

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, 2016**

**VolitionRx Limited**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of Incorporation)

**001-36833**  
(Commission File Number)

**91-1949078**  
(IRS Employer  
Identification Number)

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

**Telephone: +1 (646) 650-1351**  
(Registrant's telephone number, including area code )

**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 Exhibits 99.1 and 99.2, 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, 2016, VolitionRx Limited hosted a conference call discussing its financial results for the quarter ended June 30, 2016. The conference call was announced by a widely disseminated press release and was made available to the public via audio webcast. Furnished herewith as Exhibits 99.1 and 99.2 and incorporated by reference herein are copies of the press release and a transcript of the conference call, respectively.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of VolitionRx Limited, dated August 11, 2016.
99.2	Transcript of Conference Call held on August 11, 2016.

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**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 16, 2016

By: /s/ Cameron Reynolds

Cameron Reynolds

Chief Executive Officer & President



## EXHIBIT INDEX

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release of VolitionRx Limited, dated August 11, 2016.
99.2	Transcript of Conference Call held on August 11, 2016.

## VolitionRx Announces Second Quarter 2016 Financial Results and Business Update

NAMUR, Belgium, Aug. 11, 2016 /PRNewswire/ -- VolitionRx Limited (NYSE MKT: VNRX), a life sciences company focused on developing diagnostic tests for cancer and other conditions, today announced financial results for the second quarter ended June 30, 2016.

### Second Quarter 2016 and Recent Company Highlights:

#### *Clinical:*

- Presented highly-encouraging study results demonstrating NuQ®'s ability to detect 71% of early stage I prostate cancer cases at 93% specificity at the American Association of Cancer Research (AACR) Annual Meeting;
- Initiated study with the German Cancer Research Center (DKFZ) to evaluate NuQ®'s ability to detect pancreatic cancer following encouraging data from two previous pancreatic cancer pilot studies;
- Published study confirming stability of circulating cell-free nucleosomes (cf-nucleosomes) as biomarkers in cancer, highlighting NuQ®'s low cost and ease of use. Importantly this study demonstrates that no special blood draw requirements are needed; and
- Presented data from three clinical trials demonstrating NuQ®'s ability to detect colorectal cancer and adenomas at the World Endoscopy Organization (WEO) Colorectal Cancer Screening Meeting.

#### *Regulatory:*

- New CE marks for two NuQ® biomarker assays, NuQ®V001 and NuQ®T003, to detect the presence of colorectal cancer signatures, allowing their clinical use in 28 European countries; and
- Granted a 4<sup>th</sup> key U.S. patent for the Nucleosomics® platform's ability to detect nucleosomes in blood circulation.

#### *Operational:*

- Appointed Louise Day as Chief Marketing and Communications Officer in preparation for the commercial launch of NuQ® in Europe and the U.S.;
- Appointed Dr. Edward Fletcher, Ph.D., to Board of Directors; and
- Engaged Edison Advisors to strengthen investor relations and broaden global visibility.

Cameron Reynolds, President and Chief Executive Officer of VolitionRx, said, "CE marking another two of our biomarker assays, NuQ®V001 and NuQ®T003, which brings the total to three CE marks, helps clear the regulatory path for transition into a commercial-stage company. With the expected launch of our first NuQ® blood test later this year in Europe, our efforts over this and the upcoming quarter are focused not only on meeting these regulatory hurdles, but also making the key management appointments to ensure a successful launch."

"With respect to our first commercial product launch, the Company expects to be making announcements during September and October to discuss this in greater detail, including the specific role it will play in the screening regimen for specific countries and our market entry strategy. We have already begun our branding and labeling processes for our initial commercial product and have engaged a branding agency to assist us with the launch. We aim to have this product CE marked by the end of this year, making it potentially saleable in 2017 in all 28 EU countries."

