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NSTG - Q2 2014 NanoString Technologies Inc Earnings Call

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the NanoString 2014 second quarter financial results conference call.

(Operator Instructions)

As a reminder, this conference call is being recorded.

I would now like to turn the conference over to your host, Mr. Jim DeNike, Senior Director of Corporate Communications and Investor Relations. Mr. DeNike, you may begin.

Jim DeNike - *NanoString Technologies, Inc. - Senior Director, Corporate Communications and Investor Relations*

Thank you, Brigitte. I'm delighted to have recently joined the NanoString team and look forward to working with our analysts, investors and stockholders.

On the call with me today is Brad Gray, President and CEO, and Jim Johnson, our CFO.

Earlier today we released financial results for the second quarter ended June 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 statement.

So as I turn things over to Brad I should mention that he is fighting the stomach flu, and thank you in advance for your understanding during the rest of the call. So, Brad, if you're ready?

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

Thanks, Jim. Even though I'm feeling pretty rough today, reporting our solid Q2 results was a great motivation to get me up and out of bed. Good afternoon, and thank you for joining us on our Q2 call.

We're pleased to report strong second quarter results, with important progress across all aspects of our business. We sustained our recent momentum with a third straight quarter of greater than 50% year-on-year revenue growth, delivering a record revenue of $10.9 million. We entered a companion diagnostics collaboration with Celgene, providing our first foray into what we believe is an exciting area of growth. Finally, we continue to make important progress in the ongoing launch of our Prosigna breast cancer assay.

On the call today I will review our continued execution in each of these core areas of focus. Jim Johnson will summarize our financial performance and guidance, and then we will invite your questions.

Our first core area of focus is instruments and consumables, which have been the primary drivers of our recent revenue growth. During the second quarter we continued to add both research and clinical lab customers and now have a worldwide installed base of approximately 220 nCounter Analysis Systems. During the same period our customers used nCounter to generate peer-reviewed research articles at a pace of approximately five papers per week, recently reaching the milestone of 500 peer-reviewed publications.

Total revenues generated from instrument sales during the second quarter were $3.8 million, up 49% compared to the prior year, and we maintained a number of positive trends consistent with our prior several quarters.

First, penetration of international markets continued, with approximately half of the new systems being placed outside of North America. Second, oncology continued to be a primary driver of nCounter instrument sales, accounting for approximately 80% of new system placements. Third, the popularity of the dual-use FLEX configuration of our nCounter Dx Analysis System continued, as approximately 50% of our Q2 instrument placements were for this configuration, validating our strategy of combining cancer research and diagnostics on a single platform.

In an encouraging new development during the second quarter, a record number of our customers purchased additional nCounter prep stations. Customer feedback indicates that the primary motivation for having an nCounter system with two prep stations is increased throughput for larger projects. Therefore, we believe that this could be a positive leading indicator of future growth in consumable sales.

The second quarter was very strong for consumables, with annualized pull-through well above $100,000 per system, resulting in record consumable revenue of $5.9 million, an increase of 36% over the prior year. Consumable sales to academic customers surged during the second quarter, driven in part by coordinated purchases from nCounter users collaborating across multiple laboratories. Our biopharma customers continued to account for a disproportionate fraction of our consumable sales, contributing approximately 30% during Q2.

Our new PanCancer Pathways Panel was launched in April and made a meaningful contribution to consumable growth during the quarter. It has been the most successful new gene expression panel launch in our history. This panel offers researchers a simple and robust assay to investigate biology across 770 different genes in all major cancer pathways.

More recently, we've achieved two important milestones in our continued expansion into clinical laboratories via our nCounter Elements reagents.

First, in July, the Center for Personalized Medicine at Roswell Park Cancer Institute announced approval by the New York State Department of Health of its OmniSeq Target assay. This assay uses our technology to detect copy number variations in cancer and is the first US laboratory-developed test to incorporate nCounter Elements. We will participate in the commercialization of this assay both through sales of Elements reagents and through commercial use fees for those reagents.

Second, in response to growing customer interest in using Elements for detecting cancer gene fusions, we've introduced an enhanced that allows us to provide highly automated and specific alternatives to fluorescent in situ hybridization, or FISH-based assays, which we believe represent a market today of approximately $200 million. Our new universal junction probe design is based on technology [that was] licensed from Harvard University and was launched under an early access program at the AACC meeting last week.

