Illumina (ILMN) Earnings Report: Q3 2015 Conference Call Transcript

The following Illumina conference call took place on October 20, 2015, 05:00 PM ET. This is a transcript of that earnings call:

Company Participants

- Rebecca Chambers; Illumina, Inc.; VP of IR and Treasury
- Jay Flatley; Illumina, Inc.; CEO
- Francis deSouza; Illumina, Inc.; President
- Marc Stapley; Illumina, Inc.; SVP & CFO

Other Participants

- Tycho Peterson; JPMorgan; Analyst
- Doug Schenkel; Cowen and Company; Analyst
- Derik de Bruin; Bank of America Merrill Lynch; Analyst
- Dan Arias; Citibank; Analyst
- Jon Groberg; UBS; Analyst
- Ross Muken; Evercore ISI; Analyst
- Amanda Murphy; William Blair & Company; Analyst
- Isaac Ro; Goldman Sachs; Analyst
- Dan Leonard; Leerink Partners; Analyst
- Bill Quirk; Piper Jaffray & Co.; Analyst
- Steve Beuchaw; Morgan Stanley; Analyst
- Bryan Brokmeier; Cantor Fitzgerald; Analyst
- Tim Evans; Wells Fargo Securities, LLC; Analyst

MANAGEMENT DISCUSSION SECTION

Operator:

Good day, everyone, and welcome to the third-quarter 2015 Illumina Incorporation's earnings conference call. At this time, all participants are in listen-only mode.

(Operator Instructions)

We will facilitate a question-and-answer session towards the end of this call. As a reminder, this call is being recorded for quality and replay purposes. I would now like to turn the call over to Rebecca Chambers, Vice President Investor Relations and Treasury.

Rebecca Chambers (VP of IR and Treasury):

Thank you, Lauren, and good afternoon, everyone. Welcome to our earnings call for the third quarter of FY15.

During the call today, we will review the financial results released after the close of the market and offer commentary on our commercial activity, after which we will host a question-and-answer session. If you have not had a chance to review the earnings release, it can be found in the investor relations section of

our Web site at Illumina.com.

Participating for Illumina today will be Jay Flatley, Chief Executive Officer; Francis DeSouza, President; and Marc Stapley, Senior Vice President and Chief Financial Officer. Jay will provide an update on the state of our markets, Francis will comment on product performance, and Marc will review our third-quarter financial results as well as provide updated guidance for 2015. This call is being recorded and the audio portion will be archived in the investor section of our Web site.

It is our intent that all forward-looking statements regarding our expected financial results and commercial activity made during today's call will be protected under the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to risks and uncertainties. Actual events or results may differ materially from those projected or discussed. All forward-looking statements are based upon current information available, and Illumina assumes no obligation to update these statements.

To better understand the risks and uncertainties that could cause actual results to differ, we refer you to the documents that Illumina files with the Securities and Exchange Commission, including Illumina's most recent Forms 10-Q and 10-K. With that, I will now turn the call over to Jay.

Jay Flatley (CEO):

Thank you, Rebecca, and good afternoon, everyone.

As we reported a few weeks ago, third-quarter revenue was approximately $550 million, an increase of 14% over the prior-year period and our 16th consecutive quarter of sequential revenue growth. Despite missing revenue expectations by 3%, we witnessed strong underlying trends in many parts of the business, including total sequencing revenue growth of 21% year over year and continued clinical adoption of our technologies. Specifically, shipments to clinical and translational customers again grew more than 40% year over year, representing approximately 40% of total shipments in the quarter.

The growth of our clinical end markets continue to be supported by adoption in oncology. Third-quarter shipments to non-academic oncology customers grew 25% compared to last year. Shipments to all oncology customers has now grown to be approximately 20% of revenue. We've shared our strategy to accelerate oncology adoption via our OncoPanel and liquid biopsy programs.

We were pleased to recently launch the initial product from this strategy, the RUO version of our R1 OncoPanel, branded TruSight Tumor 15. This panel is based on initial standards defined by the Actionable Genome Consortium and is expected to drive the adoption of NGS for tumor analysis in translational research. To date, customer feedback on the content of this product has been very positive, and the IUO version is on track for release to pharma partners in the next few months. We're also making progress on the RUO version of the R2 OncoPanel, which we expect to deliver in mid 2016 and will be available for use by our pharma partners in translational research studies shortly thereafter.

We recently joined the worldwide innovative networking consortium, a global network of leading academic industry and non-profit research organizations working to make personalized cancer care a reality for non-small cell lung cancer patients. As part of the consortium, we will provide a slightly modified version of our R2 OncoPanel for use in their clinical trials beginning in mid 2016, which is expected to provide us valuable clinical utility data.

We're also making progress on our liquid biopsy program since our last update, including the recently announced collaboration with Memorial Sloan Kettering Cancer Center, which is focused on furthering the basic understanding of the biology of circulating tumor, or ctDNA in different cancer types. A series of seven clinical research studies will take place over the next three years, analyzing samples from approximately 1,000 patients, with the aim of informing the development of liquid biopsy and clinical

care. Additionally, we're beginning to see the launch of LDT products for specific ctDNA market segments from our customer base.

Our market development activities in reproductive health also contributed to demand from clinical customers in the third quarter. Sales of our preimplantation genetic screening, or PGS, products increased more than 25% compared to the third quarter of 2014. Further, we're in the late stages of enrolling patients in our STAR trial, which will measure the impact of PGFs and morphology on IVF success rates. We expect to complete enrollment in this study in early 2016 and have an analysis of interim results in the middle of the year.

NIPT service revenue, including test fees, grew approximately 20% versus the third quarter of 2014 as we performed close to 50,000 tests. We recently signed a supply agreement with council that includes access to our NIPT patent pool, our 36th customer globally that has acquired these rights. We're encouraged to see our customers develop NIPT LDTs, which further boost test adoption. Keep in mind as these licensees bring NIPT in house, revenue will decrease in services but increase in products.

