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GPRO - Q4 2011 Gen-Probe Incorporated Earnings Conference Call

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## PRESENTATION

### Operator

Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. We will conduct a question-and-answer session during the conference. (Operator Instructions). Today's conference is being recorded. If you have any objections, you may disconnect at this time. I will now introduce your host for today's conference, Mr. Mike Watts, Vice President of Investor Relations. Sir, you may begin.

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**Mike Watts** - *Gen-Probe Inc. - VP Corp. Communications & IR*

Thank you, Sherry, and good afternoon everyone. I am pleased to welcome you to this conference call to discuss our fourth-quarter 2011 business results.

00 PM Eastern time and is posted on our website at [www.Gen-Probe.com](http://www.Gen-Probe.com). After our prepared remarks today, we will take your questions for the balance of an hour, then post our script on our website for your convenience and reference.

Before we begin, let me 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 2012 financial guidance, financial condition, regulatory approvals and time lines, 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 and 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 Form 10-K and all subsequent periodic reports. Copies of these reports are available on our website at [www.SEC.gov](http://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 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 meaningful supplemental information regarding the Company's performance by excluding certain expenses and other items 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 Chairman and CEO.

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Thank you, Mike. Good afternoon, everyone.

I'm pleased to report that Gen-Probe finished 2011 strongly. In the fourth quarter, revenues were in line with our expectations, and earnings per share came in a little better than we had forecast. Clinical diagnostic revenues continued their solid growth in the quarter led by the APTIMA Women's Health portfolio, while sales of Blood Screening products increase significantly as supply-chain shipments rebounded.

Just as important, we enter 2012 with excellent momentum. We have three important new product launches -- PANTHER in Europe and trichomonas and HPV and the US that are off to good starts around the world with two more expected soon pending FDA approval.

In my remarks today, I will discuss our revenue results for the fourth quarter and spend a few minutes on our near-term growth drivers. Herm will then discuss fourth-quarter expenses and our 2012 guidance. In that context, he will highlight future investment priorities that we believe will drive sustainable organic growth for the next several years.

You will notice a consistent theme in our remarks today, a focus on one unique differentiating capability that plays a role in almost all our past successes and future plans. That is our ability to deliver automation to our laboratory customers. For example, blood banks around the world continue to value the automation and process controls of the TIGRIS system which led to significant sales of instruments to Novartis in the fourth quarter. The automation of TIGRIS is also driving continued growth in sales and market share for the APTIMA Combo 2 assay more than a decade after we launched the product for STD testing.

At the same time, TIGRIS automation is enabling adoption of two new products, our APTIMA Trichomonas assay and our APTIMA HPV test as we begin to see the early benefits of adding menu to a large installed base of insurance. 2012 will be a year in which our razor/razor blade business model really begins to pay off in Clinical Diagnostics.

Finally, the automation of PANTHER, which enhances what we've accomplished with TIGRIS but at a significantly lower cost, is making good inroads in Europe. This motivates us to add new capabilities and assays that will drive overall Company growth in the medium term.

These new projects include developing viral load assays using real-time TMA for the current PANTHER system and adding real-time PCR chemistry for the next-generation PANTHER instrument. Both of these efforts will be key R&D programs in 2012, adding expense in the short term but also the promise of sustainable organic growth for years to come.

Now, let's get into our fourth-quarter results, which I will discuss on a non-GAAP basis. Product sales establish a new record of \$155.2 million in the quarter, up 18% compared to the prior-year period. The strong growth in product sales lead to total revenues of \$158.2 million in the quarter, another all-time high and consistent with the forecast of \$157 million to \$162 million we provided in our last call.

Herm will discuss the various expense components, but let me jump down to the bottom line, where a healthy operating margin of almost 29% and a favorable tax rate led to non-GAAP earnings per share of \$0.72, another record and ahead of our last guidance range, which was \$0.66 to \$0.70 per share.



Turning to the components of product sales in the fourth quarter, Clinical Diagnostics sales were \$90.6 million, up a strong 13% compared to the prior-year period. Growth was again led by our APTIMA Combo 2 assay for detecting chlamydia and gonorrhea, which grew at a low double-digit rate globally as a result of continued market share gains. Based on recent commentary from our largest competitor, we roughly doubled their growth rate in the quarter.

As I mentioned earlier, TIGRIS has been and continues to be a key contributor to the success of APTIMA Combo 2. We now have placed approximately 275 TIGRIS systems at clinical diagnostic customers since the instrument was launched in early 2004 and the sustained level of interest from potential new customers continues to surprise us on the upside. But instrument placements don't tell the full story of how TIGRIS creates value for customers and shareholders.

Since we place most of our diagnostic systems on a reagent rental business, we generate the bulk of our revenues from assay pull-through. The extremely high throughput of the TIGRIS instrument helps it shine in this regard. The average annual revenue stream on a diagnostics TIGRIS placement is now about \$575,000 a year, a number you won't find anywhere else in the molecular diagnostics industry. Importantly, this level of pull-through still leaves us with plenty of capacity to add our Trichomonas and HPV test to the daily menu.

Let's discuss those new products now, starting with our APTIMA Trichomonas assay. As we've said at a recent investor conference, more than 80 customers in the United States or about 40% of our TIGRIS accounts have adopted or are evaluating our Trichomonas assay roughly nine months after launch. Importantly, assay revenue is just now starting to accelerate as our lab customers are very early in their own market development efforts.

