

FINAL TRANSCRIPT

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GPRO - Q2 2011 Gen Probe Inc Earnings Conference Call

Event Date/Time: Jul. 28. 2011 / 8:30PM GMT



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PRESENTATION

Operator

Good afternoon everyone, thank you for standing by. (Operator Instructions). I would now like to turn the call over to Mike Watts, Vice President of Investor Relations. Sir, you may begin.

Mike Watts - *Gen-Probe - VP, IR and Corporate Communications*

Thank you, Michelle, and good afternoon, everyone. I am pleased to welcome you to this conference call to discuss our second quarter 2011 business results. A press release announcing our results was issued today just after 4.00 PM Eastern Time, and it's posted on our website at www.gen-probe.com. In today's call, Carl will first review our second quarter product sales and pipeline

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progress. Herm will then discuss expenses and our updated 2011 financial guidance. We will take your questions for the balance of an hour then post our prepared remarks on our website for your convenience and reference.

Before we begin, let me first review our Safe Harbor policy. Forward looking guidance, financial or otherwise, is only provided on conference calls or in our press releases. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are forward-looking statements. For example, statements concerning updated 2011 financial guidance, financial conditions, regulatory approvals and timelines, the development and commercialization of new products, future results of operations, growth opportunities, plans and objectives of management, market trends and future economic conditions are all forward-looking statements.

Forward looking statements are not guarantees of performance. They involve known as well as unknown risks and uncertainties that may cause actual results to differ materially from those expressed or implied. Factors that might cause such differences include but are not limited to those discussed in our SEC filings including our most recent 10-K, and all subsequent periodic reports. Copies of these reports are available on our website, at www.sec.gov, and upon request. Gen-Probe assumes no obligation and expressly disclaims any duty to update any forward-looking statements to reflect events or circumstances occurring after this call or to reflect the occurrence of unanticipated events.

In addition our presentation today includes information presented on a non-GAAP basis. We believe these non-GAAP financial measures provide useful supplemental information regarding the Company's performance by excluding certain expenses and adjustments that may not be indicative of core business results. We refer you to the press release we issued this afternoon, which is available on our website, for a reconciliation of the differences between the non-GAAP presentations and the most directly comparable GAAP measures. Now I would like to turn the call over to Carl Hull, Gen-Probe's CEO.

Carl Hull - *Gen-Probe - President, CEO*

Well thank you, Mike and good afternoon, everyone. Gen-Probe's financial results in the second quarter of 2011 were in line with our expectations overall. A record performance by our APTIMA women's health franchise helped offset blood screening sales that were below our forecast, mainly due to supply chain issues that I will discuss with you in a moment.

Just as important, we are off to a very good start with the US introduction of our APTIMA In addition our presentation today includes information presented on a non-GAAP basis. Assay and our other major pipeline initiatives remain on track for domestic launches over the next few quarters. Now let's go into our second quarter results. Product sales were \$132.9 million in the quarter, basically flat compared to a tough comp in the prior year period. Total revenues of \$135.9 million were a couple million dollars light of the forecast we provided in our last call, which was about \$138 million. In addition to blood screening, a short fall in sales of our research products and services, contributed to the variance relative to our forecast.

Turning to margins. We are very pleased with our strong profitability in the second quarter. The non-GAAP product gross margin percentage, up 70.4%, was the highest it has been since the first quarter of 2009. Gross margin was helped by favorable product sales mix, namely strong sales of our APTIMA Combo 2 assay for chlamydia and gonorrhea detection, and by the weak dollar. This led to non-GAAP EPS of \$0.51, ahead of the guidance we gave last quarter, which was \$0.47 to \$0.49 a share.

Now let me turn to the components of product sales in the second quarter. Sales of our clinical diagnostic products were \$87.5 million in the quarter, up a very strong 18% compared to the prior year period, or 17% in constant currency. The biggest contributor to clinical diagnostics growth in the second quarter was our APTIMA Combo 2 assay for detecting chlamydia and gonorrhea. APTIMA sales grew at a mid teens rate compared to the prior year, the fastest growth we have seen since the third quarter of 2009, powering through a mixed utilization environment in the United States and continued funding challenges in Europe. In Europe, APTIMA grew solidly in the second quarter, as it has in the recent periods.



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Underpinning this performance, customer feedback on PANTHER has been positive, and we are on track to meet our PANTHER placement goals for this year. We look forward to continued growth in Europe as PANTHER installations and testing volumes increase. In the United States, we were pleasantly surprised at the strength of APTIMA in the second quarter as the domestic growth rate was only slightly below the rate of international growth.

Some of this growth continues to come from customers upgrading to APTIMA from our older PACE product which declined 26% in the quarter to less than \$3 million. More importantly, the last few months have been good ones for us in market share gains in the United States, which gives us confidence in our future trajectory. We are achieving these gains based on the high level of customer service provided by our sales and technical support team, the accuracy of our assays and the durable value that our fully automated TIGRIS system provides for high volume labs. Our field force is gearing up to extend these automation advantages to a broader customer base with the PANTHER system which we submitted to the FDA for regulatory clearance in May.

Based on customer feedback we have received at trade shows over the past few months, we are very excited about the potential for PANTHER in the United States. In addition, our upcoming PANTHER launch further supports our confidence in future growth from chlamydia and gonorrhea testing even as competition increases. To wrap up our discussion of clinical diagnostic sales in the second quarter, I would add that the acquisition of GTI Diagnostics, which we completed in December, added a few hundred basis points to product sales growth in the second quarter as expected.

In addition, the acquired franchises within our clinical diagnostics line, those being the LIFECODES transplant diagnostic products and Prodesse's respiratory infectious disease products both showed good growth compared to the prior year period.

