UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **August 11, 2015**

VolitionRx Limited

(Exact name of registrant as specified in its charter)

Delaware	**000-30402**	**91-1949078**
(State or other jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification Number)

1 Scotts Road
#24-05 Shaw Centre
Singapore 228208
(Address of principal executive offices)

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

Not applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

VOLITIONRX LIMITED
Form 8-K
Current Report

Item 2.02. Results of Operations and Financial Condition.

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

As previously announced, on August 11, 2015, VolitionRx Limited hosted a conference call discussing its financial results for the quarter ended June 30, 2015. The conference call was announced by a widely disseminated press release and was made available to the public via audio webcast. Furnished herewith as Exhibit 99.1 and incorporated by reference herein is a copy of the transcript of the conference call.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Transcript of Conference Call held on August 11, 2015.

SIGNATURE

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

VOLITIONRX LIMITED

Date: August 12, 2015

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

EXHIBIT INDEX

Exhibit Number	**Description**
99.1	Transcript of Conference Call held on August 11, 2015.

VolitionRx Limited

Second Quarter 2015 Financial Earnings and Business Update Conference Call

August 11, 2015

CORPORATE PARTICIPANTS

Scott Powell, *Director of Investor Relations*

Cameron Reynolds, *President and Chief Executive Officer*

CONFERENCE CALL PARTICIPANTS

Bruce Jackson, *Lake Street Capital Markets*

Brian Marckx, *Zacks Investment Research*

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

PRESENTATION

Operator:

Good day and welcome to the VolitionRx Limited Second 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, Vice President 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 June 30, 2015, along with a discussion of our key upcoming 2015 milestones. Following our prepared remarks, we will open up the conference call to a question-and-answer session. Speaking on our call today is Mr. Cameron Reynolds, Chief Executive Officer of VolitionRx.

Before we begin our formal remarks, I'd like to remind everyone that some of the statements on this conference call may be considered forward-looking statements within the meaning of Section 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 uncertainties.

I'd now like to turn the call over to our Chief Executive Officer, Mr. Cameron Reynolds, who will discuss the second 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 Second Quarter 2015 Earnings Conference Call. I'd very much like to thank you all for taking an interest in Volition at this very exciting time for us, and I'll start with an admission, I became a first-time father on Friday, so if I'm not my normal sparkling self, I apologize.

First of all, we'll start with the review of the important events in Q2. This included the purchase of three new automated liquid handling systems called Tecans, as in our releases, which have expedited the analysis of samples from the ongoing large clinical trials evaluating our NuQ® cancer detection platform and how this directly accelerated our clinical trials and data analysis. This increase in our infrastructure to four automated systems from one has enabled us to increase the throughput and the rate of sample analysis, allowing for faster study timelines and development of our NuQ® tests. As we discussed in the press release, we can do up to 20 plates a day now, so we've gone from a capacity of about 2,000 assays per month to around 60,000. Now, that's full capacity, running day and night, so the actual capacity we would be doing in practice will probably be more like 40,000 or 50,000 assays a month, but either way it's a massive step change in what we do, and that was a very, very key milestone for us during the quarter.

The second one is the initialization of the trial with Copenhagen, the same partners we've had before, in the 800-patient retrospective pre-cancerous polyp study. So this is a very significant study for us. As we've shown, we've had very good results in polyps in the other studies and this is a dedicated one for polyps. Polyps are a type of pre-cancerous growth, with high-risk adenoma or polyps serving as a warning for cancer, but if caught early enough and removed, the risk of subsequent cancer is significantly reduced. In essence, you are getting ahead of the curve. We've had very good detection rates before in polyps, but we've never had an ongoing trial targeting them specifically. This will allow us to study a very large number of different markers specifically targeting polyps alone and, as we've discussed previously and through all of our trials, early detection is the key, and that means early-stage cancers which we've been detecting very, very well, and, as I discussed, if you can get ahead of the curve and get the polyps, then you're in very good shape, so that's a very exciting trial for us.

