s of millions, the $20 million to $30 range. We have something very unique because our test does not cost much to run, makes the trials cheaper, and also because we need a small amount of blood, not a large amounts of feces like some companies do or a large amount of blood like all the other blood companies do typically, it means we can be part of a bigger program which is what we're looking to do. So, this is a really key difference.

If you look in the K at the end of the year, we budgeted $5 million for that process. That's something that's a range which we're very much trying to target, and if we do achieve, I think it would be a remarkable outcome for us to secure a population along the lines which we discussed, a very large recognized institution with a very large sample set.

So, it is a very key difference for us and I think it should be very well received by the market that A, we're very serious about the U.S. as the biggest market. We're also very serious about having a very large trial in the U.S., not trying to do it in small ways, and also very impressive we will not need a massive dilutive event to get us there. So, something we're very hopeful and very excited about and hope to be able to announce significantly soon that we're on that path because that will be a massive change for us.

I think the European revenue is fantastic and it makes this potentially a profitable Company from all of the revenue from here, but I think a lot of what the U.S. market wants to see is, and have been a bit skeptical of, is that we can get a U.S. product out there without spending many tens of millions of dollars. So, we're very hopeful and it's something which I think will be a very big deal when we do announce it and we do expect that reasonably soon.

Raymond Meyers:

That's great, and a follow-up on that is, I presume this is a prospect of re-enrolled study, so how long do you expect this study to take?

Cameron Reynolds:

Yes. That will be in the details but typically they take a couple of years. It depends on the more you spend the quicker it can become, but to collect 10,000 or more patients, you need a few years. It needs to be perspective— as you said, it's much better to have a big perspective elements at all which has to have, so yes, it takes a couple of years.

Raymond Meyers:

Okay. Great. Then, on the Danish side, you're running some feasibility studies for Denmark, can you update us on how those are going, what progress is being made, and are you still confident in launching that product this year?

Cameron Reynolds:

Yes, it's proceeded exactly as we outlined. The Phase 2 just got ethical approval. It's on the same time scale as we have announced, that's absolutely. It goes to the very practical questions just for listeners to understand the difference between the 8,000 person study which is now finished and validated in banks efficacy rule (phon), that is the level of test work out which is 95% of cancer. What this test is much more practical question how it fits into the healthcare system. So, to launch for a large bite size of a country taking on a program which to my knowledge no company has ever really launched a nationwide blood test in Europe for colorectal cancer in any sort of screening program. I mean, this is something very, very big. You want to make sure you're answering a very practical questions as to how the blood is collected, how many centers need to process the samples, letters, all those kind of things need to be sent out. So, that's what we're doing, and I think there's always a tendency to try to push without that, but I think if you want to make sure a launch is successful, you want think of the very practical things before you launch nationwide, in countries like Denmark is not big but you still don't want to trip over yourself on the launch. So, it hasn't— it's not taking an awful long time but it's very important that we do that to make sure if it is picked up, which is what we expect by them, that it is successful because we want to make sure the first launch goes very smoothly. So yes, that's all gone very well.

Raymond Meyers:

Very good. Then lastly, I wanted to ask if you would touch on the regulatory and commercial milestones to address the Asian market.

Cameron Reynolds:

Yes, it's a very good question. So, of course the first product we have is a Triage test which we weren't 100% certain what the market is in Asia because there are some national screening programs which would be natural for that. So, Dr. Kway has been doing a lot of work, she is very dynamic. You can see a video of her on the web outlining a lot of this. But Asia was also a very big region. Of course I'm sure everyone's very much aware of that so we're just trying to cut through in what countries are the triage tests possibly useable. So, she started in Taiwan. We have the first study underway in Taiwan already which is a huge outcome and a big milestone.

