VolitionRx Limited

Third Quarter 2016 Earnings and Business Update Conference Call

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PRESENTATION

Operator:

Good morning, ladies and gentlemen and thank you for standing by. Welcome to the VolitionRx Limited Third Quarter 2016 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'd 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 selection. This conference call is being recorded today, November 10, 2016.

I would like to turn the conference call over to Mr. Scott Powell, Vice President of Investor Relations for VolitionRx 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 third quarter ended September 30, 2016, along with a discussion of our key upcoming 2016 and 2017 milestones. Following our prepared remarks, we will open up the conference call to a question-and-answer session. Also on our call today are Mr. Cameron Reynolds, Chief Executive Officer, and Mr. David Kratochvil, Chief Financial Officer of Volition.

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 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.

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

Cameron Reynolds:

Thank you, Scott, and thank you everyone for joining Volition's third quarter 2016 earnings conference call. I'd like to thank you all for taking an interest in Volition at this very exciting time for us.

I'd first like to review some important Q3 events. The third quarter of 2016 marked an important quarter for the progress in our commercial launch of the Nu.Q™ Colorectal Cancer Screening Triage Test, also known as the Triage Test in Europe. I'm very happy to be able to announce now the completion of our Nu.Q™ Triage Test validation study last week. This means that we still expect to obtain CE Marking late this year and hope to be ready for a commercial launch in the EU in early 2017. We intend to discuss this in greater detail around the JP Morgan Conference in early January of next year.

This Test offers European healthcare system, a simple and easy-to-use blood test which can be used for Triage patients who test positive in a fecal immunochemical test, FIT, for colorectal cancer. This is very exciting as we anticipate coming to market with something that we feel meets the pressing and immediate need in several European countries. We plan to initially focus on launching our Nu.Q™ Triage Test in the EU Member States which have an aggregate screening age population of approximately 148 million people. Currently there are organized colorectal cancer screening programs in 14 of these 28 EU states with a further 10 countries offering some form of public or private accessible screening.

After much analysis, I believe that commercializing this product as single normalized assay is the quickest way to generate revenue for our proprietary Nucleosomics® platform. Being a single normalized assay,

we believe we can make the product both very cost effective for the customers and potentially give the Company a very healthy profit margin.

We also continue to make excellent progress with our clinical trials showing the depth and adaptability of our Nucleosomics® technologies, including last month at the European Society of Medical Oncology Congress, also known as ESMO, we announced strong colorectal cancer results from the first 2,000 of the 8,000 FIT positive patients in our prospective screening study conducted in conjunction with the University of Copenhagen Hvidovre Hospital. This prospective study aims to discover the ability of the Nu.Q™ Triage Test to identify patients with a false positive on their FIT in order to reduce the total number of colonoscopy referrals. The combination of the FIT test and the Nu.Q™ Triage Test in the study accurately identified nearly 97% of colorectal cancers in the FIT positive subjects and could reduce the number of colonoscopy prescribed (phon) by 25%.

As I've said at the start of this call, the validation study has now been successfully completed and the results will be presented at the upcoming ENDO 2017 Conference which is the World Congress of GI Endoscopy in February of next year.

Last week, we announced the partnership for the prospective clinical study of 30,000 people in collaboration again with the Hvidovre Hospital, University of Copenhagen, Denmark, in longer vigorous clinical studies that aims to collect 90,000 patient samples. This ambitious clinical study signifies Volition's commitment to the discovery of new types of blood tests in the middle of next decade. I'm personally extremely excited and proud of this remarkable trial.

On the regulatory front, Volition was granted a fourth U.S. patent (inaudible) method for detecting nucleosomes containing histone variants relating to our Nucleosomics® platform which detects mutations present throughout the entire Nucleosome, an approach which differs from the more common method of analyzing only the DNA strand. This patent is complementary to and will support the first three patents that we've already been granted in the U.S. and cover three of the four core epigenetic areas of our Nucleosomics® technology, including nucleosomes containing histone modifications, histone variants, and (inaudible) nucleosomes adducts, as well as methods for detecting nucleosomes.

