MDxHealth First Half 2017 Earnings Call Transcript
31 August 201; 16:00 CEST

Earnings Call Speakers:

- Dr. Jan Groen, CEO
- Jean-Marc Roelandt, CFO
- Christopher.Thibodeau, COO, U.S.

Earnings Call Transcript Contents:

Operator: Good afternoon, ladies and gentlemen, and thank you for standing by. Welcome to today's MDxHealth First Half 2017 Earnings Conference Call.

At this time, all participants are in listen-only mode. There will be a presentation followed by the question-and-answer session. At which time, if you wish to ask a question, you will need to press star one on your telephone keypad and wait for your name to be announced. I must advise you that this conference is being recorded today, 31st of August, 2017.

I would now like to hand the conference over to your first speaker today, Dr. Jan Groen. Please go ahead, sir.

Jan Groen: Good afternoon and thank you for joining us on today's call. For those of you who want to follow the slide deck, you can find the presentation on our website. I'm joined today with our Chief Financial Officer, Jean-Marc Roelandt, as well as our Chief Operating Officer, Chris Thibodeau, from the U.S.

MDxHealth made significant progress on all fronts of the business during H1 2017. And today, I'd like to talk you through some of the highlights of the first six months followed by an update for the remainder of the year. I will then hand it over to Jean-Marc who will talk you through the financials of the first half of this year, and we'll have time for some questions afterwards.

So, before we begin, I'm obligated to draw your attention to this note of forward-looking statements. For those of you who are not familiar with our

business, I'll give you a brief overview of the company starting on slide number three.

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of urological cancers.

All our proprietary genetic and epigenetic methylation-based products provide physicians with actionable diagnostic information to help manage their patients. We currently have three commercial diagnostic products on the market, ConfirmMDx and SelectMDx for prostate cancer and AssureMDx for bladder cancer.

We are the market leader in molecular diagnostics for urologic oncology. Our focus on urology means that the company today is addressing a total market of $3 to $5 billion globally. And today, we are pleased to report 2017 H1 total revenues of $24.3 million represents an 87 percent increase over the first half of 2016 and a 10 percent increase in product and service revenue.

On slide number four, titled Commercial Strategy Overview, on both sides of the Atlantic Ocean, we operate a clinical service lab that complies to the highest quality standards within our industry. In the U.S., our business model is 100 percent clinical service testing of our LDTs, laboratory developed tests, directly to urologists.

All the samples in the United States are processed at one single location in our facility in Irvine in California. In Europe, however, we have a hybrid model. We have an ISO-certified CLIA lab, selling diagnostic service to the clients, but we also sell in-vitro diagnostic kits. Recently, we launched our first CE-marked SelectMDx IVD kit and started selling the kit directly to large hospitals and commercial laboratories.

Moving on to slide number five, broad coverage in U.S. laid the groundwork to accelerate adoption of ConfirmMDx. We have, throughout the years, successfully captured markets for our lead product, ConfirmMDx. And to date, close to 4,000 urologists have ordered the test.

Near future broad outpatient is driven by payer contracts on one hand and expansion of the sales force on the other. The decision to expand the sales force was driven by increasing payer contracts, the GSA contract and recently also the Kaiser Permanente contract. We are now also in the position to expand our territories and increase the frequency of doctor visits by doubling our sales force.

After the inclusion of our test -- our ConfirmMDx test in the NCCN guidelines last year, we successfully signed up 40 new contracts. In the first half of 2016, we signed up 20 new contracts. On the commercial side, we will sign up more payers and work toward the inclusion of our test into the AUA guidelines.

Regarding Medicare, we have to date, unrestricted coverage for ConfirmMDx under a so-called CTR program. A CTR program by itself is quite time consuming for our sales reps, meaning they must complete a lot of paper work to have the test paid for. We expect to start new Medicare unrestricted studies in the coming year that will hopefully not require all the admin that is currently required for the CTR. The names of these studies are listed on the slide here, PRIORITY as well as the CARIBOU study.