The second point is we've accelerated Dr. Holdenrieder's trial at the University of Bonn looking into the 27 most prevalent cancers. We have now dedicated two of the previously mentioned Tecans to his laboratory, so he can do a very large-scale, much quicker analysis of the samples. It will be over 4,000 patients in the 27 most common cancers. So, he's aiming to start that in September/October. He's collected all of the cancers and competing conditions. He's just broadening the healthies now to make sure we have a broader of range healthy patients as possible, but that's starting in the next month or two. So that'll be a very, very key trial for us, and really, so, what breadth we have through a very wide range of cancers which we have not tried.

The next point is our partnering with two consulting agencies in Europe, Decideum and MedPass, to support our market access across Europe, once we've had it approved from a CE mark, the first CE mark and then the panel of CE marks which we anticipate in the first half of next year. This is to maximize our ability to achieve seamless and optimal entry, pricing, and reimbursement. That's why we're established with these two companies, to identify the best path forward to penetrate the UK market and facilitate the test uptake by physicians and hospitals once approved, including all key opinion leaders.

In the rest of Europe, MedPass will be providing us with strategic guidance for the entry into multiple markets, with emphasis on each country's particular economic and regulatory policies. Although there are a lot of commonalities with all the EU countries, there are obviously quite a few differences, so they're going to be picking for us the key countries we should begin with once we have the full panel targeted in the middle of next year, the first panel CE marked.

The engagement of Global Specimen Solutions is to support the initial US market entry of our NuQ® colorectal cancer test and it's significant for the US commercialization efforts. Under our agreement with GSS, we will target and select medical universities and US commercial clinical laboratories providing diagnostic testing services regulated under the Clinical Laboratory Improvement Amendments—the short for that is CLIA, C-L-I-A—as strategic collaboration partners for testing of our NuQ® colorectal cancer tests and a range of other cancers as they are developed. GSS will also develop a strategic market access plan for implementing relationships with the selected CLIA labs, including licensing and royalty modeling for CLIA laboratory development tests, LDTs, and strategic regulatory and clinical development for pre-market approval, PMA, which is submission for the FDA. Through partnering with GSS, Volition aims to license its Nucleosomics ® Biomarker Panels to CLIA labs for LDT development in the US in 2016, and prepare for FDA approval through the PMA process, as we discussed.

So, that's what's going—looking going backwards. Going forwards, one of the milestones for the remainder of this year and the first part of next year—we have several very important milestones within reach, and I'll go through them now.

Firstly, the results from the 4,800 retrospective colorectal symptomatic population trial with our friends at Hvidovre Hospital in Denmark, anticipated in Q4 2015, a lot of people ask when will that be ready. We were targeting September, which is still possible, but I think it's probably more likely to be October now we get those results through. It's processing well, we're getting through a lot of assays, but there's also—it's also summer time and it's important we get it very much right with the antibodies and the controls, so my thoughts now would most likely be finished in October and then we can announce it.

We're also working on the 14,000 prospective CRC trial with the same collaborators in Denmark. We have 2,500 samples from that set, we're expecting the next 2,500 in the next month or two, and release results in Q1 of next year in the prospective screening trial from the first batch of that 14,000. Now, we can either release the first 2,500 of the 5,000 together, and that will be determined by when we actually get the next lot of samples through, but also a very key milestone and in the not too distant future we expect it.

We're also in the process of filing for the CE mark on our first assay, as discussed, and we expect it to be approved in October or November of this year—hopefully more October than November, but we'll find out—and as we said in the press release, with the final panel around mid-year, so that we can launch our products in Europe, but of course, as we discussed in the press release, launching a product does not mean revenues immediately, it means you are legally allowed to sell. So, that's when the plans we have in place in Europe, we aim to swing into action to begin the process of reimbursing them and getting the product on the market.

We also have the potential of signing of larger trials in prostate and lung and pancreatic cancer, given the data and validation through papers in smaller trials in the next—end of this year and early next year. There's also potential for some data on other cancers from the Danish trials. Obviously, when you're looking at large numbers of people as we are, there are other cancers which are known to be in those populations, so perhaps there's a possibility of that in the same time period, as well.

