24-Feb-2015

NanoString Technologies, Inc. (NSTG)

Q4 2014 Earnings Call

CORPORATE PARTICIPANTS

Leigh J. Salvo
Principal, Westwicke Partners

James Algot Johnson
Chief Financial Officer

Robert Bradley Gray
President, Chief Executive Officer & Director

OTHER PARTICIPANTS

Patrick B. Donnelly
JPMorgan Securities LLC

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Justin D. Bowers
Leerink Partners LLC

MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen, and welcome to the NanoString 2014 Fourth Quarter Financial Results Conference Call. At this time, all participants are in a listen-only mode. Later we will conduct a question-and-answer session and instructions will follow at that time. [Operator Instructions] As a reminder, this call is being recorded. I would now like to turn the call over to your host for today's conference, Leigh Salvo. You may begin.

Leigh J. Salvo
Principal, Westwicke Partners

Thank you. On the call with me today is Brad Gray, NanoString President and CEO and, Jim Johnson, CFO. Earlier today, NanoString released financial results for the fourth quarter and year ended December 31, 2014 and a copy of the press release can be found on our website at nanostring.com.

During this call, we will make a number of statements that are forward-looking, including statements about financial projections, existing and future collaborations, future business growth, trends and related factors, interactions with third-party payers and the timing and outcome of any related reimbursement decisions, our strategic focus and objectives and the development, status and anticipated success of additional product offerings. Forward-looking statements are subject to risks and uncertainties, many of which are beyond our control, including the risks and uncertainties described from time to time in our SEC filings. Our results may differ materially from those projected on today's call. We undertake no obligation to publicly update any forward-looking statement.

Additionally, non-GAAP financial measures will be referred to during today's call. A reconciliation of these non-GAAP measures is included in today's press release, which is available on our website.

With that I'd like to turn the call over to Brad.

Robert Bradley Gray

President, Chief Executive Officer & Director

Thanks, Leigh. Good afternoon and thank you for joining us today. 2014 was another year of strong growth for NanoString. Our nCounter technology emerged as a leading platform for tumor profiling, with broad and growing acceptance in both research and clinical markets. The validation and impact of our platform was underscored by the rapidly growing body of research generated by our customers, which averaged five new papers per week and now totals approximately 650 peer-reviewed publications, up 70% compared to one year ago.

The increasing use of our platform by academic researchers, bio-pharmaceutical companies and clinical laboratories delivered revenue of $47.6 million for the full year, growth of 52% over 2013. The year finished on a high note, as we made meaningful progress across all three core areas of our business: Life Sciences, Companion Diagnostics and Prosigna. Fourth quarter revenue of $15.6 million set a new record and represented 54% growth.

Today's call will have three segments. First, I'll provide Q4 highlights in our three core areas of business. Next, our CFO, Jim Johnson, will summarize our financial performance and outlook and, finally, I'll wrap up by outlining our key strategic objectives for 2015 before opening up the call for your questions.

In 2014 our core Instrument and Consumable business remained the primary engine driving our growth, as we substantially expanded our installed base of nCounter Analysis Systems, while maintaining a high level of Consumable pull-through. We added both research and clinical lab customers, growing our installed base by 44% year-over-year, ending the year with a worldwide installed base of 264 nCounter Analysis Systems.

Many of the trends that we saw throughout the year continue to the fourth quarter. Oncology was once again the primary driver of new instrument placement, accounting for approximately 70% of new nCounter Systems placed in the quarter. The popularity of our dual-use FLEX configuration also continued in Q4, as more than half of our instrument placements were for this configuration, which we believe validates our strategy of combining cancer research and diagnostics on a single platform.

During the fourth quarter, we continued to penetrate international markets with more than half of our new nCounter Systems sold outside of North America. We now have approximately 40% of our installed base located outside the United States, with China representing our second largest market globally. We believe that these trends of nCounter adoption in oncology research, clinical laboratories and international markets are durable and will continue in 2015.

Turning to Consumables, the fourth quarter set a new record for Consumable revenue, with annualized Consumable pull-through well above $100,000 per system. A highlight of the quarter was the demand for our panel products, which more than doubled year-on-year. This growth was driven in large part by the success of our PanCancer panels, which we introduced earlier in the year. Our PanCancer Pathways Panel offers researchers a simple way to investigate the biology of 770 genes in all major cancer pathways, while our PanCancer Immune Profiling Panel is a unique offering targeted toward the dynamic field of immuno-oncology.

