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NSTG - Q3 2014 NanoString Technologies Inc Earnings Call

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the NanoString Technologies' 2014 Third 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) I would now like to remind everyone that the call is being recorded.

I would now like to turn the call over to your host, Ms. Lynn Pieper with Westwicke Partners. Ms. Pieper, you may begin.

Lynn Pieper - *Westwicke Partners - IR*

Thank you. On the call today with me is Brad Gray, NanoString President and CEO; and Jim Johnson, CFO.

Earlier today NanoString released financial results for the third quarter ended September 30, 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 and related factors, interactions with regulators and third-party payers and any related decisions, and the development and status of additional 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 publicly update any forward-looking statements.

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

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Thanks, Lynn. Good afternoon, and thank you for joining us on our Q3 call. We are pleased to report a strong third quarter results with important progress across all three dimensions of our business; Life Sciences, Companion Diagnostics, and Prosigna.

During the third quarter, we sustained our momentum to $12.3 million, a 47% increase over last year, primarily driven by strength in instrument placements and solid consumable pull-through. In addition, we delivered substantial and accelerating progress and our companion diagnostic collaboration with Celgene.

Finally, we continue to advance the launch of our Prosigna breast cancer assay, achieving our first US reimbursement milestone.

On the call today, I'll review progress in our three core areas of focus. Jim Johnson will summarize our financial performance and guidance, and then we will invite your questions.

I'll start with our base business; instruments and consumables, which continues to be the largest source of revenue growth. During the third quarter, we added both research and clinical lab customers. And as of the end of the quarter, we had a worldwide installed base of well over 230 nCounter analysis systems.

Our customers have now used nCounter technology to generate over 560 peer reviewed publications and have averaged one new publication every weekday over the past six months. Instrument revenue during the third quarter was $4.5 million, up 27% compared to the prior year. Oncology was once again the most common motivation for new instrument placements accounted for nearly 70% of nCounter systems sold in the quarter.

The popularity of the dual-use FLEX configuration also continued in Q3, accounting for approximately half of our new instrument placements and validating our strategy of combining cancer research and diagnostics on a single platform.

Since its launch about a year ago, the FLEX system is in popular with cancer centers, commercial clinical labs and CROs alike. In addition, we're continuing to penetrate international markets with approximately two-thirds of the new systems sold in Q3 going outside North America.

Consumable revenues were again strong in the third quarter with annualized pull-through well above $100,000 per system, resulting in record consumable revenue of $6 million, an increase of 37% over the prior year.

Continuing the trend we saw last quarter, demand from academic customers was high, which we believe as a result of growing recognition of nCounter as a critical platform for cancer research. Our biopharma customers once again accounted for a disproportionate fraction of our consumable sales, contributing approximately 30% of consumables from roughly 20% of our installed base.

Our consumable growth was also driven in part by the success of two recent PanCancer Panel launches, which together illustrated our distinctive capabilities in the field of cancer biology.

As we described during our last call, our new PanCancer Pathways Panel was the most successful new gene expression panel launched in our history. The panel offers researchers the simple and robust assay to investigate biology across 770 genes in all major cancer pathways.

During the third quarter, interest in the panel continue to grow as academic researchers and biopharma companies incorporated into their biomarker discovery efforts. In September, we launched our PanCancer Immune Profiling Panel, a unique offering target towards the dynamic fields on immunooncology. The Immune Profiling Panel complement our Pathways Panel and brings the new dimension of gene expression information to a field that it has historically been focused on protein-based and analytical methods, such as Immunohistochemistry. It promotes a better understanding of cancer by allowing researchers to bridge the gap between the biology that drives tumor growth and the immune response that attempts to control it.

This new panel can be applied to all cancer types, potentially accelerating the discovery and development of new therapies and predictive biomarker signatures. And the week since this launch, the new panel was proven popular with researchers and biopharma companies and we are optimistic about the commercial opportunity.

Also contributing to our consumable growth is the increasing interest in our elements reagents, which offer translational research labs, a clear path for moving their discoveries into a clinical setting. Interest in our elements reagents is growing rapidly with elements revenue up 85% sequentially during the third quarter.

Elements reagents along with our Prosigna breast cancer assay are also important to the business case for clinical labs looking to acquire an nCounter system. So far this year, interest in elements reagent has been a significant factor in the sale of 12 systems, including 5 systems during the third quarter.

