

# **An Innovative Growth Company in Molecular Diagnostics**

**30<sup>th</sup> Annual JP Morgan Healthcare Conference  
January 10, 2012**

**Carl Hull, Chairman and CEO  
Herm Rosenman, SVP and CFO**

## Safe Harbor Statement

Any statements in this presentation about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as believe, will, expect, anticipate, estimate, intend, plan and would. For example, statements concerning financial guidance, macroeconomic conditions, possible or assumed future results of operations, growth opportunities, product development and commercialization, clinical trials, regulatory timelines and approvals, industry ranking, plans and objectives of management, the market for our stock, and future management and organization structure are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by any forward-looking statements. Gen-Probe assumes no obligation and expressly disclaims any duty to update any forward-looking statements based on events after the date of this presentation or to reflect subsequent events. For more information about the risks and uncertainties inherent in our business, see our recent SEC filings, which can be found in the investor relations section of our website at [www.gen-probe.com](http://www.gen-probe.com).

## Regulation G: About Non-GAAP Financial Measures

To supplement Gen-Probe's financial results presented in accordance with GAAP, Gen-Probe uses non-GAAP measures for COGS, sales and marketing expense, G&A expense, operating income, other income, pre-tax income, income tax rate, net income and diluted EPS. Gen-Probe's management does not itself, nor does it suggest that investors should, consider such non-GAAP financial measures in isolation from, or as a substitute for, financial information prepared and presented in accordance with GAAP. Gen-Probe's management believes that these non-GAAP financial measures provide meaningful supplemental information regarding the Company's performance by excluding certain expenses and income that may not be indicative of core business results. Gen-Probe believes that both management and investors benefit from referring to these non-GAAP financial measures in assessing Gen-Probe's performance and when planning, forecasting and analyzing future periods. These non-GAAP financial measures also facilitate management's internal comparisons to Gen-Probe's historical performance and our competitors' operating results. Gen-Probe believes these non-GAAP financial measures are useful to investors in allowing for greater transparency with respect to supplemental information used by management in its financial and operational decision making.

# Presentation Outline

- **Gen-Probe overview**
- **Markets and products**
- **Financials and milestones**

# An Innovative Growth Company in Molecular Dx

- **Innovative, proprietary technologies**

- **Unique capabilities in automation**

- TIGRIS® and PANTHER® systems

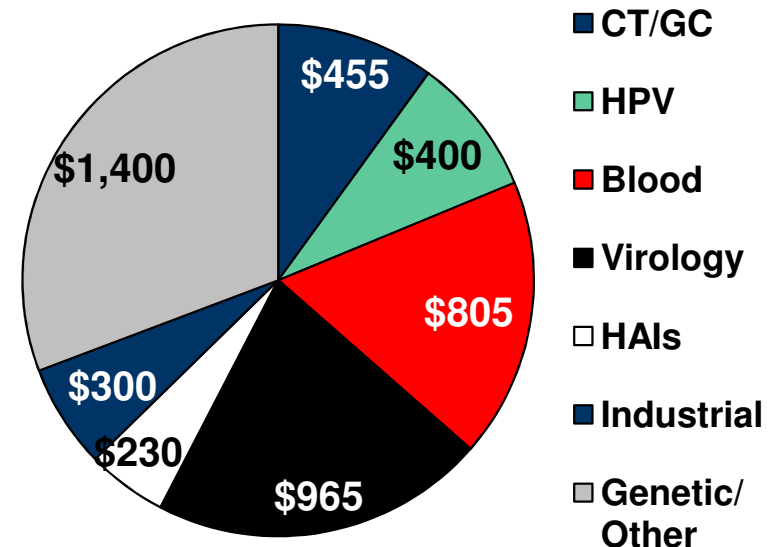
- **Plus best-in-class assays**

- Women's health: APTIMA®
- Infectious diseases: PRODESSE®
- Transplant diagnostics: LIFECODES®
- Blood screening: PROCLEIX®
- Genetic testing: PROGENSA® PCA3

- **Strong financials and important catalysts**

- Three product launches underway, two more expected in coming quarters
- Significant medium-term growth opportunities emerging, including in virology

## Major Untapped Opportunities in \$4.5 Billion\* Molecular Market



\* Piper Jaffray 2010 estimates, published 6/11.