We've also been developing a fresh corporate and product rebranding and look forward to its unveiling likely again around the JP Morgan Conference in January thanks to the considerable work being done by our Chief Marketing and Communications Officer, Louise Day.

We've also announced some important additions to our team and facilities that we believe greatly improved our commercial prospects and add depth to our corporate capabilities.

Last month, we announced the acquisition of a new research and development facility located in Crealys Science Park in the Wallonia region of Belgium, an area popular with other leading biotech and pharmaceutical companies and we expect to move into the facility by March 2017, once the new lab fitout is complete. This is yet another large step change in our Company's development. New custom design facilities divided into a 9,000-square-foot of office space and 10,000 square-feet of tailor-made laboratory space which is significantly larger than our current facilities at around 4,000 square foot. We anticipate that this exciting upgrade will allow us to increase our capacity and expand our scientific team and expedite commercialization and Nu.Q™ tests.

I would also like to welcome Dr. Philippe Willemsen who joined Volition as Chief Operating Officer in its wholly owned Belgium subsidiary last week. He brings with him 11 years of experience in the biopharmaceutical environment and cell therapy manufacturing. He joined Volition from Promethera Biosciences where he served as Senior Product Manager since 2011. This frees up our Belgium CEO, Dr. Michel to focus on the Nu.Q™ Triage CE Marking and launch of the product.

Now over to the financial side. For the quarter ended September 30, 2016, we ended with a very strong cash position with $12.5 million in cash and equivalents compared to $14.5 million as of June 30, and $5.9 million as of December 31, 2015. Following the completion of our secondary offering last month in which we raised gross proceeds of $12.4 million which is in addition to the money I just mentioned, we have the highest cash position in the Company's history which we believe puts us in a very strong financial position. We have kept very close controls of cost despite the very high level of activities announced in a wide range of areas and milestones (inaudible).

Now to finish, with the milestones for the end of this year and through next year, we are targeting many important clinical and commercial milestones. As mentioned before, we aim to receive CE Marks on the Triage Blood Test on additional CRC assays and commercially launch our first product in Europe early next year and also aggressively target the key first markets we have targeted, the first key five markets we've targeted including Ireland, Scotland, the Netherlands, France, and Denmark. We also aim to obtain more key IP in several countries including the U.S. as we continue to protect shareholder value. We also aim to present solid results from the 4,800-patient retrospective CRC symptomatic population trial as well as initial tranche from the 40,000-patient prospective CRC screening trial as a frontline test. We also aim to present results from the ongoing trials including a study at Bonn University into the 27 most prevalent cancers and we aim to announce one or more large clinical trials in pancreatic and/or lung cancer as well as initiating our first discussions with U.S. FDA, and we aim to offer additional clarity on the EU commercialization strategy, including upcoming milestones and timeline for European market access and sales of the Nu.Q™ product Triage for CRC.

This has been an exciting year and we look forward to achieving our milestones in this final quarter of 2016 as we position ourselves for the expected launch of our first product in early 2017. We expect to make announcements in the coming months to discuss commercial updates in more detail. We plan to discuss more about the specific role of our product, the specific role our product is expected to play in the screening regime for specific countries and our market entry strategy. We're proud of our clinical and commercial accomplishments so far and we look forward to completing these numerous aforementioned milestones throughout this year and next. Thank you all very much for your interest in Volition and joining our third quarter 2016 earnings conference call today. I think a very exciting time for us. We would now like to open up the call for questions. Thank you. Operator?

Operator:

Thank you. We will now be conducting a question-and-answer session. If you'd like to ask a question, please press the star, one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star, two if you'd 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 comes from the line of Bruce Jackson with Lake Street Capital Markets. Please proceed with your question.

Bruce Jackson:

Hi. Congratulations on all of the progress. If I could…

Cameron Reynolds:

Thank you, Bruce. (Inaudible).

Bruce Jackson:

Good, good. So, a couple of questions around the Triage Test. So, I'm assuming that you've selected the markers and do you have CE Mark for each of those individual tests yet, and what are some of the rate limiting factors in terms of being ready to have saleable products by early next year?