Jake Micallef, Ph.D., MBA, Chief Scientific Officer of VolitionRx, said, "We have had several important clinical accomplishments for NuQ® in this second quarter of 2016. The publication of our study in the *Scandinavian Journal of Clinical and Laboratory Investigation* confirms that results of our NuQ® test are the same regardless of when and how blood samples are taken due to the discovered stability of circulating cf-nucleosomes, a key highlight of the viability and ease-of-use of our platform. At the World Endoscopy Organization (WEO) Colorectal Cancer Screening Meeting, Jason Terrell, M.D., Volition's Chief Medical Officer and Head of U.S. Operations, presented data from our targeted clinical trial of 430 pre-cancerous colorectal adenoma patients with Hvidovre Hospital and the University of Copenhagen that demonstrated a panel of five NuQ® biomarker assays in an age-adjusted algorithm detected 75% of high-risk colorectal adenomas and 86% of stage I colorectal cancers. These are our highest adenoma detection rates yet, and they demonstrate the power of NuQ®, not only for the detection colorectal cancer, but also for pre-cancerous polyps."

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## Second Quarter 2016 Financial Results

For the three months ended June 30, 2016, VolitionRx reported a net loss of \$2.9 million, or \$0.13 per share. This compares to a net loss of \$1.9 million, or \$0.10 per share in the second quarter of 2015.

Cash and cash equivalents as of June 30, 2016 totaled \$14.5 million, compared with \$17.0 million as of March 31, 2016 and \$5.9 million as of December 31, 2015.

## Conference Call

As a reminder, Cameron Reynolds, Chief Executive Officer, will host the Company's Q2 earnings conference call today, Thursday, August 11th, 2016 at 8:30 am U.S. Eastern Time. To participate in the call, please dial 1-800-946-0706 (toll-free) in the U.S. and Canada, and 1-719-325-2352 (toll) internationally. The conference ID number for both is 1996014. A live audio webcast of the conference call will also be available via link on the investor relations page of VolitionRx's corporate website at <http://ir.volitionrx.com>.

## About VolitionRx

VolitionRx is a life sciences company focused on developing diagnostic tests for cancer and other conditions. The tests are based on the science of Nucleosomics<sup>®</sup>, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid – an indication that disease is present.

VolitionRx's goal is to make the tests as common and simple to use, for both patients and doctors, as existing diabetic and cholesterol blood tests. VolitionRx's research and development activities are currently centered in Belgium as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

Visit VolitionRx's website (<http://www.volitionrx.com>) or connect with us via Twitter, LinkedIn, Facebook or YouTube.

## Media / Investor Contacts

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## Safe Harbor Statement

Statements in this press release may be "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," "could," "would," "should," "may," "will" and similar expressions identify forward-looking statements. These forward-looking statements relate to the effectiveness of the Company's bodily-fluid-based diagnostic tests as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include the Company's failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical IVD market; a failure by the marketplace to accept the products in the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company's intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; and other risks identified in the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about the Company's business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are made as of the date of this release, 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.

Nucleosomics®, NuQ® and HyperGenomics® and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to in this press release are the property of their respective owners.



**VolitionRx Limited**

**Second Quarter 2016 Earnings and Business Update Conference  
Call**

**August 11, 2016**

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## CORPORATE PARTICIPANTS

**Scott Powell**, *Vice President, Investor Relations*

**Cameron Reynolds**, *President and Chief Executive Officer*

**David Kratochvil**, *Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

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

**Brian Marcx**, *Zacks Investment Research*

**Jan David Wald**, *The Benchmark Company, LLC*

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

## PRESENTATION

### Operator:

Good day, and welcome to the VolitionRx Limited Second Quarter 2016 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 second quarter ended June 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 example, 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.

Nucleosomics<sup>®</sup>, NuQ<sup>®</sup> and HyperGenomics<sup>®</sup> and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to on this conference call are the property of their respective owners.

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

**Cameron Reynolds:**

Thank you, Scott. Thank you, everyone, for joining Volition's second 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 will start with a review of the important Q2 events. Volition continues to make excellent progress with our clinical trials, showing the depth and adaptability of our Nucleosomics<sup>®</sup> technology.