A major milestone for the company in H1 was when the company was awarded the GSA contract, the government services agreement. This contract allows us to access the VA hospitals and introduce our ConfirmMDx test to urologists, but we still need to set individual service agreements with the respective VA hospitals.

Today, we have announced that we now have eight hospitals signed up under the GSA agreement and are now starting to receive the first samples. We will sign up more hospitals in the months to come

Moving on to slide number six, SelectMDx is gaining traction worldwide. In the U.S., we now have 13 payer contracts since the launch of the SelectMDx test on the U.S. market. We also are running several clinical studies to prepare a medical dossier for inclusion into the respective clinical guidelines in Europe as well as the United States including submission for the (MoIDx) program under Medicare to obtain coverage by Medicare.

In Europe, we successfully signed six distribution agreements and recently launched our CE marked kit. In the first half, we tested close to 1,200 patients in our facilities in the Netherlands, an increase of 390 percent over the first half of 2016. We expect to sign more distribution agreements with large hospitals and laboratories across Europe. For the rest of the world, we have now signed four distribution agreements and we'll sign up more distribution agreements in the months and years to come for SelectMDx.

To continue on to slide number seven, entitled Research Collaboration Support our Pipeline. In the first half, we signed three research collaborations, one with Exact Sciences. This agreement is purely focused on the biomarker discovery platform within both companies and technology improvements. We also signed agreements with the University of Ghent for the validation of our technology, MISH, methylation in situ hybridization. We also signed a licensing agreement with the University of Ghent. That program is for the development of liquid as well as tissue biopsy assays for urological cancers.

The third recent agreement was with the University of Maastricht. It's a collaboration agreement focusing on the discovery of new biomarkers and the development of prototype assays for kidney cancer.

Slide number eight states the H1 2017 financial highlights. We've seen a significant increase in patient testing—up to 15,000 patients for the first half, an increase of 44 percent. And Jean-Marc will talk to you about the financials in more details on this slide.

Moving on to slide number nine, prostate cancer diagnosis standard of care. So, we operate in the space of prostate cancer. The standard of care today across the world is the biopsy procedure as you can see from this slide. The biopsy by itself is not without any risk. We have seen 20 percent of the patients experience serious side effects and also the needle might miss the cancer, resulting in a high rate of negative histopathology results. So, the next question that comes up is, does this patient require a repeat biopsy, yes or no.

On slide number 10, it gives you an overview of our global prostate cancer portfolio and vision. As you can see from this slide, the SelectMDx product addresses all needs of biopsy and the market potential is 10 million men, both in the U.S. and Europe with an elevated PSA level.

ConfirmMDx addresses the question who needs a repeat biopsy. It's testing negative tissue from those patients when the results come back from pathology without any conclusion. And the question comes up, what's next? So, we test the leftover tissue and provide additional information to the physician, whether this patient requires a repeat biopsy, yes or no.

The products, InformMDx and RecurMDx, are two products currently in development. InformMDx is targeting men that have been diagnosed with prostate cancer and we will provide them the information whether this patient is dealing with an aggressive cancer or not. And RecurMDx is focusing on the treatment of patients mainly after prostatectomy. Studies are on underway and have been published recently in the respective journals.

So, our two products in prostate cancer, SelectMDx is a liquid biopsy test to identify men who will most likely benefit from a biopsy procedure or MRI. It's a non-invasive urine-based RNA test and it avoids unnecessary biopsy procedures for the patients.

Slide number 12, summary of the ConfirmMDx product. ConfirmMDx is a tissue biopsy test to identify men who might benefit from a second biopsy, a tissue test using leftover tissue from the biopsy and with a negative predictive value of 96 percent. Also, in this case, we can avoid a lot of unnecessary biopsy procedures for the patients and provide the physicians with actionable information what the next step would be.