Consumable sales to our biopharma customers and our contract research organizations were robust, accounting for over 50% of consumable sales during the quarter. This was supported by several large orders from leading biopharma companies running biomarker studies on tissue samples collected during clinical trials for cancer therapeutics. We were especially pleased by the enthusiastic use of our nCounter platform by biopharma companies, as we believe this sets the stage for more strategic relationships in the future.

Moving to our second core area of focus and growth, 2014 marked our entry into Companion Diagnostics. I am proud of the results we achieved in our collaboration with Celgene under which our technical work progressed at a rapid pace and our interactions with the FDA went more smoothly and faster than expected. The ROBUST study, a pivotal Phase III clinical trial using Celgene's Revlimid to treat DLBCL, opened earlier this quarter with numerous sites now open for patient screening based on their DLBCL sub-type as assessed by our in-vitro diagnostic assay. We anticipate that the results of this study, if successful, will be used to support a PMA filing in the U.S. and other international registrations several years in the future.

In parallel to our work with Celgene, we have commenced a new initiative to collaborate with biopharma companies on the analysis of clinical trial results using our existing clinical assays, Prosigna and the DLBCL sub-typing test. Unlike our Celgene collaboration, these translational projects do not commit NanoString to develop a Companion Diagnostic. Rather, they are designed to allow biopharma partners to explore whether one of our clinical assays could, in the future, become a Companion Diagnostic for one of their drugs.

During the fourth quarter, we entered translational agreements with two undisclosed biopharma companies, one focused on Prosigna and the other on our DLBCL sub-typing test. While these types of translational projects offer economics that are much lower than our Companion Diagnostic partnerships such as our Celgene collaboration, we are optimistic that they may lead to more substantial Companion Diagnostic partnerships with these companies in the future.

Turning to our Prosigna Breast Cancer Assay, sales in Q4 were modest, consistent with our expectation that uptake will remain limited until official reimbursement is secure. Our attention throughout 2014 was focused primarily on building the installed base of Prosigna testing sites and establishing reimbursement, and we made meaningful progress on both of these objectives. As of today, 37 clinical laboratories across 12 countries have acquired nCounter Systems with the intent of offering Prosigna testing services.

Since our last call, we have added seven new medical centers across Australia, France, Germany, Italy, Spain, Switzerland and the United States. In the U.S. market, nine labs are now offering Prosigna services and another six labs are preparing for launch. Outside the U.S., 11 labs are offering Prosigna services, while another 11 labs are preparing to come online in the months ahead.

During 2014, we began establishing reimbursement for Prosigna and have had important wins in both the U.S. and Europe. In the U.S., total covered labs for Prosigna are now more than 45 million, or approximately 20% of the U.S. patients indicated for Prosigna. In Europe, we have coverage in several regions of Spain and the governments of Germany and Switzerland have recently taken important steps toward the reimbursement of genomic testing for breast cancer for the first time.

Inclusion of breast cancer treatment guidelines will be a key catalyst for reimbursement and adoption of Prosigna. Earlier this month, the NCCN posted on our website a partial update of their breast cancer treatment guidelines. Prosigna was not specifically addressed in the partial update, and we look forward to seeing the complete update of the NCCN guidelines when they are available. We expect that the positioning of Prosigna and the discussion section of the guidelines will be important to our interactions with both the Palmetto MolDX team and the largest U.S. private payers. And we believe that favorable treatment of the discussion section could facilitate positive coverage decisions over the year ahead.

In parallel to pursuing guideline inclusion, we continue our efforts to build the body of evidence for Prosigna's clinical utility. To that end, two particularly important results were presented during the annual San Antonio Breast Cancer Symposium in December. First our collaborators in Spain presented positive results from the first

Prosigna Decision Impact Study, showing how physicians, in a real-world setting, use Prosigna to help guide their use of chemotherapy.

Second, researchers from the UK presented results from the OPTIMA-prelim study, which rated Prosigna very highly compared to other major breast cancer gene signature tests. As a result, Prosigna has been chosen over other tests for use in a major prospective clinical trial which we expect to be enrolled in the UK, beginning later in 2015. Overall, we're pleased with our progress on multiple fronts and optimistic about our continued growth.