We are also encouraged to see the recent Anthem decision to reimburse for average risk, and are optimistic that other top payers will follow suit. The availability of our next-generation solution, VeriSeq NIPT, will enhance our global opportunity. We're in the final stages of the European regulatory process for the software and hope to have CE Mark shortly. We will follow with the CE Mark on the VeriSeq NIPT product for distribution as an IVD solution early next year.

Moving to arrays, in the third quarter, we saw stabilization of market trends, despite array revenue declining 17% year over year, now accounting for less than 15% of total revenue. Genotyping orders increased approximately 26% year over year, driven by DTC and agriculture customers, while pricing was stable compared to the second quarter. We now expect 2015 array revenue to decline low double digits. We're essentially projecting essentially flat orders for the year, which bodes well for shipments in 2016.

In the ag market specifically, we believe there's an opportunity to genotype millions of samples over the next few years. As a result, we're projecting array revenue to grow slightly in 2016. Additionally, our new product introductions, including the DrugDevArray, MethylationEPICArray, and the ImmunoArray are also expected to boost demand. We have received positive customer feedback on these introductions, as order volumes are growing and shipment of the arrays will commence shortly.

In summary, while disappointed in the Q3 revenue shortfall, our conviction in our longer-term strategy and markets is stronger than ever. As we move into 2016, our product development pipeline is rich and we're excited about opening the many large untapped markets ahead.

I'll now turn the call over to Francis who will provide a detailed overview of our product results.

Francis deSouza (President):

Thank you, Jay, and good afternoon, everyone. I'm pleased to provide further details in the performance of our product families in the third quarter.

As we shared a few weeks ago, the HiSeq family of products exceeded our expectations due to demand for high throughput instruments in the Americas. On a year-over-year basis, this resulted in flat instrument revenue for our high-end portfolio, as lower HiSeqX shipments, which was expected given the record HiSeqX placements in the prior-year period was fully offset by strength in the 3000 and 4000. In spite of the challenging comparison, HiSeqX interest was strong, as orders and shipments exceeded our prior guidance. We are pleased with the health of our funnel, and as a result, continue to project quarterly orders of 20 to 30 HiSeqX units, building off of our current install base of more than 250 instruments.

Demand for HiSeq X was generated from new customers, bringing the total customer count to 25, as well as existing sites expanding capacity to initiate additional projects. One example is the shipment of 10 HiSeqX instruments to the Broad to enable the National Heart, Lung and Blood Institute's project to sequence 20,000 individuals. HiSeq 3000 and 4000 continued to generate strong interest, due in part to customers accessing improved operating economics, as well as adding capacity. HiSeq 4000 again was the leading platform sold, which lifted ASPs for the family of instruments compared to the prior year.

In the quarter, commercial customers accounted for 40% of instruments shipped. We continued to benefit from pharmaceutical and biotechnology customers purchasing systems to aid in the discovery and validation of genomic-based targets, as well as molecular diagnostic and reference laboratories ramping capacity to support NIPT and oncology-based LDTs. We remain bullish on our high throughput instrument portfolio, given its tremendous flexibility to address various budgets and scientific priorities.

Moving to our benchtop instruments, as we previously shared, NextSeq and MiSeq instrument placements were lower than we forecasted. NextSeq sales were stable, both year over year and sequentially, and MiSeq had a very slight decline over the same time period. We are confident this result was not due to a change in the competitive dynamics, as our win rates have remained stable, at greater than 80%. We received our 4,000th MiSeq order during the quarter, with clinical and forensics customers supporting demand.

Since launch, we have placed approximately 40 instruments into the forensic market, a figure we expect to continue to meaningfully ramp. Additionally, we continue to build the MiSeq menu to encourage further interest from new research and translational customers. The introduction of our TruSight HLA solution and Tumor 15 panels, coupled with our new to NGS promotion bundle have created a strong pipeline heading into the fourth quarter, as tracked opportunities have grown by more than one third compared to the level seen entering Q3.

We see this trend with NextSeq as well, as the instrument pipeline has grown significantly sequentially. Approximately 50% of NextSeq orders came from clinical and translational centers. This is an upward trend, as demand from our NIPT partners in China continued to penetrate the opportunity in the region. As a result, NIPT-specific NextSeq orders grew 60% versus the prior year. These market dynamics give us confidence that the benchtop segment will remain an important element of our portfolio going forward. In an effort to ensure that this is the case, we are continuing to add to our sales team and are heightening the focus on this segment.

In infomatics, we continued to see progress in the adoption of BaseSpace during the third quarter. App launches grew 13% sequentially, as approximately 50,000 runs were uploaded from the 3,000 instruments connected to our cloud offering. We are forecasting these strong trends to continue, based in part on the recent introduction of the BaseSpace Professional and Enterprise additions, which fully integrate LIMS solutions and advanced infrastructure upgrades.

These versions of BaseSpace will be available in the beginning of the first quarter to enable researchers to select from advanced services that are optimized to enhance their experience, while improving efficiency and sequencing labs. This introduction wouldn't have been possible without the recent acquisition of GenoLogics, a life science tools LIMS provider. Coupled with our BaseSpace offering, GenoLogics' Clarity LIMS solution will provide a seamless sample to answer solution for our customers.

I'll now turn the call over to Marc, who will provide a detailed overview of our third-quarter results.

Marc Stapley (SVP & CFO):

Thank you, Francis.

As Jay mentioned, total revenue grew 14% year over year, consistent with our preliminary estimate. On a constant currency basis, revenue grew 18%. Geographically, this result was driven by strength in the Americas, which was partially offset by lower-than-expected revenue growth in Europe and APAC, as we previously outlined. Strength in sequencing consumables and services was offset in part by instrument revenue, which declined 3% year over year to $145 million in the third quarter.