We're also getting the product regulatory approved in Singapore which means you can sell it in any one of the Asian countries which (inaudible), but as with U.S. and in Europe, the very big product is the front line test, the first test, not the triage test. So, we have been asked many times do you need to do trial work in Asia? Do the tests work? We would expect the tests to work in these populations, but the best way to show that is to have a trial in an Asian population, and there are several different Asian populations, Chinese, Indians, Malay, a few different groups, Japanese. So, we're looking to do some confirmatory trials in those countries as well. They're not very expensive and don't have to take very long, but I think given just for India and China together, a couple of billion people, it's worthwhile just showing that it works in their populations. So, we'll have some news on that, both from the triage side which we have started already and we expect to be completed soon, and also from the frontline test. We expect to do moderately sized trials in a few of the big Asian populations to show the tests work well there as well.

Now, we have no evidence that there's any differences in any regions or populations, but (inaudible) guys have spent two years answering that question, or you can do a trial in a year and answer it very emphatically. So yes, it's within the budgeting we have to do some trial work in Asia. As I said, it's not a lot of expense but I think it's very much worth doing because we really want to make sure, like everything we do, we get it right and we think ahead. We tried as a Company to very much look forward a year or two ahead to make sure that we didn't— we say we want to be a global Company, a multinational selling in many regions, you've got to start to resourcing that and doing the trial work years out to make sure you get there. That's why we have Volition America sorting out the FDA trials and the US launch, and we have a presence now in Asia really thinking all these things through because they're very important. If you're really are going to roll out and become a truly international Company, you need to do this groundwork now.

Raymond Meyers:

Thank you Cameron, that's all I have.

Cameron Reynolds:

Thank you, Raymond. Take care.

Operator:

As a reminder, if you would like to ask a question, please press star, then one.

Our next question comes from Yi Chen of Rodman & Renshaw. Please go ahead.

Assistant to Yi Chen:

Hi. This is Roshini (phon) on behalf of Yi. Thanks for taking my questions.

Cameron Reynolds:

Thank you. How are you?

Assistant to Yi Chen:

I'm good. When do you anticipate being granted regulatory approval in Singapore?

Cameron Reynolds:

The process lasts between 6 and 12 months, so it would be sometime next year.

Assistant to Yi Chen:

Okay. When do you expect to start generating revenue, and also can you provide some color on what R&D will look like in the subsequent quarters?

Cameron Reynolds:

Yes. So, the revenue side, as we've said we're working with the Danish government now we're hopeful that that would be sometime late this year where we get a lot of orders for a part of the country, or a large part of the country. It should be a very significant event. The other countries we're working on now and we'll have some more news as it comes up.

As far as R&D, I think projections, we give more of a top level answer just so far as we expect— I guess what's most important is the overall burn rate of the Company has trended in actual cash at about $2.5 million a quarter. We're about $3.2 million this quarter but there were some big exceptionals as David very well outlined. So, expect that to go back towards trend, but given how much more we're doing, the trend will go up but somewhere in the sub $3 million per quarter, just under $1 million per month range.

We're also hoping very much that we can announce some non-dilutive funding from the Belgium regions and governments, and also in the medium term we're looking for non-dilutive the funding coming from the U.S. as we launch products. So, I think altogether we're in a very strong financial position, certainly compared to the last six years and we have a good solid runway ahead of us. We have a product which we're in the process of launching and we're now with a new facility really pushing towards that front line test which ultimately is the big one. The big one is the front line test in the U.S. and in Europe for which we hope to be able to announce the very big milestone for a large trial as we talked about before of over 10,000 patients for the U.S. market.

Assistant to Yi Chen:

Okay. Thank you.

Cameron Reynolds:

Thank you. Take care.

Operator:

There are no further questions at this time. I would like to turn the floor back over to Cameron Reynolds for closing comments.

Cameron Reynolds:

Thank you everyone for joining us today for our first quarter 2017 earnings call. We really appreciate your interest in Volition and look forward to speaking with you again in the near future. Thank you very much for your time. Good bye.

Operator:

This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.