As we think about the second half of this year, we are very pleased with the early returns from our APTIMA trichomonas launch. As most of you know, our assay for this parasitic STD can be used to test the same female sample types from the same sample tube as our APTIMA Combo 2 assay. In addition, our amplified assay can be run on our large installed base of TIGRIS systems and enjoys significant advantages in sensitivity and speed compared to traditional tests. The coming out party for our APTIMA trichomonas assay occurred earlier this month in Quebec City, at the biennial conference of the International Society for Sexually Transmitted Disease Research.

At the meeting, independent researchers published the results of a study of 7,593 women who are also being tested for chlamydia and gonorrhea. Using our highly sensitive assay, the researchers determined that 8.7% of these women were infected with trichomonas, higher than the combined rate of chlamydia and gonorrhea. Interestingly, trichomonas was most common in women over 50 where 13% had the infection. And in women over 40, where prevalence was 11.3%. Building awareness of the importance and prevalence of trichomonas infections is a long-term initiative, but we believe studies such as this one are important building blocks in that effort.

More immediately, over 50 customers are already using or validating our trichomonas assay. For those who have begun commercial testing, pricing is fairly similar to that of our APTIMA Combo 2 assay. Sales are ramping nicely so far, and we are optimistic that we will achieve at least the few million dollars of trichomonas revenue that is contemplated in our 2011 guidance.

Now let's turn to blood screening. Second quarter sales were \$43.2 million, down 22% as reported, or 24% on a constant currency basis. To put this performance in context, let me remind you that in our initial 2011 guidance, we forecast that blood screening revenues for the full year would decline by a few percentage points based mainly on lower sales of TIGRIS instruments to Novartis. In addition, in last quarter's call we said that blood screening sales would fall on a sequential basis from the \$47.6 million we posted in the first quarter, which also implied a significant reduction compared to the prior year period. The percentage decline in blood screening sales this quarter is also magnified by a tough comp from a year ago. Specifically, in the second quarter of 2010, blood screening sales were \$55.7 million, more than \$5 million higher than in any other quarter last year.



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I want to be clear that we believe the strong fundamentals around our blood screening business have not changed. Blood screening remains a stable, highly profitable business for Gen-Probe, one with growth rates expected to be flat or up in the low single digits on an underlying basis.

Now I am going to spend a fair amount of time providing support for this statement. I'm also going to explain why we believe that the decrease in blood screening sales in the second quarter resulted mainly from reduced instrument revenues, supply chain fluctuations and a reduction in Novartis' inventory levels. Lower sales of TIGRIS instruments to Novartis played a significant role in our second quarter blood screening result as we had expected.

The prior year period was an exceptionally strong one for TIGRIS, driven in part by the installation of a large number of instruments in France. This led to total blood screening instrument sales of nearly \$7 million. In comparison, in the second quarter of this year, total instrument sales were only about \$2 million, creating a delta of \$5 million that accounted for a significant portion of the year-over-year change. Despite the decline in blood screening instrument sales this quarter, we do expect our sales of TIGRIS systems to Novartis to increase later this year in support of new customer demand. This should contribute to better growth rates in the fourth quarter of the year. In addition we were very pleased with the positive customer feedback on the PANTHER system emerging from the recent International Society of Blood Transfusion meeting in Portugal. Novartis remains on track to launch the instrument internationally next year.

Now let's turn to assay revenues. On a gross basis, blood screening assay sales by Novartis to end customers actually increased in the second quarter of 2011 compared to the prior year period. This speaks to the strength of our competitive position especially compared to our competitor, which recently reported a 1% decline in quarterly blood screening revenue. Although this total blood screening revenue for our joint business was up in the second quarter, our assay shipments to Novartis were nearly \$6 million less than they were a year ago, reducing our reported revenue by the same amount. Additional fluctuations in Novartis' inventory levels further reduced our reported revenues by approximately \$3 million.

Those of you who have followed Gen-Probe for a while know that our partner is contractually obligated to maintain minimum inventory levels under the collaboration as measured by months of supply. This is done both to facilitate accurate forecasting and to ensure the continuity of the blood supply. However, various factors such as shipment timing and the transition from ULTRIO to ULTRIO Plus that is now under way in international markets can cause significant lumpiness in our quarterly results. In the past, that lumpiness had been somewhat obscured by underlying growth in the overall market.

As the market has matured, however, these supply chain fluctuations can become more visible in any given period. Although we forecasted these unfavorable ordering patterns in our last call, we probably underestimated their impact by a couple million dollars which contributed significantly to the top line variance we saw relative to our prior guidance. As I said earlier, underneath this quarterly volatility, blood screening remains a stable, slow growing and highly profitable business. The total number of blood donations screened with our tests increased slightly in the second quarter, both sequentially and year-over-year. In addition prices were stable and our gross margins were up. All in all we feel good about our blood screening business today.

Novartis' customer base is sticky and we believe there may be some upside to growth in the near term. In addition to the launch of the PANTHER system, these include continued growth in emerging markets such as China, where a major evaluation of nucleic acid blood screening continues. And adjacent markets such as plasma screening, which we expect to begin contributing to revenues in 2012.

Before I turn the call over to Herm, let me provide a very rapid fire update on some of our other key pipeline initiatives. All these projects remain on track with our previously communicated time lines. First our APTIMA HPV assay continues under active FDA review. The agency has not requested an advisory panel meeting, although they could do so later in the process. Most of you probably saw the results of our pivotal clinical trial that were presented at the EuroGen meeting in Portugal in May. The data showed that our APTIMA assay has similar sensitivity but better specificity than the market leader.