Cameron Reynolds:

So, I'll answer that first one. Yes, we chose the panel a month and a half, two months ago so we could get it CE Marked this year and on our assays that we had previously CE Marked as separately for the blood marker. So, that's why we could do it as quickly as we have. So, we have CE Marked a range of them individually for the blood market as a front line test. So, we chose from those to make sure we could do it quickly enough. So, that's all— have been very good and it shows the forward thinking we had from last year to start the CE Marking progress to make sure it's a low risk launch. So, we're very confident with all of that.

As far as rate limiting, I guess there are several factors involved in the launch itself. The production of the kits, the facility we use currently is CE Certified so they can make large batches of a few thousand plates per day. So, that's more than enough for a national program production for a year in just a couple of days. So, that's not a problem. The antibodies used are all monoclonal lines that we've developed and had developed for quite a while now. So, that's not a rate limiting issue. The CE Marking is obviously a time issue. We're still confident we can get that done by the end of this year, about the end of the year, but that shouldn't be too much longer or shorter if it is. So, I don't think— there's always something that comes up and you can never guarantee anything but we're quite confident of the schedules we have, and being an ELISA platform system, the benefits apart from the cost and the ease of use and all those other things are it's a much more low risk launch because you're not relying on new equipment or your own equipment, so because they're manual ELISA plates, it comes down to the plates, the antibodies and the manufacturer, and we're very confident of all of those. So, I think we're in very good shape. I guess time— always time will tell but at the moment we're very confident and very relaxed with our schedules.

Bruce Jackson:

Okay. That's great, and then in terms of the sales and marketing components, so you've identified some countries with screening programs are good candidates for this test, what's the sales process like? Do these countries operate as the review process or a tender process, and what's the likelihood that you can get a contract signed and start generating revenue sometime in 2017?

Cameron Reynolds:

We chose five different countries and being Europe, the five customers but they're all a little different. I can discuss them with you offline in more detail, but we have done a lot of research through our full time Marketing Officer, Louise Day and also (inaudible) so we have a lot of information and attending the big Congress is where the countries screen programs, all the 10 has been very helpful and enlightening us to what they will do. As you know, we just attended the World Endoscopy Organization last month in Vienna when all of the target countries and people were there, and we've also started visiting each one of the target five countries and we've had a very good response. So, each one's a little different and we would hope very much to get some very strong traction in at least a few of them soon. We've had a very good feedback. It is absolutely a pressing need for those governments and those countries. So, we're very hopeful. It's very hard to give an exact time scale but I would be very surprised if there wasn't some very good traction next year as we launch. Because of the immediate need, it's very cost effective and colonoscopies are, capacity is a real problem in every EU country. So, we'll have a lot more information and we'll have some more information around JP Morgan, and will have visited some more of the countries in person, but we have a very solid plan and we're implementing it now.

Bruce Jackson:

Great. That's it for me. Thank you.

Cameron Reynolds:

Thank you, Bruce. Thanks for your time.

Operator:

Thank you. Our next question comes from the line of Jan Wald with The Benchmark Company. Please proceed with your question.

Jan Wald:

Good morning everyone and congratulations on the progress you're making.

Cameron Reynolds:

Thank you, Jan.

Jan Wald:

Let me push a little bit more on the question that was just asked, in terms of the sales process and I guess the (inaudible) process in Europe, you launch let's say early next year, let's say in the first quarter, you can begin to sell the product into those countries without any further regulatory process (inaudible), and the reimbursement process is probably going to take you a year or so to get, so one, am I right about that, and secondly, how do you generate cash in 2017, if that's the case?

