04-Aug-2015

NanoString Technologies, Inc. (NSTG)

Q2 2015 Earnings Call

CORPORATE PARTICIPANTS

Leigh J. Salvo
Principal, Westwicke Partners, LLC.

James Algot Johnson
Chief Financial Officer

Robert Bradley Gray
President, Chief Executive Officer & Director

OTHER PARTICIPANTS

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Michael A. Sarcone
Leerink Partners LLC

Tejas R. Savant
JPMorgan Securities LLC

Dane Leone
BTIG LLC

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

MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen and welcome to the NanoString 2015 Second 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 conference call is being recorded.

I would now like to introduce your host for today's conference Ms. Leigh Salvo of Westwicke Partners. Ma'am you may begin.

Leigh J. Salvo
Principal, Westwicke Partners, LLC.

Thank you. On the call with me today is Brad Gray, NanoString's President and CEO; and Jim Johnson, CFO. Earlier today, NanoString released financial results for the second quarter ended June 30, 2015, and a copy of the press release can be found on the company's website at nanonstring.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, prospects for expanding and penetrating addressable markets, interactions with third-party payors, and the timing and outcome of any related reimbursement decisions, our strategic focus and objectives, and the development status and anticipated success of recent and other planned product offerings.

Forward-looking statements are subject to numerous 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 publically update any forward-looking statements.

With that, I would 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. The last several months have been pivotal for NanoString. Through the achievement of many milestones, both large and small, we believe that we have positioned the company for long-term growth and leadership in the field of precision oncology.

Let me provide a few highlights. We substantially expanded the market opportunity for our products in oncology research through the launch of the nCounter SPRINT Profiler and the introduction of our unique RNA:Protein assays. We've positioned the company as a leader in the dynamic field of immuno-oncology by forming partnerships with leading academics, recruiting a Chief Medical Officer with expertise in Tumor Immunology, and forming a partnership with Merck to develop biomarker assays for KEYTRUDA, one of the highest profile cancer immunotherapies in the field.

And we have continued to demonstrate our capabilities to develop and commercialize molecular diagnostics by achieving key milestones for Prosigna including recognition in the international treatment guidelines and positive draft coverage policies from Medicare. On our call today, after briefly highlighting our Q2 financial performance, I'll focus my remarks on the tremendous progress towards our strategic objectives for the year. Jim will comment in more detail on our financial performance and outlook. And I will then make some brief closing remarks before opening up the call for your questions.

Total revenue for the second quarter was $13.1 million, with a growth of 20% driven primarily by instruments and consumables sales. We continue to rapidly expand our installed base of nCounter systems while achieving annualized pull-through of $100,000 per system for total consumables. Instrument sales were $4.4 million in the second quarter, representing growth of 17%, and bringing our worldwide installed base to over 300 systems. Instrument revenue growth was particularly strong in Asia and Europe where our distributor network made a strong contribution to growth. Life sciences consumables revenue which excludes Prosigna was $6.8 million for the quarter, up 17% year-on-year and 24% sequentially. As expected, the pace of ordering from biopharma companies and customers located in the Northeast recovered during Q2, easing the constraints on consumer revenue experienced during the first quarter.

Biopharma companies and their CRO's contributed over 30% of consumables revenue in Q2 and increased about 50% sequentially from Q1. Meanwhile, Prosigna's sales trended upward to $591,000 and showed particular strength in Europe where we have recently won several competitive tenders for breast cancer recurrence testing. Overall, we are pleased with Q2 results and the outlook for the remainder of the year. I'd now like to transition to reporting progress on each of our four strategic objectives for 2015.

Our first strategic objective for this year is to sharpen our focus in oncology by solidifying our leadership in tumor profiling and expanding into the field of immuno-oncology. Our oncology focus continues to drive nCounter system placements as approximately 70% of our instrument sales in Q2 were to labs focused on cancer. Meanwhile, the popularity of our PanCancer panels continued to growth, driving panel revenue to approximately double versus last year and setting another record. Our commitment to oncology cuts across all aspects of our business and we seek to provide best-in-class products for unlocking tumor biology, yielding insights that can lead to better therapies.