Consumable revenue was $321 million, an increase of 23% compared to the third quarter of 2014, as higher demand for sequencing consumables was partially offset by a decline in arrays. Consumable revenue represented 58% of total revenue, up from 54% in the prior-year period and the 56% we saw in Q2. As we previously shared, sequencing consumable revenue was robust, growing 36% over Q3 of last year, and $20 million sequentially to approximately $270 million.

Both HiSeqX and NextSeq utilization exceeded their respective guidance ranges. We are now forecasting NextSeq fall-through to remain elevated, and as a result, are increasing the guidance range to $100,000 to $125,000 per instrument annually. We're also raising the HiSeqX pull-through guidance range to $650,000 to $700,000 per instrument as a result of positive utilization trends across the customer base. Again this quarter, a handful of X sites accounted for more than 70% of consumable shipments. But importantly, we saw early signs of success and increasing utilization across the many remaining customers. Additionally, we believe opening up the HiSeq X to non-human whole genome sequencing will boost utilization of accounts that have access to agriculture or animal samples.

MiSeq utilization was in our projected range of $40,000 to $45,000, and HiSeq pull-through per instrument, excluding HiSeqX, was in our projected range of $300,000 to $350,000. Year to date, we have removed approximately 90 instruments from our installed base figure to account for fully decommissioned older instruments, primarily due to the success of HiSeq 3000 and 4000, replacing them in the lab. Services and other revenue, which includes genotyping and sequencing services, as well as instrument maintenance contracts, grew 23% versus Q3 2014 to $79 million. This improvement was driven by growth in NIPT services, which benefited from increased test send-out revenue, genotyping services and extended maintenance contracts associated with the largest sequencing installed base.

Turning now to gross margin and operating expenses, I will highlight our adjusted non-GAAP results, which exclude non-cash stock compensation expense and other items. I encourage you to review the GAAP reconciliation of non-GAAP measures included in today's earnings release. Also note that we have, as previously communicated, consolidated the results of our Helix joint venture into the results of Illumina , and accordingly, all subsequent references to net income and earnings per share refer to the results attributable to Illumina stockholders after non-controlling interest.

Our adjusted gross margin for the third quarter was 73.2%, flat versus the prior-year period and an increase compared to 72.4% in the second quarter, primarily due to the higher mix of consumables previously noted. Adjusted research and development expenses for the quarter were $90 million, or 16.4% of revenue, higher compared to $85 million, or 15.8% of revenue in the second quarter, due to the impact of additional headcount and outside services. Adjusted SG&A expenses for the quarter were $115 million, or 20.9% of revenue, an increase compared to $103 million, or 19.2% of revenue in the previous quarter, due to expenses associated with the Helix joint venture, GenoLogics acquisition, and outside services and higher headcount.

Adjusted operating margins were 36% compared to 37.4% in the second quarter, lower sequentially due to the impact of Helix and Genologics, as well as the impact of higher headcount. Operating margin was lower compared to the 39.7% reported in the third quarter of last year, due to increased investment in R&D and SG&A to support our long-term growth.

Our investments will continue into the fourth quarter as we grow our business to support the

opportunities ahead of us, although at a pace lower than experienced so far this year. Combining headcount growth with our previously committed investments in Helix, Genologics, ERP, facilities and collaborations, such as the one we recently announced with Memorial Sloan Kettering, we are expecting our fourth-quarter operating expenses to grow $15 million to $20 million sequentially to $220 million to $225 million.

In the third quarter, our stock-based compensation expense equaled $32 million. For the fourth quarter, we expect this to increase to $40 million due to the impact of our annual grant program which occurs in December, along with a growing employee base.

Our non-GAAP tax rate for the quarter was 28.6% compared to 21.3% in the third quarter of last year, which was lower than typical as a result of the reversal of reserves related to prior-year returns. Non-GAAP net income was $120 million for Q3, resulting in non-GAAP EPS of $0.80. This compares to non-GAAP net income and EPS of $114 million and $0.77 respectively in the third quarter of 2014. The impact of foreign exchange lowered Q3 non-GAAP EPS by approximately $0.05 relative to last year.

We reported GAAP net income of $118 million, or $0.79 per diluted share, in the third quarter, compared to net income of $93 million, or $0.63 per diluted share, in the prior-year period. This quarter includes a $25-million tax benefit resulting from the elimination of stock compensation expense that our US entity had charged to foreign subsidiaries under cost-sharing agreements over a multi-year period. The elimination of these charges was undertaken in consultation with our external audit firm, following a ruling granted to an unrelated third party in Q3. Going forward, we will no longer cross charge stock compensation expense unless or until the ruling is overturned, which we believe is unlikely based on the facts that exist today. Should that occur, we would correspondingly record a significant charge in that period.

Cash flow from operations equaled $181 million. DSO increased to 68 days compared to 62 days last quarter, due to a higher percentage of shipments in the third month, which is attributable to a combination of the typical deceleration we see in July and August, as well as our ERP implementation at the end of July. Inventory increased slightly to $234 million. Capital expenditures in Q3 were $29 million resulting in $152 million of free cash flow. During the quarter, $207 million of the 2016 0.25% convertible bonds were settled, leaving slightly more than $105 million remaining. We repurchased 188,000 shares for $37 million, leaving us with $112 million under our previously announced 10b5-1 program, and $96 million of discretionary authorization.

Turning now to our expectations for the remainder of 2015, we project approximately 18% total Company revenue growth and 21% growth on a constant currency basis, given current exchange rates. Fourth-quarter revenue is expected to be $570 million, which includes a $10-million currency headwind compared to the prior year. We have updated our 2015 non-GAAP EPS projections to $3.29 to $3.31, which includes expected fourth-quarter non-GAAP EPS of $0.78 to $0.80. These projections incorporate a full-year pro forma non-GAAP tax rate of 27%, which assumes the 2015 federal R&D tax credit and other tax extenders are passed in the fourth quarter. If these items are not passed, our annual tax rate would increase by approximately 150 basis points.