Cameron Reynolds:

So, I wouldn't say Q1, I'd say very early Q1. I'd be surprised if we didn't have the CE Mark. We plan on being late December but let's say it is like— I don't think it will be, but it'd be generating not so much but we'll be ready very soon. So, once you have the CE Mark, you can legally sell in those 28 countries and a range of other countries around the world who would accept the CE Mark. Usually the private payer markets in other countries outside the U.S., particularly in Asia and in other regions, you can use the CE Mark to sell to private payer (inaudible). So, there is some work in each country. Sometimes it comes down to the pathway needed obviously giving blood. Each country is a little different, how that will happen, whether it's your local doctor or a center. Those kind of things. We're working on some of those programs now and hope to have some news on that in the next quarter. So, there is always a little bit of work to do but we can legally sell it in those countries. There is no more work from the CE Mark point of view, but sometimes each country wants a little work done just on their own processes which we're very happy to do because we want to make sure that we do the test as well as we can, that we help where we can. There may be some— I mean, it's a very simple test but different countries, if it's a small lab where the work is done, we may do it manually or on a small machine, we're looking at a machine that does a few plates a day, or if it's a centralized facility like in France, we probably have a couple of the off-the-shelf Tecan machines to run the country. So, I mean a bit of that work to do but nothing else new regulatory wise.

Reimbursement is a little different, and again as to Bruce's question, it's very hard to give an answer for each— for the 28 countries. That's why we're targeting five first of all. But, if you look at one country you know very well, just to give an example of how it works, a lot of the screening programs are separate from the healthcare systems like in Denmark. So, they have their own budget. So, you don't need to get it reimbursed in the same manner as you would in the United States through the insurance companies. You have to convince that committee to, and the numbers we're talking although it's a reasonably large amount of money for us is a very small part of the screening program budget. So, there are some cycles in which we're working for now and we can give a lot more granularity on that hopefully in the next earnings call, but it's not— it's not a system in the same reimbursement time delays that you have in the

U.S. It's much more about trying to fit into the pathways and understanding how we do that, but we have had several meetings on that with some of the governments we're talking to. That work's well underway and I can't give any more information until we're really sure of exactly how we're going to proceed, but it is a slightly different system and we hope to have some strong news on that in the next quarter or two because we've done a lot of work already in, and I think the reaction's been exactly what we wanted. So, we can give more granularity on that when we know better ourselves.

Jan Wald:

Okay, and I guess you're concentrating on Europe but could you provide an update on the U.S. strategy?

Cameron Reynolds:

Absolutely, and that's— the work we've done in the U.S., we have done— Dr. Terrell who we took on in January full time has been excellent. He's been discussing the rollout plans for the U.S. in several different ways. The Triage Test is probably not one for the United States because the quality (inaudible) is not something widely used in the U.S. So, I've had a lot of discussions with him and he with all of other groups as to the best path into the U.S. So, our thoughts are the first test in the U.S. will be the frontline test, either as a screening of the symptomatic population. As we discussed, I believe two earnings calls ago, we're looking to do it through a 510(k) in the first instance. We've had several quotes from CROs on the 510(k)'s. We are looking in that million plus or minus to do what's the sample size needed. It's very much to our plan from what we had, but I think as we discussed on the last call, a company our size really cannot try to do too many things and I think revenue next year and the launch is a very good thing for us. So, we decided certainly for the last two quarters and probably into the next quarter, to really to focus to make sure we make this Triage Test a success because this will be a real foot-in-the-door with all the European governments. It'll show that we have a test and a platform that works and provide us with very significant revenue for a company our size. So— but, that's not to say by any means we're not serious. We're not very active in the U.S. Dr. Terrell has done a fantastic job in setting up a plan for us. So, when we push the button, if it's all ready to go, so far as what we're doing the CROs, we're putting together a strategy for the FDA to approach them when we're ready but we really didn't want to go half loaded too early. We wanted to make sure we focused on the Triage Test and succeeded. So, that's still very much under way, and once we hopefully have a successful launch of the Triage Test, then we'll fix our attention back onto the 510(k) process in the U.S. for the frontline blood test.

Jan Wald:

Okay, and I guess looking at the 10-Q that you put out, there is a discussion in there about financial reporting. Could you talk a little bit about the delinquencies and how you're fixing them?