In order to help us deliver on this promise we recruited a new Chief Medical Officer with a unique blend of expertise in drug development, molecular diagnostics, and cancer immunology. Dr. Alessandra Cesano who joined us in July brings more than 25 years of experience and an extensive scientific and executive level background on oncology that is an ideal fit for our growth strategy. Her track record of successful therapeutic development, which includes two approved cancer therapeutics will be invaluable in partnering with biopharma companies on the development of companion diagnostics.

One of the most exciting areas of oncology research and therapeutic development today is immuno-oncology, or IO for short, which looks to harness the power of the body's immune system to fight cancer. IO is becoming a major driver of NanoString's growth and we are already benefiting from Alessandra's IO expertise which includes a Ph.D. in Tumor Immunology and almost a decade of IO research experience.

During the second quarter, we established three partnerships which together have thrust NanoString into the center of the IO field. In April, we announced a multi-year collaboration with the MD Anderson Cancer Center to accelerate the development and adoption of our new RNA:Protein assays in the field of immuno-oncology and targeted therapies. In May, we announced the collaboration with the Cancer Immunotherapy Trials Network to identify biomarker assays for novel cancer immunotherapies. Both of these academic partnerships are progressing well, yielding its first experimental results just days and weeks after they were initiated.

Finally, also in May, we announced an exciting partnership with Merck which both extends our leadership in IO biomarker development and aligns with our second strategic objective of deepening our relationships with biopharmaceutical companies.

Some background on the Merck partnership should illustrate why this is such an important event for NanoString. To date, only a few IO therapies have been approved by the FDA but many more are in development. One of the first IO therapies on the market is Merck's KEYTRUDA, which is in a class of therapies known as checkpoint inhibitors. KEYTRUDA has been approved for the treatment of melanoma and is in development for many additional tumor types.

As in other areas of drug development, researchers have looked for biomarkers that might help predict which patients would benefit from checkpoint inhibitors. Until recently the effectiveness of these biomarkers at selecting patients has been mixed. Despite the fact that checkpoint inhibitors have provided some patients durable responses in previously untreatable disease, the majority of patients do not respond to single-agent treatment. Our collaborators at Merck set out to find more accurate biomarkers for predicting response to KEYTRUDA. Merck was an early adopter of our technology and now operates numerous nCounter systems across multiple research sites.

Sometime ago, they began using nCounter technology to search for gene expression signatures that identify which tumors respond to KEYTRUDA. They succeeded, and at the recent ASCO Meeting presented results showing nCounter-enabled gene expression signatures that predict KEYTRUDA response across four different tumor types: melanoma, head and neck cancer, bladder cancer and gastric cancer. About a year ago, Merck contacted us regarding these predictive gene signatures and we began discussing how we would work together to move them forward as a companion diagnostic.

We agreed to enter a partnership under which we would collaborate to explore the feasibility of developing and commercializing biomarker assays for KEYTRUDA. During the feasibility stage, which is expected to bring around $4 million in cash payments for Merck, we plan to optimize the signatures, validate their performance, and seek FDA input on the potential development program. Assuming success in this initial phase, we intend to establish a

separate collaboration that would govern and fund the development and commercialization of the resulting assay as a companion diagnostic.

We are excited about this new collaboration for several reasons. Importantly, it is a perfect illustration of the power of our business model with clear synergy between our efforts in research and diagnostics. I believe that few other companies in the field of genomics could so efficiently and confidently support Merck's efforts to move their discovery into the clinic.

In addition, this partnership validates our technology and helps establish our leadership position in IO at a time when the field is in urgent need of robust and accurate predictive biomarkers. Along with the rapidly growing use of our PanCancer Immune Profiling Panel and strong biopharma interest in our immuno-oncology RNA:Protein profiling panel. We believe our Merck partnership positions nCounter as a must have platform for academic researchers and biopharma companies developing IO therapies.

As illustrated by our Merck collaboration, the use of nCounter technology and research has the potential to yield a menu of molecular diagnostics over time. In order to be a valuable companion diagnostic partner and build a successful diagnostics business, we need an effective diagnostic commercial capability. This brings us to our third strategic objective, which is to further penetrate the clinical laboratory market with our nCounter FLEX system for Prosigna Assay and Elements reagents.