Overall, we remain optimistic about the potential for our nCounter Elements chemistry, Prosigna breast cancer assay and FLEX systems to penetrate the clinical laboratory market.

We continue to invest in innovative new products and applications, as well. We have been receiving enthusiastic customer interest in the potential use of our nCounter technology in protein expression, which was described in a January publication in the journal Science Translational Medicine. We are currently engaging in early access research collaborations with a select group of leading companies on antibody manufacturing, diagnostics and biopharmaceuticals to refine the techniques described in the original paper and demonstrate the power of the platform before potentially making a protein application more broadly available in 2015.

Development of our next-generation nCounter system, which will be targeted at the more price-sensitive research market, is progressing well. We have received our first batch of manufacturing prototypes and are currently optimizing the software. So far we like the performance that we see.

Following a recent review of the development timelines and seasonal dynamics, we have decided to target the new launch of the new system for the first half of 2015. This timing allows us to put the new system through the appropriate testing while avoiding potential disruption through a mid-quarter launch.

Meanwhile, commitments to our nCounter technology from leading cancer researchers are driving our strong instrument and consumable revenue growth today, and we believe that this will create a steady stream of potential future diagnostic products. Our research customers have already discovered and published over 25 unique oncology gene signatures, several of which have the potential to sort patients by tumor subtype and thereby match them to drugs.

This leads me to our second core area of focus and an important new avenue for our growth, companion diagnostics. In June we announced that we had entered into a companion diagnostics collaboration with Celgene that perfectly illustrates the value of this new market. NanoString research customers associated with the Lymphoma and Leukemia Molecular Profiling Project, known in the field as the LLMPP, published a paper in the journal Blood describing the development and validation of a 20-gene expression signature that subtypes diffuse large B-cell lymphoma, or DLBCL, using our nCounter Analysis System.

This new DLBCL signature caught the attention of both NanoString and several drug developers, and we quickly secured a license to the relevant intellectual property and entered the collaboration with Celgene. Under our agreement with Celgene we will support the development of Revlimid for the treatment of DLBCL by developing an in vitro diagnostic kit that will be used to enroll patients in a Phase 3 study of Revlimid for the treatment of a specific subtype of DLBCL. We believe that having a broadly adopted, global, gold-standard test to identify the subtypes of DLBCL is important to delivering the best care to patients.

The structure of this collaboration has some unique features and we believe demonstrates an attractive model for future companion diagnostic collaborations. The development of the IVD assay is being fully funded by Celgene via a $5.75 million upfront payment plus up to $17 million in development and regulatory milestones.

Also, Celgene has committed to commercial support that will ensure NanoString participates in a reasonable portion of the commercial value created, assuming the clinical trial is successful. In addition, we have retained the flexibility to independently develop and commercialize additional indications for the IVD assay, including potential partnerships with other companies developing drugs to treat DLBCL.

We are currently engaged in exploratory discussions with five other biopharma companies regarding how we can use the same IVD assay to support development of other therapeutics for DLBCL. We believe that over time diagnostic partnerships will become a meaningful growth driver for NanoString.

There are several factors that make NanoString a compelling partner for development of multi-analyte companion diagnostic tests.

First, our nCounter Analysis System has already become a central part of the biomarker discovery and validation efforts at many of the major biopharma companies, so they are familiar and comfortable with our technology. Second, our nCounter system has already been part of a successful

FDA regulatory clearance, which we believe both reduces regulatory risk and demonstrates our clinical and regulatory capabilities. Third, our strategy of decentralizing oncology testing into labs all over the world is perfectly matched to the global nature of oncology therapeutic products and resonates strongly with biopharma companies.

Our third area of core focus is the Prosigna breast cancer assay, our first in vitro diagnostic product. During the second quarter we continued to make important progress in a number of key areas of the Prosigna launch.

Sales of our Prosigna assay in the second quarter were $181,000, up from $61,000 in the first quarter. This growth is consistent with our previous commentary that we expect that US Prosigna testing volume will be relatively slow in the first two to three quarters of the year and to ramp gradually as more clinical lab providers come online, our sales team begins to educate ordering physicians and we begin to gain reimbursement. During the second quarter we made progress on all three of these dimensions of the commercial launch as well as achieving important milestones outside the United States.