Cameron Reynolds:

Delinquencies in the reporting requirements, do you mean, or in controls? Well, obviously as a small company and David can answer this (inaudible) anything beyond, but as a small company obviously we never had the three or four people necessarily for the controls in a single location, and as you're probably aware, Sarbanes-Oxley is fast approaching a company our size. So, if we're at the valuation we are now on June 30, we'll have to make all those things right next year or this year, coming year. So, we put those issues into the 10K and Q's because they are— a company our size does not have the same controls as a large company. We're very much aware of that and as part of us growing up as a company. So, we expect to probably have to do Sarbanes-Oxley next year and all those issues will have to be solved, and we take it all very seriously and I think we have controls which are certainly good enough for a small company but as we intend to be very successful and a large company, we are in the process of putting all those in place, and that's an issue for everything we do. If you think, looking at the last few months, we're getting a bigger trial with the Danish samples. We're getting a bigger facility. We're getting more staff, more admin staff because those are not costs which you want in on a very small company for the burn rate, but it's something which we obviously are taking very seriously. That includes a new

computer system, a whole lot of things which we've done a lot of work on and will come to fruition next year. But, if you look at just our burn rate for example, the net loss of course which is the figure which is used, incorrectly used but as a CEO what I'm also very, very (inaudible) how much cash is burned through and a lot of the others are accounting issues but not actual cash, cash. So, we've kept it incredibly steady this year. The rate has been $2.2 million to $2.3 million every single quarter, dead flat this year considering all the things we've been doing, all the money raisings, all the other, the trials, the product launch. It's a remarkable achievement.

The net loss is just under $3.5 million but that includes accruals and stock options and warrants and things like that, but actual cash, cash. So, if you add up the cash we have, we're in the early $20 million range and we in fact kept it flat at $2.2 million a quarter which I think is a really remarkable achievement considering all the things we do and something which we take very seriously and we take shareholders' money very seriously because we want to make sure that we have the money to really deliver on our— what we think is very exciting technology and really help as many people as we can as quickly as we can. So, all those things we take very seriously.

Jan Wald:

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

Cameron Reynolds:

Thank you. Thank you for your time, yes.

Operator:

Thank you. Our next question comes from the line of Brian Marckx with Zacks Investment Research. Please proceed with your question.

Brian Marckx:

Hi. Good morning, guys and congrats on the progress.

Cameron Reynolds:

Thank you.

Brian Marckx:

Cameron, regarding Triage, how does it work with the national screening programs in the European countries that you're initial targeting? Is it essentially a binary decision that you're either included on the screening programs or you're not included nationwide, or is there some sort of evaluation period and perhaps in local or regional areas before they would roll it out more widespread?

Cameron Reynolds:

Yes, a very good question, Brian. Ultimately as we've discussed, we've got quite advanced discussions with some of the countries we're talking to and there's very little pushback on the sort of the cost because it isn't a huge cost for the systems. They have a pressing need and it's a lot of money for us, but obviously for national screening program it's not going to break the budget so to speak. So, a lot of it comes down to how it actually would work in practice which as I discussed with Bruce a little earlier, comes down to the type of platform we launch on. So, they look at it in terms of the pathway, design study which can take a few months, perhaps three or four or no more than six, where they need to make sure the labs can run that many samples on that sort of machine. People will attend either one facility or the local GP that kind of issue.

For example, Denmark has half a dozen regions so we wouldn't want to— but it's kind of a little different but France has a national screening program. It's very centralized where almost a lot of it goes through one center for such a large country where some countries are more decentralized. It's still horses for courses for different countries but just to use Denmark. Obviously we've worked with them quite closely. We look to the very first product launch in one or two regions at the most to make sure we really get it right because you don't want to launch everywhere just to be— get it done quickly and then make mistakes because obviously as human lives we're dealing with, you want to make sure we do the best thing for the patients, but it's not a two-year trial or anything. It's a pathway. So, it's used on real patients, in real centers, in real regions but we'd be as keen as any government, especially in the first one or two countries to make sure we take those small number of months just to really make sure we get it right so that we have a successful launch, that the countries are happy, that we save lives, and we save the country's money. So but it's not, that's one or three quarters type timing, not redoing the study, the results we have are in the— well it will be 8,000 patients in total in Denmark, all of who are positive, so those numbers are very statistically significant because about 6% of them have cancer so you will have a lot more cancers than a screening population trial, I mean a front line screening population trial. So, they're very significant trials. They're very statistically significant. It would just come down to pathways so— but this is all— these are all issues we've been dealing with for many months now. We've had a lot of meetings discussing at which relevant parties in the governments and we're very confident we have a plan that we can implement and hopefully it'll continue to go well.

