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SCHEDULE 14A
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SCHEDULE 14A INFORMATION

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Roche

Investors/Analysts Conference

London

Diagnostics – Session 1

Q&A Session

Unidentified company representative

Welcome to Diagnostics sessions. We're happy to have you here. Quite a bit of interest.

From the floor

The question I'm trying to understand is what's going to happen to the pricing of the market for sequencing. It just seems to be that there is already over capacity and obviously there will be huge opportunities at some point in the future when you move into the clinic, so big volume uplift, but in the meantime, the pricing is going to come progressively down. So I'm just trying to understand if it was $13b, or 13 years and $3b and now it's $1,000 and it will be $500 and $200 and $100. I'm just trying to understand what's going to happen to the overall pricing and what the IP benefit of having the sequencing provides to your companion diagnostics effort and your pharma effort because it me it's almost as if you're buying $300m of EBIT which I'm sure you believe the synergies will grow a bit faster than it has done in Illumina to provide you with strategic capability to commercialise companion diagnostics in the future. In itself, the technology is over capacity meaning pricing is coming down very rapid. So I'm just trying to understand your view in terms of price, volume and therefore, sort of revenue and profit outlook for sequencing as an independent business.

Daniel O'Day

Sure, sure. So on the pricing side, I mean it's clear that pricing has come down significantly over the years as you mentioned. I don't think that will continue at the repetitive pace that it has in the past 10 years. I think we're really achieving an efficiency level in both the chemistry and the density of the chips that we're really getting to a level where I think the $1,000 mark and that mark is really going to be a market. I don't think we're going to see go down to $100 so to speak. So I think we're reaching, to a certain extent, the price limits in the technology.

It is an attractive margin today. Let me speak a little bit to your over capacity and to the volume aspect of things. I feel we're just starting to tap into the potential volume here. First, in the research setting, yes, some of the genome centres have sufficient capacity now, but with the launch of platforms like MiSeq I think there is tremendous opportunity to take this beyond some of the capacity constraints that go along with sending samples and things to large genome centres and bring it more into key cancer centre hospitals, other research labs. So I think the volume effect is still incredibly significant and I believe the penetration into research still has a lot to go in terms of the volume side of things.

Eventually, also in the mid-term and I don't think this will be, by the way, a black and white situation. One day it's in the research setting, the next day it's in a clinical setting. It's very much of a shade of grey and I also think in different countries, depending on the regulations, it will move more or less quickly into the diagnostic aspect. But today what's true is that there are very few patients around the world that are being sequenced as they enter into a cancer centre.

I mean if you go to the MDM into the world of [catarines], some of the key centres around the world, they are doing some sequencing for some patients and they're doing some limited sequencing. They're doing either 50 genomes or 100 genomes or 200 genome type panels. So we haven't begun to crack I think, the potential, as it goes into the clinical setting in the mid- to longer-term where we'll see, in my opinion, as you have more complex genetic variations being able to be acted upon, we'll see the volume increase and I believe we'll see it being routine practice in the future at cancer centres, just to use on example. There are many other disease states where it is used today in HLA and de-sequencing, in virology, genetic disorders. So I believe this momentum will increase.

Now also, the technology, and there is a price point, back to the price point, that is reasonable. That it is reasonable to expect that people will also use this in a clinical way and reasonably, if it's used in a way that's very connected with therapy intervention, I also believe that reimbursement will come in these countries with these patent applications as well.

So step one, deeper penetration into the research setting. Step two is really getting into the volume setting in the clinical arena and clinical field.

Sorry, there was an end to your question that I'm not I answered.

From the floor

Well no, that's very helpful.

Daniel O'Day

Okay.

From the floor

I guess at the moment you've got a scenario where there is bottlenecks to kind of get into the greater volume setting and with a competitor trying to catch up and gain volumes growing 18% where Illumina is at 60%, they're just trying to sort of find new methods and therefore, there isn't a sort of rational pricing structure today. Certainly it's lack of capacity. There's more supply than you can deal with capacity. You're kind of saying that price pressure will alleviate. You'll hit a price point at $1,000 or whatever it is based on the value of the sequence from a clinical perspective and you'll see stabilisation.