In prostate cancer, we announced results from a 537-patient clinical trial conducted with the Surrey Cancer Research Institute at the University of Surrey in the United Kingdom. A single NuQ<sup>®</sup> assay, biomarker assay, detected 71% of early stage I prostate cancers at a 93%-specificity. This is significantly higher than the most common blood tests currently used to detect prostate cancer, the Prostate Specific Antigen, otherwise known as PSA, which is reported to detect only 53% of prostate cancers at a 73%-specificity. We plan to commence additional trials in prostate cancer in the future. In pancreatic cancer, we announced a large, 750-patient clinical trial with the world renowned German Cancer Research Center which is better known as DKFZ to access Volition's proprietary Nucleosomics<sup>®</sup> platform for noninvasive detection of pancreatic cancer.

We expect results from this retrospective study in late 2016 or early next year 2017. Also, in conjunction with the University of Copenhagen, we published a new study in the *Scandinavian Journal of Clinical and Laboratory Investigation* that confirms the stability of circulating cell-free nucleosomes as biomarkers in cancer. These findings are very significant, because for accurate results in any blood test, it is important to confirm that the results of the test are the same regardless when and how the sample is taken.

The results highlight another key step in the path to commercialization of our first product, because they show that patients do not need to fast prior the sample is being collected, nor the NuQ<sup>®</sup> results meaningfully change over the course of a day or even a whole month for a patient.

We also made significant progress towards the commercialization of our blood test for colorectal cancers in both U.S. and Europe. In April, we announced the CE marking of two additional blood-based diagnostic assays for the detection of colorectal cancer. The biomarker assays, NuQ<sup>®</sup>V001 and NuQ<sup>®</sup>T003 identify and analyze fragments of chromosomes called nucleosomes circulating within the blood for the presence of cancer signatures. We have now CE marked three NuQ<sup>®</sup> biomarker assays, which again is another important step towards the commercialization of our first products in Europe.

We have also made some important expansions to our team. Last month, we announced the appointment of Dr. Edward Futcher to our Board of Directors. He holds a Ph.D. in physics from the University of London and has extensive experience in engineering and management in emerging technology companies. His background makes him a valuable asset and a resource as we prepare the first product for launch.

In April, we also announced the appointment of Louise Day as Chief Marketing and Communications Officer. Louise will lead Volition's communications and develop the Company's branding and global marketing strategy in preparation for the initial market entry of its NuQ<sup>®</sup> blood test for cancer. She brings tremendous product experience from her past work with companies such as Zeneca and Reckitt Benckiser.

For the quarter ended June 30, the second quarter of 2016, we had a very strong cash position with \$14.5 million in cash and equivalents compared with \$17 million as of March 31, and \$5.9 million at the end of last year. We have kept very close controls on cost, despite the high level of activity in a wide range of areas and milestones reached; something which we are very proud of.

Looking forward to milestones for 2016 and 2017, we have targeted many important clinical and commercial milestones. We aim to receive additional CE marks on assays and commercial launch of our first product in Europe in early 2017. We'll obtain more key IP in several countries including the U.S., as we continue to protect shareholder value. We will announce one or more clinical trials in pancreatic cancer or lung cancer and we aim to present results in ongoing trials including the Bonn University study of the 27 most prevalent cancers. We also aim to present final results from our 4,800 retrospective symptomatic population trial, as well as the first tranches of the prospective 14,000 colorectal study with Hvidovre Hospital in Denmark.

Importantly, we will offer additional clarity on our EU commercialization strategy, including upcoming milestones and the timelines for European market access and sales of NuQ<sup>®</sup> for CRC. We also aim to initiate our first U.S. FDA trials.

This has been an exciting first-half of 2016 for the Company and we're looking forward to moving into commercialization stage in early 2017 for the launch of our first product in Europe. With approximately 150 million Europeans of screening age, this is a very exciting opportunity for us.

We achieved another important milestone this quarter with two additional CE marks, which again just closer to commercialization in Europe. With a very strong cash position, we believe we are sufficiently capitalized and well-positioned to execute on this commercialization strategy this year.

Now, very importantly, with respect to our first commercial product launch, this has moved forward well over the summer, and we expect to make announcements during September and October to discuss this in greater detail. We plan to discuss more about the specific role our product is expected to play in the screening regime for specific countries and our market entry strategies during the coming months. We have already begun our branding and labeling processes for this product and have also engaged a branding agency to assist us with our first product launch.