In support of elements commercialization, we've recently announced the collaboration with the Brigham and Women's Hospital in Boston to accelerate translation of genomic discoveries in the clinical cancer diagnostics. Using elements reagents, clinical assays will be developed to detect gene expression, copy number variation and fusions from a diverse range of tumor samples. We are excited to partner with the Brigham to accelerate the process of taking innovative assays that last mile from late stage translational research to clinical validation and use.

Finally, we remain on track for the launch of our next generation nCounter system in the first half of 2015. As a reminder, this product will be a single instrument with a smaller footprint than our current system and will be targeted at the more price sensitive research market. This system will run the same chemistry with our current system that are lower throughput. We are excited about the market opportunity for this product and look forward to its introduction next year.

Moving now to our second area of focus, our Companion Diagnostics program made substantial progress during the third quarter. To date, the stellar piece of our companion diagnostic strategy is our collaboration with Celgene, under which we are supporting the development of REVLIMID for the treatment of diffuse large B-cell lymphoma or DLBCL.

Our Celgene collaboration is progressing even more smoothly than we had expected and I'm extremely pleased with the great partnership with Celgene and proud of the performance of our diagnostic development team. Since initiating the collaboration in March, we are focused on locking down assay procedures, subtyping algorithms and GMP manufacturing processes, as well as agreeing other regulatory path with the FDA.

So far the technical work is tracking according to schedule. Our interactions with the FDA is going even better than initially planned, leading to the acceleration of several milestones. In total, we achieved $5 million in milestones, which contributed to $1.1 million in collaboration revenues during the quarter.

Looking ahead, we expect the REVLIMID Phase III study to begin enrolment by the first quarter of 2015. Patients will be enrolled based on their DLBCL subtype as assessed by our in vitro diagnostic assay. And a result of this study, if successful, will be used to support our PMA filing in the US, several years in the future.

In parallel, we are engaging with many other biopharma companies regarding how we might collaborate and support their drug development initiatives. These discussions cover areas including other DLBCL therapies, the targeting of breast cancer therapies using the molecular subtypes provided by Prosigna and the development of companion diagnostics based on new discoveries made by our biopharma and academic customers using nCounter technology.

We are increasingly confident that over time companion diagnostic partnerships will become a significant driver of growth and cash flow for our business.

Turning now to our third core area of focus; during the third quarter, we made considerable progress in the launch of the Prosigna breast cancer assay, our first in vitro diagnostic product.

Prosigna sales in Q3 were $272,000, up from $181,000 in the second quarter. During the third quarter, seven additional labs took steps to become future Prosigna sites, bringing the worldwide total to 30 planned laboratory sites across 12 countries. Most of the Prosigna revenue growth in Q3 was from the US market, where we currently have 6 labs actively offering Prosigna testing services and then other 7 preparing for launch.

We are particularly pleased with the enthusiasm for Prosigna expressed by cancer centers and large hospitals. Since our last call, two additional NCI designated comprehensive cancer care centers have acquired nCounter systems with the intent of launching Prosigna testing. City of Hope in Los Angeles and the University of Arizona Cancer Center. Cancer reimbursement remains a top priority with a dedicated market access team focused on generating positive coverage decisions. This team made important steps forward in Q3.

In August, United Healthcare, the nation's largest private insurer, entered into a contract with LabCorp to provide coverage for Prosigna. In September, we had another important event at California's Medicaid Group, Medi-Cal and formed as that they will be covering Prosigna, representing close to 6 million covered lives.

And just last week, Provident Health Plan indicated that they will be covering Prosigna as well. Total US coverage for Prosigna as a result of this initial wave of positive coverage decisions is now more than 45 million lives or approximately 20% of the US patients indicated for Prosigna.

And we are pleased with this initial wave of positive coverage decisions. We still have a long way to go until every eligible US breast cancer patient has access to Prosigna. With the 2014 NCCN guideline update still forthcoming we do not, at this point, expect a Medicare coverage decision under Palmetto's MolDx program before the first half of 2015.

We expect Prosigna growth to remain modest until Medicare and additional reimbursement executed.

Outside the United States, we continue to lay the foundation for broad, long-term adoption of Prosigna. During the quarter, we met regulatory requirements to market Prosigna in Australia, New Zealand and Hong Kong. Four additional centers outside the US now plan to begin offering Prosigna testing services, including two labs in Australia. This brings the number of labs outside the US planning to provide Prosigna testing to a total of 17; of which 7 are currently providing testing.