On slide number 13, is a diagram of how our products fit in the diagnosis of cancer. So, starting first in men with elevated PSA level north of 3 milligrams per ml would be eligible for SelectMDx test. We provide a risk score, high risk or low risk. High risk means follow up this patient with either an MRI scan or a biopsy.

If the MRI is positive, it still would trigger a biopsy procedure. The biopsy procedure follows a ConfirmMDx test. A high risk ConfirmMDx test could also trigger an informed test and means an additional intervention done by the physician. For those patients that are negative with the ConfirmMDx test and negative or low risk with the SelectMDx test, they will fall back into the follow-up of these patients with the PSA test on an annual basis.

On slide number 14, I'll share with you the success we have seen with both products today since launch. So, for ConfirmMDx, we tested over 65,000 patients since we launched this product on the U.S, market. And the SelectMDx test launched on the U.S. market as well as the European market—we tested today over 10,000 patients.

Slide number 15 gives you an indication of the market opportunities for both products. SelecMDx has been pressing on the European market as well as the U.S. markets with 10 million men, and ConfirmMDx is only available on the U.S. market with 1.5 million subjects. So, the total addressable market opportunity for these products is north of $5 billion.

Slide number 16, we talked about the success of global commercial strategy of the Company. And looking at the patients, the physicians, the feasibility, and the credibility of the company for both products, ConfirmMDx and SelectMDx. So, in total, we have tested over 75,000 patients with both ConfirmMDx and SelectMDx, where we'll be able to forego a lot of unnecessary procedures.

On the physician side, we have provided many of the physicians with actionable information and today—close to 4,000 physicians have ordered our tests. We have a strong brand name in the market, both in the U.S. and in Europe. And all the products that's currently on the market for prostate cancer are supported by more than 60 scientific publications.

From a credibility standpoint, the ConfirmMDx test, for example, is covered by Medicare. We recently signed up the VA contract and also Kaiser Permanente and the test—the ConfirmMDx is included in the NCCN guidelines.

On slide 17, our new product that we recently launched on the market for bladder cancer, AssureMDx. This gives you an overview of the market opportunity for AssureMDx, and this product will only be available on the U.S. market. So, the total number of patients on an annual basis that will get the referral to see a urologist is 1.8 million. Those numbers of patients you want to quickly filter out if they're dealing with bladder cancer, yes or no.

However, the test can also be used for the follow-up of the patients, once they have been diagnosed with bladder cancer. So, today, it's about 300 -- 630,000 men and women undergoing a cystoscopy procedure, which is quite an invasive procedure.

So, once you're being diagnosed with bladder cancer, on an annual basis, roughly 80,000 patients in the first two to three years need to be followed up by a cystoscopy. It's quite an invasive procedure and the AssureMDx test can forego several of these cystoscopy procedures.

On slide number 18, bladder cancer diagnosis standard of care. The standard or care today for the diagnosis of bladder cancer is the identification of cancer cells in urine by collecting the urine sample or performing a bladder wash, followed by a cystoscopy or followed by a laboratory analysis called cytology where we look at the presence of cancer cells with fluorescent probes.

Slide 19, so the addressable market for our AssureMDx test in the U.S. is north of $500 million. So, we're looking at 1.8 million patients with hematuria, blood in urine. We're also looking at 630,000 cystoscopy procedures. And we also do know that 3,000 so-called missed diagnoses is based on this procedure and it also shows that 38,000 patients are undergoing unnecessary cystoscopy procedures. So, this tells the story there's absolutely an unmet diagnostic need for the product like AssureMDx for Bladder Cancer.

So, similar to the slide of SelectMDx and ConfirmMDx, this particular product is a combination of methylation and mutation testing and it's a PCR-based assay with a high negative predictive value of 99 percent. Also, the sensitivity is extremely high, 93 and 89 percent for specificity.

Like our other reports, it immediately provides actionable information for the urologist and can recommend whether a urologist should start the cystoscopy procedure or CT scan. But on the other hand, for the patient, it also avoids a lot of unnecessary cystoscopy procedures.