Trichomonas sales increased sequentially in each quarter of 2011 and added nearly 1 point to total product sales in the fourth quarter. In addition, January represented our best month of Trichomonas sales, continuing last year's momentum and giving us confidence in our trajectory for 2012.

As a point of reference, it took approximately 23 weeks after FDA clearance for us to record our first \$1 million in US Trichomonas sales. The second \$1 million took less than 10 weeks while the third \$1 million took less than eight weeks. This defines a sales chart that is progressing in the proper direction, up and to the right.

We had similar high hopes for our APTIMA HPV assay, although our launch is at a much earlier stage since FDA approval was just granted in the fourth quarter. We spent a fair amount of time in our last call discussing the advantages of our next-generation HPV assay, so I won't repeat that today. Suffice it to say that our key message of about 25% fewer false positive results is resonating nicely with customers.

I will remind you, however, that our APTIMA HPV assay also runs on the TIGRIS system, which remains a powerful draw for high-volume customers who are eager to improve their own operations. Our primary competitor in this arena has said that 90% of their HPV business comes from large labs. This puts them squarely in our sights, since many of these customers already have one or more TIGRIS systems for chlamydia and gonorrhea testing.

Now, with the approval of our HPV and Trichomonas assays, these customers can test hundreds of samples daily with any of our three assays on the TIGRIS system. This testing occurs from the same primary sample with less than an hour of hands-on time, boosting efficiency for the lab within a single shift. No other company can offer this kind of synergistic Women's Health menu today, let alone the ability to run all of the assays on a single automated platform.

To extend our leadership in automation and to further leverage our core instrument development capabilities, we recently announced efforts we have underway to develop a small stand-alone instrument to facilitate the de-cathing and transfer of liquid-based cytology specimens to the TIGRIS, PANTHER and other systems. We expect this new instrument to be commercially available next year.

Overall, we are extremely pleased with the customer interest in our HPV value proposition, which is based on TIGRIS automation and substantially improved performance as a next-generation screening assay. Many large customers are evaluating our product, and we have already recorded our first commercial sales a couple of months sooner than we expected. We look forward to providing you with more color as the launch progresses.

To ramp up our discussion of clinical sales in the fourth quarter, Prodesse revenues were up slightly compared to the prior year, but short of our expectations as the flu season got off to a very slow start and remains mild thus far.

On the other hand, our LIFECODES transplant diagnostics products performed well in the quarter. The former GTI diagnostics, which we acquired in December of 2010, added a few hundred basis points to product sales, as expected. The financial benefits of this acquisition have now annualized, so our growth estimates for 2012 are fully organic.

Now, let's turn to Blood Screening revenue in the fourth quarter. Sales were \$62.1 million, up 30% compared to the prior-year period. As we forecast in our last call, this resulted primarily from increased shipments of both assays and instruments to Novartis Diagnostics, our commercial partner in Blood Screening. These higher shipments essentially compensated for supply-chain fluctuations that hit our results earlier in the year. Compared to the prior-year period, approximately half of the \$15 million improvement came from higher assay shipments and half from increased instrument orders, primarily reflecting continued strong placements in China and other emerging markets.

We were not overly concerned with the negative supply-chain fluctuations earlier in 2011, so by the same token, we don't want to overstate the importance of the positive uptick in the fourth quarter. Underlying our strong reported number, global donations were essentially flat in the fourth quarter, consistent with the market environment we have described over the last few years.

Before wrapping up, let me quickly say that we continue to make progress with the FDA on the two major products still under US regulatory review, our PROGNSA PCA3 assay and the PANTHER system. On PCA3, we think we are close to approval after a long review process that is typical for oncology products. We believe our PCA3 assay will add significant clinical value for clinicians and patients who are contemplating the need for repeat prostate biopsy.

Regarding the PANTHER submission which was filed in May of last year, our best guess for clearance continues to be sometime in the first half of 2012. This would be well within normal bounds for a complex instrument 510-K.

Outside the United States, we feel very good about our progress with PANTHER. We met our goal of placing a few dozen instruments internationally in 2011 and reliability remains high. Assay revenue is picking up as customers complete validations and more systems come online for regular testing. PANTHER related revenues added more than 100 basis points to product sales in the fourth quarter, even excluding instrument shipments to our commercial partners, Novartis and Roka. Due in part to the positive customer feedback we have received on PANTHER, we are aggressively pursuing avenues to increase the depth of menu on the system and to broaden its appeal to potential customers.

Customers love PANTHER and our engineering and marketing teams have embraced the challenge of increasing its utility further. For example, our development of viral load assays for the PANTHER system is proceeding well. These tests, which employ real time TMA chemistry, will be our largest assay development program over the next couple of years, utilizing many of the dollars that were allocated to HPV. Our viral load assays remain early in development, but we continue to expect our first international product introductions around 2014.

Another way we are striving to increase the reach of PANTHER is by adding real-time PCR capabilities for the next-generation system. The ability to combine isothermal amplification with thermal cycling on a single instrument is a significant technical accomplishment, one that reflects the creativity, innovation and expertise of our measurement development team. Initially, adding real-time PCR to the PANTHER system will provide a proprietary platform for our Prodesse respiratory assays in the 2015 time frame. As PCR-based flu customers install the next-generation panther system, they can also run APTIMA Women's Health assays, increasing potential pull-through. Further down the road, we plan to develop additional assays that will be able to participate in emerging markets that historically have been dominated by PCR chemistries.