Since our last call, we have continued expanding our clinical installed base as our popular dual-use nCounter FLEX once again drove the majority of new instrument sales. Clinical labs have also continued to adopt Prosigna and today the number of Prosigna sites has increased to 47 clinical labs across 13 countries with a total of 29 laboratories worldwide actively offering Prosigna testing services. Just as importantly, we have achieved major milestones with Prosigna that demonstrate a growing capability in diagnostic commercialization that, over time can potentially be leveraged across an entire menu of tests.

During the past few months two influential breast cancer guidelines were updated to acknowledge Prosigna for the first time. In May, the St. Gallen International Breast Cancer Guidelines were updated to recognize the power of Prosigna to inform treatment decisions and spare low risk breast cancer patients' unnecessary chemotherapy.

More recently the NCCN published the full update to their breast cancer guidelines acknowledging that the PAM50 gene signature that underlies Prosigna has been clinically validated for prediction of prognosis. These guideline updates were in line with our expectations and we believe establish a solid foundation upon which we can continue to build the market for Prosigna.

We also continue to generate compelling clinical data that strengthens the case for Prosigna's clinical utility and may help improve Prosigna's positioning in the future guideline updates. For instance, at ASCO our collaborators presented several new studies highlighting Prosigna's ability to inform physician treatment decisions, including a study which demonstrates Prosigna's ability to predict response to chemotherapy.

Most importantly, in May, Prosigna received a favorable draft local coverage determination by Palmetto GBA through its MolDx Program. The draft policy provides coverage for Prosigna's entire intended use population, including patients with both node-negative and node-positive disease. The public comment period for this draft policy has now closed and we're waiting for Palmetto to finalize the policy. The policy will become effective 45 days after it is finalized.

The positive MolDx decision is an important milestone for several reasons. For one, the MolDx policy is expected to initially be adopted in six states, including North Carolina where LabCorp is running all their commercial

Prosigna testing. Thus, the MolDx policy, when finalized, will provide what is effectively national coverage for patients tested through LabCorp. In addition, the MolDx process is viewed as one of the more sophisticated and influential technology assessments in the U.S. and we believe the decision is likely to positively influence the coverage policies of other Medicare carriers and private payors. Finally, this milestone is a demonstration of our reimbursement teams' ability to effectively convey to payors the analytical validity, clinical validity and clinical utility of Prosigna.

Our fourth strategic objective is to expand our addressable market. We achieved this objective in July with the launch of our single most important new product of the year, our low-cost nCounter SPRINT Profiler. The nCounter SPRINT represents a major step forward in making nCounter technology more broadly accessible to researchers. It provides the same highly precise nCounter chemistry as our previous systems, but with a smaller footprint, and a sample throughput and cost tuned to the needs of individual researchers. Using a microfluidic processing card, SPRINT integrates sample prep and analysis into a single instrument, minimizing manual steps, while further streamlining the overall workflow.

The system throughput has been designed to accelerate the sample-to-insight for individualized experiments on an instrument sized to fit on a laboratory bench top. In combination with our suite of PanCancer Panels and custom CodeSets, SPRINT provides the individual cancer researcher with a complete solution for translational research. We estimate that the availability of SPRINT will increase our serviceable market to two times to three times what it is today and has the potential to accelerate the growth of our installed base in the coming years.

The expanded nCounter line up now includes three instrument systems, each targeted at a different customer segment. For clinical laboratories interested in the Prosigna assay and biopharma companies interested in assay development on an FDA-cleared system, we offer nCounter FLEX. For the core laboratory, we offer the nCounter MAX, which is based on our higher-throughput research system, updated with an enterprise software that provides enhanced security, controlled access and automated data transfer.

For the individual researcher, we offer an affordable nCounter SPRINT. Reaction to this offering has been positive in the three weeks since launch, and we look forward to developing an expanded sales force funnel in the quarters ahead.

Also during the quarter, we began working with a select group of customers to field-test our new RNA:Protein assay, which allows simultaneous detection of gene and protein expression. Interest has been high, and thus far, we have limited the access program to five customers: three biopharma companies and two academic labs. The feedback has been positive and we look forward to moving this product towards full commercial launch later in the year. We expect this unique RNA:Protein capability to further differentiate our technology and expand our strategic advantage in the field of tumor profiling.

Now, I'd like to turn the call over to Jim to review our financial results and provide financial guidance.