I will now hand over to Jean-Marc to go through the financials in more detail.

Jean-Marc Roelandt: Thanks, Jan. The total revenue amounted to $24.3 million, up 87 percent from the first half of 2016. However, the first half of 2017 included the sale of our colorectal cancer-related patents to Exact Sciences. This one-time payment of $15 million included royalties, which had accrued since July of 2016, but which were unpaid.

As a result, the net impact of this transaction on our revenue for the first half of 2017 amounted to $12.1 million. The first half of the last year also included royalties and milestone payments from Exact Sciences and looking at product and service revenue only, in other words, excluding income from Exact Sciences for both periods, the first half of 2017 saw a growth of nearly 10 percent compared to the first half of 2016. This growth results from growing patient test volumes, which increased by 44 percent with the same number of active reps in the field of 27. This volume increase is largely attributable to the early success of SelectMDx, which contributed 35 percent of total H1 volumes.

This is, however, not fully translating into revenue growth as the revenue recognition rates are still low in this early stage of payer adoption. This is the main reason why the revenue recognized as a percentage of net billings remains at 50 percent. A slight improvement for ConfirmMDx was offset by a lower rate for SelectMDx.

This will continue to improve as the number of payers under contract for both products will continue to increase. In H1, an additional 21 contracts were concluded and four new positive medical policies added.

Turning to the gross margin, we continue to improve the gross margin for ConfirmMDx, but here as well the improvement has been offset by the lower

gross margin on SelectMDx, which is expected to increase as both volumes and reimbursement levels increase. Overall the gross margin remained at a steady level of approximately 60%.

The organization has further developed in the course of 2016 with the build-out of a European strategy for SelectMDx. The effect for the full six months of initiatives such as the reinforcement of management and commercial team has resulted in an increase of SG&A by 17 percent year-on-year. Another important driver of SG&A going forward will be the recent expansion of the sales force in the U.S. aimed at grasping the mounting opportunity for our product portfolio in the U.S. as evidenced by significant contract wins, such as the government service agreement and the Kaiser contract, giving us access to two large closed healthcare networks.

The buyout transaction with Exact has enabled us to continue to invest in the further development of the business and in the building of brand awareness across Europe and the Middle East. Cash collections for ConfirmMDx and SelectMDx, which are a key indicator for future revenue recognition amounted to $10.8 million, up 31 percent from the same period last year.

Collection times remain long as many claims require appeal and review upon initial denial by the insurance companies. However, in 2016, we were awarded with a unique CPT billing code which is expected to facilitate collections and reduce the working capital requirement associated with continued growth of ConfirmMDx.

Meanwhile, the cash positions stood at a healthy $30.5 million at the end of June. Volume growth of 44 percent in the first half of 2017 was delivered with the same number of 27 active sales reps in the field. The resulting 10 percent revenue growth lays the foundation for further accelerated growth as we went into the second half of the year with 50 reps, building increased adoption across the U.S.

Together with the initial contribution of the contract with Kaiser Southern California and increasing access to VA hospitals, we expect strong growth in

the second half and maintain our full year guidance on revenue growth of 55 to 75 percent, excluding royalties.

I'll now hand over the call back to the operator for the Q&A.

Operator: Thank you very much. Ladies and gentlemen, we will now begin the question and answer session. As a reminder, if you wish to ask a question, please press star one on your telephone keypad and wait for your name to be announced. The first question comes from the line of Stephanie Put from Degroof Petercam. Please ask your question.

Stephanie Put: Hi. Good afternoon. Thank you for taking my question. I was trying to grasp a bit more about the impact of the expanded sales force. As I understand this will be the main growth driver in the second half of the year. Could you detail when they were hired exactly and if they were already active in the first half of the year?

Maybe -- could you also say what the cost is for sales representatives? And in addition to better understand the sales cycle, could you give us an idea of the number of tests that a representative currently is selling on average and how this has evolved versus last year? Thank you.