Strategically, we believe that adding viral load assays and PCR chemistry to PANTHER will provide important sources of organic growth over the immediate term. Our successful ongoing launches of PANTHER, Trichomonas and HPV have reminded us just how much fun it is to have new products and our R&D investments in 2012 are a down-payment on maintaining that continuous flow of new product innovation in the future.

Before I turn the call over to Herm, let me wrap up by reemphasizing the commercial value of our well-established lead in automation. On the foundation of TIGRIS, Gen-Probe has built two vibrant market leading, highly profitable franchises in Women's Health testing and Blood Screening.



Our financial performance in the fourth quarter of 2011 speaks to the success of our strategy. 2012 and 2013 will be years in which we strengthen these franchises with the new assays that you've heard a lot about, HPV and Trichomonas, and the new instrument, PANTHER, that extends our competitive advantage in automation. These launches are proceeding well and we expect them to underpin low double-digit organic growth this year, an acceleration compared to the recent past.

At the same time, we are acutely focused on maximizing the value of PANTHER to customers and shareholders. For example, the R&D investments we are making today will begin to pay off in 2013, '14, and '15 as we introduce additional assays and capabilities for the PANTHER system that have the potential to drive sustainable, profitable growth for the foreseeable future.

So I hope you can tell, we're pleased with how we finished 2011, excited about our prospects for double-digit growth in 2012, and confident that the years beyond will hold great promise as well.

Now I'd like to turn the call over to Herm. Herm?

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

Thank you, Carl. Good afternoon everyone.

I'll start by reviewing collaborative research revenue, which was \$1.4 million in the fourth quarter, down 62% from the prior-year periods. This decrease was due, as expected, from Novartis hitting their cap for reimbursement of PANTHER Blood Screening development costs earlier in 2011.

Royalty and license revenue was \$1.6 million in the fourth quarter, down 16% from the prior-year period, due mainly to lower royalties from Novartis related to the plasma testing market.

Now let me turn to quarterly expenses, which I will discuss on a non-GAAP basis. Gross margin on product sales was 66.7% in the fourth quarter, compared to 69.5% in the prior-year period. As we forecast in our last call, gross margin was down due to increased sales of low-margin TIGRIS instruments to Novartis. These instrument sales of course are a necessary precursor to higher-margin assay sales down the road. If you back out the effects of all instrumentation from our fourth-quarter results, gross margin on product sales would have been 72.8%, 60 basis points higher than the comparable number from the prior-year period.

Research and development expenses for the fourth quarter were \$28.2 million, up 5% compared to the prior-year period due primarily to the addition of GTI's R&D programs.

Marketing and sales expenses in the fourth quarter were \$17 million, up 13% compared to the prior-year period due mainly to strategic investments in our European commercial infrastructure and the addition of GTI's cost structure.

General and administrative expenses were \$15.6 million in the fourth quarter, 6% higher than in the prior-year period, again due mainly to the addition of GTI's cost structure.

Total Other Income in the fourth quarter was \$400,000, roughly half the level of the prior-year period. This decrease, which we forecast in our last call, was due mainly to foreign exchange losses.

Our effective tax rate in the fourth quarter of 2011 was 27%, better than we expected, primarily due to the utilization of foreign losses and higher ex-US sales. Obviously, this translated into a nice benefit on earnings per share in the quarter.

Our weighted average share count in the fourth quarter was 46.9 million, lower than the prior-year period due to the completion of our (technical difficulty) buyback. So, on the bottom line, all this nets out to \$0.72 of non-GAAP earnings per share in the fourth quarter, a new record and ahead of the guidance we gave in our last call.



Cash conversion was strong in the fourth quarter. We generated operating cash flow of \$53.4 million in the quarter while spending \$7.2 million on property, plant, and equipment, leading to record free cash flow of \$46.2 million.

Moving on to the balance sheet, we closed 2011 with \$368 million in cash, cash equivalents, and marketable securities, lower than at the end of 2010 due to significant stock repurchase activity. Yet, we still maintain about \$2.50 of net cash and equivalents per share. This is net of \$248 million of short-term debt on which we pay interest at less than 1% pretax.

Now, I would like to turn to our 2012 financial guidance. As I said in our press release, we expect to return to low double-digit organic revenue growth based on new product launches that Carl discussed. We forecast a similar rate of bottom-line growth as we invest in commercial resources to ensure that product launches are successful in R&D projects that will drive our next wave of growth. We expect to achieve this level of bottom-line growth despite headwinds from unfavorable foreign exchange rates, lower nonoperating income, and higher taxes.

I will provide our 2012 guidance on a non-GAAP basis that excludes acquisition related intangibles amortization, other transaction related expenses, and restructuring charges. Full GAAP guidance is also included in our press release.

Beginning with product sales, we forecast that Blood Screening revenues will grow slightly in 2012 driven by progress in emerging markets, Novartis' entry into plasma testing, and a contractual step up of 100 basis points in our share of collaboration revenues related to hepatitis C containing assays.