In conclusion, we believe the investments we are making are necessary to drive product innovation, as well as market development and expansion, enabling us to catalyze the broad adoption of genomics in 2016 and beyond. Having said that, we continue to be diligent about the nature and timing of our investments.

Thank you for your time. We will now move to the Q&A session. To allow full participation, please ask one question and rejoin the queue if you have additional questions. Operator, we will now open the lines.

QUESTIONS & ANSWERS

Operator:

(Operator Instructions)

Our first question comes from the line of Tycho Peterson from JPMorgan.

Tycho Peterson (Analyst - JPMorgan):

Hi, thank you. I'm going to try to squeeze two in because I think they are important. But as we think about what happened in the benchtop market this quarter, can you maybe just give us some comfort that this is truly a resourcing issue and not a market demand issue, in light of what we've heard around reimbursement and other factors. And then as a follow-up, Marc, I'm wondering if you're willing to give us any parameters around OpEx for 2016. Obviously with Helix and other factors, we need to be thinking about some of the headwind. Thank you.

Jay Flatley (CEO):

Tycho, I think the benchtop result was due to a combination of factors. Clearly, more feet on the street would help. We think there are opportunities that we didn't get over the finish line just due to time and sales focus during the quarter. As you can imagine, with products selling really well at the high end of the product line, it's always a challenge to get the sales force to focus on lower-end machines that have smaller contribution to their quotas. Having said that, there are also some geographic impacts. As we mentioned, Japan has been doing very poorly and that's a very rich market for MiSeq, and probably accounted for a material portion of the shortfall that we had in MiSeq. And that's clearly a demand funding problem, hopefully temporary, in Japan. So I would say it's a combination of attention to that part of the market overall and overall time spent selling those products, as well as some localized market demand issues.

Marc Stapley (SVP & CFO):

Tycho, on our operating expense for 2016, we're in our normal budget cycle. Nothing unusual about that right now, and we're going through that at the moment. I think probably the best thing to focus on is the prepared remarks that I gave around our Q4 rate; that clearly gives you a sense of what the exit rate is for the year. And the items that I specifically called out are clearly going to -- most of them are going to have an impact in 2016. In particular, we've called out Helix, which is about a $0.10 impact on 2016.

Tycho Peterson (Analyst - JPMorgan):

Okay, thank you.

Operator:

Our next question comes from the line of Doug Schenkel from Cowen and Company.

Doug Schenkel (Analyst - Cowen and Company):

Good afternoon, guys, and thank you for taking the question. So a number of competitors have launched product enhancements or new instruments in sequencing and adjacent areas over the past year. These developments, combined with a couple weaker-than-expected quarters and uncertainty about the growth outlook heading into 2016, have heightened focus on what we should expect the return to be on your investment in R&D. Recognizing that you're still targeting an open-ended growth opportunity, your development track record in the space has been unrivalled over the past decade.

And also noting that you don't want to outline your game plan too specifically for competitive reasons and also because you don't want to stall the market, I'm just wondering what you can tell us, knowing what you know about your new product development efforts. And I guess more specifically, or maybe to cut through all of this, Jay, would you just comment on how you would describe your enthusiasm and excitement about the portfolio, as you think about the growth outlook and competitive dynamics over, say, the next 12 to 24 months, and how does that compare to where we were, say, a year or two ago. Thank you.

Jay Flatley (CEO):

Let me start by saying, as I think I commented in my opening remarks, Doug, that we have a very rich portfolio of product opportunities. In fact, our challenge isn't figuring out what to do next; it's figuring out what to pick from among a wide variety of incredible opportunities in new markets we can approach. We're probably putting less of a percentage of our total R&D investment into platform technologies, because we're broadening our investment horizons over the software space, sample prep products like NeoPrep. It's very important for us to deliver these full sample to answer solutions. But having said that, the actual dollars going into platform development are higher than they've ever been. And we have great products in that pipeline; obviously we can't talk specifically about what those are or when they may come to market.

Having said that, we also have a slightly different market position today than we did a few years ago. And by that, I mean that when we develop a product today, that product development tends to be more complex than it was a few years ago, because we're dealing now in regulated markets. The products and the manufacturing processes around these products need to be vastly more robust, they need to have much more complete levels of documentation. Clearly in the clinical products, we need to be running clinical trials. And all of those incremental R&D expenses are not things that directly translate into new product introductions, but really enable opening up new markets in the regulated space. And on the sales and marketing side, of course, we are now working very hard in the market development area, and we're not drafting behind other companies who are ahead of us in sequencing. And therefore, we have to make larger expenditures to open up these new markets earlier than they otherwise might be open.

Operator:

Our next question comes from the line of Derik de Bruin from Bank of America.

Derik de Bruin (Analyst - Bank of America Merrill Lynch):

Hi, good afternoon.

Jay Flatley (CEO):

Hi Derik.

Derik de Bruin (Analyst - Bank of America Merrill Lynch):

Hey, couple of quick ones. So the HiSeqX pull through was certainly higher than I anticipated. Do you see that furthering -- do you see that accelerating in 2016? And how do you look like the non-human opportunity in HiSeqX reagents?

Jay Flatley (CEO):

Yes, the trend line looks really good, and that's the reason that we felt comfortable bumping the range up for HiSeqX. We're clearly going to watch that here over the next few quarters and see what our prediction looks like for 2016. Clearly, for those customers that have access to large numbers of non-

human samples, opening up the organisms that you can run on a HiSeqX is going to have a huge impact.

And there's a couple very specific customers who are going to run very large studies because we did -- we made that change. So I think that will help the overall averages. We continue to work with those customers at the low end of the curve who are using their instruments at low utilization rates, and I think the biggest impact we can have is getting that collection of customers up from nominal utilizations up to the mid range of utilization. If we can be successful doing that, it will continue to push the overall number up into 2016.