We are also aim to have our EU commercialization strategy, including upcoming milestones and timelines for European market access and sales of NuQ® tests for colorectal cancer. We also aim to have our US commercialization strategy, including the FDA and CLIA strategy, finalized this year and early next, with the first partner with GSS to enter their CLIA certified lab market and medical universities in the US. We plan to initiate a bridging US FDA-endorsed trial with our ongoing large trials in Europe, which will be designed to provide the clinical data with patient populations more representative of the US ethnicity, to support the PMA submission for the potential FDA approval of our NuQ® tests for the early detection of colorectal cancer. In parallel, we aim to license our NuQ® Biomarker Panels for the US for development as an LDT in 2016, as we talked about, through the CLIA labs, and provide Volition with some revenue while proceeding with the FDA approval process.

The current IP position, we filed two new patents this, in the second quarter, and we are continuing to look for more patent opportunities. We are aiming to try to get our first US patents issued in the same timeframe. So, that it should be another big milestone for the Company, but that's obviously not within our complete task, but we are pushing it as hard as we can to get our first US patents issued, which would be a huge milestone.

We continue to believe that blood and other body fluids, most notably sputum, offer the best platform through which to screen for cancer, because the tests are non-invasive, convenient, have the opportunity for higher compliance, versus other complicated unpleasant and/or invasive tests which often require separate doctor visits and/or advanced preparatory, work such for 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 tests to be administered during regular 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 very 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 into 2016.

We also have a very active upcoming investor relations calendar. We're presenting at Wedbush tomorrow in New York City, which is very exciting for us, and thank you for the team at Wedbush for inviting us. This is the biggest conference we've ever been invited to. We're also presenting at the Rodman & Renshaw Conference, September 9, in New York, and at the MicroCap Conference, October 8, in Detroit, and perhaps with some more ones in the same time period this year, as we continue to really get the message out there. We also have non-deal road shows planned throughout September and October in New York, Boston, Philadelphia, Chicago, and Milwaukee and Minneapolis, as we continue to build investor awareness of VolitionRx.

Thank you all very much for your interest in VolitionRx and for joining our second quarter 2015 earnings conference call today. I'll open up for questions, but before I do, there was just one thing I wanted to mention. I think you noticed from our financials, as of June 30, we still had over $9.3 million left in the bank, in cash and equivalents. So, as you can see, we're very carefully managing the financial process. We're continuing to keep a very lean, very focused company on getting the products out there, by doing a very large number of trials. I think our cash management and the ability to stick to the financial targets we have so far has been a very big strength of the Company and we will continue to be as careful as we can with all of our investor's money, to make sure the money is used as wise as it can be to get the best data we can from the trials and also through the process of launching our products as soon as we can, once the trials are finished, assuming the data is good, in Europe and in the US, and then worldwide. So, I think it's been a very successful quarter financially, as you can tell, for the Company, as well.

So, thank you. I'd like to open up to any questions.

Operator:

Thank you. If you would like to signal for a question, please press 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, press star, one to ask a question. We'll pause for just a moment to allow everyone an opportunity to signal for questions.

Again, it is star, one to ask a question. We'll go first to Bruce Jackson with Lake Street Capital Markets.

Bruce Jackson:

Hello, good morning.

Cameron Reynolds:

Good morning, Bruce. How are you?

Bruce Jackson:

Good. Nice job on the expense control this quarter.

Cameron Reynolds:

Thank you.

Bruce Jackson:

If we could talk about some of the clinical trial milestones here with the two studies in Denmark. So, now we're looking to have completion of the retrospective study in Q4 and then—does that include the release of the data or would there be some additional time required to analyze the data?

Cameron Reynolds:

No, I think it's very reasonable to assume Q4, hopefully in Q4, but we'll see, but that would be releasing of the data, so that's a good point. I'm not saying when the trials finish, that's data release time. So, yes, data release time. Public data release.

Bruce Jackson:

Thank you. Yes, and then given that we're fairly close to the end of the trial, would you say that your line of sight on that completion date is—how confident are you in that completion date?