In Clinical Diagnostics, we expect our APTIMA Combo 2 assay to continue growing solidly in 2012, benefiting from market share gains on TIGRIS as well as the PANTHER launches in both Europe and the United States. We also forecast good growth from our LIFECODES transplant diagnostics franchise. Last, but certainly not least, we anticipate a few percentage points of incremental product sales growth from our new assays, namely Trichomonas, HPV, and PROGENSA PCA3, which will help us cross into double-digit territory overall. Obviously, these contributions will be greater in the second half of the year than the first based on anticipated approval timing and the resulting sales ramp.

Collaborative research revenues should be higher than in 2011 based on a \$5 million milestone that we anticipate earning from Novartis in the second half of 2012 when the PANTHER system is launched internationally for Blood Screening.

Royalty and license revenues are forecasted to be similar to 2011 levels.

All this adds up to our total revenue guidance of \$630 million to \$655 million, which represents about 11.5% growth at the midpoint, an acceleration compared to 2011.

Working down the income statement, we forecast product gross margin of between 68% and 69.5% in 2012, roughly the same as last year. Foreign exchange is expected to be a headwind to gross margin at current levels, masking the underlying improvement that we expect to see in our core products.

As Carl alluded to, both research and development and sales and marketing expenses are expected to increase substantially in 2012. In the case of R&D, significant resources will be devoted to the two new instrument programs that we announced in January, to the viral load assays on PANTHER and to complement our Women's Health assays such as HPV genotyping and Trichomonas on PANTHER. In addition, we are still spending on the mandatory long-term follow-up of women enrolled in our APTIMA HPV trial. Together, we forecast that these projects will cause R&D expenses to increase by more than 10% in 2012.

We recognize this is a significant investment, but we believe it is warranted in 2012 by both discounted cash flow and strategic analyses. In addition, we remain committed to achieving significant leverage from our R&D spend over time.

In terms of sales and marketing, we have said many times before but that this expense line will grow faster than revenue in 2012 as we invest in European commercial expansion and successful launches of our new products. We only get one chance to launch Trichomonas, HPV, PANTHER and PCA3, and we want to do it right. We expect to achieve good leverage from G&A expense in 2012, even as we incur significant legal costs



associated with our patent infringement lawsuit against Becton Dickinson. All of this should lead to an operating margin that is fairly similar to 2011 levels, ranging from 26.5% to 28%.

Below the operating income line, we expect some headwinds that would drag on earnings per share growth in 2012. Specifically, we forecast a significant decrease in Other Income due to lower cash balances and the absence of realized investment gains that added nearly \$6 million to our results in 2011.

You might recall that, in our last call, we guided to a significant drop in Other Income in the fourth quarter 2011 and forecast that this run rate would continue into 2012. In addition, our tax rate is likely to increase to between 30.5% and 32.5% in 2012 as we cannot count on releasing reserves tied to expiring audit statutes, which benefited us in 2011. Please note that our guidance assumes that the federal R&D tax credit will be reinstated late in 2012 as it has been in recent years. This means our tax rate will be higher in the first three quarters of 2012 and lowest in the fourth quarter.

We anticipate a diluted share count of roughly 47 million shares as we do not currently have an authorized share repurchase program.

All this leads to our 2012 earnings per share guidance of between \$2.50 and \$2.68 on a non-GAAP basis. At the midpoint, this represents approximately 11% growth over 2011 despite lower nonoperating income and higher taxes.

In addition, I should point out that our guidance incorporates recent foreign exchange rates, which are subtracting about \$4 million from our anticipated 2012 revenues and roughly \$0.05 from EPS. So on a constant currency basis, assuming the same rates as in 2011, our 2012 guidance would be that much higher. It appears that recent foreign exchange rates have not been incorporated into most Wall Street estimates, given their inherent volatility.

In terms of the pacing of quarterly results, we anticipate a steep sequential ramp in revenue and earnings as the year progresses. The primary drivers of this are new product sales that are expected to increase over the course of 2012 and certain expenses that are front-end loaded.

Specifically, in the first quarter, we expect revenues of between \$148 million and \$152 million. This is much less than the fourth quarter of 2011, primarily due to lower anticipated shipments of Blood Screening assays and instruments to Novartis. In addition, we're not getting much help from the flu season, which is very light to date.

Operating expenses are forecasted to increase materially in the first quarter, again due to the timing of discrete R&D projects and other activities leading to earnings per share of between \$0.48 and \$0.52 in the quarter.

In closing, let me summarize the financial section of our conference call by saying we had a solid finish to 2011 with revenues in line with our expectations and earnings ahead of forecast. We enter 2012, an important and exciting year for the Company, with the wind at our backs due to several new products that are performing well so far. We believe these new products will help us return to double-digit growth on the top line this year. At the same time, we're very deliberately choosing to invest in NPV positive R&D projects that will drive our next wave of growth. We anticipate double-digit earnings growth at the midpoint of our guidance range despite headwinds from foreign exchange rates, lower nonoperating income, and a higher tax rate.

Now, I would like to turn the call back over to Mike.

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**Mike Watts** - Gen-Probe Inc. - VP Corp. Communications & IR

Thanks, Herm. I'd 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 Tardif, Senior Vice President of Marketing and Corporate Development; and Kevin Herde, Vice President of Finance 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.