I would now like to turn the call over to Jim Johnson to review our financial results and provide financial guidance.

James Algot Johnson

Chief Financial Officer

Thanks, Brad. The company had a strong fourth quarter, a total revenue of $15.6 million, up 54% versus the fourth quarter of 2013. Instrument revenue for the quarter was $6.3 million, up 20% over a strong comp and fourth quarter of 2013. Consumable revenue was a record $7.2 million, up 69% and well above our historical benchmark for annualized pull-through of $100,000 per system. The growth in consumables reflected more than the typical volume of large orders from biopharma customers.

Prosigna test kit revenue remained modest at $156,000. We recorded $1.4 million of collaboration revenue for the quarter. Most of this relates to our Celgene collaboration, with modest contribution from an exploratory collaboration with a pharma company involving an ongoing Phase II study. During the fourth quarter, we received an incremental $1 million milestone from Celgene, which brings the total cash received under the collaboration to date to nearly $12 million, with $2.9 million recorded as revenues since inception in March of 2014.

Gross margin on products and service revenue for the quarter was 53% compared to 52% a year earlier. R&D expense was $5.4 million compared to $4.5 million in the fourth quarter of 2013. The increase reflects increased investment in the advancement of our nCounter technology, including the engineering and testing of our Next-Generation system, as well as costs related to diagnostic development, including the Celgene collaboration.

SG&A expense was $15 million for the fourth quarter, up from $9.1 million a year ago. The increase versus the prior year reflects Prosigna launch costs, expansion of our commercial team and increased administrative costs to address the company's growth. Stock based compensation expense contributed significantly to the overall growth in the operating expenses. It totaled $1.3 million for the fourth quarter of 2014 compared to $380,000 a year earlier.

Our press release includes the schedule of non-GAAP financial information, which shows our operating results and default pre-IPO preferred stock have been converted to common stock. On a non-GAAP basis, our net loss for the quarter was $9.7 million, or $0.53 per share, compared to $7.5 million, or $0.51 per share, in the fourth quarter of 2013. You should refer to that schedule for a detailed reconciliation of GAAP and non-GAAP results. We ended the year with $72 million of cash investments.

Now I'll turn to our financial guidance for 2015. We're currently projecting total revenue of $58 million to $61 million for the year, which includes collaboration revenue of $2.5 million, primarily from our existing collaboration with Celgene. Potential new Companion Diagnostic collaborations represent upside to this guidance. Following the announcement of new collaborations, we intend to update our guidance to reflect related revenue impact.

Total products and service revenue is projected to be $55.5 million to $58.6 million for the year, reflecting growth of 25% to 31% over 2014. Expect this growth to accelerate as we progress through the year due to the impact of new product launches and sales personnel hired in late 2014 and early 2015 who are expected to reach full productivity in the second half of the year. We've included $2 million of Prosigna revenue in our guidance, reflecting an assumption that Prosigna will be positively described in updated NCCN guidelines, leading to additional reimbursement wins in the second half of the year. In the interim, however, we expect modest uptake to continue.

There are some other expected revenue trends that I'd like to highlight. With respect to instrument revenue, we plan to release our new Gen 3 system in mid-2015 and expect initial revenues in the third quarter. As a result, we anticipate instrument revenue growth will moderate in the third quarter while the funnel for the new lower priced system builds.

With respect to Consumables revenue, for the installed base of our current Gen 2 system, for the full year, we expect to maintain consumable pull-through at or near the $100,000 per system we've generated historically. However, consistent with our experience over the past three years, we expect pull-through in the first quarter of the year to be somewhat lower on a per system basis than in the other three quarters.

We expect gross margin on product and service revenue in 2015 to continue to fluctuate from quarter-to-quarter, depending on the mix between consumables and instruments. For the year in total, we expect overall gross margin to be in the range of 53% to 55%. On a quarterly basis, ignoring the impact of revenue mix, we expect it to move upward over the course of the year, consistent with the growing scale of our consumables manufacturing operation. As a reminder, collaboration revenue is excluded from our calculations of gross margin.

After making the significant investments to grow our business over the past two years, we expect operating expense growth to moderate in 2015 and remain relatively consistent with our fourth quarter 2014 run rate. We're expecting total operating expenses of $77 million to $81 million for the year, which represents an increase of 6% to 12% over 2014. We expect operating expenses to include approximately $5 million to $6 million of stock based compensation expense for the year.