Daniel O'Day

Yes. Obviously Illumina has a lot more information on this than I do. I think this issue between supply and demand is a temporary one. It's not a permanent one. I think there is also logistics involved with sending samples around the world to these genome centres and other things and the closer we get the technology to the clinical sites, to the researchers to eventually the clinics, I don't have a concern about supply and demand in this area. I think there is tremendous demand that is untapped right now. That as the technology comes out on price points and availability, I have no doubt that it will continue to be this.

From the floor

Okay, and I just have one very quick second question.

Daniel O'Day

Yes sure.

From the floor

When it comes to FTC and ongoing collaborations, there is a general thinking, and we're just trying to understand, how many other deals Illumina has done with other

companies, which parts and certain parts of the market or the potential issues there and what overall it means from a FTC perspective?

So I understand from the conference call you talked about some of the complementary technologies but on the face of it we're looking at 60 plus, 15, a market share in the 70s now if the deal goes through which, on the face of it, is quite significant. In terms of just trying to understand what proportion do you feel the sales are at risk from an FTC perspective? What proportion of sales are at risk from collaborations having to split out?

Daniel O'Day

Yes, I mean I think at this stage we've started the regulatory filing process. Our feeling is that the competitor space is robust. That's our feeling. The process now needs to continue. I wouldn't want comment on any specific collaborations that Illumina has. I'm not the right person to comment about that. But from our perspective, we will now follow the regulatory review process and again quite confident that the regulatory space is robust to allow the process to continue.

From the floor

A couple of quick follow ups then. Just on the timing of that longer-term move into the clinic, that seems to be quite a long way ahead. It may be 10 years away until that comes to fruition. Is that something you're looking at? That would suggest that the MPV is a little bit challenged from that point of view. Have you done anything around timing?

The second thing, just following up from what Alexandra said in the main session, just in terms of write-offs with technology, how sure are you given this is a very large acquisition this is the right technology? I know you mentioned that you've looked at other players in the field, but this is much bigger as was mentioned 454 or NimbleGen that was written off.

Daniel O'Day

Thanks for asking that question again because I never got a chance to answer it for Alexandra, so I want to get to that.

Sorry now your first point?

From the floor

The first point was just the timing in terms of really getting to that nominal stage.

Daniel O'Day

Right. Again, I don't think it will be something that happens in two years' time, in five years' time, in 10 years' time. It is happening today. I mean today a cancer centre in Germany in Heidelberg I visited about two or three months ago, they're doing excellent sequencing on every patient that enters. So it's happening today in environments where also from a regulatory perspective it can be used, but granted, it's a small proportion of sequencing turnover in sales today. So I think the business case is robust because it's going to be a blend.

The first thing is the penetration to the research field has just begun as far as I am concerned. There is tremendous more penetration that can occur there and exactly when it comes into the clinic in a broad sense will depend also on the ability to have a highly accurate technology, one that can have reliable consistent results which also are the exact same qualities that you need to get IVD approval of these platforms. So even though there will be some of this activity in the large cancer centres, I think the combination of Roche and Illumina together are in the best position to be able to take the world leading sequencing technology today and as fast as possible get it into a stage where it can be regulatory approved in different markets around the world. It's clearly going to happen at different paces, but as that happens, I think that will open up then the penetration.

I don't think it's 10 years away that you get to a critical mass and this being used in the clinical setting, but I do think it's several years away. I think it will take some time to really get this be routine and then we'll see a ramp up at that particular time.

So I wouldn't want to comment more specifically on that. Obviously, in our estimation of the business, we have some estimates on that, but I do believe that combination of the penetration to the research and the integration to the diagnostics makes the business case very robust.

On the second question relative to technologies, in fairness to Alexandra's question, I'm not sure we were comparing apples to apples there. So what I want to comment on is the maturity of acquisitions. So in diagnostics we do a lot of acquisitions and for we, for a variety of reasons, we acquire technologies at all different levels of maturity.

454 for instance was at the forefront of the emergence of sequencing. It was a new technology and the same thing goes for something like Viran Diagnostics that we acquired a professional diagnostics business. That's a new technology in coagulation monitoring, platelet function that we're going to further develop and grow.