We aim to have this product CE marked by the end of this year 2016, making it saleable in early 2017 in all 28 EU countries. We are very proud of our clinical and commercial accomplishments in the first-half of 2016, and look forward to completing these numerous aforementioned milestones throughout 2016 and 2017.

Thank you all very much for your interest in Volition and for joining our second quarter 2016's earnings conference call today, at this very exciting time for our Company. We would now like to open up the call to take your questions. Operator?

**Operator:**

Thank you. The question-and-answer session will be conducted electronically. If you would like to ask a question, please press star, followed by the digit one. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Once again star, one at this time to ask a question, and we will pause for just a moment.

Our first question we'll hear from Bruce Jackson with Lake Street Capital Markets.

**Bruce Jackson:**

Hi, good morning, and congratulations on all the progress this quarter.

**Cameron Reynolds:**

Thank you, Bruce. Yes, it's been a good one.

**Bruce Jackson:**

So, if we could just talk about the timeline or the pathway for getting the first commercial test on the market. I believe— so first question is, have you set the panel test yet for the colorectal cancer test? Second, if you have, how many markers are in it and how many do you have to have CE marked by the end of the year? Then, with the launch in early 2017, are we talking Q1? Those are my first three questions.

**Cameron Reynolds:**

So the short answer to the first question is yes, we've chosen the panel. We are not disclosing what that is now. We want to— we'll save the thunder for September and October for the product, sales, the marketing, the branding, as you know, Bruce, there are some big conferences in September and in October in Europe for the product side. So, we'll be announcing all of that, what the product is, what the branding is, and the reasons we think it will sell, in that timeline.

But, yes, we aim to have the panel CE marked this year, which I think is achievable. That's currently our guess-shot and I think it is achievable. We've already started the branding process and the product. So, we will be beginning discussions with potential clients and customers this year.

As you know, Louise Day has joined us and she has been very hard at work on all of that. So, we are talking very early. If we do get it CE marked this year, which I believe we will; if not, it will be very early in 2017. We are not just at the starting line then. We're doing a lot of preparatory work, so we can really hit the ground running in 2017. So certainly Q1, I can see no reason why it wouldn't begin by then. But I would certainly hope and think we will have it CE marked this year. If not this year, it will be early next year and we'll start right away.

**Bruce Jackson:**

Okay, great. Then, one other question on the U.S. regulatory strategy, where do we stand with that right now?

**Cameron Reynolds:**

Yes, good question. Dr. Terrell has been devoted to them actually a few weeks ago. As you probably remember, we've taken on Jason as our Chief Medical Officer for the U.S. and he is heading up the investigation of the 510(k) as well as the process to the PMA for the product pipeline, which we're building now. He has done a lot of work on identifying CROs and the 510(k)s that are needed.

I think our strategy is exactly the same as we discussed last time, which is we'll look to the 510(k)s in adjunct in one or several cancers to start with and then PMAs in one or two of the bigger cancers as a screening test. But, he has done a lot of work on that. We'll announce those outcomes when we make some final decisions on what that will look like in the coming months.

But, he has done a tremendous amount of work. He has done an excellent job and we're really making sure we get that right. So, we'll make announcement of that once we make some final decisions.

**Bruce Jackson:**

Okay, yes, just with the FDA specifically, have you had any conversations with them yet?

**Cameron Reynolds:**

We have not. Now, we really want to get it right - as you know with the FDA it's got to be correct - we want to make a very good impression right off the bat. So, we focused our efforts in the product pipeline on this first European product, which we will have some news very shortly, as we discussed, in September and October. The U.S. process, we're still working hard on making sure we get it right—but we will approach the FDA when we have a near final package and we're not quite there yet, so the answer is no.

**Bruce Jackson:**

Okay. That's it for me. I'll hop back in queue.

**Cameron Reynolds:**

Thank you very much, Bruce. Have a great day.

**Operator:**

Next we'll hear from Brian Marckx with Zacks Investment Research.

**Brian Marckx:**

Good morning, Cameron.

**Cameron Reynolds:**

Good morning. How are you?