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Second, the US clinical trial for our HPV genotyping assay on TIGRIS is underway. We expect this product to be an important complement to our HPV screening assay for those physicians and labs who want to identify genotypes 16 and 18 and 45. We expect to submit a PMA application for this test next year. Third we have also begun a clinical trial for our trichomonas assay on PANTHER. This should be a nice addition to our existing menu of women's' health products and broaden the appeal of the instrument to more [load] at volume labs. We expect to launch this product in Europe and follow 510-K application in the US within the next 12 months. And fourth, the FDA has confirmed the date for a meeting of their immunology advisory panel to review our PROGENSA PCA3 assay for prostate cancer. The meeting will be held on October 14. Extensive internal preparations are underway and in preparation for launch we are also making plans to beef up our medical marketing capabilities in the urology field.

As you can tell there is a lot happening at Gen-Probe. We are rapidly approaching potential approvals for PANTHER, HPV and PCA3 in the United States which we expect to accelerate the new product cycle that has just begun with our trichomonas assay. We are building out a full menu of tests on PANTHER as well as a complete and complimentary portfolio of women's health products. And all the while driving we are profitable growth from mature market such as chlamydia/gonorrhea, where we hold lasting leadership positions.

Herm will now review non product revenues, expenses, and our updated 2011 guidance. Herm?

Herm Rosenman - *Gen-Probe - SVP, Finance, CFO*

Thank you, Carl, and good afternoon, everyone. Collaborative research revenue was \$1.6 million in the second quarter, down 61% from the prior year period. This decrease was due, as expected, due to Novartis hitting their cap for reimbursement of PANTHER blood screening development costs earlier this year. As Carl said, we look forward to introducing PANTHER in international blood screening markets next year. Royalty and license revenue was \$1.4 million in the second quarter, down 22% compared to the prior year period due to a number of small variances.

Now let me turn to quarterly expenses, which I will discuss on a non-GAAP basis. Gross margin on product sales was very strong in the second quarter at 70.4%, significantly better than the 66.7% margin we reported in the prior year period. Gross margin also increased on a sequential basis despite lower sales of high margin Prodesse influenza products in the second quarter. This speaks to stable pricing in our core franchises and our ability to drive operational efficiencies. Gross margin benefited mainly from a favorable sales mix, most notably higher sales of APTIMA assays, decreased sales of low-margin TIGRIS instruments to Novartis and favorable currency fluctuations.

Research and development expenses for the second quarter were \$27.7 million dollars up 2% compared to the prior year period due primarily to the addition of GTI's R&D programs. Marketing and sales expenses in the second quarter were \$17.5 million, up 11% compared to the prior year period due mainly to strategic investments in our European commercial infrastructure and the addition of GTI's cost structure. As we have said before, expect marketing and sales expense to continue rising more rapidly than revenue as we invest in the European market and prepare to launch new products in the United States.

General and administrative expenses were \$17.3 million in the second quarter on a non-GAAP basis, 21% higher than in the prior year period. This increase was due to three primary factors. First, the addition of GTI's cost structure. Second, outside legal costs associated mainly with our patent infringement lawsuit against Becton Dickinson. Incidentally we do not have an update or ruling from the Markman hearing that was held in May. And third, the increase in our share price has had a significant affect on our non cash stock compensation expense, which hits G&A costs heavily. Our non-GAAP results exclude \$2.7 million of transaction-related amortization expense consistent with last quarter as well as \$1.4 million of transaction-related and restructuring costs. Total other income in the quarter was \$3.8 million on a non-GAAP basis, an increase of 48% compared to the prior year period.



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During the quarter we realized approximately \$2.1 million in gains on sales of high grade municipal bonds which helped offset the increase in our share count and higher stock compensation expense. For the rest of the year we forecast that other income will return to sub \$1 million levels on a quarterly basis, as we redeploy cash into stock repurchases and cash balances shrink accordingly.

Turning to taxes, our effective rate in the second quarter of 2011 was 33.1% on a non-GAAP basis, in line with our expectations. Our weighted average share count in the second quarter was 49.3 million, basically flat compared to the prior year period, due to our higher share price. A higher share price puts more previously-granted options in the money and therefore adds them to our diluted share base. Higher share prices also increase our share count by reducing the number of shares soon to be brought back under the treasury stock method. So on the bottom line, all this nets out to \$0.51 of non-GAAP earnings per share in the second quarter, ahead of the guidance we gave in the last call which was \$0.47 to \$0.49 .

We achieved good results on the bottom line based on a number of offsets throughout the income statement. Higher than expected sales of APTIMA women's health care products counterbalanced softness in blood screening and research products and services. Very good gross margins canceled out higher G&A expenses. And realized gains made up for a higher share count and stock compensation expense.

We continued to do an excellent job of converting earnings into cash. We saw a strong operating cash flow of \$45.4 million in the second quarter, more than double GAAP net income of \$22.3 million. Purchases of property, plant and equipment were a little higher than usual in the quarter at \$12.5 million, mainly due to investments in our Manchester, UK, manufacturing facility, but we still generated free cash flow of \$32.9 million.

Moving on to the balance sheet, we closed the second quarter with \$529.4 million in cash, cash equivalents and marketable securities. During the second quarter, cash balances benefited from \$20.9 million received from employee stock option exercises. Net of \$248 million of short-term debt, on which we pay interest at less than 1%, we maintained nearly \$6 of net cash and equivalence per share, which provides us tremendous strategic and financial flexibility.

Now I would like to turn to our updated 2011 financial guidance, which we have tweaked based on our results in the first half of the year. I am only going to spend time today on the specific line items that have changed. As a reminder, our guidance is on non-GAAP basis that excludes acquisition-related intangibles amortization, contingent consideration adjustments, other transaction-related expenses and restructuring charges. On the top line we are tightening our revenue guidance range by \$5 million on both the high and low ends. We now expect total revenues of between \$575 million and \$590 million in 2011. This revenue guidance includes collaborative research revenue and royalty and license revenue that are expected to be roughly equal to their second quarter levels for the balance of 2011.