Those types of acquisitions carry with them different types of considerations than something like buying a world leader in tissue diagnostics Ventana and clearly, buying a world leader in sequencing and micro rays I just done think they're comparable in terms of the momentum they have, the ability for them to have already penetrated the marketplace and the ability for them to keep ahead of other

technologies, which has been the case with Ventana and I believe has been the case with Illumina.

So I'm not sure that comparison, or that direct comparison, suggests that we wrote off a small amount of intangible assets for NimbleGen and 454 would equate magnitude wise to the same around the write-offs on a large acquisition. That logic breaks down for me because of the nature of the two different acquisitions.

From the floor

Some people are saying that Illumina has the second generation technology but a third generation is yet to come. That would seem to be the risk here in terms of developing forward. Is that fair?

Daniel O'Day

Yes, I mean terminology in this field is interesting. Some people use first, second, third, fourth, but suffice to say that we consider Illumina to be a next generation sequencing technology and there are all the technologies that are in feasibility in right now which are single-strand, single-read type technologies. But those are in feasibility and we know, we have experience with those type of technologies that along the path to becoming real there are a lot of hurdles clearly.

The other thing to consider, and we obviously have experience within the Roche Group, the other thing to consider is if you look at even the announcements that Illumina made at JP Morgan in terms of their ability to bring the throughput and the costs down in their current system, the competitive distance between the next generation technology and the promise of the future of single-strand is getting more and more narrow in fact. I mean I think these next generation technologies continue to do more than most people in the field ever thought they could do. So it's also another important consideration as we look at risk of new technologies coming to the marketplace.

Having said that, I just want to be also very clear that in order to stay ahead, in order to continue to stay ahead with the types of portfolio that we have throughout our diagnostics division we have to continue to invest and we need to continue to invest in Illumina technology to make sure that it stays competitive and stays ahead of the competition. But when you have a market leading position and when you have momentum, that in the past has been a very powerful predicator for how things work out over time.

From the floor

I believe this will be a question on the transaction of Illumina, proposed transaction of Illumina. I don't want to ask [inaudible]. Can I assume that you were aware of the

starting trend in price? Maybe more clearly, were you aware of the announcements of the competitor about their $1,000 when preparing your offer?

And second quick question, Illumina has 60% market share and Roche has 10%. Of course you can define the market differently, but how intensive work is done on antitrust issues and are you comfortable about this transaction going through again regarding [strategy]?

Daniel O'Day

Sure, sure. In terms of what we were aware of or not, we were aware of everything until we launched the hostile transaction which was last Wednesday. So clearly, all that knowledge went into the consideration of what we think is a very attractive offer for Illumina shareholders. That's the answer to that.

In terms of the FTC issues, again, to be a bit repetitive, we have proceeded ahead with the regulatory filings. In this space it's a robust competitive space and we feel confident in the fact that we submitted the regulatory filing and that we can proceed ahead with the transaction accordingly. But obviously it is contingent upon the regulatory authority's review of the material and the approval accordingly.

From the floor

I think it was asked in this session this afternoon. Can you help us understand what the return on invested capital has been on the Ventana deal I guess now we're several years down the line and might give us some insight into how we should think about this transaction from a cash perspective as opposed to an earnings perspective?

And the second one, I guess we're getting back to my first question around what it was, but just in terms of trying to understand the synergy between pharma and the Illumina acquisition, what it does to our diagnostic business, I guess does it give you answers in terms of time, in terms of developing these things with your pharma colleagues? Will it provide a sort of bundling cost approach so you'll be able to apply cancer care per se, breast cancer $300,000 per patient and you'll provide a full service to the authorities, to the payer, to the individual etc? I'm just trying to understand the synergy between the two parts and how that could provide a synergy which others may not be able to leverage?

Daniel O'Day

Sure, sure. So I think first of all on the return on invested capital, we don't provide specific figures on that. What I can say is the Ventana transaction has been very, very successful. I mean when we look at the growth rates of Ventana today, particularly the growth rates ex-US, when we look at the penetration of new technologies, new science on that, when we look at the benefit that it has created synergistically across our division, I mean as Severin mentioned and I will also emphasise, the fact that we

have total solution offerings for our customers allow us to continue to grow faster than the market as the number one leader in diagnostics.