**Brian Marckx:**

Good. Given that the significant part of your initial commercialization plan in Europe is being covered under the national healthcare programs, I'm wondering if you can kind of talk about what the process is that's involved in being covered under some of the programs there and what are kind of the major criteria that they will look for to determine whether your test will be covered under the programs?

**Cameron Reynolds:**

Yes, absolutely. We've looked at this quite a lot, and obviously, it's a very large market with 28 different countries and over 600 million people in the different countries. Each market is a little bit different. We focused our efforts on countries where we have a natural advantage; most obvious would be United Kingdom, Belgium, France, Holland and Denmark. Obviously, we have a close relationship with the government programs there.

So, we have begun to have a plan of attack, so to speak, from which of those to go to and what process. In essence, it means in the larger countries you have one client which makes up 90% of the business. So, if you do manage to get into one of those groups, you get a very large order from scratch. We've also taken on to Decideum last year, who are our market access specialist and they've been tremendously helpful in providing information country by country.

But, our aims and the plan is, as it was last quarter, which is to target a small number of countries which have slightly varied systems in each, and we'll be making a lot of announcements as to the specifics for those as I discussed in the conference in September and October. We have looked at a lot of detail. We'll be announcing a lot more detail than we have. But that's the overall strategy, using our consultants.

Louise Day has a tremendous experience in products in the Europe as well, and we're taking on some great people to help us with that. Having been around as long as we have and worked in as many cancers as we have with lot of different governments, we have a lot of in-depth knowledge. As probably aware, quite a few of our team members are British who've worked NHS and have good experience with that.

Our Chief Scientific Officer has also worked with World Health Organization. So, he is very familiar with lot of different things. So, in between all of that, we'll announce the product details, our estimation of the market size and an idea of what that would look like, if the product is successful in the next couple of months, as I said in September and October. But we've put a lot of thought into it and I think everyone will be very happy with our plans when we announce them. That would be my expectation.

**Brian Marckx:**

Cameron, I assume that clinical evidence is certainly going to be one of the major criteria that are going to be involved in the decision-making process...

**Cameron Reynolds:**

Absolutely.

**Brian Marckx:**

...and potentially the price, I guess. Is there anything else that kind of stands out as something that you need to meet to get covered under these programs?

**Cameron Reynolds:**

Yes there will actually, and that will be covered in the first product launch in the product pipeline. We've thought about it very long and hard. Of course, as you say, it's got to be accurate to make sense of the actual programs. We put a lot of thought into what the product should look like in the first one of the ranking—the first cab off the rank if you will in the product pipeline we have. It's not as always, because obviously as it perhaps, you think it would be, but we have done a lot of thought and I think we've reached a very good conclusion as to the first product which we'll be announcing.

But it comes down to accuracy, it comes down to price. I think one thing which we have, which is very unique is we have the ability to kind of do a lot of different things, given the very low cost of our products that's very cost-effective and very adaptable as you talked about. Sometimes the easiest way into market is as an adjunct to a current testing program, so you don't have to throw the table over, if you will, to get a good chunk of revenue.

I think, if you look at our major competitors, when you are in the hundreds or \$500, \$600, you really only have one choice, and that's to be start marketing as a sort of frontline screening test. So, we have a lot of options, we've looked at lot of them with a very, very good well-experienced team and we're making those announcements, but I think we made some very good decisions and we'll announce them in September/October.

**Brian Marckx:**

Okay, good. Wondering if you can comment what your thoughts are on USPSTF guidelines that were updated recently covering Epigenomics procolon tests, and what that might mean for NuQ<sup>®</sup>, if and when they come to the U.S. market?



**Cameron Reynolds:**

Yes, it's always an issue now, and I guess, as you know, the USPSTF had issues with both Exact and in level some of Epigenomics. But similar, I mean, for things like specificity and to some degrees, price considering what the problem is. So, I think we are ok, we have a lot of people looking at that very carefully.