Derik de Bruin (Analyst - Bank of America Merrill Lynch):

If I can just do a quick follow-up on that

Jay Flatley (CEO):

It's a collection of different issues. In some cases, they don't have samples. There's a couple cases of what we call vanity purchases, just wanted to be in the club purchases. There are clearly a couple of examples of customers who didn't quite realize what it takes to run a large-scale sequencing center, and that's where what we're doing with the software infrastructure we're putting around the HiSeq systems, the HiSeqX systems, is beginning to help those customers a lot, because they now have the ability to control samples and requeue samples and create a pipeline of data analysis. So those are the easy ones to move forward. The more challenging ones are the ones that have indirect sample access or less sample access, or the ones who just don't have a program behind the system, and there's not a lot of those but there's a couple.

Derik de Bruin (Analyst - Bank of America Merrill Lynch):

Great, I'll get back in the queue. Thank you.

Operator:

Our next question comes from the line of Dan Arias from Citibank.

Dan Arias (Analyst - Citibank):

Yes, hi afternoon. Just wanted to ask maybe a high-level question on instruments. Francis, you mentioned that the NextSeq accounted for, I think 50% of clinical placements. Just curious how the other 50% is shaping up for the MiSeq and HiSeq in the hospital setting, if we just wanted to get a holistic understanding of the placement trend there.

Francis deSouza (President):

Sure, what I talked about is, I certainly talked about NextSeq and NIPT, and said that NIPT-specific NextSeq sales grew 60% year on year. And other than that, we're seeing a pretty broad sort of distribution of instruments that are bought into the clinical market.

Dan Arias (Analyst - Citibank):

Okay, so is that to say that if you took the three buckets, they would all be the same size in terms of commercial hospital placements, trends per quarter?

Francis deSouza (President):

Not the same size, but you're seeing a distribution across all the buckets. We're certainly seeing new to NGS customers primarily going into the MiSeq instrument family. And so to the extent that a lot of these

are new to sequencing -- next-gen sequencing as a whole, they tend to go into the MiSeq instruments. And if they are doing follow-on sales, then they tend to migrate up into our higher-end portfolio.

Jay Flatley (CEO):

Very often in the translational category, we see more of the higher-end instrument. So HiSeq will be used when you're trying to do discovery or trying to figure out what methods to run and you're trying to screen through lots of samples to develop the final application. And then very often, it gets deployed on MiSeq when you get through the translational stages.

Dan Arias (Analyst - Citibank):

Got it. Okay, thank you very much.

Operator:

Our next question comes from the line of Jon Groberg from UBS.

Jon Groberg (Analyst - UBS):

Hi, good afternoon. So Jay, on the last -- when you did your pre-announcement, you went out of the way to talk about you were maintaining your 15% to 20% growth in 2016. And just listening to some of the moving parts, it sounds like, I think, arrays are going to be flat to up slightly in 2016, services may be down a little bit as you migrate to products on the NIPT side. So can you maybe just talk about what it is that gives you the confidence that you can grow 15% to 20% in 2016?

Jay Flatley (CEO):

Yes, sure. The first thing I'd say is that every year we see, unless something catastrophic happens from a competitive perspective, we see a significant growth just on the consumables from the instruments that we placed the year before. So that's a great baseline to build on. Average risk is going to be a big factor for us in 2016, so I think that we will begin to see in the first half of the year, maybe the second or third approval from major payers for average risk. And that will begin to move that market ahead very, very quickly.

We suspect -- we've been saying this for a couple quarters now, but we do expect Japan to come back in 2016. The infrastructure is in place and the money is going to start flowing back into Japan during 2016, so that will be huge for us because Japan has been our single most troubled geography by a wide margin over the past 18 months. So any recovery in Japan is going to have a huge positive impact for us. And as we noted in the script, arrays were a pretty big drag overall in 2015 from the growth rate perspective. And having that come back to being flat to positive is going to be a big help to us as well.

Marc Stapley (SVP & CFO):

To some extent, I'd say it also had an increase in our population sequencing services revenues slightly as the gel --.

Jay Flatley (CEO):

As gel ramps up.

Marc Stapley (SVP & CFO):

Yes.

Jon Groberg (Analyst - UBS):

Just a quick follow-up, Jay. Would you -- a question I get a lot is on sequencing instruments, given where you've been with Xs, would you expect those to be up in 2016, sequencing instruments?

Jay Flatley (CEO):

Instruments overall or HiSeqXs?

Jon Groberg (Analyst - UBS):

Instruments overall, sequencing instruments overall.

Jay Flatley (CEO):

I don't think we're ready to give that level of guidance here today, Jon. We're working through right now what the components of our forecast look like for next year. We do think we'll have a good instrument year next year, but we're not ready to guide to the specific growth rates of instruments versus reagents next year.

Jon Groberg (Analyst - UBS):

Okay, thank you.

Operator:

Our next question comes from the line of Ross Muken from Evercore.

Ross Muken (Analyst - Evercore ISI):

Good afternoon, guys. You obviously launched a cancer panel in the quarter. You've got a key product on the discovery side that you talked through. Can you talk a little bit about, one, the early market response there, and then two, what your conversations are like with pharma partners and FDA and all the other constituents in terms of the pushes and pulls on adoption of some of these type of products?

Jay Flatley (CEO):

Sure. Well, the early indications on the TruSight Tumor 15 are very positive, as I mentioned in the script. It's too early to have any revenue slope on that. We just launched the product, so way too early to comment with actual evidence. But the content that we put on that panel was done in collaboration with the AGC, and these are the thought leaders in the field, so we think we have the content right.