## QUESTIONS AND ANSWERS

### Operator

(Operator instructions). Bill Quirk, Piper Jaffray.

### Dave Clair - Piper Jaffray & Co. - Analyst

It's Dave Clair here for Bill. I guess the first question -- given that we are three months into the HPV launch here, is there any change to your pricing strategy and what are you hearing feedback from accounts so far?

### Carl Hull - Gen-Probe Inc. - Chairman, CEO

Well, Dave, we've pretty much made it a practice not to discuss our pricing strategies in public forums. I think it is fair to say you are saying a market space that has had increased competition over the last nine months with the entrance of Roche and us into a space that previously was really dominated by one party. I think that you could expect different people to have different reactions. Our point of view is we have a differentiated offering, both in terms of automation and assay performance, and we intend to capture the value associated with that differentiation.

### Dave Clair - Piper Jaffray & Co. - Analyst

Okay. Then a quick follow-up here on guidance, what kind of -- what are the assumptions between the high end and the low end? What is the delta there?

### Herm Rosenman - Gen-Probe Inc. - SVP Finance, CFO

Well, you know, as we have said in the past, the way we handle the guidance is we generally take a look at the upside-downside; we do our forecasting from the bottom up and then we take a look at from the top down on what the ranges could be for things like foreign exchange effects and the like. That is pretty much how we go about doing that.

### Operator

Jon Groberg, Macquarie Capital.

### Jon Groberg - Macquarie Research Equities - Analyst

Thanks a million for taking the question. I guess, Carl, obviously if you look at the guidance from what you're expecting for the year, the big question is obviously the significant ramp that you must be expecting in the second half. Can you maybe talk a little bit about with -- and a lot of that would be (inaudible) you alluded to in HPV. So you have the TIGRIS instruments there. You have to run them in batches. Obviously very automated for the batches that you run. Can you maybe talk a little bit more specifically about your customers that are running, that are doing this, that are running Trich and the feedback they're getting? What gives you the confidence that you're going to see that big ramp in the second half?

### Carl Hull - Gen-Probe Inc. - Chairman, CEO

Sure, Jon. I think there's several elements to it. First, it's just the practicality associated with introducing new products and building momentum. I think the example I gave of doubling time, if you will, for Trich that we experienced this past year in the United States gives you a good example



of that. So we've got couple of things working in our favor. The first is the PANTHER installed base in Europe. Those instruments, as I said, have been coming up and getting validated and becoming fully operational. So those start to kick in and we expect continued placements in Europe. Those will begin to generate revenue in the back half of the year.

As we launch PANTHER in the United States, we're really not expecting that in and of itself to be a big contributor this year, while it's very significant contributor in '13 and '14 as those instruments do just like in Europe become more mature placements and are really up and running.

As we look at Trich, we're just seeing continued strong interest, especially from major laboratory customers. They have the sales channels that get the word out and develop the market and develop the demand. That effort is ongoing. As I said, we've been very pleased with the results thus far and the discussions I've had with many of our major customers directly, they're thrilled with the product offering and it allows them to expand the menu and services that they offer their customers. So you combine that with Trich, you look at HPV, we do think of HPV in the United States as likely to be a discontinuous variable. In other words, it's going to be a couple of big accounts will influence the overall shape of the marketplace, so very hard to protect those kind of things, but they won't happen right away. They'll take some time to implement. So that's kind of how we see it.

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**Jon Groberg** - *Macquarie Research Equities - Analyst*

So just as a follow-up, just to be clear, so I think, in the past, you had thought maybe HPV within a year or so you can get kind of that similar market share that Hologic had gotten. Just to be clear, it sounds like you're saying it could be a little bit lumpy as you go throughout the year. Then just to kind of follow-up here, you got any revenues out there for PANTHER for Blood Screening, do you anticipate that internationally, you getting sales for that in 2012? Thanks.

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Well, let me parse out a couple of different things to answer your question kind of working backwards. With PANTHER for Blood Screening, I don't think you'll see significant assay revenues in 2012. There is however a \$5 million milestone payment once it's commercialized for Blood Screening, and that is baked into our numbers.

With respect to HPV, if I wasn't clear, we do expect to see a number of accounts adopting it. I mentioned earlier we have already achieved our first commercial revenues and have customers ordering and reordering. We're quite pleased with that at this stage in the launch. So I think that will go on throughout the course of the year.

What I was referring to is that you may see really big upsides against our baseline forecasts if a big customer or two decides to move in our direction. But, again, all of that stuff is likely to be back-end loaded.

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**Operator**

Bill Bonello, RBC Capital.

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**Bill Bonello** - *RBC Capital Markets - Analyst*

Sure. Just a question and maybe a follow-up on the guidance. I'm just trying to understand a little bit more the gross margin guidance. Maybe you can give us a quantification of sort of the basis point impact of the currency impact on gross margin in 2012.



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

It's within our range of 68% to 69.5% gross margin. We basically look and sensitize it \$5 million or \$10 million. million I'm not going to tell you, but you know, some number like that on either side, and so that is included in the range that we have out there.

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**Mike Watts** - *Gen-Probe Inc. - VP Corp. Communications & IR*

It's Mike. So that FX effect, as you might recall, falls straight to gross margin, so that is the single biggest item affecting the gross margin percentage for 2012.