Backing these out, the mid-point of our guidance still assumes high single digit growth in product sales for the year. Underlying this will be solid growth from our women's health, transplant diagnostics, and Prodesse business, the addition of GTI and a slight decline in blood screening sales. Of our anticipated new products, we have only included trichomonas revenue in our 2011 guidance, so depending on timing, anticipated regulatory approvals should have us well positioned for a return to low double-digit growth in 2012, consistent with the goals we outlined at our analyst day back in December.

Turning to expenses, we are raising our gross margin guidance slightly to 69% to 70% to reflect our strong results in the first half of the year. We expect other income to total about \$5 million in 2011, an increase from our last guidance based on investment gains realized in the second quarter.

We now forecast that diluted shares will total 49 million for the year, up slightly based on our higher share price over the last several months. On the bottom line all this leads us to our new non-GAAP earnings per share guidance of \$2.28 to \$2.37 on a fully diluted basis. The \$0.03 reduction in the top end of our range is due mainly to an increased share count and stock option expense, resulting from our higher share price. More specifically the combination of these two factors has clipped our internal



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forecast by almost \$0.10 this year compared to our budget. We have made up some, but not all, of this variance with our higher gross margin percentage, cost-savings across the business and non operating items.

Now let me highlight a few items related to the timing of results over the second half of the year. In the third quarter we anticipate that total revenues will increase by a few million dollars on a sequential basis, probably to around \$140 million based mainly on continued growth in our women's health and transplant diagnostics businesses and slightly more favorable ordering patterns in blood screening. On the expense lines we expect budget timing to drive R&D costs up substantially in the third quarter to more than \$30 million. Sales and marketing costs are expected to increase sequentially while G&A expenses are forecast (inaudible -- technical difficulty) from second quarter levels. On the bottom line, we forecast that these puts and takes will lead to third quarter earnings between \$0.53 and \$0.55 per share on a non-GAAP basis.

We are well aware that this third quarter guidance implies a big fourth quarter on both the top and bottom lines. This has been our internal assumption all year, and there are several reasons for it.

In terms of revenue, we anticipate that ordering patterns and blood screening will be more positive in the fourth quarter. Supplies to both assays and TIGRIS instruments. We also believe that women's health sales will continue their steady growth buoyed by recent market share gains in the United States, and PANTHER placements coming on line in Europe. Finally, we forecast that Prodesse sales will increase according to a normal seasonal influenza pattern. At the same time we forecast that all our major expense lines, R&D, sales and marketing and G&A, will be lower in the fourth quarter than in the third. Coupled with higher gross margin dollars this would obviously magnify the benefits of strong revenue down to our bottom line.

In closing, let me summarize the financial section of our conference call by saying that strong growth in our APTIMA and women's health franchise, and good profitability enabled us to exceed our earnings goals in the second quarter of 2011. We are on track for a successful full year in line with our original goals and well prepared for multiple upcoming new product launches that have the potential to [boost] our overall growth rate. Now I would like to turn the call back over to

Mike Watts - Gen-Probe - VP, IR and Corporate Communications

Thanks, Herm. I would like to introduce the members of management who are joining us for Q&A today. We have Bill Bowen, Senior Vice President and General Counsel; Eric Lai, Senior Vice President of R&D; Eric Tardif, Senior Vice President of Marketing and Corporate Strategy; and Kevin Herde, who is our Vice President and Corporate Controller. In order to ensure broad participation in today's Q&A session, please be courteous and limit your questions to one plus a related follow-up, then jump back into the queue.

Operator, we are ready to take the first question.

Mike Watts - Gen-Probe - VP, IR and Corporate Communications

Michelle, are you ready?

QUESTIONS AND ANSWERS

Operator

I apologize, my phone was muted. (Operator Instructions).



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Mike Watts - Gen-Probe - VP, IR and Corporate Communications

Michelle, we had a queue about 15 seconds ago.

Carl Hull - Gen-Probe - President, CEO

It seems to have disappeared. So, I don't know if you have a technical issue on your end? And to those of you still --

Operator

(Operator Instructions).

Carl Hull - Gen-Probe - President, CEO

We apologize for that. We appear to have had some difficulties, but it is reloading, so give us just a second. Okay, we are ready for our first question, Michelle.

Operator

Just one moment, please. Our first question is from Peter Lawson with Mizuho Securities. Your line is open.

Unidentified Participant - Mizuho Securities - Analyst

Hi, guys, this is actually Eric filling in for Peter.

Carl Hull - Gen-Probe - President, CEO

Hi, Eric.

Unidentified Participant - Mizuho Securities - Analyst

Just on the -- the IOM is scheduled to update 510-K policy, or potentially update 510-K policy. I was just kind of wondering if you have any ideas, any thoughts on the particular issues that may come up or how you might be positioned for any changes that you think may or may not occur.

Carl Hull - Gen-Probe - President, CEO

Yes, Eric, it is a very important question, and I think that the answer is do we know what is going to be in it? No. I believe that the IOM has been doing a length examination, this is probably almost year two of the study, and the results are scheduled to be released tomorrow. We certainly understand that the FDA has asked the IOM to look at some of the most significant issues with respect to the 510-K approval process and that those will each be important considerations for all of the companies that are involved in this space. What we can tell you is that the first part of this year the FDA released the issue -- or released their recommendations and changes that they were planning on making, not including those that they punted to the IOM. We felt reasonably comfortable with them. We understand the nature of the regulatory changes that they are making and we are well-equipped to deal with those.



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The IOM results will then address some of those thornier issues and we expect that the FDA would have to go through their normal rule-making process in order to implement any of the changes. It is also possible that the IOM will make some recommendations that will require legislative changes that may take a longer time. I think in short summary, we think that any changes that tighten the regulatory process will probably be manageable by companies that have sophisticated regulatory capabilities like Gen-Probe. We think though that for smaller companies and those perhaps without that track record of regulatory success, some of those changes may be much more significant. Time will tell and we will see tomorrow what they come out with.