The challenge, of course, with respect to the regulated markets here is that we really need to sell this into research segments only; we can't sell this as a diagnostic product. So it will be used initially by research and translational customers, by pharma companies as we get into the IUO phase of these products. And we're still evaluating the extent to which we decide to put this product versus the R2 product through the FDA as an IVD or whether we do both. And that decision is pending, and it depends a bit on where the FDA winds up with the LDT guidance.

And I think we're going to have some updates to the LDT guidance here over the next quarter or so, and that will give us a bit more visibility on how and to what extent and what the timing will look like on LDT regulation. And that will help inform our decision to put any of these products through as IBDs. The underlying challenge here, of course, is that if it takes multiple years and large clinical trials to get one these through the FDA and LDTs are not regulated, it's very hard to ever have an IVD product that would wind up being competitive a couple years after you submit it or begin the clinical trial work on a lockdown challenge we're facing.

The other area that we're working on of course is reimbursement, and that was also alluded to in a prior question. And it's a challenging area for many of our customers. It's something that we and others are working on. We're beginning to work directly with the payers, as we've mentioned before, to try to begin to demonstrate very clear health economic outcomes from the use of sequencing in oncology, in rare undiagnosed diseases, and in other areas to begin to get the payers over the hump of reimbursing these products.

And the last thing I might say that, again, we've mentioned before, is part of what we're trying to accomplish here is to set more explicit standards in the marketplace. You can imagine the challenge that the payers have with the diversity of oncology panels that are coming into the market, all sequenced with slightly different methods, different sample preps, different depths, different software. It's a bit of a nightmare for them to sort through that and figure out which of those they should reimburse. So what we're doing with the AGC is an attempt to begin to set some standards around what the content and the methodology should be for sequencing and oncology to allow the payers to make earlier, more timely decisions.

Ross Muken (Analyst - Evercore ISI):

Thank you, Jay. Maybe Marc, just again, not to belabor the point and repeat Tycho, but just trying to understand the pacing. As we think about the step up, Q4 versus Q3 on OpEx, obviously a portion of that is the stock comp. As we think about the other elements, it seems like some is going into commercial, and then also, you have your natural Q4 R&D ramp that will be the jump-off point for next year, and you had pretty high operating margin incrementals in Q1 and Q2 of this year. So I guess as we think about it, should we be in investment phase for at least the next several quarters, and then depending on what the back half of next year is, we could see some more expansion? I'm not looking for numbers, I'm just looking directionally maybe or qualitatively how to think through that at least next two-, three-quarter pacing.

Marc Stapley (SVP & CFO):

Well, I think clearly as I mentioned, our pacing on certain investments is slightly reduced compared to where it was in the first half. But you're right, I gave you the jumping-off point. Bear in mind that from that jumping-off point, we're going to have the full-quarter effect in Q1 of the hiring in Q4, which is clearly continuing. And we're going to have the 2016 hiring, which is part of our budget process, which we really haven't finalized yet.

So I clearly can't give you any direction around that because we're still working through it. But we're clearly going to be continuing to hire and grow our business at a certain pace yet to be determined. I'll look forward to giving more qualitative and quantitative information on that when we've finished our budget and we give guidance. But I think what we've given so far with respect to Q4 is probably the best representation of the jumping-off point on which to build from thereafter. And then add to that some of the specific investments that we have talked about, and assume there's going to be other things that we need to do in 2016 that we haven't budgeted for or planned for yet.

Jay Flatley (CEO):

And Ross, just to add a bit to that, consistent with our long-term commentary, we're very comfortable with operating margins around the 55% range -- 35% range, sorry, (laughter) 35% range. And as we get above that, and this year, we got up into 39% plus territory, we look really hard at whether we're investing fast enough to continue the growth, whether we're investing enough in our new product opportunities, whether we're developing the markets. And where we fall in that range, between the 35%-ish up to high 30%s will depend on what the platform of opportunities are that are ahead of us. And we evaluate that every year, and some years are bigger investment years, and some years are years where we reap the

advantage of the investments we made the years before. And so we'll come out and give you more specs on that as we get into guidance for next year.

Ross Muken (Analyst - Evercore ISI):

That's perfect, guys, thank you so much.

Jay Flatley (CEO):

Thanks, Ross.

Operator:

Our next question comes from the line of Amanda Murphy from William Blair.

Amanda Murphy (Analyst - William Blair & Company):

Hi, good afternoon. So just a follow-up maybe for Francis and Marc. So in terms of the X10 guidance that you gave and the 20 to 30 shipments, and then looking at your backlog, can you help us or give us some context around what you're assuming in terms of capacity expansion versus new customers? Obviously the Broad had a nice expansion there, but would expansion or is expansion something that you're assuming in that number or would that be upside? And then also just thinking about X5 versus X10 would be helpful, thank you.

Francis deSouza (President):

Sure, so the number we gave in terms of 20 to 30 units a quarter includes both, customers that are new customers as well as customers that are coming back and expanding their fleet. And we've continued to see in the previous quarters a good mix of both. And as we look at the pipeline for the future quarters, we continue to see a healthy mix, again, of customers that are new customers to the X family, as well as some expansions like we highlighted. So that continues to be built into our plans for the X going forward.

Marc Stapley (SVP & CFO):

And on the X5, X10, we've always tried to guide towards not thinking about those as separate instruments within the family, just think about the X family. And the primary reason for that is the X5 is often a kind of stepping stone to the X10, and we do expect many, not all, but many customers who buy an X5 to migrate to the X10 over time.

Amanda Murphy (Analyst - William Blair & Company):

Do you see the expansion kind of in chunks like the Broad, or are we looking at one-off adds here and there?

Francis deSouza (President):

We see both, honestly. We see ones that have reached 10 and are buying a number. We see some that started at 5 and are already looking at stepping their way up towards 10, and then we see some that are 10 and adding onesie, twosies, so really we do see that mix.