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

In addition, we also have a high amount of instruments in there as well, so that is going to affect gross margin too. In our prepared script, you could see there was a couple of hundred basis points between the net margin that is reported and what it would've been if you take instruments out. There's going to be significant instrumentation every year.

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**Bill Bonello** - *RBC Capital Markets - Analyst*

Okay, that's helpful. Just in terms of a follow-up on the Q1 revenue guidance, it looks like you're looking for sort of exceptionally low growth at the low end of the guidance. I appreciate a limited flu season and the ramp in the back half of the year, but what else in Q1 would make growth just so much lower than what it has been over the last many quarters?

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

Well, certainly for the last quarter on a sequential basis, there's a huge amount of Blood Screening assay revenue and instrumentation. That's going to be the biggest one.

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**Bill Bonello** - *RBC Capital Markets - Analyst*

Right. But it's lower than sort of where you have been trending prior to that?

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

Well, I mean, as we said in the prepared script, Bill, the flu has been very weak and, you know, certainly the biggest one I can think of off the top of my head is going to be Novartis.

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**Operator**

[VJ Kumlar], Deutsche Bank.

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**VJ Kumlar** - *Deutsche Bank - Analyst*

So I guess my first one was CPA (inaudible) I know that Roche recently had their assay approved. Could you guys talk about sort of what you're seeing in that marketplace?

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**Carl Hull** - Gen-Probe Inc. - Chairman, CEO

Yes, VJ, I can give you a little color, and maybe I will ask Eric to step in here as well. Roche has not, as you know, been a significant factor in the overall market for CT/NG here in the United States. Obviously much different outside the United States where they had a historically strong position. Let me ask Eric to tell you what we understand about the most recently cleared assay.

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**Eric Tardif** - Gen-Probe Inc. - SVP Corp. Development & Marketing

Yeah, thanks for the question. It is our understanding that, for now at least, that their CT/NG assay is cleared on a limited set of sample types and so that clearly limits the uptake that they can target. Also, they continue to be at a disadvantage from an automation point of view. So we're watching the development, but right now, it does not appear to be a significant commercial impact for us.

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**VJ Kumlar** - Deutsche Bank - Analyst

Okay. My follow-up was -- or I guess my next question was on cap deployment. Could you talk about what the focus will be in '12? I know you're ramping up on (inaudible) building up your commercial organization, but like you said, you've fulfilled your existing buyback program. So what is the focus?

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**Carl Hull** - Gen-Probe Inc. - Chairman, CEO

Yes, I think our philosophy, if you will, remains unchanged here. We've demonstrated the Board's view that there's really two major uses of our strong operating cash flow. The first of those is clearly strategic acquisitions when they make sense to us. Eric and his team are active in that area, scanning the opportunities that exist and failing opportunities to utilize cash in that fashion, we think buybacks have made historical sense. I think our philosophy is going to stay that way for the time being.

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**Operator**

Dan Leonard, Leerink Swann.

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**Dan Leonard** - Leerink Swann & Co. - Analyst

Thank you. Can you talk a little bit about the performance of APTIMA Combo 2 in the US during the fourth quarter? Was it still growing? Is there still PACE conversion or competitive takeaways to be had in the US market?

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**Carl Hull** - Gen-Probe Inc. - Chairman, CEO

Hey, Dan. Why don't I ask Mike to answer that for you.

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**Mike Watts** - Gen-Probe Inc. - VP Corp. Communications & IR

Yes, Dan, APTIMA had another good quarter in the US and internationally, up double digits in the US. Some of that of course is PACE conversion. The PACE is a pretty small product left for us right now. The biggest chunk was market share gains, so we are enthusiastic about that.

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**Dan Leonard** - *Leerink Swann & Co. - Analyst*

Thanks, Mike. Then my follow-up, on the guidance for 2012, Herm, I know you have a lot more visibility in your blood business than you used to. Is there anything we should be aware of in terms of quarterly cadence of that blood revenue throughout 2012?

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

We hope not.

**Dan Leonard** - *Leerink Swann & Co. - Analyst*

Okay.

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

We think that's ramped back to normal inventory levels, yes.

**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Dan, I think we will pay as close attention to it as we can. It is a complex logistical relationship that we have with our partner, and we know what to be paying attention to.

**Operator**

Jon Wood, Jeffries.

**Jon Wood** - *Jefferies & Co. - Analyst*

Thanks a lot. It doesn't sound like you've rolled up your guidance this way, Herm, but I'll ask this anyway. If PCA3 and PANTHER are not approved in the US, can you still hit the bottom end of your revenue forecast for the year? Then I will just do my follow-up quickly. Can you give us cash flow outlook for '12, CapEx included if you have it? Thank you.

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

Well, our guidance rolls up with assumptions that both assays -- I think we implied that in our prepared comments -- are improved approved. We said probably for the instrument PANTHER by midyear. PCA3, we talked already in the past about discussing labeling with the FDA, and that normally implies you're getting closer to the finish line. In terms of cash flow, we mentioned a few times in the \$13 million to \$15 million of cash flow per month, intending to spend roughly in the \$40 million to \$50 million per year. If that gives you enough to work with, Jon.