Unidentified Participant - *Mizuho Securities - Analyst*

Great, thank you for that color. And just on a modeling issue, did you break out how much total new acquisitions contributed to the top line?

Carl Hull - *Gen-Probe - President, CEO*

We didn't break it out, Eric, because we don't really manage the business that way. What we have said before, is that we -- the only one that's in there is GTI right now. And what we have said before is that we expect that would add a few hundred basis points to product sales growth, so you can infer from that about what it was.

Unidentified Participant - *Mizuho Securities - Analyst*

Great, thank you.

Carl Hull - *Gen-Probe - President, CEO*

You bet.

Operator

Our next question is from Bill Quirk with Piper Jaffray. Your line is open, sir.

Bill Quirk - *Piper Jaffray - Analyst*

Thanks, good afternoon, everybody.

Carl Hull - *Gen-Probe - President, CEO*

Hey, Bill.

Bill Quirk - *Piper Jaffray - Analyst*

So first question, Carl or Herm, if we could parse guidance down between clinical diagnostics and blood screening, would it be fair to say that the clinical diagnostics essentially had a positive bent to it based on the results thus far? And then obviously given some of the supply chain issues and what have you at Novartis, that obviously has a negative bent to it? As we think about the global guidance for the Company?

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Carl Hull - Gen-Probe - President, CEO

Yes, I think that's correct, Bill.

Bill Quirk - Piper Jaffray - Analyst

Okay, great.

Herm Rosenman - Gen-Probe - SVP, Finance, CFO

You got it, Bill.

Bill Quirk - Piper Jaffray - Analyst

Sorry, Herm?

Herm Rosenman - Gen-Probe - SVP, Finance, CFO

I said, I think you got it.

Bill Quirk - Piper Jaffray - Analyst

And then secondly, Carl, you mentioned in your prepared remarks that you've had some recent share gains in chlamydia and gonorrhea. Can you talk at all if this is at all influenced by the recent trich approval and/or the fact that accounts knew that you were going to be coming out with this new product?

Carl Hull - Gen-Probe - President, CEO

Interesting question, Bill. Let me think about it for a second. I would say that what we are seeing and what we're referring to in the current quarter results is probably independent of trich. These were closes and competitive take aways that were in the pipeline before the trich approval was announced and so I think they stand on their own. As you know the other vendors in the area haven't really delivered good automation solutions. So we find that proven success with TIGRIS works pretty well there. Now on a go forward basis we do think trich will be important to people and may actually allow us to accelerate some of those competitive conversions, but time will tell.

Bill Quirk - Piper Jaffray - Analyst

Very good, thank you.

Carl Hull - Gen-Probe - President, CEO

Thank you.

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Operator

Our next question is from Mr. Anand from Natixis. Your line is open.

Ashim Anand - *Natixis Bleichroeder - Analyst*

Thanks for taking my question, guys. I was wondering if you guys would like to comment on -- the [NICE] recently advised against Lucigen [FH20] in favor of comprehensive genetic analysis. I assuming there isn't much revenue effect, but if you can kind of talk about it, what affect it might have and also just in terms of industry, how the regulators are thinking specific mutations versus comprehensive analysis.

Carl Hull - *Gen-Probe - President, CEO*

Yes, Ashim, it is a very good question and probably one that is more complicated than I am capable of answering. I think that first of all, the direct impact of that on our total business is tiny. It is not a significant factor. Secondly you are seeing regulators and advisory bodies all over the world try to wrestle with the issue of companion diagnostics, and it is clear that they have reached no conclusions that are definitive or consistent that I can see. I think the -- as you look at the bigger markets, the FDA in particular is really wrestling with the issue of companion diagnostics. They just put out a draft guidance document on it, and I think that for those of us in the diagnostics industry, we are not sure that it changes terribly much what use to be there, it just mandates the fact that pharma companies are going to have to do these things in tandem, and that they're going to have to have their diagnostic approved or they are not going to get their drug approved. So that's obviously a big change from their perspective, but it still means we have a lot of work to do to get companion diagnostics clear.

Ashim Anand - *Natixis Bleichroeder - Analyst*

And would you guys like to tell us how much [banter] equipment you have placed in Europe??

Carl Hull - *Gen-Probe - President, CEO*

Well, Ashim, we are not going to give the specific number on a quarterly basis, but we will tell you we are on track to hit our full year guidance which would be a handful of dozens -- a few dozen placements. It looks really good right now, and we are quite comfortable with that.

Ashim Anand - *Natixis Bleichroeder - Analyst*

Thank you.

Carl Hull - *Gen-Probe - President, CEO*

You are welcome.

Operator

Tycho Peterson with JPMorgan Chase, your line is open.

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Tycho Peterson - JPMorgan Chase - Analyst

Hi, good afternoon. Maybe just following up on the Europe question, can you just talk a little bit about the PANTHER adoption, new customers versus displacements, utilization in the field and then any comments on mix between diagnostic labs and HPV?

Carl Hull - Gen-Probe - President, CEO

Yes, Tycho, I can, and I think it is an important question because it goes to the heart of, did we get our assumptions right going into it. I think in general, what we are seeing is pretty consistent with what we anticipated. I would say that around 60% of our placements so far have been competitive take aways. When we see those competitive take aways they are coming from Roche and BD on the chlamydia/gonorrhea side, and Abbott and Qiagen on the HPV side. So we are right where we thought we would be. We also have the opportunity to upgrade long-standing accounts from our semiautomated systems and that is going on as well. I think -- as I mentioned I think in the last call, we are devoting more resources to getting these customers up and running fully faster, and we are seeing them run both APTIMA Combo 2 and HPV. More customers run APTIMA Combo 2 only, some customers run HPV only, and the remainder are a mix. And so all that's pretty consistent with what we were hoping and the volumes they are running are also consistent with our forecast.