Jay Flatley (CEO):

And often it's driven by the specifics of what happens to their models. So the case of Broad, it was the award of a major new program, and those are the situations that cause customers to sometimes buy 5 or 10 new ones. We've had -- there's another very large customer we have that tends to buy in large chunks as they open up new parts of the market they are going after. And then in contrast, the ones who buy in

onesie, twosies, are just expanding what they are already doing.

Amanda Murphy (Analyst - William Blair & Company):

Got it. Thank you very much.

Jay Flatley (CEO):

Thank you.

Operator:

Our next question comes from the line of Isaac Ro from Goldman Sachs.

Isaac Ro (Analyst - Goldman Sachs):

Hi, good afternoon, guys. Thank you very much. I wanted to start with a question on -- actually both questions on the diagnostics market opportunity. And one would be, I think as was mentioned earlier that there was some set backs around reimbursement this quarter from a lot of the customers that you have, and I was wondering if you could update us on what you think you guys can do to help those customers get paid for doing more complex tests like tumor profiling, like immuno-sequencing. And then maybe thematically, what you're hoping to see from the regulators over the next 12, 18 months, whatever time frame you're comfortable with?

Jay Flatley (CEO):

It's a number of things we're doing there, Isaac. We're working through some of the trade agencies or trade consortia to begin to influence the actual regulations themselves or the reimbursement statements that came out from CMS. So that we hope will have influence to get what we think is misguided results there fixed. At the same time, we're doing all of the things that I mentioned before, trying to create standards which helps reimbursement, ultimately getting products through the FDA, which assists with reimbursement as well. And clearly we're working outside the US in all of the other reimbursement situations to try to get products approved there. We talked a lot about what's going on in Europe with CE-IVD, and it's much easier to get our products through in Europe. And so that's a really important focus for us, particularly in NIPT.

Francis deSouza (President):

And they are also doing work, in some areas, we're actually doing clinical trials like the STAR trial, to demonstrate the value of NGS and the IVF process. And so there are a number of areas where we are actually supporting trials or actually doing trials ourselves to accelerate that process.

Isaac Ro (Analyst - Goldman Sachs):

Got it. Thank you, Francis. Maybe a follow-up on the technology side. You guys obviously have done a great job innovating on the equipment over the years for all customers, and curious, as you think about what kind of engineering needs to be achieved to make this technology more accessible. You didn't mention NeoPrep, and I'm curious how important is that to, for example, making the sample prep process easier? Just maybe thematically what kind of engineering areas of focus you have to help enable the market? Thank you.

Jay Flatley (CEO):

NeoPrep is a very important product for us, and the underlying technology there of digital fluidics will become increasingly important. We bought ALL because we saw that technology as being fundamental

to improving ease-of-use of our technology over a long period of time. And it will take many embodiments as we look at our pipeline here over the next three to five years of products that will use that in derivatives of that methodology.

But to open new marketplaces, with the goal of getting down ultimately to perhaps every hospital even, these technologies are going to have to get incredibly simple to use, and that's the track we're on. And we've made tremendous progress; NeoPrep is just one step in that direction. An awful lot of work has to go into the software side, and the progress we've made with BaseSpace in the app store is a huge help there as well. Getting rid of the challenges for the small institutions of storing and moving and managing and sharing data, BaseSpace takes care of all that heavy lifting and gives them instant access to many, many applications. So we have to sell that on the back end of the sequence or the front end and increase the overall integration. And you'll see us over time increase our focus on solution selling, where we're not selling a box and then a sample prep kit and then an individual software package; we're selling one part number that embodies the full solution that the customer is looking for. And you've seen the early embodiments of that in forensics and HLA.

Isaac Ro (Analyst - Goldman Sachs):

That all makes sense. Thank you very much.

Operator:

Our next question comes from the line of Dan Leonard from Leerink.

Dan Leonard (Analyst - Leerink Partners):

Thank you, just a follow-up to John and then also, so Isaac's question. How sensitive is your 15% to 20% outlook through 2016 to progress on the reimbursement front? You spiked out NIPT and [Anthem], but I'm not sure what else needs to happen.

Jay Flatley (CEO):

Well, it clearly has some sensitivity to what happens in average risk, so I'd say that's the area of sensitivity. I don't think it has much sensitivity in 2016 at least to what happens, for example, in reimbursement of cancer oncology panel. That's still probably in the noise level for us in 2016.

Dan Leonard (Analyst - Leerink Partners):

Got it, thank you.

Operator:

Our next question comes from the line of Bill Quirk from Piper Jaffray.

Bill Quirk (Analyst - Piper Jaffray & Co.):

Great, thank you and good afternoon, everyone.

Jay Flatley (CEO):

Hi, Bill.

Bill Quirk (Analyst - Piper Jaffray & Co.):

First question is a bit of building off Amanda's, and so thinking about the reiterated X placement guidance, how many potential X customers do you think there are today, given the exiting applications?

And I know that we've talked at long length on different conference calls about opening up the system further, and I know you have no plans to do so now, but would that number change should you change that decision down the road? Thank you.

Jay Flatley (CEO):

If, by that, you mean if we opened it up to exomes, would the number get bigger, the answer is yes. The number would definitely get bigger. Twenty-five customers is beyond -- way beyond our initial expectations for this, as you know, and we continue to see customers coming forward that surprise us. Almost every quarter we get a customer that, wow, we never thought that this customer would have interest in the X technology. I do think opening up to other organisms will increase the number of customers as well. There are a number of sites that want to do very large-scale ag programs, and the X technology could be the exact solution to open up some new market segments there. So we don't know what the actual number is, but certainly, having 25 customers after seven quarters is a pretty darn good start.

Bill Quirk (Analyst - Piper Jaffray & Co.):

Very good, and then just a real quick one on Helix. Jay, any update in terms of new partners into that program?