## 2011 Was a Good Year for Gen-Probe

- **Although macroeconomic conditions and healthcare utilization remained challenging, Gen-Probe continued to grow**
  - Core STD business benefited from US share gains, European expansion, upgrades from PACE® products
  - Blood screening sales affected by supply chain fluctuations, but underlying business remains solid
- **Ex-US launch of PANTHER system going well**
- **Received US approval for two key new tests on TIGRIS system**
  - APTIMA trichomonas assay and APTIMA HPV (human papillomavirus) assay
- **Two more important products pending at the FDA**
  - PROGENSA PCA3 assay and PANTHER system
- **Initiated new R&D projects to maintain new product flow and drive sustainable growth**



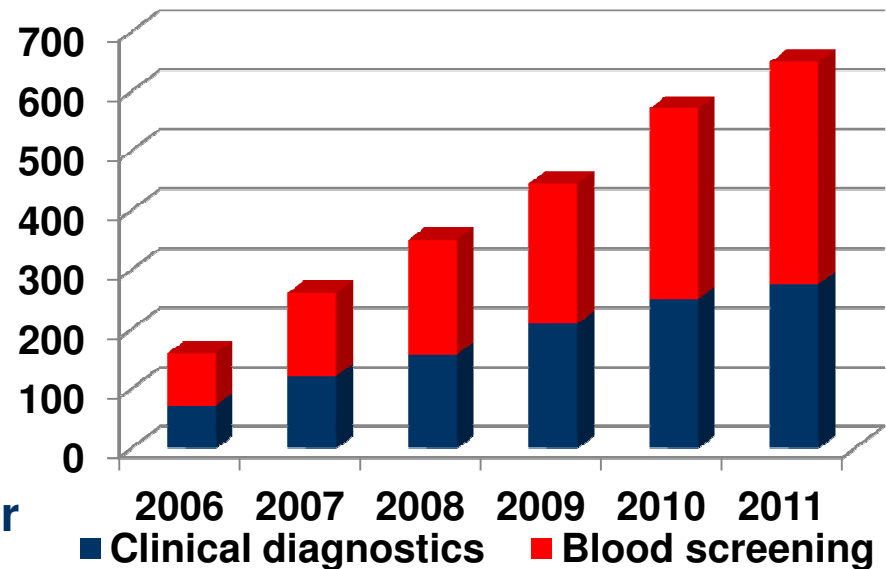
# Presentation Outline

- Gen-Probe overview
- **Markets and products**
- Financials and milestones

# TIGRIS System Meets Unique Needs of High-Volume Labs

- **Launched in 2004**
  - APTIMA STD portfolio
  - PROCLEIX ULTRIO®, WNV assays
- **Integrated, high-throughput instrument that automates all molecular testing steps**
  - Actively defending IP portfolio
- **Among most successful molecular instruments**
  - Demonstrates power of automation to address chronic labor shortages in labs
  - More than 640 instruments installed worldwide at end of 2011
  - Average diagnostics placement generates >\$500,000 in annual revenues

**Cumulative TIGRIS System Placements**





# PANTHER System Will Revolutionize Our Industry

- **Offer automation to low-, mid-volume labs**
  - Drive growth from menu expansion
  - Provide opportunity to consolidate platforms
  - Increase access to global markets
  - Provide full automation to current users of DTS system
- **Builds on success of TIGRIS systems while improving:**
  - Flexibility, functionality and cost
- **Capabilities of chemistry, immunoassay systems provide unique competitive differentiation**
- **Commercial status**
  - Launched in Europe in late 2010
    - Achieved 2011 placement goal, assay revenue growing steadily and contributing to overall product sales growth
  - Filed US 510(k) application with APTIMA COMBO 2® in May 2011
  - Over long-term, menu expansion provides opportunity to place > 1,000 systems in markets totaling > \$1 billion