Cameron Reynolds:

Reasonably confident. Yes, I think it's progressed extremely well. Our team's done a helluva job in—we've developed quite a few new assays and the antibodies, as well as the controls. It's progressed very well. I think October is a reasonably strong—you know, I'm sure you've been involved with trials for a long period of time, but I would be reasonably confident in that timeframe.

Bruce Jackson:

Okay.

Cameron Reynolds:

Reasonably confident.

Bruce Jackson:

Okay. As confident as you can be right, so?

Cameron Reynolds:

Yes. Things happen with public trials, but it has proceeded very well. We've done a lot of assays, there's just a few things to tidy up, but there sometimes can be delays. But that would be a reasonably strong expectation.

Bruce Jackson:

All right. Then, is there any linkage between the retrospective trial and the prospective trial? So, are they running in parallel or are they—is it something where you get the prospective trial done first and then—I'm sorry, the retrospective trial done first and then you do the prospective samples?

Cameron Reynolds:

Yes, very good question, Bruce. Basically, we have four Tecans now, two, with Dr. Holdenrieder and two are in our lab, so that's a massive increase, but we have a lot of trials going. So, we're definitely focused on the 4,800 and we've done a few assays in the—sorry, in the 2,500 of the prospective 14,000. So, they are slightly concurrently, but obviously once we've finished the 4,800 trial there'll be a lot more capacity on the Tecans, and with roughly half the number of samples we currently have in the prospective, compared to the symptomatic, it can go a bit quicker.

So, the short answer is they are being done at the same time, but obviously with a huge amount of data being done on the retrospective. When that is finished, the prospective will speed up a lot. But, there's also other issues with the prospective. We getting a larger number of samples coming in, sometime in the next month or two, sometime in Q4, so then we'd want to think do we want to release 2,500 or do the whole 5,000 just for a large sample size. So, that's decisions we'll make, but it will go a lot quicker once we've finished this big tranche in the 4,800.

Bruce Jackson:

Okay.

Cameron Reynolds:

Does that answer your question?

Bruce Jackson:

It does.

Cameron Reynolds:

Yes.

Bruce Jackson:

Then, just one group of questions on the US commercialization side. So, you've engaged the contract research organization to help with your LDT strategy. Does that strategy require that you have CE mark on the first panel in order to like start selling the kits?

Cameron Reynolds:

No, the LDT market is you know—I guess you know a lot about it, but LDTs are developed by the lab in the US, so we license the knowledge to the lab. I'm not an expert on this area, but from what I understand—I can get you a more full answer offline, but from what I understand they're not linked. You can develop an LDT and go through the process separately. That's my understanding.

Bruce Jackson:

Okay, and then can you comment on any of the details on the US regulatory pathway? So, for example, what will be the next steps you would want to take in order to move that forward?

Cameron Reynolds:

Yes, good question, Bruce. So, basically, the CLIA lab is concurrent with our FDA process, we're licensing to CLIA labs to go through that process, but, as we've always talked about, the FDA to us is very much the main game. So, we think our trials in Europe, particularly in Denmark, are very, very good trials, they're about as good as you can get. We will most likely take on also full-time FDA—not full-time for us, but the people who are specializing in just the FDA process, and panel members to give us advice from the FDA, but what we're thinking—the line of sight, what we're thinking now is we will get some more expert advice once we have the data from Denmark, as we discussed in this call.

We're also looking to do a—I think the most reasonable request from the FDA would be for a bridging study in the US partly focusing on different ethnicities. So, we've had some discussions with different groups who can provide us with that, and we'll get some very high level advices to see the package of retrospective, prospective and a bridging study, if that would be a very good package to take the FDA.

Now, given everything else going on, I can't see us taking all that to the FDA much before sort of the first half of next year, but you know how it works, you request a meeting, but we want to be fully armed with the trials in Europe and the plan for a bridging study, so that if that is a concern of the FDA's, which is possible, we can have that already planned and the outline of what we would do, so it can be done very expeditiously.

Bruce Jackson:

Okay. That's it for me. Thank you for taking my questions.

Cameron Reynolds:

Thank you. Thank you very much.

Operator:

We'll go next to Brian Marckx with Zacks Investment Research.