James Algot Johnson

Chief Financial Officer

Thanks, Brad. Total revenue for the second quarter of 2015 was $13.1 million, up 20% versus the second quarter of last year. Total product and service revenue was $12.5 million, up 22% year-over-year. Foreign exchange rate fluctuations reduced the growth in both total revenue and total product and service revenue by approximately 3 percentage points.

Instrument revenue for the quarter was $4.4 million, up 17% over second quarter 2014. System sales were strong outside North America, generating over 60% of total instrument revenue, with particularly strong growth from our distributors. The quarter also included the sale of our first two SPRINT systems to the Broad Institute.

Total consumable revenue, including Prosigna, was $7.4 million, 23% higher than a year ago, and above $100,000 per system on an annualized basis. Life sciences consumables were $6.8 million of this total, up 17% year-over-year. This is consistent with the guidance we provided last quarter of $1 million to $1.5 million of sequential growth over the first quarter.

Within life sciences consumables, we saw a recovery in our biopharma pull-through and from customers in the Northeast after Q1 weather-related issues subsided. Also, we continued to see the shift away from custom consumables to panels, with panel sales representing over 40% of total life sciences consumables revenue for the quarter.

Prosigna test kit revenue grew to $591,000, another step-up from the previous quarter. We continue to see increasing momentum in the demand for Prosigna kits, particularly outside the U.S. where our localized testing model clearly resonates.

We recorded $568,000 of collaboration revenue for the quarter and most of this relates to our Celgene collaboration, with modest contributions from the new Merck collaboration beginning in June, and a small exploratory research collaboration.

Gross margin on product and service revenue for the quarter was comparable to the second quarter of last year at 53% and gross margin during the quarter benefited from increased panel volume in consumables, which was generally offset by the impact of a higher proportion of instrument sales sold through distributors, which generate lower margins than direct sales.

R&D expense was $5.8 million compared to $5.3 million in the second quarter of last year. The increase largely reflects investments in the development of new nCounter products and technology. SG&A expense was $12.8 million for the second quarter comparable to the $12.9 million reported a year ago. This flat trend reflects cost efficiencies resulting from the changes to our sales and marketing organization that occurred in the first quarter of this year.

Stock-based compensation expense was $1.7 million for the second quarter of this year compared to $1.3 million a year ago. Consistent with our increased revenue and moderated operating expense growth, we saw a decline in our net loss for the quarter. Our GAAP net loss was $12.4 million or $0.66 per share compared to GAAP net loss of $14.1 million or $0.78 per share in the second quarter of last year. During the quarter, we raised approximately $12.5 million net of expenses, through our ATM facility. We ended the quarter with $53 million of cash and investments.

Now, I'll turn to financial guidance, which we are updating in light of our new collaboration with Merck. We are raising our total revenue guidance to $60 million to $63 million for the year, which includes $4.5 million of collaboration revenue. Previously, we had projected revenue in the range of $58 million to $61 million, including $2.5 million of collaboration revenue.

Although we expect to receive approximately $4 million of cash this year from the new Merck collaboration, not all of that will be recognized as revenue in 2015. Just like with our Celgene collaboration, revenue recognition will lag the receipt of cash, and so we're raising our 2015 collaboration revenue guidance by just $2 million.

There is no change to our guidance for total product and service revenue. It remains at $55.5 million to $58.5 million, including $2 million of Prosigna revenue. Overall, for the full year, we continue to expect consumable revenue to be at or above the $100,000 per system we have generated historically.

In Q3, we expect a modest sequential increase in instrument revenue with a more meaningful step up in Q4, consistent with our historical seasonal patterns, and as the funnel for the new SPRINT system begins to mature. We continue to expect that most of the impact from SPRINT sales in the current year will occur in the fourth quarter.

For the full year, we continue to expect gross margin on product and service revenues to be in the range of 53% to 55%. And as a reminder, collaboration revenue is excluded from our calculation of gross margin. For operating expenses, we continue to expect $77 million to $81 million for the year, including approximately $6 million to $7 million of stock-based compensation expense.