Jay Flatley (CEO):

None that we've announced, but we have a very rich pipeline at Helix. In fact, it's so rich now that we've begun to stop trying to bring new ones into the ecosystem. We're trying to bring up the ones that we have and nurture the agreements with the ones that are in the pipeline. So we've got a pretty big portfolio of opportunities there, and we continue to be really excited about the prospect of having a suite of applications at the time we launch this.

Bill Quirk (Analyst - Piper Jaffray & Co.):

Got it, thank you.

Operator:

Our next question comes from the line Steve Beuchaw from Morgan Stanley.

Steve Beuchaw (Analyst - Morgan Stanley):

Hi, thank you for taking the questions. That was a good one. It's just a quick one following up on the X. If you looked at the, let's say the work flows that you've seen historically on the HiSeq platform overall for human versus non-human whole genomes, how would you say that they compare to each other? It would just be really helpful for thinking about how the change to the operability on the X impacts the funnel, thank you.

Jay Flatley (CEO):

Maybe you could clarify that for me, Steve, a little bit. What do you mean the difference in the work flows?

Steve Beuchaw (Analyst - Morgan Stanley):

In terms of the volumes, so human whole genomes versus non-human whole genomes.

Jay Flatley (CEO):

Yes, well I would say that human has been the dominant part of the whole genome market for obvious

reasons that we are all trying to study human disease and make those connections or determinations about the association of the genome with disease and the impact of environment as well. The challenges are different when you're doing plants and animals. In some of the plants, the genomes aren't deployed, and so they are much more difficult genomes to sequence. But if we could sequence them routinely, then there would be a lot more sequencing going on in corn and wheat and some of the more complex crops.

I think the early work that will get done here is in the animal space, probably bovine in particular. And there will also be a lot of work done in model organisms, so mouse and rat I think will be huge applications. And the samples there are -- you can essentially get as many as you want compared to human, obviously, and you can modify those organisms in ways that let you study them as a model system that you can't do in humans. It's a very different kind of work set. The work flow is the same, but the end goal of the study is quite different.

Steve Beuchaw (Analyst - Morgan Stanley):

Got it. Thank you so much.

Operator:

Our next question comes from the line of Bryan Brokmeier from Cantor Fitzgerald.

Bryan Brokmeier (Analyst - Cantor Fitzgerald):

Hi, good afternoon. Jay, you called out the strong growth in clinical and translational demand. Could you provide some details on how that varied across various geographies and how that might change over the coming quarters as you introduce the cancer panels into Europe with the CE Mark and slowly start coming into the US?

Jay Flatley (CEO):

Sure, so I'd say the US was far and away the strongest geography. If you look at NIPT specifically, Europe was very strong in NIPT because of all of the tech transfer agreements we've been able to do in Europe. And of course, we can't do those same types of agreements in the United States. So the clinical adoption, while the volumes tend to be lower in any given site because it's much more fragmented, the number of customers we have in Europe is way higher than those that we have in the US. We tend to sell more instrumentation in Europe as a result of that. Just because of the geographic weakness in Japan and the lack of clinical adoption overall there, it's been a very weak market in the clinical side. China's pretty good. Obviously, driven by NIPT and hopefully soon by PGS and IVF markets as well.

As we look forward, I think the adoption of the OncoPanels will probably again be led by the US if we ever get to the point where we get an IVD approval, because we think we're lined up to do that quickly. And we're at a point where the technology won't be obsolete by the time we ever got it through the FDA, then I think that would cause an inflection point in the curve in oncology in the US.

Bryan Brokmeier (Analyst - Cantor Fitzgerald):

Okay, thanks a lot.

Operator:

Our next question comes from the line of Tim Evans from Wells Fargo Securities.

Tim Evans (Analyst - Wells Fargo Securities, LLC):

Thank you. Jay, you cited the competitive head-to-head win rate as the reason giving you confidence

that the issue in the desktop market is not a competitive thing. What gives you confidence that your sales force is properly aligned and you're seeing all of the opportunities out there? And I guess the second question I had was what is driving the Q4 guidance to be lower than the implied guidance that you gave last quarter? I know you said that Q4 demand was higher I believe than Q3 demand in the desktop market, something you said on the last call. So what's creating the reduction in guidance there in Q4?

Jay Flatley (CEO):

Well we can never be sure that we're seeing every account in every sale out there, but we have a very big sales force now and it would be shocking if we missed more than handfuls of potential sales that happened in any given quarter. The only exception of that might be China, where it's a very big geographic market and it's impossible to cover all of the laboratories there. So some of our larger competitors may have more feet on the street in China, so there may be a few opportunities that we're missing there. But around the rest of the world, we're quite confident that we're getting to all of the major accounts. Including in places like Europe, many of these sales happen through tenders, so they are publicly available. So we see them and we know where the NIH grant money is going in the US from the academic side. So we're pretty confident in our win rate. Marc, do you want to talk about the guidance?

Marc Stapley (SVP & CFO):

Yes, essentially it comes down to the things we talked about on our pre-call. And a couple of things that impacted Q3 in particular are our perspective on Japan is one of the key drivers, and then our view on our ability to get everything done that we need to get done in Europe. Europe has to grow sequentially to achieve that, and so we're very focused on making that happen. And then on the desktop, benchtop side, we're coming off a lower jumping-off point in Q3 sequentially. So I think those factors combined is what led us to take down, effectively take down our Q4 guidance as we went from 20% to 18% for the year.

Tim Evans (Analyst - Wells Fargo Securities, LLC):

Okay, thank you.

Operator:

I'd like to turn the call over back to Rebecca Chambers for closing remarks.

Rebecca Chambers (VP of IR and Treasury):

Thanks again, [Lauren]. As a reminder, everyone, a replay of this call will be available as a Webcast in the investor section of our Web site, as well as through the dial-in instructions contained in today's earnings release. Thank you for joining us today. This concludes our call and we look forward to our next update following the close of the fourth fiscal quarter.