Focusing on the US, we currently have five labs actively offering Prosigna services, including large commercial labs LabCorp, ARUP and Genoptix, and hospital systems UPMC and Providence Health Care. Another six labs are currently preparing to launch Prosigna, including new additions Thomas Jefferson University and Core Diagnostics, in Palo Alto.

Our oncology sales team is now fully deployed and focused their effort during the second quarter on forming strong and productive working partnerships with their counterparts at LabCorp and introducing Prosigna to oncology practices. We estimate that since the beginning of April we've reached over 300 oncology practices, with over 2,200 sales calls, including over 100 joint sales calls with LabCorp. We were encouraged by the physician interest that these efforts have generated.

However, many oncologists are not willing to prescribe a test if there is a risk their patient will be billed for it. In order to facilitate access among eligible patients whose insurance does not yet cover Prosigna, as well as to cover eligible patients who are uninsured, we launched in mid-July a Prosigna patient support program.

Clinical labs participating in the program are eligible to receive free Prosigna kits to replace any kits used in providing Prosigna tests not covered by insurance for qualified patients enrolled in the program and who meet certain income criteria. This program is expected to facilitate access to Prosigna for patients who would not otherwise afford the test, accelerating the uptake of Prosigna and generate a steady volume of insurance claims that will help motivate payers to update relevant coverage policies.

As reimbursement comes online, we expect to convert physician interest in Prosigna into testing orders. Our market access team is working diligently to remove the reimbursement barriers. They are actively engaged with all of the top 10 private payers, and we're pleased with the team's access and level of engagement. We look forward to additional progress with these payers in the coming months.

Despite considerable progress in many areas, we expect that some payers will be more challenging to convert. For example, like approximately 75% of new diagnostic technologies evaluated over the past three years, Prosigna was initially determined by the Blue Cross Blue Shield Technology Evaluation Center, or TEC, to not meet its criteria for inclusion. We plan to continue our dialog with the TEC while simultaneously engaging directly with individual Blues plans, which can make coverage decisions independent of the TEC's conclusions.

On the Medicare front, during the second quarter two Medicare Administrative Contractors, or MACs, which together cover more than 8 million lives, have indicated their intent to process claims for the Prosigna test. Because these carriers do not publish medical policies related to breast cancer testing, we'll be looking forward to confirming their coverage as claims are paid in the months ahead.

Securing Medicare reimbursement through Palmetto's MolDx program remains a focus for the team. Since submitting our application in March we've held several meetings with the MolDx team. In June the MolDx team released on their website updated guidance documents on their clinical test evaluation process, or CTEP. As a result of these new guidelines, in late June the MolDx team requested that we modify our application to address the new guidelines and respond to questions raised during their initial review.

Based on our most recent interactions, we believe that the MolDx coverage determination and what, if any, additional information we will need to provide in connection with our application, will be strongly influenced by the update to the NCCN guidelines expected later this year. We do not expect MolDx to make a coverage determination until sometime after the NCCN guideline update.

We submitted a request for inclusion into the NCCN breast cancer treatment guidelines during the second quarter. Our request was supported by a strong body of evidence, including our FDA-cleared label and six peer-reviewed papers describing Prosigna's performance.

The submission process for NCCN inclusion is somewhat different from other submissions, as there is no additional [other] opportunity for interaction once the request has been submitted. We understand that the guidelines committee met during July, but we do not expect to receive any feedback from the committee until the guidelines are made public. The exact timing of the NCCN guideline update varies from year to year but typically occurs between September and December.

During the second quarter we continued to steadily lay the foundation for broad, long-term adoption of Prosigna outside the United States. The number of labs outside the US planning to provide Prosigna testing has continued to grow and has increased to a total of 13. As of today, six of these labs are actively providing Prosigna testing.

We are currently focused on cultivating local physician champions for Prosigna and pursuing the private payer market while in parallel applying for government reimbursement. In Spain we have received positive reimbursement decisions from government payers in the Catalunya and Madrid regions, while we have recently submitted our application for public reimbursement in Germany. Meanwhile, our German decision impact study continues to steadily enroll patients and is expected to complete by the end of the year.

We also continue to pursue regulatory approvals to extend Prosigna into new markets. I'm pleased to report that we have recently received market approval from the Australian Therapeutic Goods Administration, clearing the way to market Prosigna in Australia. In the US we have submitted to the FDA an application that would expand our US Prosigna label and patient reports to include risk of late recurrence, which may help inform the use of extended adjuvant therapy.