I don't want to make off the cuff comments to service part of that. We've obviously looked at it very carefully. But we are engaging the best consultants we can find in the United States and we're using very top-notch CROs to work with on the trials, which we aim to have. So, we'll come out with that. But we do have something which is different from the others. I think, obviously, Exact had to make their own biosphere, because their test is complicated and expensive. It's not something we run in normal clinical procedures. It can never really be an adjunct. It can never— and Epigenomics has its own issues. It needs a lot of blood. It's not that accurate— particularly accurate early, as I am sure you're aware.

So, we have something so we certainly want to look at the others for the paradigm we are in. But, I think we also have a different system, a whole different approach. Our overall approach is to be very cost effective, to be as accurate as we can, and really be a part of lot of different things rather than a quite an expensive test that starts as a standalone.

I think given that, I think if anyone was to look at the balance sheet of the companies in the space, they tend to lose hundreds and hundreds of millions of dollars before they become successful. We certainly aim not to do that. We've spent about \$25 million, if I was to do as a rough outline up until now, and I think we can make revenue in a very smart and very nimble way to really get the balance sheet strong without having to do it the way the other companies have. That will require a slightly different approach from the other companies.

That includes what the USPSTF have said, Preventive Services Task Force. But that includes a lot of discussions with clinicians and doctors, looking to be parts of systems before we overturn them and create a whole new paradigm. So, we'll be making a lot more announcements about that, but that's the general strategy we have.

**Brian Marckx:**

Potentially, this suggests when they update their guidelines in the future, and NuQ<sup>®</sup> is on the U.S. market, that potentially they update the guidelines including your tests as well.

**Cameron Reynolds:**

Yes, that would certainly, absolutely.

**Brian Marckx:**

Yes, okay. Thanks, Cameron.

**Cameron Reynolds:**

Thank you for your time, Brian.

**Operator:**

We'll move onto Jan Wald with Benchmark.

**Jan David Wald:**

Good morning, and again, congratulations on the progress you've made.

**Cameron Reynolds:**

Jan, thank you very much. It's been a busy summer. Luckily the weather in here has been terrible so it's been fine being at work.

**Jan David Wald:**

Probably a busier fall.

**Cameron Reynolds:**

Yes, no, it's going to be conference season right through September, October, November, so it's going to be busy one.

**Jan David Wald:**

Well, I guess, just in—you've selected your set of assays for the European CE mark. Could you talk a little bit about what the accuracy is? What the sensitivity and specificity of the suite of assays is?

**Cameron Reynolds:**

Yes, we will be making full announcement of that in the September, October timeframe, once we've packaged it all up with the branding, so we'll be announcing all of that in September and October. I don't want to steal the thunder from the product launches. But, we think it's a very viable product and we think it's got a very good market for the product and that all will be announced.

But, I don't want to steal the thunder in mid-August earnings call. We've done a lot of work on it. We'll be announcing the sensitivity, specificity, the aim of the product, the branding and the first markets we are targeting in Europe very soon.

**Jan David Wald:**

Okay, and will you have an investor call when you announce those things?

**Cameron Reynolds:**

Yes, we will.

**Jan David Wald:**

Okay.

**Cameron Reynolds:**

Absolutely.



**Jan David Wald:**

I guess, in terms of reimbursement in Europe, going to— well, you're going to target, I guess, a few countries at the start. But CE mark, let's say, end of this year or first quarter of next year, when should we expect reimbursement to happen so that you can really begin to commercialize?

**Cameron Reynolds:**

We'll be making some predictions. I don't want to make it off-the-cuff now, because obviously that's a very important question for guidance. I think what we'll know in September/October timeframe and we'll be able to announce is the target market where we're targeting, the size of that market and the countries we will be targeting initially and the size of those markets.

I think you probably have to wait until later in the year until we have a good feel as to which ones of those will or won't be part of the story in the short to medium term. But yes, so expect some news on that later, but I don't think it would be wise for us to make those predictions now. I think it will probably be when we announce the product and what it is and its accuracy, we'll start to have a better idea.

But, I would expect to be making more outlines of the market size itself and what the product is and the branding in the short-term. Then, I guess, it is analysts' job to try to join the dots in the short-term. But we expect to make guidance but we want to make sure that it's reasonably accurate before we make predictions, and I don't think we could accurately predict that today. But we'll give some good guidances to market and the rest of it, the market size.