Jan Groen: Well, Stephanie, thank you for your detailed question regarding our sales force. So, as indicated, we have hired our additional reps, doubling our sales force up to 50 reps at the moment, all being in the field right now. They were trained a couple of weeks ago in August and they're actively participating and selling our products—both SelectMDx and ConfirmMDx.

The other question regarding the sales performance and the number of tests that per rep they are selling, we have not disclosed those numbers to the market.

Stephanie Put: OK. Maybe some ballpark numbers?

Jan Groen: I can give you a little bit color around—imagine if a rep is starting, he's not right out of the gates. He's selling hundreds of tests. So, there's a little ramp up needed.

Operator: Thank you. The next question comes from the line of Lenny Van. Please ask your question.

Lenny Van Steenhuyzen: Hi and thank you for taking my question. I was wondering also on the expansion of the sales team, how much of an impact that would be on SG&A cost namely in the second quarter – in the second half of the year and how would this compare to the first half of the year?

My second question is actually on R&D costs, how do you see this going forward, are they going to remain stable? And my last question is on the timeline of acceptance for the SelectMDx test in the NCCN and EAU guidelines, can you give an indication of when application and approval might be expected? Thank you.

Jean-Marc Roelandt: So on the SG&A and on operating expenses in general, we can expect an increase compared to the first half of last year. And, I think at a minimum, we should expect the same level of increase as we encountered on the second half of last year, and that was 17 percent.

So, with the sales force expansion and the further investments in the European build-out of the SelectMDx strategy, I think we should reasonably expect to be at least at the 40 million mark for the full year. R&D, basically stands at a stable level as a percentage of revenue of around 20 percent, if you also include the expenditure that is capitalized.

And obviously, the overall spend and the overall operating expenditure depends on the level of capitalization and that depends whether our development projects meet the criteria for capitalization in accordance with international accounting standards. Jan, do you want to take the question on SelectMDx?

Jan Groen: Sure. Lenny, your question regarding the inclusion of the SelectMDx product in the respective clinical guidelines whether it's the NCCN or EAU guidelines: what's necessary like I shared with you in my presentation is that the company generated enough studies – clinical studies and publications in order to submit this to the committee to be able to be included in the respective clinical guidelines.

So, there are only a few slots per year that you can submit your package. It will remain to be seen if we have enough data for submission this year, for sure next year and then still waiting for the inclusion of the test in one of these guidelines. So, I cannot give you a clear answer. This will be a year or two from now but probably will be in that ballpark.

Lenny Van Steenhuyzen: OK, thank you very much.

Jan Groen: And there's one more question that I forgot to answer from Stephanie regarding the cost of a sales rep per year. The standard in our industry regardless of MDxHealth or any other player in the U.S., fully allowed cost for the company, salary, travel and everything else, bonuses is in the ballpark between 180 and 200K.

Operator: Thank you. The next question comes from the line of Howard Halpern. Please ask your question.

Howard Halpern: Thanks for taking my question, guys. This is more of a longer term question in terms of how volume growth and revenue recognition. How is that going to narrow over time in the next couple of years?

Jean-Marc Roelandt: Well, it's going to narrow, I mean the gap on the first quarter is caused by SelectMDx for which we have low revenue recognition levels in the early stage of reimbursement. So as Jan just explained, we'll have to go through the same motions that we did with ConfirmMDx to increase the number of payers under contract and increase the reimbursement per test.

And based on that improved collection history, we'll be able to recognize more revenue than we do today. That's how the gap between revenue growth and volume growth will disappear over time.

Howard Halpern: And if that narrows, would SG&A expense go down because you won't have to go through the appeal process and such?

Jean-Marc Roelandt: Yes, it is indeed quite a significant investment to obtain reimbursement but obviously as the volumes grow, we will have a growing payer base to deal

with. So, I'm obviously not expecting a linear increase but it's also not the case that we will see large potential savings as volumes increase.