Also on the international work front, we completed enrolment in our German decision impact study and expect that results will be presented sometime next year.

During the current quarter, we are initiating a decision impact study in France involving eight institutions. In December, the result of our Spanish decision impact study will be presented at the San Antonio Breast Cancer Symposium, along with several other studies on Prosigna and PAM50.

Finally, we continue to strengthen our already compelling body of clinical evidence for Prosigna. In October, the Journal of Clinical Oncology published an analysis of data from over 2,100 patients showing that the risk of recurrence score generated by Prosigna predicts the risk of late distant recurrence after five years of endocrine therapy. The results show that Prosigna can identify a patient population where the risk of late distant recurrence is so low that it maybe be spared the prolonged endocrine therapy. These results in combination with previously published clinical studies demonstrate the potential for Prosigna to inform both the use of chemotherapy and the use of extended endocrine therapy based on a single risk score.

Overall, we are pleased with our momentum on multiple fronts and optimistic about our continued growth. I would now like to turn the call over to Jim Johnson for a review of our financial results and financial guidance.

Jim Johnson - *NanoString Technologies, Inc. - CFO*

Thanks, Brad. Financially, our performance for the quarter was once again strong. Total revenue was $12.3 million, up 47% over the $8.4 million recorded for the third quarter of last year. Instrument revenue for the quarter was up by 27% compared to Q3 2013 and consumable revenue came in at a record $6 million, up 37% from $4.4 million from the third quarter of last year.

The growth in consumables was broad-based across all major geographies and is particularly strong among our academic customers. Prosigna breast care revenue was modestly higher as anticipated at $270,000 for the quarter. We recorded $1.1 million of revenue from the Celgene collaboration in the quarter. In recall with our accounting method, we only recognize a fraction of the cash that has received are contractually due from Celgene.

Contractually we achieved $5 million at milestones in the third quarter, which were shown as accounts receivable at September 30th and are subsequently been received in October. This brings the total cash we see them as a collaboration to date to nearly $11 million, $1.7 million recorded as revenue since inception. The remaining $9 million that shown as deferred revenue on our balance sheet as of September 30, which will bring into our P&L as revenue as we complete our work on the collaborative project over the next several years.

Gross margin for the quarter was 53% compared to 55% in the third quarter of last year. As a reminder, we calculate gross margin based on product and service revenues only and exclude collaboration revenue from the calculation. There are several reasons for the decrease in gross margin. Last year, our gross margin benefited from several very large sales to biopharma customers, which has a reasonably low per unit costs as well as certain favorable overhead costs variances during the period. This year we had a much higher proportion of our sales go through distributors, for which our margins are lower.

R&D expense was $6 million compared to $3.8 million in the third 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 $12.5 million for the quarter, up from $8 million a year ago but flat sequentially. The increase versus the prior year reflects Prosigna launch costs, including the establishment of our oncology sales force, investments to build our lab-based sales channel and increased administrative costs to address the company's rapid growth.

Stock-based compensation expense contributed significantly to the overall growth in operating expenses. In total, the $1.3 million for the third quarter of 2014 compared to $280,000 a year earlier. Perpetually this include the schedule of non-GAAP financial information which shows our operating results with all pre-IPO preferred stock had been converted to common stock.

On a non-GAAP basis, our net loss for the quarter was $9.8 million or $0.54 per share compared to $6.4 million or $0.44 per share in the third quarter of 2013. You should refer to that schedule for a detailed reconciliation of GAAP and non-GAAP results. We ended the third quarter with $68 million of cash and investments.

So now turning to our updated financial guidance for 2014. We're now expecting total revenue for the year of $46 million to $48 million, which represents growth of 46% to 53% over 2013. In modeling for the fourth quarter of the year, there are several factors that should be considered. With instruments and consumables, we expect to see our normal seasonal pattern and relatively stronger performance in the fourth quarter as compared to the third quarter driven primarily by an increased instrument demand.

For Prosigna, the longer than anticipated timeline to achieve Medicare reimbursement and the Prosigna revenue in the fourth quarter is again likely to be modest. We don't expect to see a significant inflection from this trend, until such time as we begin to see a positive impact from Medicare coverage.

Regarding the Celgene collaboration, if all goes according to plan, we expect to achieve an additional $1 million milestone in the fourth quarter, after which the remaining milestones will be tied to regulatory approvals several years in the future. With the faster than anticipated progress this year, we now expect collaboration revenue for the year to be $3 million to $3.5 million.