## **New Instrument Programs to Extend Automation Lead**

- **Leverage core competencies to broaden, deepen customer relationships**
- **Adding PCR (polymerase chain reaction) capability for next-gen PANTHER system**
  - Game-changing flexibility to run traditional TMA, real-time TMA and real-time PCR with full automation
  - Provide proprietary platform for PRODESSE PCR assays initially
  - Broaden potential installed base and pull-through opportunity for APTIMA assays
  - Enable participation in emerging markets such as companion diagnostics
  - Expected to launch in 2015, contributing to medium-term growth
- **LBC (liquid-based cytology) automation**
  - Small, standalone instrument to automate de-capping and transfer of liquid-based cytology samples to TIGRIS and PANTHER systems
  - Facilitates use of APTIMA assays for CT/GC, HPV and trichomonas beginning in 2013

# Gen-Probe STD Franchise Remains Robust

- **Chlamydia and gonorrhea are most common bacterial STDs**

- CDC reported 1.3 million cases of Chlamydia in 2010, most for any condition
- Yet HEDIS data indicate < half of sexually active women are tested

- **\$492 million market in 2011**

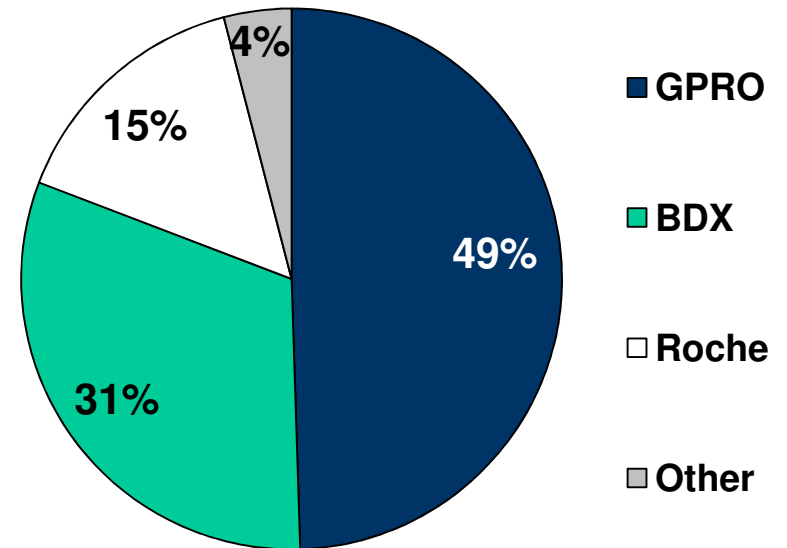
- \$344 million in US, +3%
- \$148 million ex-US, +10%

- **APTIMA COMBO 2 assay on TIGRIS system remains growth driver**

- Sustainable competitive advantage based on best combination of sensitivity, specificity, reproducibility, sample flexibility and scalable automation
- Despite headwinds, APTIMA franchise growing based on Europe, US market share gains, conversions from PACE products

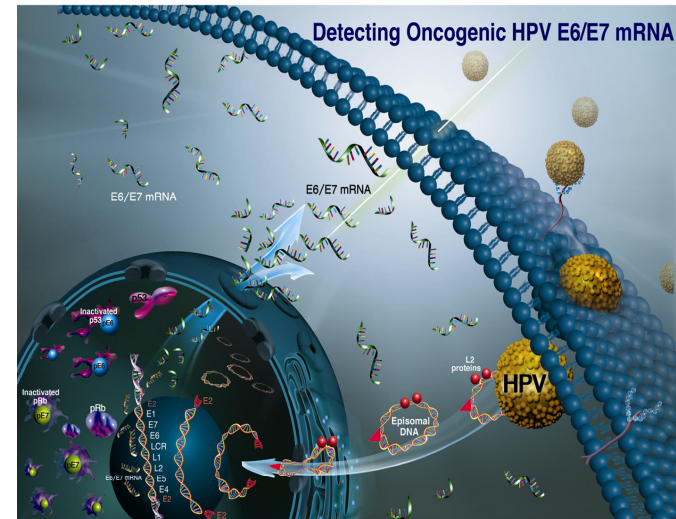
\* Data are year-end 2011 Gen-Probe estimates.