Tycho Peterson - JPMorgan Chase - Analyst

And then I just wanted to make sure I understood the guidance correctly. I think you talked about lower expenses in the fourth quarter. I'm just trying to reconcile that with the launches and maybe additional color you can provide on kind of beefing up the urology marketing capabilities that you talked about for PCA3 would be helpful too.

Carl Hull - Gen-Probe - President, CEO

Tycho, let me ask Herm to comment on the first part with respect to the guidance and I will ask Eric Tardif to comment a little on the commercial plans.

Herm Rosenman - Gen-Probe - SVP, Finance, CFO

So we said that the third quarter is going to be our highest quarter in terms of over \$30 million in R&D. We have a number of things ramping up there. Probably the major one is starting on the virals, both in terms of specimens and starting -- actually starting the work there, we've got some additional -- we've got the HPV PANTHER trials. So we've got a number of major things starting in the third quarter and that's going to be just naturally lower in the fourth. We said we see continued spending in sales and marketing, that's going to happen in the third, but it's just going to happen to be less in the fourth. In terms of G&A it's primarily going to be BD litigation expenses which will be lower in the fourth quarter.

Carl Hull - Gen-Probe - President, CEO

And Eric?

Eric Tardif - Gen-Probe - SVP, Corporate Strategy and Marketing

Hi, Tycho, it's Eric. So in the case of urology, our plans for commercialization there aren't yet final because the product has not been approved. We're not right now planning to build a large [inaudible -- background noise] urology sales force, but we are considering a more targeted medical marketing effort. So we don't envision a huge cost, but it will certainly contribute to an expansion of our sales and marketing expenditure going into next year.

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Tycho Peterson - JPMorgan Chase - Analyst

Okay. And then last quick one, can you quantify the share gains in blood and maybe comment on whether volumes were up? I am just trying to reconcile what the underlying growth rate is there.

Carl Hull - Gen-Probe - President, CEO

Yes, they were small, Tycho. There were slight fluctuations, but we are up a little bit while the other guy is down a little bit. So you can kind of infer that from what Roche had to say.

Tycho Peterson - JPMorgan Chase - Analyst

Okay. Thank you.

Carl Hull - Gen-Probe - President, CEO

You bet.

Operator

Our next question is from Bill Bonello, with RBC. Your line is open.

Bill Bonello - RBC Capital Markets - Analyst

Yes. I just have a question on your latest thoughts on the use of cash. Herm, you mentioned it is an important strategic asset, but it's one that you've had for four plus years, now. Just curious if you have any intention of maybe getting a little bit more aggressive on share repurchase especially in light of what has happened with the stock as of late.

Herm Rosenman - Gen-Probe - SVP, Finance, CFO

Yes, I think -- we are committed to utilize the authorization we have, roughly \$100 million left on it, Bill. We will continue on that path as the year goes on. In addition, we continue to look at strategic acquisition potential. The use of cash really hasn't changed.

Bill Bonello - RBC Capital Markets - Analyst

Okay. That's all I had.

Carl Hull - Gen-Probe - President, CEO

All right. Thank you, Bill, appreciate it.

Operator

Amit Hazan with Gleacher, your line is open.

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Amit Hazan - *Gleacher & Company - Analyst*

Thanks, hi, guys, can you hear me okay?

Carl Hull - *Gen-Probe - President, CEO*

Sure can.

Amit Hazan - *Gleacher & Company - Analyst*

Oh good. The first question I have is regarding HPV and your thoughts around -- early thoughts, I guess, around marketing plans. We heard from Roche in recent months, in recent weeks, that they are building their sales force directly to the OB/Gyn and I am wondering if you are planning any kind of a strategy that is similar to that outside of just calling on the lab to either the OB/Gyn or the physician -- I'm sorry, or the patient?

Eric Tardif - *Gen-Probe - SVP, Corporate Strategy and Marketing*

I will take that question. This is Eric, Amit. I think the question is a little bit similar to the urology question. As we look into going into next year there certainly is going to be a mix required of marketing efforts to support the HPV program. Some of it centered on the lab, some of it centered on the physician, and carrying the message into the -- carrying a clinical message into the market place. Our plans aren't final yet, there, and we have a little bit of time so I don't think we intend to communicate them right now. But you will certainly be hearing more about it as the year progresses.

Carl Hull - *Gen-Probe - President, CEO*

I think, Amit, I could add to that by just saying that, look, the notion of the direct sales force and direct promotional activity probably depends heavily on the success or sustainability of the strategy of branding HPV tests and getting physicians to request specific brands of HPV tests. As you might imagine, laboratories don't necessarily like that or support it. They are in the business of being as efficient as they can be and think that they are in a pretty good position to determine appropriate technologies. So for example, nobody has a branded amylase test that you ask for. And so I think it is going to depend on a view of the physician and the market as to whether in today's environment it is sustainable to differentiate in that fashion, and that's something we have a view on and it will become apparent over the next couple quarters.

Amit Hazan - *Gleacher & Company - Analyst*

All right, and kind of sticking maybe to a related question on HPV then, I think I am going to tee this one up for you pretty good. The new IOM guidelines that have been -- that came out, that have been in the press to cover co-pays for DNA-based HPV tests, specifically say DNA-based HPV tests. Do you think that is something that is in a way kind of worded to benefit the current players and not players like yourself that are coming on the market? Or do you think that is just something that has to do with the fact that your test isn't approved yet?

Carl Hull - *Gen-Probe - President, CEO*

No. I think when you look at those IOM recommendations, they are really focused on the notion of eliminating co-pays for important preventative services in order to allow patients to take full advantage of those and encourage them to do so, so we think that the way that that's written just reflected the fact if you looked at the market at the time that they were developing the guidelines, that's what there. I don't anticipate that a DNA/RNA distinction would be a sustainable one.