Our anticipated GAAP operating loss for the year is now expected to be lower in the range of $41 million to $47 million. Previously, we had guided to a range of $43 million to $49 million. We continue to expect interest expense of approximately $4 million for the year, bringing our revised GAAP net loss guidance to $45 million to $51 million. We still expect capital expenditures of $4 million to $5 million, approximately half of which will 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. In summary, NanoString is at a key inflection point. We have delivered solid growth while achieving multiple critical milestones in rapid successions. Any one of these milestones alone would be a major event for the company. After achieving them in a short burst over just a few months, we believe we are emerging as a truly different company, poised not just to deliver growth quarter-after-quarter but year-after-year. We are proud of these recent achievements and optimistic about our future.

I would now like to open up the line for questions.

QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions] And our first question comes from the line of Steve Beuchaw with Morgan Stanley. Your line is now open.

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Q

Hi. Good afternoon and thanks for taking the question. My first question – well, actually I'll ask two. Both SPRINT. So I wonder if you guys have looked at the evolution of the funnel not just for SPRINT but for FLEX and MAX now that, that product has been on the market for several weeks, and made any attempt to assess whether the SPRINT launch have any – having any impact on the traction with FLEX and MAX? And then, I'll go ahead and ask my follow-up, because it's related. And the follow-up is also on SPRINT. Brad, you again made a comment that the launch of SPRINT can take the landscape of addressable labs to two times to three times what it was with just Gen 2 or MAX. Can you remind us how it is you get to that figure? What are the data points you're looking at? And thanks again for taking the questions guys.

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Thank, Steve. So the reaction to the new instrument line-up has been very positive. What it's done is it's effectively changed the nature of the dialog that our sales people are having in the field over the last three weeks.

From a dialog [ph] and wherein (52:32) the past, one of the first concerns of the customer would be whether they could afford our technology, to a dialog where, a conversation that's about which of our several instruments is the right one for the customer. And we do believe that with this new product line, with three different instruments targeted at three different segments, we have an expanded offering that will grow our addressable market. So in the first three weeks, we have not seen the availability of SPRINT have a major impact on traction for MAX and FLEX, it's early days. We are working hard to make SPRINT sales incremental to our normal customer sales in the past. And as a result, I think for Q3, we think, for unit placements low to mid-single digit units is a reasonable start in Q3, and we're going to go it from there.

Let me go to your next question then, why are we confident we're going to be able to grow into this larger addressable market? Before we set out to develop the SPRINT system, we commissioned and executed conjoined market research. And what that market research study attempted to do was understand the way that customers, researchers makes a trade-off between features like throughput, or number of genes that our system could look at, and cost and footprint; the major engineering input to our design process. And through that conjoined market research what we discovered was, there is a segment of individual researchers who we weren't really reaching with the traditional nCounter MAX and FLEX configurations who have lower throughput needs, approximately half of what a full lab would need and who really wanted a system that costs in the range of $150,000 or less.

And really it was for that segment that we built the SPRINT. And then, we quantified through our market research how many more customers were in that segment that we weren't yet reaching compared to the one we were, two times to three times as many researchers. So it's really on that basis that we have estimated that we'll increase our overall addressable number of placements to two times to three times what it is today with the addition of SPRINT.

Steve C. Beuchaw
Morgan Stanley & Co. LLC

Q

Okay. Thanks, Brad.

Operator: Thank you. Our next question comes from the line of Tycho Peterson with JPMorgan. Your line is now open.

Tejas R. Savant
JPMorgan Securities LLC

Q

Hey, guys. Can you hear me?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Just barely Tycho. Here we go.

Tejas R. Savant
JPMorgan Securities LLC

Q

This is actually Tejas on for Tycho, Brad. How are you? So my first question is actually on the consumable pull-through that you expect to see on SPRINT, and I know it's still very early, but just from a modeling perspective, when you speak about the $100,000 in pull through for nCounter, does that include the SPRINT ramp in the back half of the year as well, or is that independent of that number?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

It's including the SPRINT ramp in the back half of the year, Tejas. So with SPRINT placement just beginning with a few in Q3 and more in Q4, we do not expect SPRINT to contribute meaningfully to consumable pull through during the current year. Our experience when we place instruments is that, typically the first consumable order comes in the quarter subsequent to the instrument placement. So for instruments placed in Q3, we have our first orders in Q4, and for instruments placed in Q4, we have our first consumable order in – not until the New Year. So we don't expect consumable pull through in 2015 to be meaningfully impacted by the SPRINT launch. And in terms of [ph] long-term (29:41)...