Our operating loss for the year is expected to be in the range of $42 million to $49 million. Interest expense is expected to be approximately $4 million for the year. However, if we decide to borrow any of the incremental $15 million available to us under our existing term loan agreement, interest expense would be higher. Finally, total capital expenditures are expected to be $4 million to $5 million for the year, of which approximately half is expected to be funded by our landlord as leasehold improvements.

So, with that I'll turn it back over to Brad to wrap up.

Robert Bradley Gray

President, Chief Executive Officer & Director

Thanks, Jim. We entered 2015 in a position of strength, stemming from the continued traction we have achieved in our Life Sciences business. Our fundamentals are sound, with a growing worldwide installed base and strong consumable pull-through. Our entry into the clinical diagnostics market provides the potential for meaningful upside, as our Prosigna launch progresses and our Companion Diagnostic program matures.

I'd now like to highlight four strategic objectives that we will pursue during 2015. First, we plan to sharpen our focus on oncology, where we believe our technology plays a unique role and provides us with a strategic advantage. We will seek to solidify our leadership in tumor profiling, while expanding into the field of immuno-

oncology. Our commitment to oncology cuts across all three of our business areas, as we aspire to provide best-in-class products for unlocking biology from tumor samples and yielding new insights and therapies and improving patients' lives.

In recognition of this, we recently restructured from two independent commercial organizations, one for Life Sciences and another for Prosigna, to a single commercial organization, empowered to sell our entire suite of products and targeted primarily toward academic medical centers and biopharma companies. We believe that this approach strikes the optimal balance between effectiveness and efficiency in reaching the leaders in oncology who are our customers and our partners.

Immuno-oncology is a dynamic field in which we are already engaged through the launch of our PanCancer Immune Profiling Panel. In 2015, we plan to build on our current momentum and relationships, introducing additional assays and collaborating closely with leaders in the field at both academic centers and biopharma companies. We expect immuno-oncology to become an important part of our business in the future.

Our second strategic objective is to deepen our relationships with biopharma companies, including building a pipeline of Companion Diagnostics. In 2014, biopharma customers drove a substantial fraction of our growth in Instruments and Consumables and today represent over 20% of our installed base. In 2015, we expect to continue growing our product sales to biopharma customers while also evolving our relationships with them to be more strategic and, ultimately, to become a trusted Companion Diagnostic partner.

While we have not factored revenue from the potential new Companion Diagnostic collaborations into our 2015 guidance, we are optimistic that we will have the opportunity to enter into one or more such collaborations this year and, that over time, Companion Diagnostic partnerships will become a significant driver of our growth and cash flow. Our optimism stems from our numerous ongoing dialogs with biopharma companies interested in Prosigna and our DLBCL sub-typing test, as well as the biomarker signatures discovered by some of the more than 30 biopharma companies who are currently using our nCounter technology.

Our third strategic objective is to further penetrate the clinical laboratory market with the FLEX configuration of our nCounter system, our Prosigna breast cancer assay and our Elements Reagents. We plan to increase our focus on working with hospitals and cancer centers, where our value proposition of decentralized breast cancer testing resonates most strongly. In addition, we are continuing our effort to demonstrate Prosigna's clinical utility and look forward to presenting the results from several new studies at major meetings later this year.

Our fourth strategic objective is to expand our addressable market by launching new products with broad affordability and appeal. Historically, we've offered instruments at a price – at prices that were affordable primarily by labs which shared the equipment across multiple users. As a result, the pace of our installed base growth has been restricted by capital budgets and long sales cycles. In mid-2015, we expect to launch a new lower cost nCounter system designed to meet the needs of individual researchers at a much more affordable price. We expect that this launch will increase our addressable market to two to three times what it is today.

We are currently in an intensive internal verification and validation phase that once completed should allow us to skip beta testing and go straight to full product launch. In parallel, we plan to introduce an application allowing researchers to simultaneously profile both the gene expression and the protein expression of a sample on a single instrument system. We believe that this multi-element application will broaden the appeal of our technology to researchers who have traditionally focused more on proteomics and provide another distinctive capability, not generally available from other technology platforms.