**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Hey, Jon, it's Carl. I'll be a little bit more direct. To the first part of your question, I think the answer is yes, we can't do that but you have to temper that, right? As I said earlier, PANTHER contributions to assay revenues in the United States given an assumption of clearance in the first half would not be terribly significant overall whereas they're much more important in 2013. As you do know, we continue to sell PCA3 as an analyte specific reagent here in the US and as a kitted product outside of the United States, so there will be base business that goes on. It's not like it is going from zero to some big number.



**Operator**

Ashim, Anand, Natixis.

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**Ashim Anand** - Natixis Bleichroeder - Analyst

Thanks for taking my question guys. I was wondering. What was the growth rate of revenue in Europe for 2011?

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

In Europe, I'll do it for diagnostics, was in the high single digits.

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**Ashim Anand** - Natixis Bleichroeder - Analyst

So, in terms of guidance, to the extent that you can comment, obviously you guys have been doing extremely well in Europe, high teens growth. However, the situation in Europe has changed. However, it is very demographic-based, you know, Southern Europe, Northern Europe, et cetera. So to the extent Europe affects your guidance, if you can comment on that?

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**Mike Watts** - Gen-Probe Inc. - VP Corp. Communications & IR

It's Mike. Let me just clarify one thing too on the numbers. So sorry, I think we're going back and forth between Blood Screening and Diagnostics, but diagnostics, ex-US, which is how we look at it internally, was up around 20% for the year, so nice, strong growth there.

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**Ashim Anand** - Natixis Bleichroeder - Analyst

Okay. So, overall, how you guys are thinking about Europe in this year in terms of your guidance? In terms of the various variables, where does it stand? Obviously, there are new products and stuff like that. So just if you can give us general commentary how much you're worried about Europe, or you're not worried about Europe, so just general anything general you can comment on?

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**Carl Hull** - Gen-Probe Inc. - Chairman, CEO

It's Carl. I'll take a shot at it. I think, for us, it was sort of a good news/bad news, right? The good news is we didn't have a whole bunch of business in Europe prior to this that was at risk. That's equally the bad news, so we've been trying to build it out.

I think, from the point of view of headwinds, you're hitting on the things that are probably much more significant to our business potentially than in the United States on a much, much, much smaller basis. So I would tell you that as we look at it right now, we think that the growth we are seeing with APTIMA Combo 2 across the board, coupled with the launch of PANTHER and the menu expansion of PANTHER, should be two good drivers even in the face of economic headwinds overall. And keep in mind that we're not operating a capital-intensive model where it is necessarily for customers who are cash strapped to come up with a significant investment to adopt our technologies. So that would be my take on it.

Mike, do you have anything you'd like to add?

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**Mike Watts** - *Gen-Probe Inc. - VP Corp. Communications & IR*

The only other thing I would add is that most of our business in Europe, it that goes back to what Carl said, good news/bad news, is in the major industrialized markets, it is the UK, it's Germany, it's France, so those economies certainly have not been as impacted as severely as some of the Mediterranean countries.

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**Operator**

Quintin Lai, Robert Baird.

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**Quintin Lai** - *Robert W. Baird & Co. Inc. - Analyst*

A question a little bit on the R&D pipeline. You talked about real-time TMA, real-time PCR. Maybe give us -- explain what your strategy is there? What assay do you see being real-time TMA focused, and why bidding on real-time PCR on the heels of that, or do you envision your platform to have capabilities to do both?

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Let's start off with the question of real-time PCR just period. I think we mentioned that one of our focuses is coming up with the right long-term platform for the Prodesse business and our ability to expand and leverage that. After a lot of careful thought and evaluation of the alternatives, we concluded that integrating real-time PCR onto PANTHER was an optimal solution for that, so that was one very important factor in our thinking.

The second piece of it is, as you look at the future of the business, there are many assays that can be done easier or better with one technology or the other, whether it is qualitative TMA, quantitative TMA, or quantitative PCR. We don't want to be in a situation where we're locked into having only one hammer. We like having multiple different hammers so that we can go out and add menu as customer needs dictate, not as technological limitations dictate. So that is really our thinking. If you look at the long-term development of the market, and a lot of the stuff today that is considered early-stage clinical markers that are being validated or being run perhaps in (inaudible) settings, a lot of them are on PCR type platforms. They may make good sense for us to be thinking about as part of our portfolio five years or 10 years down the road.

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**Quintin Lai** - *Robert W. Baird & Co. Inc. - Analyst*

Thank you for that. That's got it.

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**Operator**

Isaac Ro, Goldman Sachs.

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**Isaac Ro** - *Goldman Sachs - Analyst*

Thank you for taking the question. If I could just start on the investments you are making on the expense side this year with regard to new products. Maybe if you could just add a little more color. You mentioned R&D and the growth rate there, but for sales and marketing, just maybe qualitatively some of the things you need to do to be successful against your goals in HPV and in PCA3 in terms of sales force, that kind of stuff?

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Yes, Isaac. It's Carl. I think the most important things that we're looking at on the non-R&D side are really in the commercial support of the new product launches. So, you saw us build out Europe, and we're comfortable that Europe, at the scale that it is at right now, is well-equipped to

support business that is there right now. But we have some pretty high expectations for growth in Europe, so you could expect us to see -- or you could expect to see us expand our sales and field service capabilities as that business expands.