Tejas R. Savant
JPMorgan Securities LLC

Q

Got it.

Robert Bradley Gray
President, Chief Executive Officer & Director

A

...you may be wondering, for modeling purposes, what we would say about the long-term pull through of SPRINT; it's early days still. Clearly, we're targeting a segment who by definition have fewer samples to process and less budget to spend than a core lab does. So we do expect it to be meaningfully less than a typical MAX or FLEX customer has been. But it's too early for us to provide specific quantitative guidance on that.

Tejas R. Savant
JPMorgan Securities LLC

Q

Got it. And then last quarter I know you've spoken about this lead generation program that you've put in place for driving SPRINT placements. Can you share with us the extend of, that you can in terms of touch points, how many of these are new to NanoString customers who couldn't potentially afford an nCounter? And how many of these are existing users who are potentially looking for a different use case?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Sure. So we've started preparing for the SPRINT launch late last year with a new lead generation program and the objective was to go back to customers who really haven't been able to afford an nCounter in the past or because they were individual researchers had never – who never really engaged with a company, because that was not the customer segment that we targeted.

So the lead generation and I'd say the initial funnel development is primarily focused on, a) customers who were we know had been interested in the past in an nCounter, who likes the technology, who likes the capabilities, but whose budgets were not sufficient for them to purchase. So we began reengaging with those customers again in the first half of this year.

And the second group was individual researchers who we had never really had a substantial coordinated outreach to in the past. And what we did was, through a substantial internal effort, we combed through the literature and cancer research and genomic research to look for individual researchers who are publishing papers and applying for grants that's focused on the kind of gene expression work that has been the core use of nCounter in the past, and we began to target marketing at those individuals, even in advance of having announced the availability of SPRINT.

And so what we're doing today is converting that initial engagement into more of a sales dialog. And the typical sales cycle for capital equipment in this price range is between three months and six months, so it will take some time to convert that interest into unit placements, but we think we've done a very good job of laying the groundwork.

Tejas R. Savant
JPMorgan Securities LLC

Q

Got it. And then just one final one here from me on Prosigna. Given that you have the guidelines piece of this now mostly in place, are you slightly more optimistic of your Prosigna contributions in the back half of this year? And has there been any change in the tenor of your conversations with peers post NCCN inclusion?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

So – I'd say absolutely – I'd say the risk in the back half of our guidance has been reduced substantially by some of the progress in the first half of the year. That being said, it's still very early days and things like MolDx guidelines and NCCN guidelines are mostly going to have a 2016 impact. The implementation of the MolDx policy, for instance, could take – could still take months and therefore not be completed and effective until very late in the year. So that doesn't have a meaningful – necessarily an impact in 2015. And NCCN guidelines really are allowing us to kind of go back and reengage with payors, give them an update about the acknowledge of the prognostic power of Prosigna. And again, those will take – it will take time before those dialogs yield revised medical policies, and then those revised medical policies will take time before they yield kit sales. So all of these dynamics are all very positive, they're in line with our expectations overall, but they are really setting the stage for growth in 2016 rather than impacting the second half of 2015.

Tejas R. Savant
JPMorgan Securities LLC

Q

Got it. Thanks, Brad.

Operator: Thank you. Our next question comes from the line of Jeff Elliott with Robert W. Baird. Your line is now open.

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

Q

Yeah. Thanks for the question and congrats on a really successful second quarter. I guess my first question is really a follow-up to the last question, is really – following the NCCN guideline update in your conversations with payors, what's your sense – did the payors get the wording in that guideline update that they needed in order to move forward?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

I think it's early days still to know the answer to that Jeff. I think the guideline update does provide some payors what they were looking for, which is an acknowledgement by the experts in the field who've reviewed the literature that our test does what it says it does, which is to identify low-risk patients who may be spared the need for adjuvant chemotherapy, because without chemotherapy their outcomes are going to be good. So definitely, I would expect there'll be a subset of payers for whom that is sufficient. I am sure there will be other payers who are looking for even stronger wording than we've got in this round of guidelines. And the good thing about the guidelines is that they are updated from time-to-time and we have continued to generate strong evidence since the submission to the NCCN guidelines in June of 2014 that we hope will improve our position over time.