Later this week, data from this new multi-omic application will be showcased at the AGBT meeting in Marco Island, Florida and we look forward to a beta launch of our first multi-omic panel at the AACR meeting in April.

Together, we expect the launch of our lower cost nCounter and multi-omic applications to broaden the addressable market, further differentiate our technology and build our strategic advantage in the field of tumor profiling.

In conclusion, these four strategic initiatives are designed to solidify the role of our company and technology at the center of cancer research and diagnostics. We believe that successful achievement of these objectives will drive growth and value creation, not just in 2015 but, over the long term. We look forward to updating you on our progress against these initiatives in future calls.

I would now like to open the line for questions.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] Our first question comes from Tycho Peterson of J.P. Morgan. Your line is now open.

Patrick B. Donnelly
JPMorgan Securities LLC

Q

Thanks. It's actually Patrick Donnelly in for Tycho. I guess, Brad, for you on the NCCN update, can you give us a feel for your confidence level on being included in the next update? And then, best idea on timing, are you kind of thinking mid-March around that?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Yeah. Thanks for the question, Patrick. I wish I could provide more visibility into the NCCN process, but I can't. As you know, the NCCN guidelines are developed in a closed process by a committee of breast cancer experts. And once NanoString submitted its application last summer, we really had very little visibility into the ongoing proceedings. So, it's hard for me to speak to a level of confidence about whether we'll be described and how in the discussion section.

That being said, as we said many times, we believe our submission was a strong win. It included an FDA clearance, numerous peer-reviewed publications including a head-to-head study against the tests that's already included in the guidelines, and we believe that it's a strong package that the guidelines committee should be compelled to speak to in their discussion.

In terms of timing, what we understand is that traditionally the full guideline updates for breast cancer have appeared in about the same time that the JNCCN, the NCCN's journal, issued its annual breast cancer issue. According to the JNCCN Editorial Calendar, the April issue is meant to be dedicated to breast cancer. And if that continues according to plan, we would expect that the full guidelines would be released around that time or as early as mid-April, when the electronic – I'm sorry, mid-March when the electronic copy of that issue would appear online.

Patrick B. Donnelly
JPMorgan Securities LLC

Q

Okay. So, the confidence level hasn't changed. We shouldn't read into the fact that your – including some revenues, assuming that the approvals happening, your confidence level is the same as it was, call it, five months, six months ago?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Correct.

Patrick B. Donnelly
JPMorgan Securities LLC

Q

Okay. And then I guess just on the nCounter Next-Gen system – I appreciate the color on you're going to skip the beta launch – what possible hiccups could happen with the internal review? And what's the confidence level on that kind of mid-year target for launch?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Our confidence level is high. The program is going very well so far. We've received manufacturing pilots. We've been putting those pilots through their [ph] phases (00:26:55). We'll be receiving more manufactured pilots and inventory over the weeks and months ahead. That being said, the reason we put an instrument through so many rigorous tests is to discover any bug that may be there before it's released into the market, and there's always a modest risk that something would turn up. Thus far, we haven't seen any kind of showstoppers, and we remain on track.

Patrick B. Donnelly
JPMorgan Securities LLC

Q

Okay. And last one, I guess on the revenue guidance. You said there's no Companion Diagnostics – no future Companion Diagnostics partnerships included. I guess, if you got one of those, how much upside do you think it could have in terms of revenue for 2015?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Patrick, it's very – it's obviously very hard to say in the abstract. These structures – these collaborations can be structured in numerous different ways, which have important implications for a revenue recognition. I wouldn't hazard a guess about what the revenue contribution in 2015 from a new deal would be. I think the one benchmark we have is the Celgene deal from 2014, which contributed about $3 million in in-year revenue. But it's hard to say whether the next – the accounting treatment of the next collaboration would be similar.

Patrick B. Donnelly
JPMorgan Securities LLC

Q

Okay. That's fair. Thank you.

Operator: Thank you. Our next question comes from Steve Beuchaw from Morgan Stanley. Your line is open.

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Q

Hi, guys. Good afternoon. Thanks for taking the questions. I actually just have a couple of clarification questions on the guidance for 2015. And at risk of being uncreative, I'm going to follow-up on Patrick's questions on Gen 3 and Prosigna. First let's go to Prosigna. So, you guide for, I believe, you said $2 million of contribution in 2015, which is a fairly substantial step-up relative to 2014.