**Jan David Wald:**

Okay. I guess, just for my sake and then I apologize to others if this is really redundant, but would you go over what you take as adjunctive use? How it's going to be used with other tests or things just sort of where— are we sound clear on what that means?

**Cameron Reynolds:**

Yes, absolutely. I think, you're probably familiar every single cancer currently has some sort of diagnostic from the reasonably good to the appalling, and currently every system is kind of set for that cancer. So, typically what you try to do is become part of a system to help with the clinician to make a decision in conjunction with the current test, rather than just trying to replace it right off the bat.

Now, I think, we're certainly aiming to replace a lot of current systems. Clinicians are quite naturally quite conservative. It takes them a few years and you need a lot of data for them, I mean, Exact, I mean, on how long; and they're still selling 40,000 kits a quarter, 50,000 whatever it is. It takes a long time. If you look at something like CA 19-9 in— take pancreatic cancer, just one example. We estimate, I mean, there are tens of millions of them sold. So, if you can be cumulative with the current biomarker, it's a lot less risky for a doctor to use it in conjunction with rather than just replace what they've been using for a long time.

Then we certainly would expect that once that comes with your marker, you've got a few years of good sales. Then you can look to replace the current marker rather than being in conjunction with it. But, I think it's a much more easy way into the market. If you think of it this way, also Exact in some respect there is an adjunct to FIT. If you look at their results, the FIT is a very important part of their test. So, they're in essence an additive to FIT. But, if you look at other cancers, CEA is used in colorectal quite a bit and we've done our results in colorectal often with CEA.

If you look at CA 19-9, in ovarian it's CA-125, they are all used for different reasons and often for a lot of reasons. So, what you look to do is make our test with that useful, so it's the lowest risk option to the clinician to actually use our test in the first instance. By that, I think, I mean, as you can see we burned just a few million a quarter. We don't need a lot of revenue to become successful so we don't have to raise hundreds and hundreds of millions of dollars like some companies to implement our program.

So, we'd like to become part of systems, and given our small resources, I think that's the smart way of going in the short-term, while we become the dominant test in the medium term.

**Jan David Wald:**

So, you think you will be able to do that without having to do clinical studies to show that you actually provide a benefit if it's used adjunctively, or is it just enough to say here is our specificity and sensitivity, and along with this they have—you just feel better about the results?

**Cameron Reynolds:**

Pretty much all of our trials in the last couple of years or a very large number of them have included the current biomarker in them. If you look at in colorectal, we've got data from the colonoscopies from FIT, from CEA. If you look in pancreatic, we've added in CA 19-9. If you look at lung, we're also looking at trials that include low dose tomography just to see how we mix with it. So, absolutely you need to have current data with head-to-head, and it's in conjunction before we you can have—you can't just guess and think oh, (inaudible) together. You absolutely need to do them together in the same population, which is exactly what we've done in a lot of the cases.

**Jan David Wald:**

Okay, and just so I don't go wild on this, my experience is that it takes a year to a year-and-a-half to get reimbursement once something is approved in Europe. Is that a timeline that I should be thinking about or is it going to be shorter than that?

**Cameron Reynolds:**

Yes, you're certainly correct in assuming that's currently a reasonable timeline. I mean we may be shorter than that. We are certainly hitting the ground, running. But, I think if you're looking for a benchmark for what other groups have taken that would be reasonable. I think we do have something which is different which will be quite saleable, but, yes, it always takes longer and costs more as a couple of very wise investors said early on.

We aim to be a Company with a product pipeline, which we have and actually pushing that product pipeline into use, which makes us a whole different sort of Company. But obviously it does take time. But what we're very careful of is we are keeping a very tight control of cash, as you can see from our burn rate.

I mean, for a Company which is launching a product, which is running a range of clinical trials and a lot of regulatory work to be ready - if you look at the difference in cash, it is \$2.5 million from the last quarter. It's a remarkable feat not to be burning tens of millions like other companies. So, if it does take a little bit longer, it won't be taking a huge amount of capital.

**Jan David Wald:**

Yes, you've done a great job managing your finances. Thanks a lot.