Finally, we continue to strengthen the already compelling body of evidence for Prosigna. We have recently learned that another paper describing Prosigna's ability to assess risk of late recurrence has been accepted for publication in a major oncology journal.

Overall, we are pleased with our momentum on multiple fronts and optimistic about our continued growth.

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

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

Thanks, Brad.

From a financial perspective, the Company had another strong quarter. Total revenue for the second quarter of 2014 was $10.9 million, up 51% over the $7.2 million reported for the second quarter of 2013.

Instrument revenue for the quarter was up 49% compared to Q2 2013, and consumable revenue was the largest driver of growth. At $5.9 million, it was up 36% from $4.3 million for the second quarter of last year. Prosigna test kit revenue was modest, as expected, at $181,000 for the quarter, and up roughly threefold from the first quarter this year.

The proportion of our product and service revenue from outside North America continued to grow, driven by our expanding installed base, from 28% in the second quarter of last year to 34% this quarter.

In the second quarter we began recording revenue from the Celgene collaboration. Although we received $5.75 million upfront and we have the potential to receive additional milestones by the end of this year, the amount we will record as revenue in 2014 is much less.

The accounting rules require us to recognize revenue over the projected five-year development period at a rate proportional to the costs that we incur, not when the cash is received. As a result, a substantial portion of the cash we receive in 2014 is deferred and will be recorded as revenue in future years. For the second quarter, collaboration revenue was $618,000.

Gross margin for the quarter was 53%, compared to 51% in the second quarter of last year. We calculate gross margin based on product and service revenues only. In other words, we exclude collaboration revenue from the calculation. Product mix was relatively similar between the two periods and had little impact on the comparison. The gross margin improvement we're seeing is generally from increased scale and related cost efficiencies in our consumables manufacturing operations.

R&D expense was $5.3 million, up 45% over second quarter of 2013, and the increase reflects increased investment in the advancement of our nCounter technology, including the engineering of our next-generation system, as well as costs related to the Celgene collaboration.

SG&A expenses was $12.9 million for the quarter, up substantially from $6.7 million a year ago. The increase reflects Prosigna launch costs, including the establishment of our oncology sales force; investments to expand and guide revenue growth from our lab-based sales channel; and the increased costs of being a public company.

Operating expense for the quarter included $1.3 million of stock-based compensation expense, compared to $257,000 a year earlier.

In early April we entered into a term loan agreement with Capital Royalty which provides the Company with up to $45 million of available borrowing capacity. In April we drew the first $20 million of this facility, which was used to pay off our previously outstanding $18 million (inaudible). In doing so we incurred a prepayment premium of approximately 2%. We prepaid the $990,000 end-of-term payment and wrote off other related deferred costs. The resulting charge to the interest expense in the second quarter was approximately $1.4 million in total.

Note that we've included a schedule of non-GAAP financial information in our press release, which, among other things, shows our operating results as if all pre-IPO preferred stock had been converted to common stock. On a non-GAAP basis our net loss for the quarter was $10.5 million, or $0.58 per share, compared to $6 million, or $0.65 per share, in the second quarter of 2013. Please refer to that schedule for a detailed reconciliation of GAAP and non-GAAP results.

We ended the second quarter with approximately $80 million of cash and investments, and together with additional borrowing capacity of up to $25 million under our new term loan agreement we believe the Company is well positioned to carry out its business plan.

Now I'll revisit our financial guidance for 2014. We continue to guide to total revenue of $45 million to $50 million for the year, which represents approximately 43% to 59% growth over 2013. Based on our current visibility, we are tracking towards the midpoint of this range.

In modeling for the second half of the year, there are several factors that should be considered. In our base business we expect to see our normal seasonal pattern, with relatively stronger performance in the fourth quarter compared to the third quarter. For the reasons that Brad discussed related to reimbursement, Prosigna revenue is likely to be only modestly higher in Q3 compared to Q2.

And the Celgene collaboration work is going extremely well, and we now expect to be near the high end of the range of guidance we previous provided for the year, or $2.5 million. But the majority of this revenue is expected in the fourth quarter due to the timing of milestone payments that would increase the amount potentially recognizable as revenue.