So, my question is, what's behind that? If the visibility on the NCCN process, for very understandable reasons, is still really low and MolDX visibility is, of course, still really low, are you taking the view that you can get to that level without the NCCN as a function of expanding coverage? Asked another way, if you've got the NCCN, would it potentially drive upside to that figure? How does that number come about? Thanks.

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Sure. Thanks, Steve. Let's talk about what's in that $2 million guidance number for Prosigna. First, it's split about 50/50 between the U.S. market and the ex-U.S. market. And that split represents, more or less, the revenue split we experienced for Prosigna in 2014. In the U.S., as Jim said, we do assume a positive description in the NCCN guidelines. And we also assume that that full guidelines will be updated along the timeframe that I just described, which would be in the April timeframe and around the time the JNCCN breast cancer issue is expected to appear. And we would expect that we would be able to use that guideline update to gain some incremental reimbursement in the second half, but we don't expect contribution from a major positive MolDX decision in 2015.

On the other side, outside the U.S., on that other million dollars, we would assume that we continued our gradual penetration of those regions that we're already operating in. Some of that will be in regions where we have government reimbursement, like Spain and emerging reimbursement in Germany and Switzerland. Others would be private pay business that we've been enjoying since our launch and some of the revenue could be associated with the clinical study I mentioned in the UK that we began in the second half. So, I think it's a relatively modest number overall. Though it is a step-up certainly from our current run rate, we view it as a continuation of the trends and the assumptions that we just described.

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Q

Got it. Exactly what we needed. And then on Gen 3, Jim, you mentioned that there would be some, I want to say volatility, though it's probably an overstating a little bit. In the third quarter, as the system comes out, you build the funnel, I would imagine the sales force needs to redirect its efforts to some extent. Can you give us a sense for, number one, how much of an impact you're expecting from the Gen 3 launch as it is a bit of a distraction in the second half? And then, number two, building on your comment that you expect some acceleration in terms of instrument revenue in the back half, how you're thinking about the Gen 3 versus Gen 2 instrument mix as we get to the fourth quarter and perhaps beyond? Thanks so much, guys.

James Algot Johnson
Chief Financial Officer

A

Okay. Thanks, Steve. So, basically after the Gen 3 launch, we're going to have a segmented product line. We think that Gen 2 should still be the choice of many customers, clinical labs will like the diagnostic capability, obviously, biopharma customers, the FDA clearance and the high throughput, and Core Labs also high throughput. So, first of all, we think that there's a minority of our instrument purchases who would have bought Gen 2 will opt instead

for Gen 3. So, – but nevertheless there is going to be a minority fraction of those customers who are going to be looking at the new system.

And at the same time, as you know our launch strategy is sort of a hard cut over with the new system as opposed to a slow, soft launch. And so it's going to take time for that funnel to build. So, in the first quarter of launch, the dynamic we see is that there will probably not be the rapid uptake of the new system and it will take approximately a quarter for that funnel to build. And at that point we expect that the increased size of the opportunity for the Gen 3 system to make up for that and actually result in higher instrument revenue growth percentages.

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Q

Okay, guys. Thank you so much.

Operator: Thank you. Our next question comes from Jeff Elliott from Baird. Your line is now open.

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)

Q

Hi. Good evening, guys, and thanks for the question. First one here is on Next Gen. Any update on the, I guess, the list price or pull-through you're expecting on the instrument?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Not at this time, Jeff. We'll plan to provide some more updates on that obviously at the time of launch.

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)

Q

Got it. Okay. That's fair. And Jim, looking at the guidance, what have you assumed for FX? I think it's pretty relevant this year just given the growing international installed base. So, what are your assumptions for I guess revenue on the margin side for FX?

James Algot Johnson
Chief Financial Officer

A

Yeah. I know that's a question that's on the tip of people's mind these days. For us, fluctuations in foreign exchange rates have really had a negligible direct impact on our revenue, because historically less than 10% of our revenue has been built in foreign currency. So, when we're looking at guiding for 2015, we didn't really make any specific assumptions for FX changes on our 2015 revenue guidance. But indirectly, of course, continued strengthening of the U.S. dollar could indirectly impact demand for our products and discounting the products in foreign markets. But I think that that's implicit in our guidance.