Leading Global Market Share\*



# APTIMA HPV Assay Expands Women's Health Franchise

- **Human papillomavirus (HPV) causes cervical cancer**
- **Approximately \$300 million market**
  - Growth opportunities in US, Europe
- **APTIMA HPV assay targets disease progression markers, runs on TIGRIS system**
  - Approved by FDA in October 2011
    - Similar sensitivity, better specificity than first-generation test
    - Studies involving ~ 45,000 women
  - HPV testing is highly concentrated, providing opportunities for Gen-Probe automation
  - Good initial commercial interest; first commercial sales already recorded



# Launch of APTIMA Trichomonas Assay Going Well

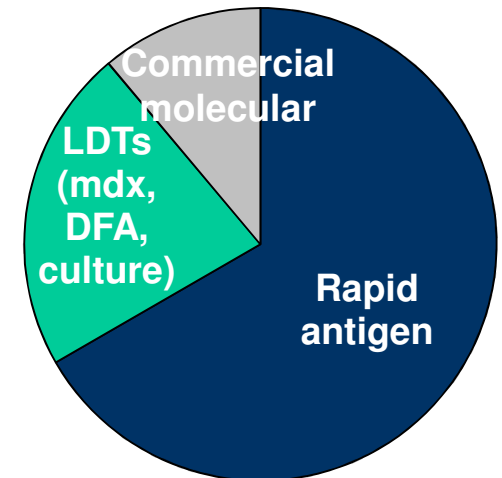
- ***Trichomonas vaginalis* is world's most common curable STD**
  - 8.7% prevalence in 7,593-woman study, higher than Chlamydia and gonorrhea combined
- **If untreated, can cause significant complications**
  - Responsible for premature births and low birth weights
  - Risk factor for pelvic inflammatory disease, tubal infertility
  - Increases HIV susceptibility and risk for transmission, HPV persistence
- **APTIMA Trichomonas assay FDA-cleared in April 2011**
  - Same samples and specimen types can be tested on TIGRIS installed base
  - Improved sensitivity, ease of use provide opportunity to expand \$50 million market
  - More than 80 customers adopted or evaluating
- **Launched on both TIGRIS and PANTHER systems in Europe**



# Prodesse Broadens Infectious Disease Portfolio

- **Acquired Prodesse in 2009**
- **Strategic rationale**
  - Provide differentiated infectious disease tests for Gen-Probe's sales force to sell to existing customers
  - Add platform-independent, content-focused business in real-time PCR
  - Accelerate R&D output of molecular assays
    - Launched four new assays since acquisition
  - Attractive margins and cash flow
- **Good progress since acquisition**
  - Molecular flu tests continue to gain share versus EIAs

**US Market for Influenza Diagnostic Tests\***

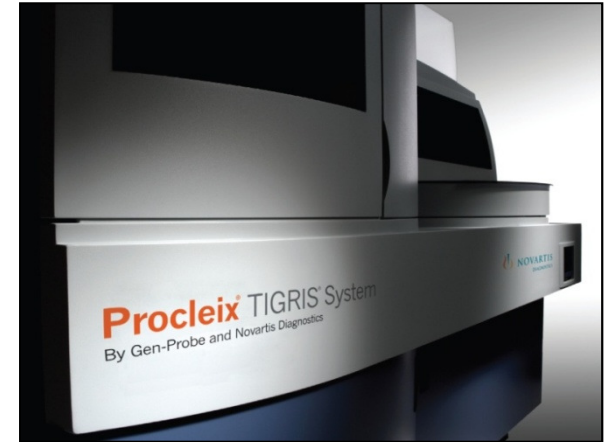


\* Estimated opportunity of ~ 9 million tests in “average year.”