We've also narrowed our expected range for gross margin on product and service revenues to 53% to 54%. For operating expenses, we've narrowed the range to $71 million to $73 million for the year, including approximately $5 million in stock-based compensation expense. Our operating loss for the year is now expected to be in the range of $45 million to $49 million.

We continue to expect interest expense to be approximately $4 million and capital expenditures are now expected to be between $4 million and $5 million for the year. With the $5 million received from Celgene and the $10 million of additional borrowing under our term loan agreement, both of which occurred in October, we expect in end of the year with approximately $70 million of cash and investments.

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

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Thanks, Jim. In summary, we sustained our momentum during the third quarter demonstrating progress in all three dimensions of our business. Our fundamentals are strong with a growing installed base around the globe and solid consumable pull-through driven by our compelling offerings in the field of oncology.

With our first major reimbursement wins under our belt, the commercial success of Prosigna is a question of when, not yet.

Finally, our first companion diagnostic collaboration is off to a great start, showcasing our capabilities to the biopharma community and setting the stage for more such partnerships in the future. We look forward to updating you on our progress during future calls. I'd now like to open the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Tycho Peterson with J.P.Morgan.

Tejas Savant - *J.P.Morgan - Analyst*

Hey, guys. This is Tejas in for Tycho. Just to kick things off here. I mean in terms of nCounter placements in the quarter, did you see a sequential step down? I mean it looks like you had about 14 to 15 as a quarterly run below in the 9 unit to 10 unit range, is that right?

Jim Johnson - *NanoString Technologies, Inc. - CFO*

Hi, this is Jim. I think there is a little bit of confusion, perhaps; we don't really provide precise installed base numbers. So you can't really do the math looking at one quarter disclosure from the next. On our August conference call, we said we had approximately 220. On September 30th, we've said we had well over 230. So, you can't conclude from our disclosure the number of systems agreed during the quarter. But if you look at our instrument revenue during the quarter, you can see that the sales of systems are much higher.

Tejas Savant - *J.P.Morgan - Analyst*

Right. And any comments on throughput, is that sort of trending up as well on a sequential basis?

Jim Johnson - *NanoString Technologies, Inc. - CFO*

Consumable pull-through has been strong in each of the last two quarters. In particular, we've seen a nice resurgence in academic interest in consumables and so there is strong performance driven by that customer set. And then our panel plots have been extremely popular as we described during the call.

Tejas Savant - *J.P.Morgan - Analyst*

Okay. Yeah, go on.

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

I just want to say, one other thing to add is, the customer activity in the summer months during the third quarter is generally a little bit slower as well. So that has more -- there are some early bit of seasonal impact.

Tejas Savant - *J.P.Morgan - Analyst*

Got it. Now turning to Prosigna, I mean, how should we think about inclusion in the preliminary CMS CLFS schedule that was out in October, does that have any impacts on NCCN guideline inclusions or clinical coverage?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

No, these are independent of that. So the CMS royalty you've referenced does not impact inclusion in NCCN guidelines and we don't expect it to impact the MolDx decision. The NCCN guidelines are typically updated in the fourth quarter of every year. So we would expect that those guideline updates are forthcoming and we expect those to be an important factors in the MolDx discussions, but we expect that conversation and the digestion of any new guidelines will take some time. So we wouldn't expect MolDx decision until the first half of next year, but we don't expect it to be impacted by some of the CMS activities you referenced.

Tejas Savant - *J.P.Morgan - Analyst*

I see. And then the two max which you had indicated on the last call, have they begun to cover the test now?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Yes. I believe we have had -- our customers have had claims processed in those regions.

Tejas Savant - *J.P.Morgan - Analyst*

Okay. Great. Thank you.

Operator

Dan Leonard, Leerink Swann.

Justin Bowers - *Leerink Swann - Analyst*

Hi. Good afternoon, guys. This is Justin on for Dan. Congrats on some of the commercial progress with Prosigna. Just curious on the OUS offerings, what are the payment, kind of the paradynamics with the labs that are offering the test now, and then with the four new plans you're going add as well?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Sure.

Justin Bowers - *Leerink Swann - Analyst*

I'm sorry.

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Yeah. I'll start with the United States. In general, governments are the payers, are the primary payers who cover the needs of the breast cancer patients and to a lesser extent there is private pay patients. So in most of the countries where we place instruments outside the United States, our strategy is to place instruments in leading academic centers where the physician, scientists there can advocate for reimbursement with our government, while beginning to test private pay patients.