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)

Q

Let me clarify that, Jim. Do you mean that your guidance assumes rates where they are today hold constant, or you just haven't made any assumptions for any FX change whatsoever?

James Algot Johnson
Chief Financial Officer
A

Yeah. Roughly speaking, roughly unchanged from where they are today.

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)
Q

Okay. Got it. All right. Then, I guess, I appreciate the color there. I think it's really useful as we got to update our models. Hypothetically, assuming you don't get the NCCN commentary that you're hoping, which – I do think that it's unlikely. But if you don't get that, how should we think about OpEx in that scenario? Is that something – would you kind of dial that back for the rest of 2015 if that were to happen?

Robert Bradley Gray
President, Chief Executive Officer & Director
A

I think it's a little early to discuss what we would do operationally in a scenario where we don't end up in the description of the NCCN guideline. Obviously at all times we're looking at the best and highest use of our operating expense dollars and we have to think about the investment in both Prosigna versus our other product lines. And then within Prosigna, the investment in clinical data versus commercial activity and reimbursement. Today, we've really focused our investment on the activities we think are most important instrument placement in new Prosigna sites, as well as reimbursement activities.

And part of the efficiency we sought in the commercial reorganization we described was a more focused effort on those two activities, really dialing back some of the straightforward promotional and detailing activities direct to oncologists. So, we are cognizant of the need to constantly look at the mix of our commercial expense and investment. And we won't be specific, at this point in time, about how we would manage a situation without guidelines but we would plan to update you at that time.

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)
Q

Got it. And one last one from me here. Of the 20%, I guess, of life that you do have under coverage for Prosigna, what level of reimbursement are they covered at?

Robert Bradley Gray
President, Chief Executive Officer & Director
A

Our understanding is that the labs who are receiving a reimbursement under those policies are receiving it at around the same rate that the other genomic tests for breast cancer are being reimbursed, which is nearly $4,000 per test.

Jeff T. Elliott
Robert W. Baird & Co., Inc. (Broker)
Q

Got it. Okay. Thanks, guys.

Operator: Thank you. [Operator Instructions] Our next question comes from Justin Bowers of Leerink. Your line is now open.

Justin D. Bowers
Leerink Partners LLC

Q

Good afternoon. Brad or Jim, could you – just thinking about the Gen 3 box a little differently too, what is the contribution, maybe as a percentage of instrument growth or revenue growth, next year that you guys have factored in the guidance?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Yeah. Hey, Justin. This is Brad. I think we're not currently breaking that out at this point. I think that we were pretty clear on the timing of the launch being mid-year and, therefore, revenue contribution starting in Q3 and Q4 and then building in Q4 as the funnel grows. So, I think you can deduce from that. It's obviously a minority of our overall instrument revenue. But we're not – I don't think we're not going to be any more specific than that at this point in time.

Justin D. Bowers
Leerink Partners LLC

Q

Okay. And then just in terms of the commercial changes you made. Could you talk about, maybe just elaborate a little there on the restructuring? And then did you add any sales coverage in the fourth quarter?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Sure. So, yeah, I think on the restructuring, I think what we've come to realize over the past year is that oncology has really become the primary market we serve and, at the same time, the lines between the traditionally demarcated research and clinical testing have really blurred. It's also become clear that at this stage of our Prosigna launch, the most critical commercial activities are those geared toward establishing new sites and reimbursement. So, we took a look at what we thought would be the most efficient and effective commercial channel and decided to move from the two independent commercial channels, one the life sciences and one the diagnostics, to a single one focused on academic centers, clinical labs and biopharma companies. And so that, we think, is the right mix for us today, taking advantage of the power of our technology to decentralize testing into these hospitals and academic centers and foregoing increased investment in detail into oncologists at a stage in the Prosigna product launch where reimbursement is not yet widespread.

Justin D. Bowers
Leerink Partners LLC

Q

Okay. Understood. Thank you.

Operator: Thank you, and I'm not showing any further questions at this time. I'd like to turn the call back over to management for closing remarks.

Robert Bradley Gray
President, Chief Executive Officer & Director

Well, thank you all for taking time this afternoon to hear about our Q4 and full year results. We look forward to seeing you at AGBT and other conferences coming up soon. Thank you.

Operator: Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program, and you may all disconnect. Everyone have a good night.