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Amit Hazan - *Gleacher & Company - Analyst*

All right. Thanks very much.

Carl Hull - *Gen-Probe - President, CEO*

Thank you.

Operator

Quintin Lai with Robert W. Baird, your line is open.

Quintin Lai - *Robert W. Baird - Analyst*

Hi. Good afternoon. Good morn -- Good afternoon. Sorry, long day. Okay, so looking at the share count, you kind of mentioned that because of the high share price, the Q2 numbers were higher. But if I look over the quarter, I mean the stock kind of went up and then came down. Is it an average share price or is it share price at the end of the quarter and then if it is an average share price shouldn't the share count in Q3 and Q4, unless you are assuming the stock is going to go back up to where it was, kind of moderate?

Herm Rosenman - *Gen-Probe - SVP, Finance, CFO*

Well it is the average for the quarter. You have to kind of look at it day by day, Quintin. You are exactly right. It also goes back to our plan, and where we thought the stock would be at certain points. But by definition with the treasury stock method as the stock goes up and closes the quarter at a higher average, by definition it's going to be diluted, right?

Quintin Lai - *Robert W. Baird - Analyst*

Right. Okay. So here is my related follow-up, do you have any comment on the share price volatility [and maybe some of the news things] that have followed with that?

Carl Hull - *Gen-Probe - President, CEO*

No, we don't have any comment.

Quintin Lai - *Robert W. Baird - Analyst*

Well, I had to try.

Carl Hull - *Gen-Probe - President, CEO*

Indeed.

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Quintin Lai - Robert W. Baird - Analyst

All right. Thanks.

Carl Hull - Gen-Probe - President, CEO

Yes, you bet. Thank you.

Operator

Brian Weinstein with William Blair. Your line is open.

Brian Weinstein - William Blair - Analyst

Hi, guys, just wanted to clarify a comment. I think you said in the script that there was some new customer demand for TIGRIS and blood screening. Was that referring to the trial in China, or were there other things that you expect to happen here in the second half?

Carl Hull - Gen-Probe - President, CEO

Yes, Brian, thanks. It is related to both China and new business that is being closed pretty much outside of the United States and the major European markets. So Novartis is getting some good traction. They see some up sides there, and I think their anticipation is that they are going to need several more instruments than they originally forecast.

Brian Weinstein - William Blair - Analyst

Okay. And then on Prodesse, you've had it for awhile now and it has gotten you access to PCR. Just kind of wondering what additional products that are you developing here, especially in light of what is seeming to be a tougher differentiation as other companies come on the market to kind of where Prodesse's products were previously.

Eric Tardif - Gen-Probe - SVP, Corporate Strategy and Marketing

Yes, Brian, this is Eric. I will take that. I think, first of all we are still very pleased with the acquisition. It is performing certainly to expectations. And in terms of the related products that we are taking a look at, there are adjacent categories that make a lot of sense. Obviously we are right now concentrated in the flu category, and we are looking at other categories outside of that, that will help diversify that offering. But for the time being we feel very good about our competitive position with that business. And we are looking into branching other categories that are going to help kind of sustain that differentiation.

Brian Weinstein - William Blair - Analyst

Okay, thanks.

Carl Hull - Gen-Probe - President, CEO

Thank you, Doug -- or Brian, sorry.



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Operator

Our next question is from Doug Schenkel from Cowen. Your line is open.

Doug Schenkel - *Cowen & Company - Analyst*

Hi, good afternoon and thank you for taking the questions.

Carl Hull - *Gen-Probe - President, CEO*

Hi, Doug.

Doug Schenkel - *Cowen & Company - Analyst*

Following up on I guess one of Amit's questions a couple back, given what's going on with healthcare reform and broader economic concerns here in the US, are you feeling at all incrementally more positive about your ability to gain traction with hospitals and making the pitch that they should stop sending out HPV's as a means of capturing better economics, meaning keep it in house and keep control, keep the economics?

Carl Hull - *Gen-Probe - President, CEO*

Yes, I think that is in fact what is -- what we see happening, Doug. It has clearly been a driver of business in chlamydia and gonorrhea over the years as well. And I think now that many of those hospitals have already acquired capacity in the form of TIGRIS to do that testing incrementally, adding HPV, if they are sending it out, it makes a lot of sense to them. And certainly as we think about the future with the launch of PANTHER in the United States and the ultimate menu there, I think that is going to be a key driver.

Doug Schenkel - *Cowen & Company - Analyst*

And I guess a related question. Given again what is going on with the economy and the uncertainty, did you see anything abnormal in terms of the pacing of sales during the quarter? Maybe more directly anything that you heard in terms of physician office visits and broader healthcare utilization and any pressure on pricing related to these dynamics?

Carl Hull - *Gen-Probe - President, CEO*

Yes, I think -- look, I think on utilization it is clearly a mixed picture. The [Imus] office visit data shows overall declines, but OB/Gyn as a category, which is obviously very important to us, were up slightly. I think as we see it generally, testing volumes at our key customers have been up and look pretty good right now. But funding pressures still continue to affect the public health sector unquestionably, and that doesn't seem to be easing. I think with all of that taken together that's what the quarter looked like. And we still had a good -- very good quarter in diagnostics. Could it have been better under different circumstances? Yes, probably. And as we think about the price issues, I don't think these types of things directly contribute to price pressures and our pricing has certainly remained stable.

Doug Schenkel - *Cowen & Company - Analyst*

Okay. Thanks again for taking the questions.

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Carl Hull - Gen-Probe - President, CEO

You bet you.

Operator

Isaac Ro from Goldman Sachs, your line is open.

Unidentified Participant - Mizuho Securities - Analyst

This is actually Jeff in for Isaac. Thanks for taking the question.

Carl Hull - Gen-Probe - President, CEO

Hi, Jeff.