And obviously, the gap between revenue recognition, growth and volume growth will also be narrowed by the progress that we make on ConfirmMDx. One of the essential events for us was the awarded CPT code. That becomes effective in January of 2018. That will drive much shorter collection times, improve statistics on collection and increase revenue recognition.

Howard Halpern: OK. And one last one about the sales reps, how much coverage of the U.S. will you have now with the 50 representatives?

Jan Groen: Yes, so I will hand over that answer to Chris Thibodeau, our Chief Operating Officer in U.S. Chris?

Christopher Thibodeau: Hi there. Actually, we'll have 100 percent coverage of the U.S. at this point with all 50 reps in the U.S.

Howard Halpern: OK, OK, thanks that's great. Thank you.

Operator: Thank you. The next question comes from the line of Chris Redhead. Please ask your question.

Chris Redhead: Two questions, the first question is you now said with the 50 reps you have 100 percent coverage of the U.S., that's right, isn't it?

Christopher Thibodeau: Hi, this is Chris Thibodeau, I'll step in. So it appears with the 50 coverage, we've just seen significant growth but we're not going to rule out further expansion.

As Jan mentioned earlier with the recent launch of the AssureMDx for bladder cancer product there's some anticipated expansion of indications in a year or two ahead. Opening up additional populations of patients could help with our tests and we may then explore further expansion of the sales force to increase coverage.

We could have reps visiting clients on a more frequent basis to talk about multiple products that might assist in urology settings. So for now, 50 is

going to get us some significant growth but at the same time we're not ruling out the potential for further expansion to gain greater market adoption.

Chris Redhead: So next year, you'll expand with another 20 reps and it's is going to be incremental and you'll see how it goes, right? Is that basically what you're saying?

Christopher Thibodeau: I think that's yet to be decided. I think it comes down to what we see in terms of growth and the opportunity to capture market share as reimbursement increases and we've seen opportunity to seize more market share. I think that we want to reserve judgment and leave that as an option.

Chris Redhead: In terms of the cost of goods, you got around about 60 percent, right, just – your gross margin is about 60 percent. Do you anticipate with the volumes that would improve somewhat or where do you think that will go?

Jean-Marc Roelandt: We're obviously continuing to look for ways of improving the ConfirmMDx assay from an operational point of view. So, there is certainly still room for improvement on that front but for ConfirmMDx, the improvement on the margin will come from increased collection and resulting revenue rates and there is still sufficient room as you know.

I just indicated earlier that we recognized 50 percent of what we built, so that's a natural area for growth of the margin. On SelectMDx, obviously it's on both fronts that we will drive the margin up that is both volume as well as reimbursement levels. And there as well, we continue to increase operational efficiency of the test as well.

Chris Redhead: OK, great. The last thing is I did notice that there was an NCCN panel last week. So, I guess the next one will be – I think as far as I can work out in terms of the early prostate panel is they only seem to appear sort of once or maybe twice a year. So, I guess you must be at least 12 months away from the next panel …

Jan Groen: No – well, that's not correct, it was a different panel. This was the early screening panel and it depends on what category your product fits.

Chris Redhead: It would be in the early screening panel wouldn't it?

Jan Groen: It's not a screening test, no.

Chris Redhead: Well …

Jan Groen: It's absolutely not a screening test. It's an add-on test after the screening has taken place.

Chris Redhead: OK.

Operator: Thank you. The next question comes from the line of Justin Scott. Please ask your question.

Justin Scott: Yes, hello, I got three questions. One of which addresses the repeat of an earlier question that Stephanie asked and you broke up so badly that I think most of us missed the answer.

And the question that Stephanie asked was, could you give us a sort of more precise timing as to when the sales force went from 27 to 50, was this very sudden or done within three weeks? Did it start during the first half and completed as we entered August? So, a little bit of timing on the sales force growth.

And then the second question which Jan was answering and I don't know if you want to disclose precisely how many tests they sell. But, Jan was giving some description of sort of the framework or the trajectory of the new sales person to experienced sales person what that trajectory would look like and I wonder if you could repeat his answer for the benefit of the rest of us.