**Cameron Reynolds:**

Thank you. We are all big shareholders, so it's very important to us.

**Jan David Wald:**

Again, congratulations on the quarter.

**Cameron Reynolds:**

Thank you.

**Operator:**

As a reminder it's star, one if you would like to ask a question. Next we will move to Yi Chen with H.C. Wainwright.

**Yi Chen:**

Thank you for taking my questions. Can you give us any— some thoughts or expectations regarding the potential sales ramp or revenue expectation in Europe during 2017?

**Cameron Reynolds:**

Hi, Yi, how are you? Yes, I think as I earlier discussed, basically we'll outline in September what the overall market is for the product which we'll be targeting, the countries which we'll be targeting, and roughly the size of the market if they were successful. I think from what Jan just said before, it's very tough to know right now.

We will be starting those discussions this year. We have some lined up and we'll have some discussion this year. But right now I think it will be a little reckless to try to predict exactly which ones of those will or won't do, in what order. But it's a considerable market, and I would certainly hope to have some revenue next year, but it's tough to predict exactly how it's going to go. But, I think we have a good product lined up I believe, and I believe that will become a lot clearer in September/October, when we make those announcements. But, I don't think we are going to be announcing predictions for revenue- we'll be very bright man to predict that in the short-term, because of the uncertainties.

But, what I can say is we have a very good idea. We have a good plan. I believe we have a good product, and I believe it's an immediate need. So, I am hopeful, but you don't really know until you've cracked into it. So, I'd expect an update sometime in the first quarter or second quarter of next year to basically see how it's going, but in the short-term I don't think that's something we're comfortable doing.

**Yi Chen:**

Thank you. Just a quick-up follow-up, do you have— can you provide us with any idea regarding a potential— the size of potential sales team and what kind of selling and marketing expenses should we expect in 2017?

**Cameron Reynolds:**

Yes, good question. I'll give you both kinds of answers. I think some people have sort of always expected us to have an Exact sized sales force, which is tens of millions, I think the budget is \$30 million a quarter. That's certainly not even within 100 miles of what we intend to have.

I do not expect our burn rate to be up in any way near a large multiple next year for all of this. We have the key Management person currently on board and currently in our burn rate, Louise Day, who has tremendous experience in this area. We've taken on the Decideum as our consultants who have very good experience in Europe and they've given us a great background work.

I would see it much more as several key people we hired to target those countries, and we're not going to be targeting 28 countries from day-1. That would be tough to do. We'll be targeting a handful of key countries, anyone of which if we were to get would be a very significant amount of revenue.

So, think of it more as a handful of executives. Again, we're not going to be producing the antibodies ourselves. We're not producing the kits ourselves. So, there is no need for a massive facility. We have announced and we will be moving into some slightly larger facilities in Belgium, actually a lot larger. But the cost again is very low and is like everything we've done, we've extremely careful, extremely cost-effective.

So, yes, if you think of it on the zero to, I guess, a level of tens of millions a quarter, think of it as a handful of people at the very most, and that would be in the back-half of next year. At the moment, we're handling it internally with the ways of our consultants and our Belgium team, obviously, speak French; some of the francophone countries and have been very helpful.

We've also given Gaetan Michel who is our CEO in Belgium, a product management role and he has been very helpful and he will be very active in helping us marketing the product along with Louise. So, the short answer is it will not be a large increase at all I believe.

**Yi Chen:**

Thank you.

**Cameron Reynolds:**

Thank you. Thank you, Yi. Have a good day.

**Operator:**

There are no further questions. I would like to turn the call back over to Cameron Reynolds for any additional or closing remarks.

**Cameron Reynolds:**

Thank you, everyone, I know it's the middle of August. I very much appreciate you all being on the line and hearing of our plans of the product pipeline and our launch. I think it's going to be a very exciting September, October, November for us. I'm really looking forward, as I previously said on the call we will be making further calls with more details on the product and the market and the branding in the coming months.

I really hope you can also make that call. I hope you all appreciate the work we have, and I think as we did it, it's going to be a good way forward for us. Thank you very much for your time.

**Operator:**

That will conclude today's call. We thank you for your participation.