Based on these revenue expectations and the related impact on product mix and our actual gross margin in the first half of the year, we are adjusting our gross margin guidance to 52% to 55% from the previous 55% to 58% for the full year.

For our operating expenses, we continue to expect a total of $70 million to $75 million for the year, split approximately one-third to R&D and two-thirds to SG&A, including approximately $4 million to $5 million of stock-based compensation expense.

Our operating loss for the year is still expected to be in the range of $40 million to $50 million. We continue to expect interest expense to be approximately $4 million for the full year, and our expectation for capital expenditures remains at $3 million to $4 million for the year.

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

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

Thanks, Jim.

Our momentum increased through the second quarter as we continued to execute our strategy to become an integral part of cancer research and diagnostics. We are rapidly growing our installed base of nCounter systems in both research and clinical labs as the interest in our dual-use FLEX systems and our Elements chemistry validate our strategy of combining cancer research and diagnostics on a single platform provided by a single company. The addition of companion diagnostic partnerships puts us at the nexus of cancer researchers, drug developers and treating physicians and represents a substantial new axis of growth.

Our Prosigna commercial team is having its first wins, but we expect momentum to build as reimbursement comes online in the quarters ahead.

We look forward to updating you on our progress during future calls. I would now like to open the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Tycho Peterson, JP Morgan.

Tycho Peterson - *JP Morgan - Analyst*

First on Celgene, just wondering, you talked in the initial press release about additional indications, so can you maybe talk whether you've had any discussions around indications beyond DLBCL? Also, how quickly could you partner the original product with other companies? And then what's the pipeline for additional diagnostic collaborations like the one you have with Celgene?

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

Great. So speaking first to the DLBCL assay that we're in the process of developing for Celgene, I think there's substantial interest from other developers of therapeutics for DLBCL today. Those -- that interest will take some time to convert into additional collaborations, but really as soon as the assay is available for use, hypothetically we could begin working on the enrollment of a different study or the retrospective analysis of samples that we're collecting in previous studies.

So in terms of our development milestones, I would expect that time, that we would hit that point in time around the end of this year. So that's, I think, the time frame for some of those other DLBCL discussions.

The relationship with Celgene is going extremely well, and I think part of our motivation for working with such a top-tier biopharmaceutical company was the opportunity to grow that relationship over time. And, while there's nothing specific to discuss, my expectation is that we will explore those opportunities with Celgene, and my hope is that we will expand the relationship over the long term.

In terms of the pipeline of additional companion diagnostic work, there are several different sources of potential diagnostics, and we are -- we have a team that's very focused on understanding them. One is from our biopharmaceutical companies -- customers themselves. About 20% of all of our research systems are placed in biopharma, and the objective of the scientists using them is generally to determine panels of biomarkers that could predict response to the drugs they're developing. So that's one great source that we intend to mine.

The other, which is more similar to what we did in the DLBCL case, is, of course, identifying some great work from our academic research customers that's captured the imagination both of NanoString and drug companies, and that's a great source. And, as I mentioned during the script, there have now been 25 gene expression-based oncology assays that have been published and more that haven't.

And then, finally, Prosigna and the in vitro diagnostic we're developing for DLBCL are products that are in development, and obviously they represent very interesting avenues to support drug development in breast cancer and DLBCL, respectively. So there's a number of different sources of potential companion diagnostic content, all of which we're currently evaluating.

Tycho Peterson - *JP Morgan - Analyst*

And then you mentioned in your comments the PanCancer Panel launch. Obviously we saw FDA's letter to Congress this week. Can you maybe just talk a little bit about how you think this may play out in particular for the PanCancer Panel?

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

Sure. So the PanCancer Panel is a research use-only product. It is not intended for use as a clinical assay, and, in fact, if we had an impression or facts that suggested that one of our research customers was redeploying it as a clinical assay we would stop selling the assay to them. It is really designed to be a research tool that comprehensively probes the biology of cancer, helping identify which pathways are important so that those pathways can then be explored more deeply. So I do not expect the FDA [LDT] guidance to impact that PanCancer Pathway product at all.