Jean-Marc Roelandt: OK.

Justin Scott: Or if Chris is on, he could take that.

Jan Groen: Yes, I will refer to Chris regarding the build of the sales force because we started recruiting sales people as of June but he can give you all the details when they were in the field and also your last question as well. So Chris, please.

Christopher Thibodeau: Yes, hi there again. So yes, as Jan mentioned we started recruiting for the build-up in June and July. We did complete the recruiting and interviewing process and really completed sales training in early August. So, we now effectively have our entire sales force out in the field and out there running.

As Jan mentioned earlier, there is a ramp time for new representative. We usually believe at three to six months in the reps are really hitting their full stride. But you know, some are higher performers early on, some are lower performers but on a whole we expect in the second half of the year to get some lift from the increased size of the sales force.

Justin Scot): So that was Stephanie's question, my second question is, if it looks to me as I passed out the numbers and break them out from comparing to last year report that ConfirmMDx, the sheer number of tests plateaued, stumbled, was down sequentially from second half last year and was at best flat, maybe down a little bit from first half of '16.

And in particular, that seemed to happen in the first quarter because you had a stronger recovery in the second quarter of the first half. And I was wondering if you could talk a little bit about what might have been going on with ConfirmMDx in the first quarter of this year and what's the change, so that last two months of the half are very strong.

Jean-Marc Roelandt: One comment from me purely on the numbers is that what you worked out from our disclosure is correct. So, we do see ConfirmMDx being flat compared to the same period last year. That's why we emphasize that we achieved that with the same number of active reps in the field.

So in itself, that is not surprising. That we're down from the second half is also correct, but here as well, no surprise as the second half of the year has historically been the stronger half of the year. I'll let Chris comment on the reasons, but in particular, the first quarter of every year is extremely seasonal. So, these trends are confirmed from our part but absolutely not surprising.

Jan Groen: Chris?

Christopher Thibodeau: Yes, hi there. There are couple of factors that contribute to this of course, but one of the reasons we've been focusing on driving adoption in the client setting, trying to focus on contracted, insured patients, trying to work with clients to make sure that they're identifying patients where we do have contracted coverage, whether that be Medicare and/or other contracts that we have. And that, hopefully, will lead to a higher reimbursement on the per test basis.

Secondly, as we look at every year, we see the seasonality. You know, in the U.S. healthcare system there's a process by which patients have their insurance covered typically by their employer. However, a component or a portion of their care is an out-of-pocket expense and so during the course of any given year, it resets in January and you have something called a deductible which must be satisfied.

So for instance if you had a maximum of 10,000 out-of-pocket – maximum of 10,000 coverage, maybe the first 20 percent, up to $2,000 will come out of your pocket. And then, the rest will be covered by your insurance. So copays and deductibles play a big role in Q1 because everyone has a reset.

So often, if it's not a life or death situation and often, don't get me wrong, prostate cancer can be very dangerous. But if there's a window of time in which you might order an assay or a procedure which is expensive, often you may delay that until that patient actually incurred some other expenses and they started to satisfy some of those insurance requirements. So often we see a dip in Q1.

Conversely, why we also usually see a lift in Q4 is that most of the patients have actually had their copay, their deductible satisfied – or their deductible satisfied by the end of the year. So then, there's a window of opportunity to say, well, if there's no additional out-of-pocket expense for patients. So, physicians would be more apt to order an expensive assay or procedure at that point in time. So hopefully, that helps address some of the seasonality.

Justin Scott: No, that's a good point. I'm aware of that. Actually, the doctors try and manage avoiding the deductible. So Chris while I got you on, a generalist

question if I might. What is the impact on the salesman's visit to the physician of now having more than one product and potentially three products?

I mean one could argue in that the short time zone in the busy physician's day, it's harder to keep the attention on ConfirmMDx when you're also presenting SelectMDx but alternatively one could argue that it opens the door to the physician and you become more of a solution provider in diagnostics. I know it's early stages, but what are your salesmen reporting back to you on the impact of now having more than one product as they access the physician?