Unidentified Participant - Mizuho Securities - Analyst

Hi. Looking at the midpoint of the operating margin guidance for this year of 27% to 29%, so taking that and looking at where you guys were last year, it's about 200 basis points of margin expansion. Looking out at the new products coming out next year as well as all the incremental investment in sales and marketing, are you guys comfortable with a similar level of margin expansion or are we going to be in less that type of environment?

Carl Hull - Gen-Probe - President, CEO

I don't really want to go into 2012 at this point. It is a little bit premature to do that. It will certainly be an issue that factors into our thinking about 2012 and how we guide it when we get there. But in general what you are seeing today in those improvements reflects, as Herm said, improved mix, especially as we have a lot of APTIMA business. If we expand the trich business rapidly, I think that will also continue to be a favorable trend. And then as we look at the Company itself we are really focused on operational efficiencies and we think in the longer term some of the investments that we are making, say in consolidating the European manufacturing in Manchester, and for example part of the investment thesis when we acquired GTI was to improve the profitability of LIFECODES. So we are looking actively for ways to continue that.

Unidentified Participant - Mizuho Securities - Analyst

All right. Thanks. And then switching over to chlamydia/gonorrhea for the second, and the strength in the quarter. How much of that was accelerated conversion of APTIMA -- from PACE to APTIMA versus true share gains or utilization improvements?

Carl Hull - Gen-Probe - President, CEO

Well, you can see from the numbers and back calculate it, we said that PACE was down 25% and it's down at about \$3 million so not much of that growth was really just attributable to PACE conversions. I think it is really more of the competitive take aways.



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Unidentified Participant - *Mizuho Securities - Analyst*

All right. Thanks a lot.

Carl Hull - *Gen-Probe - President, CEO*

You bet.

Mike Watts - *Gen-Probe - VP, IR and Corporate Communications*

Operator, I think we have time for one more question and then we will have some brief closing remarks, maybe two we go quickly.

Operator

Thank you, our final question is from Spencer Nam, Madison and Williams. Your line is open.

Spencer Nam - *Madison Williams and Company - Analyst*

Thanks for taking my questions. I will be very quick so I can give another person a chance. First question, so PANTHER in the US, with this FDA -- people talking about pressure from the FDA to scrutinize these approval processes. Are you seeing anything different that you hadn't seen before, for example when you are going to a TIGRIS versus PANTHER? Any difference in the FDA's attitude or approach to approval?

Carl Hull - *Gen-Probe - President, CEO*

Well, obviously I don't want to comment on the specifics of our interactions with the FDA around a particular product for obvious reasons, but I would say that as you talk to other people in the industry and you see some of the work being done by (inaudible) and other industry associations, it is fairly clear that the FDA has become, if you will, I don't want to say more rigorous. They have always been fairly rigorous. But have become much more challenging in the review processes, enforcement activities are up generally across the board, and can be quite challenging for a number of folks. So we are seeing much more action with the FDA in product reviews than there has been. As you look forward at the potential changes to the 510-K process, those could be very significant. Again, we always like to remind people that a lot of the concerns about the 510-K process have to do with devices. Now, we are always lumped in the devices and diagnostic space. But relatively infrequently our diagnostic products are a particular concern in the use of the 510-K pathway. And often for example in our business when we do microbiology related submissions, which are many, even in our 510-K's, we include clinical data. So it's not quite the same as people perceive it about the device side of the business. So I think answer is the FDA is getting tougher and you have to have sophisticated and extensive regulatory capability to stay up with it and we feel that we do.

Spencer Nam - *Madison Williams and Company - Analyst*

And then a quick question, how long did you know about the PCA3 panel date?

Carl Hull - *Gen-Probe - President, CEO*

I think we learned in the last couple weeks, something like that.

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Spencer Nam - *Madison Williams and Company - Analyst*

Great. Thanks very much.

Carl Hull - *Gen-Probe - President, CEO*

All right, Spencer, thank you. And operator we do have time for one more question.

Operator

Jon Wood with Jefferies, your line is open.

Brandon Couillard - *Jefferies & Company - Analyst*

Great, thanks. This is Brandon Couillard in for John. Herm, did the guidance contemplate any share repurchase activity and/or any de-leveraging?

Herm Rosenman - *Gen-Probe - SVP, Finance, CFO*

It does. We intend to be active with our authorization. I mentioned before that we have roughly, a little bit more than \$100 million left, and we intend to use that throughout the rest of the year.

Brandon Couillard - *Jefferies & Company - Analyst*

And then quickly on the trich backlog, would you characterize the interest there as coming from competitive take aways or these greenfield opportunities from those customers so far?

Carl Hull - *Gen-Probe - President, CEO*

Yes, we wouldn't characterize it as a backlog. It is just the launch process and getting everybody up and running. I think it is actually a little bit of both. There are clearly existing methods that are out there today, but they are not very easily done and not readily scalable. So I think some of the interest we are seeing is from those areas and then this will also be an opportunity because of the common sample type for other laboratories that may not be doing the testing to add that capability.

Brandon Couillard - *Jefferies & Company - Analyst*

Great. Thank you.

Carl Hull - *Gen-Probe - President, CEO*

You bet, thank you. And Michelle, thanks for your help today, and thank you all for your questions. I would just like to wrap up by saying Gen-Probe's second quarter financial results were in line with our expectations overall as strength in women's sales offset softness in blood screening due to supply chain fluctuations. On the bottom line, strong profitability enabled us to exceed our stated EPS goal for the quarter. And we also remain excited about the pipeline. As the very early success of our trich launch and the performance of PANTHER in Europe gives us confidence in future US product launches. Before we sign off let me remind you that our prepared remarks will be posted on our website momentarily, and we encourage you to refer to them if you missed

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a fact or a number during the call. Thank you for your time and attention today. And please call us if you have any follow-up questions.

Operator

Thanks very much for participating in today's call. You may disconnect at this time.

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