I mean this is a very real phenomenon effect. When you go into a pathology lab and you can offer them a Cobas 4800 on the molecular side and a benchmark and the tissue diagnostics side and you can tie this together, it's a very important strategic leverage in synergy that we have vis-à-vis the competition.

So I would say overall we're very pleased with the transaction of Ventana. I think it has delivered on the business case that we have. It's delivered on the synergies that we expected and it has really been integrated well into the Group.

In terms of the Illumina forward-looking uniqueness in the Roche Group, I would focus first and foremost on those same types of synergies that we have with Ventana. So I mean the Illumina synergies come from being able to have a distribution and a commercial synergy immediately. I mean taking the Illumina products into a sales and service organisation throughout the world that can bring it first into the research segment and eventually into the diagnostic segment, that's number one.

Number two, I think the unique synergy is bringing this to in vitro diagnostics is really a hurdle. We know this in the past and the unique characteristics that Roche has in terms of being able to develop the product, get the product to the regulatory authorities and get it into the commercial house and reimbursement, I mean these are all things that Roche has a lot of experience on and we drive it.

So the most important synergies we see in the transaction are really within the diagnostics division and the diagnostics group.

In addition, over time, we think we can leverage the benefits of diagnostics and pharma also with sequencing. This will come as we have an IVD platform in sequencing, as we have the need for the types of complexity that sequencing gives to a complex genetic mutation and how that might then play into a particular pharma or product or products in terms of how that's generated. But I think that's really more of a longer term issue, synergistic issue, that we see within the Group and I would suggest the shorter ones are really within diagnostics itself.

Unidentified company representative

Maybe I can just sort of add with the pharma side, I think that when we look forward and particularly in the area of oncology and the mutations that we will be discovering it may need a sequencing base test. If those products, those medicines need a sequencing base test, we need a standardised platform ready to launch it onto. So I think as Dan said, this is a longer-term thing, but given that we're the leader in oncology and all the work that we're doing, this is also fitting into that space as well.

From the floor

In terms of [inaudible] you talked about, can you remind me what the goal was and presumably may well have exceeded it now? So just trying to understand where this synergy is flowing through within the diagnostics business and with MD now those have been exceeded slightly further down the line.

Daniel O'Day

I won't comment on the specific business case we had inside Roche, but I would say that clearly one of the key goals was to take at the time a market leading technology in pathology and bring it from what it was, a predominantly US based business, into the rest of the world. If you look again at the growth rates just in 2011, you know we had 20% plus growth outside the United States, we have around 12% or so within the United States and that leads us to our overall 15% growth rate and that is not just a one year effect. I mean that's been happening now multiple years in a row. So I think the immediate sales synergies that come out of this have certainly met our expectations, or exceeded our expectations accordingly.

Then equally, when you look at the inter-play between tissue diagnostics and let's say molecular diagnostics, I mean I think this example of acquiring NTM and this piece of kinase assay is a very powerful one because here you've got the opportunity to take the world leading screening technology in terms of you HPV Cobas 1400 assay which is really to identify which women are at risk of cervical cancer and then triaging them to this P16 assay that says yes you're at risk but do you actually have disease and P16 then will indentify whether you have disease.

So again, the ability to co-develop these two, to use samples from the same clinical trials, to eventually bring these technologies to a pathology lab, or a major healthcare screening lab in a country I mean this is something that I think is very unique. That's just one example.

We had the same thing in oncology in terms of the overlap of let's say EGFR mutational analysis, so there are many different ways to look at these mutations and it's not a uni-dimensional problem, it's a multi-factorial problem and our ability to leverage our development programmes and eventually our commercial programmes here are unique.

Part of the Bioimaging acquisition that we did a couple of years ago in tissue diagnostics, it's a software based digital pathology imaging base but it has the vision to go beyond that. It has the vision to really bring all the results from a particular cancer patient into one report that a pathologist would read and then consult with the oncologists on the best treatment for patients. You would think that is standard practice in a hospital today and in fact it's not. I mean you have tests being done all over the place. You've got pathology tests, you've got tissue tests and the ability to pull this together, I think every cancer patient deserves this and I think this is again

one of the unique capabilities of combining now sequencing with these other technologies to bring this into the clinic in the mid- to longer-term.