We have had some early reimbursement wins in -- from government payers and particularly in Spain, where both the region around Madrid and the region around Barcelona have agreed to cover Prosigna. In addition, we're running a series of decision impact studies in European countries that are designed to really demonstrate to the government that the use of Prosigna has the potential to improve decision-making in breast cancer, ultimately saving the money in the long-run. So that's our current strategy in ex-US.

Justin Bowers - *Leerink Swann - Analyst*

Got it. Thanks. And then on -- you mentioned the Spanish study, you're going to present in December at San Antonio. And I think you mentioned one or two more, could you just remind us of those and timing?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Sure. We have three -- according to the decision impact study, we will really talk about three decision impact studies. The first was executed in Spain and it completed enrollment over this year. That would be presented in December at the San Antonio Breast Cancer Symposium. Second in Germany, it has just completed enrollment and we would expect that to present data -- the data from that study would be presented in 2015. And finally, we are just initiating a decision impact study in France and we haven't specified the timelines for that study.

Justin Bowers - *Leerink Swann - Analyst*

Thank you. And just one more quick one on the next gen nCounter, where are you guys in that process?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Sure. Well, we remain on track for a launch in the first half of 2015. Developments is ongoing. We have continued to work on the manufacturing prototypes that we received over the summer and we're focused on -- we have a team focused on optimizing the software and putting those instruments through their phases. Then once the software is optimized, we had moved into the verification and validation phases.

Justin Bowers - *Leerink Swann - Analyst*

And any target for initiating early access or not that far ahead yet?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Well, no. I always said the data is that, we expect that. It will be commercially launched in the first half of next year.

Justin Bowers - *Leerink Swann - Analyst*

Okay. Thanks a lot.

Operator

(Operator Instructions) Jeff Elliott, Robert W. Baird.

Jeff Elliott - *Robert W. Baird - Analyst*

Hi, guys. Thanks for the questions. First one is on the insurance coverage you mentioned in the press release. I guess, can you walk us through how you get to that total number, you mentioned in the total number of percent of lives covered?

Jim Johnson - *NanoString Technologies, Inc. - CFO*

Well, so there are two different numbers mentioned there, Jeff. And one of each will walk you through than the other. The 45 million lives covered is the simply the sum of the lives covered under the private insurance plans and the government insurance plans that we've announced today. So 30 something million lives from the UnitedHealthcare, 8 million lives from two Medicare carriers that we announced in the last call, 6 million lives from the Medi-Cal and then smattering of these smaller plans brings us to approximately 45 million in total covered lives. But worth remembering that the indicated population for Prosigna is postmenopausal breast cancer patients and those patients are distributed evenly across all health plans. So we have a separate model that estimates based on the age of various populations and plans. The coverage of that indicated these population and with just 45 million lives we've achieved approximately 20% of coverage.

Jeff Elliott - *Robert W. Baird - Analyst*

Got it. Okay. That's helpful. And sticking with Prosigna here, I guess you look at some of the investments you've made so far and then obviously in light of that the ramp has been a little bit slower than, at least, the sell side had previously assumed. How do you think about continued investment in Prosigna near-term kind of given some of the uncertainties around uptake in ultimate reimbursement. I guess -- specifically I'm thinking of this sales force you brought out early this year, I mean how do you think about those sort of investment in light of the ramp kind of where we're at?

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

We have hired -- as a reminder for everybody, our market access team is about 5 individuals in the US and 15 sales reps to begin the process of educating physicians around the country. And that is, for us the [right scale] obviously reimbursement is the primary gating factor for any physician prescribing Prosigna. And so, the market access team is very hard at work and very focused on that.

With 15 sales reps around the country, what we're able to do is begin educating physicians about Prosigna, driving trial usage in those -- in that fraction of the market that is covered today, especially the United Healthcare covered patients who could have testing performed at lab 4, and then partnering between our oncology sales force and our instrument sales reps to placed instruments in these leading cancer centers in large hospitals around the country to build an install base in anticipation of future reimbursement.

Jeff Elliott - *Robert W. Baird - Analyst*

Okay. Thank you.

Operator

Thank you. I'm not showing any further questions at this time.

Brad Gray - *NanoString Technologies, Inc. - President & CEO*

Well, thank you all for your interest in NanoString Technologies and for joining our Q3 call. We look forward to continuing to update you in some of our future Investor Meetings. 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 great day.