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

Q

Okay. And then, I think during the prepared comments, you mentioned in the collaboration line there was another smaller research collaboration that contributed revenue. Can you shed any more color on what that is. Is that on a biopharma collaboration, or what is that?

James Algot Johnson
Chief Financial Officer

A

Yeah. Hey, Jeff. This is Jim. It's basically like a pilot study. It's related to a Phase 2 study where they're using our assay to evaluate whether it has the ability to help select patients for a subsequent study which would be a Phase 3 study. And in that instance it would, if successful, it would transition most likely to a companion diagnostic collaboration.

Robert Bradley Gray
President, Chief Executive Officer & Director

A

So it's a research, a pilot study with a biopharmaceutical company, to be clear.

James Algot Johnson
Chief Financial Officer

A

Right.

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

Q

Okay. So your guidance doesn't assume that that kind of flips over to a larger collaboration this year, does it?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

No.

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

Q

Okay. Great, thanks guys.

Operator: Thank you. Our next question comes from the line of Dan Leonard with Leerink Partners. Your line is now open.

Michael A. Sarcone
Leerink Partners LLC

Q

Hey guys. This is Mike Sarcone filling in for Dan Leonard. Can you elaborate on the feedback you're receiving about your RNA:Protein assay from the five customers that are currently using it?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Sure. So the question was what have been the feedback to the RNA:Protein assay so far. I think, the first feedback have been excitement. A number of biopharmaceutical companies and researchers were very intrigued by the possibility to measure both of these [indiscernible] (37:28) in a single assay. They were so intrigued that they were willing to do something which is very unusual, which is pay to participate in a product access program for a product that's effectively in beta testing, and they all paid a material sum of money for access to 96 samples worth of our assay. So far, these groups are in various stages of running their samples. We've been through training and validation with most of them. And the first wave of data is coming back. So I'd say it's a little early for us to share with you some of the results they're seeing, but I think the feedback on the concept and the experience has been positive so far.

Michael A. Sarcone
Leerink Partners LLC

Q

Great. Thank you.

Operator: Thank you. [Operator Instructions] And our next question comes from the line of Dane Leone with BTIG. Your line is now open.

Dane Leone
BTIG LLC

Q

Hi. Thank you. Congrats on the quarter, guys.

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Thanks, Dane.

Dane Leone
BTIG LLC

Q

So, in terms of the dimension, the MolDx covering North Carolina where LabCorp runs all their Prosigna testing. Just to kind of couch expectations for the out years or 2016-2017, when we think about the Prosigna program, there's kind of two variables. One is a hurdle for people to be allowed to use it, i.e., insurance coverage; and another one is that the motivation to use it. You made progress on both fronts. But I guess the question is, to really see a ramp in utilization, what do you feel to be the hurdle? If we go back in history of third-party, complex test sales, you really do need very clear pricing for the test. So I guess one question would be, when do you think you'll get clarity in terms of pricing specific reimbursement for the test itself?

The second is, where do you think you're at in the timeline of convincing people to you use it?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Yeah. So, I agree with the kind of framework that you described Dane that there are two issues; reimbursement being a gating item and then demand being, of course, important for generating prescriptions of the test. Really before you get through the reimbursement hurdles, the kit manufacturers, it's nearly impossible to generate demand. So we think the MolDx decision for Medicare, which is the largest group of patients out there in our intended use population will be substantially improved with the MolDx decision. So to kind of quantify that, when we look at our intended use population today, we think that post-MolDx, if you think of MolDx as effectively providing national coverage decision for Medicare, something like 65% of our intended use population will be covered. And that will be meaningfully increased. You could say to a physician, the majority of your patients will have coverage which is much better than it is today.

And in terms of the pricing that is coming with the MolDx, we would expect pricing to be established around the same time that the coverage policy would become effective. We have provided information to MolDx to help support them in that effort of doing the gap-fill. And we'd expect to probably have clarity on pricing from the minute that the policy is effective. So we won't expect a pricing overhang, or a pricing uncertainty, I should say.