Much more importantly though is the United States. Thinking about it really from two perspectives. One is the launch of PANTHER in the US and then the second of course is just the continuing growth of the business and how we're going to spend marketing dollars for the launch of the new products.

I'll ask Eric to comment on the market spend here just a minute second, but thinking again about sales and service, we have intentionally not expanded the US sales and service organization in front of the PANTHER launch. We wanted to time it more closely to when the instrument is actually available. We have a very detailed plan that we've put together over the last nine months of where we want to add resources, what kind of resources we want to add. The majority of them will be field-based in support of the actual launch of the instrument. So that is how we're kind of doing it operationally.

Let me ask Eric to comment on the market stuff.

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**Eric Tardif** - *Gen-Probe Inc. - SVP Corp. Development & Marketing*

Yes, I think, on the marketing side, we're in a nice position that we're launching two important, new, differentiated products in the US in HPV and hopefully PCA3 this year. In both cases, I think there is a need to carry a message, in some cases to clinicians and certainly to labs. And so we've signaled this for a while that while we're not planning on building a large physician-oriented sales force, we certainly will invest to be able to get a clinical message out into the marketplace. That is a big part of the expansion you will see.

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**Isaac Ro** - *Goldman Sachs - Analyst*

Great, thanks. Just a follow-up on Prodesse actually. I think when you guys purchased the asset, it was running about \$15 million annualized in revenue. I understand of course this year was a tough flu season, but if we look at sort of a normalized growth rate for that business going forward, how are you guys looking at your goals for that portfolio of assets and technologies?

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**Eric Tardif** - *Gen-Probe Inc. - SVP Corp. Development & Marketing*

Yes, I would say that it is obviously very contingent on how the flu season goes. Last year was a nice growth year for Prodesse off a stronger flu season than in the previous year. This year, we have been modeling an average flu season which so far hasn't come to pass. So that business continues to do well in terms of gaining market share in some cases and fending off an increasing number of competitors. Certainly, as we look out in the future with PANTHER becoming available as a proprietary platform, we look at that as a major growth engine for Prodesse.

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**Isaac Ro** - *Goldman Sachs - Analyst*

Okay, thanks a bunch.

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**Operator**

Tycho Peterson, JPMorgan.

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**Tycho Peterson** - *JPMorgan Chase & Co. - Analyst*

Good afternoon. A question maybe just on some of the incremental R&D spend here. I mean you've got kind of the announcements you made earlier this year on the new instruments. Obviously, you've got some follow-up work on APTIMA HPV in terms of studies, and then some near-term stuff in terms of porting over additional assays to PANTHER. Can you help us think about are you able to put any of that into buckets? How much of the incremental R&D is going to be on follow-up studies versus some of these longer-term projects versus the incremental spend on putting assays over to PANTHER?

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

It is a good question that we probably won't answer for you at the level of detail that you would like. We have a very clear view internally of where those funds are going to go and how we're going to apply them. I think what you see us doing right now is making a combination of investments on what we term derivative products, so you can think about new assays using existing formats. So that could be a new Prodesse assay or it could be a new TMA assay on one of our instruments, versus breakthrough investments, which really fall more in the category, say, of what we're doing with the next generation of PANTHER and adding real-time PCR to it.

So from a portfolio view, Eric and his team have us look at those investments in the major buckets of type of spend. Once we determine that, we strive to have a balanced set of investments, so we're not doing all derivatives on the one hand, but we're also not doing all breakthrough projects on the other.

Eric, I don't know if you'd want to add anything?

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**Eric Tardif** - *Gen-Probe Inc. - SVP Corp. Development & Marketing*

No, I think that's the right way to look at it. It's all about striking balance and positioning us for the next wave of growth a few years out with the key projects we just announced.

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**Tycho Peterson** - *JPMorgan Chase & Co. - Analyst*

But on the follow-on studies that you've talked about previously, should we think about those rolling off later this year or early next year? How do we think about the magnitude of when those will start to wear off?

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Yes, the HPV follow-up, which is probably the most significant, finishes sometime late next year.

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**Tycho Peterson** - *JPMorgan Chase & Co. - Analyst*

Then on the chlamydia/gonorrhea, I know you had the question earlier on Roche. Can you talk about within the core business how you are thinking about pricing trends for chlamydia/gonorrhea specifically? You're withdrawing PACE sufficiently from the market this year. Is that right? I know it's a small piece of the business, but I'm just wondering about that too.

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**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Yes, that is correct. I would tell you that the pricing trends of CT/NG have been stable as a board for a long, long period of time. That's something that we look at extremely carefully, and we have seen no negative impact at all.



**Tycho Peterson** - *JPMorgan Chase & Co. - Analyst*

Okay, thank you.

**Carl Hull** - *Gen-Probe Inc. - Chairman, CEO*

Operator, it looks like we're at the bottom of the hour here, so we've got a couple of concluding remarks. So, with that, I will just wrap up by saying we appreciate your time today and thanks for your questions.

Our fourth-quarter financial results were solid. We look forward to a year of accelerating topline growth in 2012 driven by the new products that build on our core competency in automation. We're also excited by the opportunity to leverage our PANTHER platform with new assays and capabilities will generate long-term sustainable growth.

In closing, 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 a fact or a number during the call.

Thanks for your time and attention today. Please call if you follow-up questions.

**Operator**

Thank you for participating in today's conference. You may now disconnect.

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