Brian Marckx:

Great. Thank you.

Cameron Reynolds:

Thank you, Brian. Thanks for your time.

Operator:

Thank you. Our next question comes from the line of Yi Chen with Rodman & Renshaw. Please proceed with your question.

Yi Chen:

Hi. Congratulations on the progress you've made so far.

Cameron Reynolds:

Thank you, Yi.

Yi Chen:

So, I've got several questions. So, the first one being, so what exactly will be your pricing strategy for the new Triage assay? What's the likely gross margin that you'll be expecting moving forward? So, that's my first one.

Cameron Reynolds:

Okay. I'll start dealing with them one at time or— I'll deal with them one at time, otherwise I'll— so yes, so the pricing. So, obviously the— as a single normalized assay, that's a scientific way of saying two assays, it isn't going to cost us a lot to make. So, the profit margins— obviously the first few batches you don't quite make quite as much as when you really get into full swing, but we're looking to charge in the EUR50 range for the single normalized assay which is really talking a small amount per assay that's a

very, very healthy margin, north of about 70% or 80%. I can't give exact details because we got some fine details but it's extremely healthy margin and it's something which is very— it takes— and it's very easy to sell because it saves them a lot of money and a lot of lives, it's what we do. So, it returns a much— we're doing the health economics now. We can publicize that once we're finish and all but it's a very economically sound decision for them. Unlike most things which cost them money, this saves them a lot of money or allows a lot more people through the same system which is ultimately what they want.

Yi Chen:

Okay, thank you. Then my second question will be, so based upon the current volume of FIT tests that you're seeing in the EU, what volume can we reasonably expect for the Nu.Q™ tests?

Cameron Reynolds:

That's a very good question. We can answer that once we've known country-by-country but I can talk in generality. So, if you take the entire— or, I can give you the overall potential European market which is the top market we'll never get the full amount, and then I can give you sort of a feel for country-by-country, how many tests that would entail. If you just want to do the numbers for what's potentially in 5 or 10 years' time, there's approximately 150 million Europeans of screening age. About 6% are FIT positive, if they were all to have them, which they won't so I'll cut them down but just take that number, makes about 9 million, 9 million being 6% of 150 million, and then if they do it every two years, which is a normal screening program, that's about 4.5 million a year, but if you take compliance into account at about two-thirds which would be the maximum, digital maximums, you're looking around 3 million tests per year at the most. That's not what we expect of course, just as (inaudible) and the arm waving is the total market. So country-by-country, a small country, you're looking between 30 million, 40 million, 50 million, to have 20,000 to 50,000 tests per year. You know talking more like Ireland, Holland, Denmark, under 100,000. If you're talking France, or Germany, United Kingdom or England, you're looking in 100,000 to 200,000 FIT positives per year. So, it depends on your view on which country and when, but if you— some countries do not have FIT programs yet but we have riding so you're on the second wave become part of the solution before they start, rather than try to fix the program that's not working. But the easiest target is obviously trying to fix programs which are FIT test now that have just become overwhelmed with colonoscopies, but the second wave we aim to approach the countries which are about to get into the FIT programs to fix it before it breaks if that makes sense.

So, if you were to just stipulate overall, 3 million would be the theoretical maximum, maximum. Obviously not what we expect, but you get that in chunks of between 30,000 to 200,000 tests depending on the size of the country you sign up, and if you're looking at a 80% margin which is probably reasonable, I mean as a product margin, it would take in the range of five, six countries depending on the size to become profitable as an organization for that current burn rate.

Yi Chen:

Okay, and then my last question will be, what's your expectation for the sales ramp up in 2017?

Cameron Reynolds:

We have not given guidance on that as of now and I think we've done a lot of work and we're very active, but I think we're probably more willing to do that on the next earnings call when once we've had the CE Mark granted, which again we expect late next month or at the most in January, and we would have a lot more meetings with those target countries. So, I don't think we're prepared at the moment to issue guidance on that. David is that correct?