From the floor

So there is no sort of specific CHF100m figure then?

Daniel O'Day

For Ventana itself?

From the floor

Yes, that you promised and there's no update on that made. Thank you.

Daniel O'Day

But it is for sure delivering.

From the floor

Sure, I understand that.

Unidentified company speaker

Any other questions?

From the floor

Just one title up there, am I right in thinking Illumina is more of a global reach than Ventana was and if that's correct, would you be thinking about the actual cost synergies as well as revenue synergies or not for Illumina?

Daniel O'Day

What do you mean by cost synergies?

From the floor

Sales force.

Daniel O'Day

No. I think the answer to that is definitely not. First of all, this is not a cost synergy equation; this is a growth synergy. But to your previous question, is the balance better

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with Illumina than Ventana, I wouldn't want to necessarily exactly compare the two, but again, bottom line is that Illumina has about 55% of the sales coming from the US today and 80% of their sales are coming from large genome centre academic centres.

Now clearly, some of those genome centres are outside the United States of course, but the sales force structure is very different than what we have in our let's say our applied science group.

Our applied science group in our country is 130 countries around the world is geared towards large, medium, small size research centres. There is not, in my opinion, tremendous overlap in terms of those customer bases, so I think there is an ability to immediately get sales synergies out of this and drive this into the research audience.

I mean we have people on the ground in these countries selling a variety of technologies that can immediately start selling Illumina technologies after the close of the transaction.

From the floor

I'll just ask on the diabetes business, I guess that was something you were looking at potentially spinning off and subsequently decided to keep it. Can you just try and help me understand with the new launch how you feel that business is going to be now and if there is going to be a point in the future where you feel that this is now a small part of diagnostics, we're going in a different direction, you may reassess spinning it off as opposed to keeping it in-house?

Daniel O'Day

I mean we've had no consideration of spinning it off. It's an important part of our business. Diabetes, as you know, is one of the key global health problems around the world. The incidence is growing on a yearly basis unfortunately and, as you go into emerging markets as well, the access to healthcare is increasing. So we see diabetes overall as an important aspect to our business and our strategy there is to really continue to move towards more complete care of patients with diabetes.

In other words, what I mean by that is beyond just the standard blood glucose testing into really a continuum of care with glucose meters, with the pumps and eventually continuous glucose monitoring so you get closer and closer to this artificial pancreas and that's what we're investing in and in particular, our patch pump technology that we acquired through Medingo we will be rolling out further this year in Europe. This is going to be a really important new advancement there because it will take the durable pump which has advantages but also disadvantages and a certain market penetration and with the patch pump we feel we can get to a lot more insulin users than we could with the durable pump and connecting that in with our blood glucose meters allows us to get this continuum of care moving in diabetes.

So on the contrary, diabetes is an important business for us and one we continue to invest in and I think one that will continue to grow with the incidence of diabetes all over the world.

From the floor

Is this Nano launch, are you ahead of current competitors or does it move you up to them?

Daniel O'Day

We think the Nano will be a very competitive patch pump. There are some early entrants in the patch pump environment but we think the unique features of this, of our patch pump, semi-disposable allows us to have a very competitive product when it comes to the market.

From the floor

Yes, just to follow up the previous question on the Illumina acquisition and the research market, in the rationale, which current or future research areas where you really targeting when you've picked up the Illumina company? Which ones are you really going for?

Daniel O'Day

What type of research area?

From the floor

Yes, which type of research areas yes. I mean there would be some specific ones.

Daniel O'Day

It is being used in a lot of different research areas. Obviously in the field of oncology today for the occasional analysis, but as well in heredity diseases and genetic disorders. In all aspects of medical clinical research where genes are a cause or a potential cause of a disease, that's where it's being used at this stage. Everything from your basic research setting to a more clinical operation setting with let's say pharma companies or government funded trials. More and more, particularly in the cancer area, there are very few trials that don't incorporate some type of sequencing mutational analysis into their trials as an example. But it covers everything from basic research to the more clinical research.

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From the floor

So do you think it’s going to be sold in all the way from small up to la