Obviously, the regulation of lab-developed tests by the FDA brings good things and bad things for a company like NanoString. On the positive side, as a provider of a platform that's FDA cleared and with the capability for clinical development and regulatory submissions, we're well positioned to manage to bring new tests to market in a world where the FDA makes it more difficult for a new LDT to come to market, so I think that's fundamentally good for our business. Obviously, with our push of FLEX and nCounter Elements into the use of lab-developed tests, that could move in the opposite direction. But net net I think additional regulation is more likely to be good for NanoString than bad.

Tycho Peterson - *JP Morgan - Analyst*

All right, and then last one on the model, just the reduction in the gross margin guidance, just so we're clear, I mean, that's really a catch-up from the first half, because we're thinking about the Celgene revenues coming in at 100% margin or so later this year, so why wouldn't that maybe offset?

And then on the comments on the MAC, you said there was an agreement to process claims (inaudible) the push-out of the MolDx decision, but does that mean the MACs are actually going to be paying claims? So for the back half of the year if you could just comment on both those that'd be helpful.

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

Okay, Tycho, this is Jim. Why don't I start with the question about gross margin? There are several factors that impact our gross margin that are difficult to predict, and they vary from quarter to quarter. Mix is probably the most significant between instruments, consumables and Prosigna kits. Geographic mix also comes into play, and then even within our consumable products the mix amongst those, the various types of consumables.

So, yes, obviously we now know how the first six months have played out. We can make better predictions about how those things are going to impact the second half of the year.

Now, you mentioned specifically the Celgene revenue. When we're calculating our gross margin that we're guiding to and that we reported in our comments, we don't include the Celgene revenue in that. It's basically just product and service revenues.

So you're right, I mean, you can look at the Celgene revenue as 100% margin-type revenue, but truthfully if we tried to figure out what the cost of that revenue is there's some amount in our research and development expenses that relate to that. So from an accounting and reporting perspective we've been told that we should keep that separate.

And so, you're right, if you included that it would probably be not too far away from what our original margin guidance was. But under kind of the pure standards of the accounting rules, we're reducing the range to 52% to 55%.

And over the long term I think the trends that we expect to drive higher margins are still there. We still expect that with increasing scale and some of the new products that we plan to introduce over the next few years, that the long-term trend towards higher margins is still intact.

Tycho Peterson - *JP Morgan - Analyst*

Okay, and then just lastly on the MACs. I mean, you mentioned that they're agreeing to process claims. You also talked about the push-out of the MolDx decision. So just to clarify, you're expecting these claims to be paid in the back half of the year?

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

Well, so, it depends on the geographic region, Tycho. So there's a number of Medicare carriers around the country. We're engaging them all, included MolDx, Palmetto via the MolDx program.

The two what I'll call wins that we experienced in Q2 that I described were not Palmetto. They were other Medicare carriers with smaller numbers of covered lives. But that is a -- it's a positive step forward, because patients who are tested in those regions we believe will now have their claims processed by their Medicare carriers, and we're engaging many of the other carriers with the hope that we can get some of those wins, more of those wins.

The MolDx decision covers geographically North Carolina as well as California, which is a really important geography for us, because that's the location of LabCorp's central lab in North Carolina and Quest's and Genoptix's central labs in California. And so that's the single most meaningful Medicare carrier decision, and that's why we've highlighted it repeatedly in our updates to the Street. That's obviously going a little slower than we expected it to, based on the changes in the CTEP guidance that were put out in July -- in June, rather.

Tycho Peterson - *JP Morgan - Analyst*

Okay, thank you.

Operator

Dan Leonard, Leerink.

Dan Leonard - *Leerink Swann - Analyst*

Just one quick one. On the Prosigna patient support program, how do you envision that rolling out? Is that something that your partners are going to actively advertise, and do you think this is something that could help bridge the gap between where we are today and getting reimbursement for Prosigna?

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

Yes, Dan, thanks for the good question. It is something that our clinical lab partners are absolutely embracing, because, of course, for them it mitigates the risk of unpaid claims and it mitigates the blowback from physicians who may receive a bill for Prosigna testing, which is a very unpleasant conversation to have with a physician. So we think it's unlocking even more energy within LabCorp, and we anticipate that it will with the other labs, that will increase the promotional activity on Prosigna and get some trial usage by physicians around the country.

So this is a technique that, of course, is used very often by clinical lab providers, CLIA labs who are launching new tests. And so it's -- there's a good track record of these kinds of programs accumulating unpaid claims, which forces payers to engage in the adjudication of those claims, which gets Prosigna the attention we believe it deserves on the payers' medical policy agendas. And so that's -- we expect that dynamic to play out here.