David Kratochvil:

Yes. We're currently not providing guidance but I think you're exactly correct in terms of the timing on when we should have a better indication of what's happening in the marketplace and how quickly things will be adopted.

Yi Chen:

All right. Thank you so much.

Cameron Reynolds:

Thank you very much, Yi.

Operator:

Thank you. Our next question comes from the line of Bruce Jackson with Lake Street Capital Markets. Please proceed with your question.

Bruce Jackson:

Hi. I just wanted to see, ask a follow up question on the new product pipeline.

Cameron Reynolds:

Okay.

Bruce Jackson:

So, with the— you've got the pancreatic, the lung and the prostate in the pipeline, is pancreatic still your lead candidate in terms of the test that's going to follow after colorectal or are you— any thoughts maybe moving the party's around?

Cameron Reynolds:

Yes. We part the others— we'll have our new facility up and running in the end of Q1 we think or early Q2, we got to fit out the new lab and those kinds of things but then we can really do more than one or two things well at the time. So, we've— pancreatic is still very much the next (inaudible) off the rank. We've been working on some other markers which we're reasonably excited about in pancreatic cancer. So, that's the reason and we have a large study already signed up with the DKFZ German group. So, that's something which if the Triage gets the traction we expect and we have the extra lab space, that would be the first to come off the room very much and I think it's something which will really add a lot of value to the Company if it's successful. So, we have the samples. We're working on some new markers that are old markers to run the trial and having the samples themselves, it would—once we press the—when we decided to pull the trigger on the trial, again it could go very quickly as we have samples, with the antibodies. In the background, we're developing our existing markers as well as a few new ones for pancreatic. So, that's something which wouldn't take a lot of time once we do, and don't underestimate I guess the— I haven't discussed it. No one's asked in this call. So, I'll quickly mention it, but the new study we have with the Hvidovre Hospital in Copenhagen for those 30,000 patients. Don't forget in that population, not only are we getting 30,000 patients of relatively senior age, which will mean there's a lot of other diseases and cancers in those patients, which will include a lot of other pancreatic as well. So, we'll have a longer treatable samples meaning the same person in several time periods over six years not only in colorectal looking for interval cancers, which I'm sure this means people will be afraid of getting cancers in between screenings. This will tell us which people did get that and how we can find them, but also a wide range of lung, pancreatic and other cancers which will be able to use our markers on as well, and the examples I think are absolutely brilliant for the Company. It allows us to answer a lot of questions in colorectal and also answer a lot of questions in a range of other cancers including pancreatic, and

given there's a 120 data points per patient, we know a lot of lifestyle factors, obesity, smoking, every other major cancer and other major disease, it's really quite a remarkable study and something which I know it's not something in the market necessarily looks like in the short term, but something I couldn't be prouder of this organization and as our people to be looking at such a large study and a longitudinal study. It will mean we'll know how early we could have found cancers and collecting 120 data points is just second to none in my mind of any study and the power and the ability to collect it, and it's a real credit to the Danish collecting those kind of samples. Collecting that much data on that many people is just breathtakingly complicated and it's something which we work with them now and this will be our fourth trial with them, they've been amazing partners up until now and collected amazing samples. So, we couldn't be happier and that fits into all the cancers we're doing, as well as pancreatic. So, it's something which I'm immensely proud of as a Company and working with the Danish again is truly an honor.

Bruce Jackson:

All right. That's great. Anyway, that's it for me on the questions. Thank you very much.

Cameron Reynolds:

Thank you very much.

Operator:

Thank you. There are no further questions at this time. I would like to turn the call back over to Mr. Reynolds for any closing remarks.

Cameron Reynolds:

Thank you very much everyone, and thank you all for taking an interest in Volition at another exciting time for us as we transition the Company from research to production and actually having our first product in revenues. I couldn't be happier and prouder of the team we have, the trials they're running and the work we're doing. It is very exciting at this time for us and it's all coming together very well, and I look forward to updating you further as we reach these milestones in the coming months, particularly the CE mark and the product launch, as well as the other trials and background work which we have going on. So, I thank you all very much for your time.

Operator:

This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.