Brian Marckx:

Hey, good morning, Cameron, and congratulations on your new fatherhood.

Cameron Reynolds:

Thank you, very much. Yes, it's a fantastic week.

Brian Marckx:

In terms of the CE mark, you expect the initial CE mark in Q1 and the full panel by mid sort of…

Cameron Reynolds:

Q4, the first one, I would think is a strong expectation of this year for the first one.

Brian Marckx:

Okay.

Cameron Reynolds:

Then the first half of next year for the full panel.

Brian Marckx:

Okay. How many additional markers are on the full panel and do you have to CE marked? Do you have to have each additional marker CE marked for the full panel?

Cameron Reynolds:

Yes, good question, Brian. The data will determine what the best panel is and that's always a mixture of accuracy versus cost. Europe is quite cost sensitive, as I'm sure you're aware. So, we'll make a determination once we have all the data as to what we think is the optimal number for the panel. Our estimation would be in the range of three or four assays at the moment, perhaps four or five, we'll see. It's not that much extra cost per one, but obviously when you're in a very price sensitive market—we're already very, very cheap, but cost effective would be good, just to see how that is, but that will be data driven.

Secondly, on the point of the extra CE marks, the plan is we will CE mark each individual assay as they come up, and then based on the studies we have, we will also CE mark the first panel. Now, we'd see ourselves improving the panels as we go, because we're doing a tremendous amount of ongoing work in the prospective, as well as the 800 study, and we have a lot of samples and we're developing new assays all the time. So, it was always our intent to—once we have a product which we think is viable, we would launch and we'll continue to improve it. But that's a very good thing in Europe. It's not like the FDA process where it's not set in stone, but it's difficult to change year-on-year. But in Europe, because we can CE mark each individual assay, and then as a panel we can update that without a lot of work, compared to the FDA, over changing the actual nature of the assays. So, we would see ourselves launching the first one and then, assuming we have better and better data on new assays, we could do the same thing again, CE mark each individual assay and then CE mark each panel as they become a product.

The CE mark process is a lot of paperwork, but once you have the first one done, it becomes simpler and simpler for each one, because you've done—a lot of it is repeatable paperwork, it's redoing the validation studies, which are being done for us in Germany, and preparing the paperwork. So, I mean, it is a considerable amount of work, but it's a lot less for the second and third and fourth ones than the first one was, and of course we're developing a lot of institutional experience and all that consultant work. So, I would see them being an easier process for the second, third and fourth than they were for the first.

Is that that how you see it, Brian?

Brian Marckx:

Yes, yes, that's great. What are the other study data that will be used to support the follow-up CE mark? I assume the initial CE mark's mostly going to be the 4,800 retrospective data and then the follow up—go ahead?

Cameron Reynolds:

Yes, sorry. Actually the CE mark, the CE mark more pertains to they're produced properly, safely, and the accuracy of each individual assay for the actual assays. So, for example, you can do it in several hundred patients to get the CE mark, which will be a subset from the Danish samples, but obviously for reimbursement purposes, you want a big a study as possible, so that's where we'll use the data from the 4,800 and from the prospective. So they're really two different products, so to keep in mind, the symptomatic population is the first product, so that's the first samples, and then we'll have CE marks for the panels we hope, assume, as long as the data continues to support a screening product, which will be from the screening trial. So, you use several hundred patients to get the CE mark and then you—for reimbursement and for people to actually want to buy large numbers of the tests, we'll be publishing and putting the data in for the panels on the larger trials.

Brian Marckx:

Do you have any insight in terms of reimbursement? Are there competitive tests in the market that you can kind of ballpark off of what to expect in terms of reimbursement in various parts of Europe?

Cameron Reynolds:

Yes, each country's a little bit different and some are insurance based, the national health here is very government based, so they are a little different and they all have different programs. The markets for—the only other blood test currently being marketed for screening is Epigenomics. The exact figure you can have, but I think it's in the region of 100 euros plus. I think to be really competitive, if we want to break into the large populations from the government programs, we need to be a lot less than that, and, again, we need to do a lot more market access, but we'd probably need to be reasonably competitive with FIT, FOBT, and that would be in the 20 to 30 euro range. There are lots of costs involved in a fecal test, obviously if you're mailing it out in the process and following up, which you wouldn't have in a test which is just given by your doctor. But I think to be competitive, my estimation would be we'd need to be in that kind of range, but I think we've discussed before the cost of our tests are very cost effective to do, so there's a very strong profit margin at those prices, but we need to do more market access.