Dan Leonard - *Leerink Swann - Analyst*

Got it. Thank you.

Operator

(Operator Instructions)

Jeff Elliott, Robert W. Baird.

Jeff Elliott - *Robert W. Baird - Analyst*

Just to follow up on Dan's question first, on the Prosigna patient support program, is this somehow -- are you mitigated from a -- I guess protected from the downside of this one, or have you reserved something? And how should we think about the size of that investment?

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

Yes, so I'll maybe speak to the dynamic and I'll let Jim talk to the accounting. I think this program doesn't cost us very much, because all that we are on the hook for or at risk for is replacement kits, Prosigna kits, to labs who ran kits and didn't get reimbursed. And, as we've described in the past, the incremental cost of goods on a Prosigna kit is extremely low. So the total magnitude of the investment that this requires is relatively modest.

We believe the net effect on revenue will be to increase it because we've removed a major objection in the physician office about trial use. And so we expect testing volumes to go up, and that will be a net positive effect on our revenue line, as well. So we think it's a very good investment.

Jim, do you want to speak to the accounting treatment?

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

Sure. It's complicated, obviously. Whenever you get into revenue accounting, it is -- it's complex. But the program has been structured along the lines of what most major drug companies have done for their drug replacement programs. And so we believe that generally speaking when we are shipping product to these labs we'll be able to book revenue.

And where I guess you could say the impact of the program comes into play is that subsequent test utilization will be partially absorbed by free kits that are given in replacement. So it does impact the amount of revenue that we will be recording. It's diluted by essentially the patients for which the claims are not paid and for which free kits are distributed then to be used for subsequent patients. It's probably a little bit confusing, but hopefully that answered the question.

Jeff Elliott - *Robert W. Baird - Analyst*

Yes, that's helpful. And just I guess to follow up on Tycho's question on the two MACs that are now covering it, can you say where do they come in from a reimbursement standpoint, and who are they covering it for? I guess what does the coverage decision that they've offered look like?

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

Well, they -- first, as I mentioned, these two Medicare carriers do not publish medical policies that I can point to to describe their -- the intended use of Prosigna or the types of claims that they are willing to process. So I can't point you to a source document.

We believe that they are going to process claims for the intended-use population of Prosigna, which is hormone receptor positive early stage breast cancer, both node negative and node positive in one to three nodes, in women who are postmenopausal. That's the FDA-approved label, and that's my expectation of the patients who would be covered.

The way that Medicare carriers work are the relevant carrier to any given patient is the carrier that actually covers the geographic jurisdiction where the test is performed. So this is most important to cancer centers and commercial labs who would be running tests in those jurisdictions.

Jeff Elliott - *Robert W. Baird - Analyst*

Okay. Thank you. And then on the desktop instrument, what other steps do you have to I guess to complete the development there, and any updated thoughts on how you'll position that from a pricing standpoint?

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

Yes, so the remaining steps are now that the hardware, the manufactured hardware is in house, we're going to continue to make tweaks and optimization to the software to optimize the technical performance of the instrument. So I would describe it as engineering optimization in the software domain is the remaining set of tasks. So I think that's relatively low risk from a technical perspective, as we've described in the past.

We're not providing an update on pricing or positioning at this time. As we have in the past, we're going to keep those details relatively close to the vest in an effort to ensure that we don't have a dynamic where customers end up waiting for a new system that they're trying to guess the performance characteristics of.

Jeff Elliott - *Robert W. Baird - Analyst*

Got it. And then just one last one here on Australia. Congrats on that approval. How should we think about your commercial approach in that market?

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

In our ex-US markets we've taken a mix of direct and distributor approaches. In Australia we have a very strong distributor on the life sciences side that we expect also to be our distributor on the Prosigna side. So in that market we'll be working through our distributor.

Jeff Elliott - *Robert W. Baird - Analyst*

Got it. All right. Thank you.

Operator

Thank you. And I'm not showing any further questions at this time. I'll now turn the conference back over to you, Mr. Gray.

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

Well, thank you all for joining our call today, and we hope you have a great evening. Thank you.

Operator

Ladies and gentlemen, this concludes today's conference. Thank you for your participation, and have a wonderful day.