Christopher Thibodeau: That's a really great question because it's part of our overall strategy. As you mentioned, getting physician time can be challenging in the initial stages with new clients as you're building that relationship. However, as we developed a client base over the course of the last several years, certainly with our existing clients, they heard quite a bit about ConfirmMDx.

And over the course of the last, 12, 18 months, they started to hear a lot about SelectMDx. We're gaining adoption there. Our reps historically, when we had a smaller sales force, can only really cycle through their territories rather infrequently, right? So they may end up getting in – maybe once every three or four weeks.

Sometimes more often, sometimes less but they're making cycles through. Now with an increasing product portfolio, our reps have something new to talk about with those existing clients but of course opening opportunities for entry points. So for instance, perhaps a urologist hasn't yet adopted ConfirmMDx but they're very interested in SelectMDx. And then, we can segue right on to ConfirmMDx or vice versa, and the same will apply with AssureMDx.

So giving the reps, let's say, a deeper tool bag with more options to go talk to their physicians. Since the sales call enhances the relationship with the client as you pointed out we now become more of a one-stop shop, more of an overall solution for various needs that they have. But also the increasing sales force with that increased product portfolio will allow greater frequency of visits.

And that's an important component here that our reps now with 50 in the field should be able to go and visit their clients on a weekly or bi-weekly basis. And that in itself, I can tell you, will make a significant contribution in terms of assay adoption. Whereas doctors are excited about the test that we offer, often we're changing their practice. We're changing the way they manage their patients over the course of the last 10 to 30 years.

And so that frequency of visit is really critical, so that we don't miss the opportunity to help any given patient. And I think that frequency of visits is going to lead to broader adoption for ConfirmMDx and SelectMDx and of course AssureMDx as we really roll that out. But, I think that the overall portfolio as we increase it, really makes us a broader and a stronger solution overall. So, it's an exciting time as we add more products and we increase the sales force. We think the combination is going to be powerful.

Justin Scott: My final question is a financial question regarding SelectMDx contrasting the margin model of the U.S., Europe and the rest of the world. Without getting into precise gross margins, could you give us a feel for the framework or the shape of the three different models for selling SelectMDx? One of which is when it's the lab test very much like ConfirmMDx.

The second is the kit model and the third is the distribution model where a third-party is selling it but it's still coming to your lab. And I wonder if you could contrast that with the U.S. in terms of what the revenue number is and what the profitability between those three models is?

Jean-Marc Roelandt: I won't go into the detail. I mean it's still very early days for SelectMDx in Europe and obviously as you rightfully point out with the kit being sold, manufacturing costs are pushed to the labs performing the test and part of the commercial costs are also pushed to the distributors.

So obviously, we have to settle for a lower margin overall in the lab – on the lab service. SelectMDx will yield comparable margins than for ConfirmMDx and I think at this point in time that's the only guidance that we can provide.

Justin Scott: Understood. But can I just sort of ask a little bit on the revenue numbers, then? I mean which generates – I presumed the lab test generates the highest revenue per test, the distributed the next and the kit the lowest, and I was wondering roughly revenue from kit to lab, is it – can you give some sort of scale instead?

Jean-Marc Roelandt: Well, that hopefully will largely depend on reimbursement results for SelectMDx. We have a list price for the U.S. for SelectMDx of $500. We're currently increasing adoption, looking for the market value and trying to set reimbursement levels.

I'm not going to comment on that because any disclosure could interfere with those efforts but the ultimate reimbursement level will basically give us the answer how this compares with our kits. I don't think we disclosed the kit price but as you would expect and as you pointed out, it is lower than what we expect as an average between reimbursement level for the lab service in the U.S.

Justin Scott: Thank you very much.

Operator: Thank you. There are no more further questions. Thank you very much for participating. Your call now is finish.

END