We're doing a lot of market analysis now in the countries which we're looking to target. So, it'll be driven a little bit by what's possible to be reimbursed by the governments and private payers, as well as what the price points are, and I think they're a little different in different countries. But that's why we've hired experts to tell us in MedPass and Decideum to make sure we hit the right notes. But any of those price points, we would see ourselves being quite profitable, because when you're looking at an ELISA it's a very low-cost production.

Brian Marckx:

In terms of your initial thoughts on sales and marketing in Europe, are you leaning towards a direct sales force or distribution?

Cameron Reynolds:

No, I don't think in any market our preferred method would be—I do not think in any market our preferred method will be direct sales force. I think you've seen from Exact and they seemed to have quite a success doing it, but I don't see a need to do that. They're expensive. There are tremendous numbers of people who sell ELISA platform tests at a tremendous number of labs. I would see it that companies that have a new test which is not part of the existing infrastructure will need to have their own sales force, as I would understand exactly, but I don't think there's any need for us to do that. I think, at the most, we would be hiring several key people to help us with key opinion leaders and dealing with the providers in between, and when you're dealing with national programs there's no need for sales forces.

Obviously, with national screening programs, the client basically is one group, which is the government, so there's no need for a large sales force. But our definitely preferred model, that will be borne out in our analysis from our experts, but our preferred model is only when very much needed to have any real sales force is ourselves and I do not see that being necessary in any or very many markets, because the infrastructure for ELISA tests, for blood tests is so large, and pretty much any lab in the world can run ELISAs, so I don't see why we need to, and they all have their own sales force typically depending on the groups, but every country and every group has companies which assist with this. So I see our expertise very much being in the IP, developing the test, and licensing and selling them through existing infrastructures.

Brian Marckx:

All right. Thanks Cameron.

Cameron Reynolds:

Thank you.

Operator:

As a reminder, it is star, one to ask a question. Again, that is star, one if you have a question. We'll go next to Yi Chen with H.C. Wainwright.

Yi Chen:

Thank you for taking the question. Can you comment on whether there's any—whether there's any existing CPT code in Medicare that you can use for your tests?

Cameron Reynolds:

Yes, very good question. I'm not an expert, I'll give you the advice we've been given and this is what I understand. There are existing CPT codes for ELISAs and off the top of my memory it's around $17 per assay, but I'm not 100% certain, but that was what I was informed by a few people and a few consultants. The US is probably more accuracy driven than just price. So, if you were to stack four or five of those codes together with all the other costs, you're looking probably in the $80 to $100 range. That's my understanding of existing CPT codes. Of course you can apply for a new one as a package, if you're looking to get more than that, but I think, certainly once we're a mature product, assuming everything goes to plan, I would see ourselves wanting to be very widely used and in that cost range, because as we discussed before with the European tests, it's very profitable anywhere near that price point. So, I think our focus would very much be to try to get the test as widely used as possible, and make it as cost effective as possible, given it's such a simple platform and it can be very much used in a normal clinical procedure. Is that answering your question?

Yi Chen:

Yes, thank you.

Cameron Reynolds:

Thank you.

Operator:

That concludes today's conference call. I will now turn—or excuse me, today's Q&A session. I will now turn the call back over to Cameron Reynolds.

Cameron Reynolds:

I'd just like to thank you all for attending the conference call. As we discussed, it's a very exciting time for the Company and things are progressing extremely positively for us. We're really working through these trials and we'll be having some major data points through the end of this year. When they're released, we'll obviously be informing the market. We're also doing a very extensive public relations/investor relations process. So, thank you all very much for your interest in the Company and I look forward to speaking to you over the coming months. Thank you for your time.

Operator:

That concludes today's conference call. Thank you for your participation.