On demand, I think what we hope and expect is that once reimbursement is available, the commercial organizations, the laboratories that are providing the test, like LabCorp, like Quest, like Genoptix, like [indiscernible] (41:54) that they will be motivated in a way they aren't today to promote the use of Prosigna to their existing customers. And when you think about those national labs, they are very – they touch a large number of patients and a large number of physicians, so they do have, we believe, the capability to drive market share once they're properly motivated. So, we see reimbursement as the key gating event to begin generating demand, but it'll take time, as you point out and that will be a dynamic that we'll talk more about as we get closer into giving 2016 guidance.

Dane Leone
BTIG LLC

Q

And so, in terms of the model, who will be doing the direct education to clinical oncologists in terms of ordering the test...?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

NanoString has a modestly sized commercial organization that can, in a very focused way, provide that education and then we will be relying on the laboratory test providers to help us with that, and that ought to be from both the commercial labs, and of course, the cancer centers and hospital systems who have also adopted the test.

Dane Leone
BTIG LLC

Q

Okay. Okay, thank you. That's very helpful. In terms of the collaboration revenues, can you just help us with the pacing of it? So as a step function to hit that for – I think you guided to about $4 million for the year now. Is the step function for that in the third quarter or the fourth quarter versus what you just printed obviously?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

So yeah, the guidance was $4.5 million for the year. I think that it's hard to predict the breakdown between Q3 and Q4. It's entirely tied to the amount of work that's done in each quarter. And so I think it's safe to say that with the new Merck collaboration, it's still ramping and I would say it's reasonable to assume more of that revenue in the fourth quarter than in third quarter for that reason, but it's a real wonky calculation that you have to do for accounting purposes. So, we tend to focus more on big picture, which is $4 million of cash. And it may vary from quarter-to-quarter in terms of how much is recorded as revenue, but it's very difficult to make definitive predictions about it.

Dane Leone
BTIG LLC

Q

Okay. So best guess is that we should be modeling a little bit and bulk of it probably in the fourth quarter and maybe a modest step up into the third quarter?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Yeah. I can't make any definitive guidance, but I think there's logic that would say more work being done in fourth quarter than in third quarter.

Dane Leone
BTIG LLC

Q

Okay. And then on the outlook for the biopharma [ph] CRA (45:16) revenue, are we looking for kind of the normal sequential ramp in the back half Q-on-Q. Do you think there's any additional catch up from the weak 1Q that we would see in the back half, or are we kind of caught up there?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Yeah. I think we believe we're more or less caught up at this stage biopharma consumable revenue contribution in the second quarter was about 30% of our total Life Sciences consumable revenue, that's virtually identical to what it had been in the second quarter of 2014. So I think we're back towards being normalized. And I don't think I have any specific guidance to provide about the sequential growth through the course of the year. Other than to point out that last year was extraordinary. You may recall that in the fourth quarter of last year, biopharma contributed 50% or more of our overall consumable revenue, and I do not think that we can guide to that pattern, [ph] it won't (46:32) repeat itself every year. So, I think, the big picture here is overall we expect consumable revenue to be at or above our $100,000 annualized pull-through benchmark through both Q3 and Q4.

Dane Leone
BTIG LLC

Q

Okay. And then, I guess the last one from me. So the instrument guidance that you gave is more so weighted, I guess, for the fourth quarter versus the third quarter as you build the funnel, with a couple of systems with FLEX, but presumably you get a bit more placements in the fourth quarter?

Robert Bradley Gray
President, Chief Executive Officer & Director

A

Yes, the fourth quarter is always our strongest instrument quarter for reasons that the way the end of year budget flush tends to work on the capital equipment budget side. So even absent the SPRINT launch, we expect a strong fourth quarter, and of course, the dynamics of the SPRINT launch are that the funnel is building, and we would hope to see sequential growth from Q3 to Q4

Dane Leone
BTIG LLC

Q

Okay. Excellent. Thank you very much.

Operator: Thank you. And I'm showing no further questions at this time. I would like to turn the conference back over to Mr. Brad Gray for any closing comments.

Robert Bradley Gray
President, Chief Executive Officer & Director

Thank you all for joining our call today. Before we finish, I'd like to invite you to join our first ever Investor Day which will be held in New York on the morning of Friday, September 11th. Please contact us for details and I look forward to seeing many of you there.

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