# Blood Screening Remains a Terrific Business

- **A very solid franchise**

- Approximately 35% of product sales, strong margins and cash flow
- Leading global market share in dollars, high barriers to entry
- Underlying donation volumes essentially flat, with a few percent of variation in either direction



- **Key PROCLEIX products detect HIV, HCV, HBV and WNV**

- More than 370 TIGRIS systems at blood banks worldwide

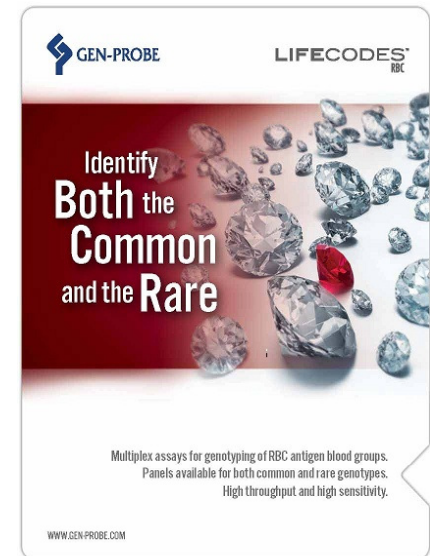
- **Partnership with Novartis provides improving economics over time**

- **Over time, growth opportunities from PANTHER system, new markets and geographies, emerging pathogens**



# HLA Testing Franchise is Growing

- **Human leukocyte antigen testing done to ensure compatibility of organ and bone marrow transplants, monitor transplant recipients**
- **Entering HLA market was primary strategic rationale behind Tepnel acquisition in 2009**
  - Highly specialized, highly technical customer base and favorable long-term market dynamics
  - Overall market approaching \$400 million, growing in low-double digits
  - Investing Gen-Probe resources to drive market share gains
- **Since acquisition, have broadened LIFECODES portfolio with multiple new product launches**
  - Subsequent acquisition of GTI, which develops and manufactures LIFECODES antibody products, broadens and strengthens our HLA business





# Genetic Testing Provides Long-Term Growth Potential

## ■ Prostate cancer

- Very common, yet current testing methods generate “false positive” results and unnecessary biopsies
- PROGENSA PCA3 assay is highly specific, may help meet unmet clinical needs in prostate cancer diagnosis
  - Clinical research studies in >4,000 men and published in >50 peer-reviewed articles
- PROGENSA PCA3 assay marketed in Europe
- PMA submitted to FDA in 3Q10, advisory panel meeting not needed

## ■ Sequencing

- Collaborative research underway with Pacific Biosciences
- Ability to provide highly multiplexed assay results of long-term importance in high-growth diagnostic segments



# Virology is Next Major Opportunity

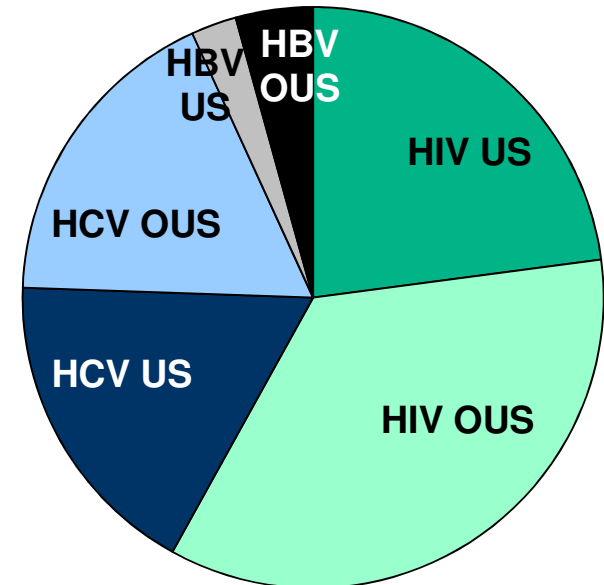
- **Real-time, quantitative capabilities of PANTHER system enable us to enter large market**

- 26 million HIV, HCV, HBV tests in 2011
- ~ \$900 million market with mid-single-digit growth
- Significant customer overlap lends itself to platform consolidation
  - 90% of US CT/GC labs also test for HIV and HCV
  - Virology assays typically run in smaller volumes

- **Anticipated Gen-Probe commercial strategy**

- Develop all three tests for OUS markets initially
- Product introductions in 2014 timeframe
  - Contribute to medium-term growth
- Deliver full PANTHER automation, improved workflow and lower sample volume

**\$908 Million Global Virology Market in 2011\***



\* Gen-Probe internal estimates.

# Presentation Outline

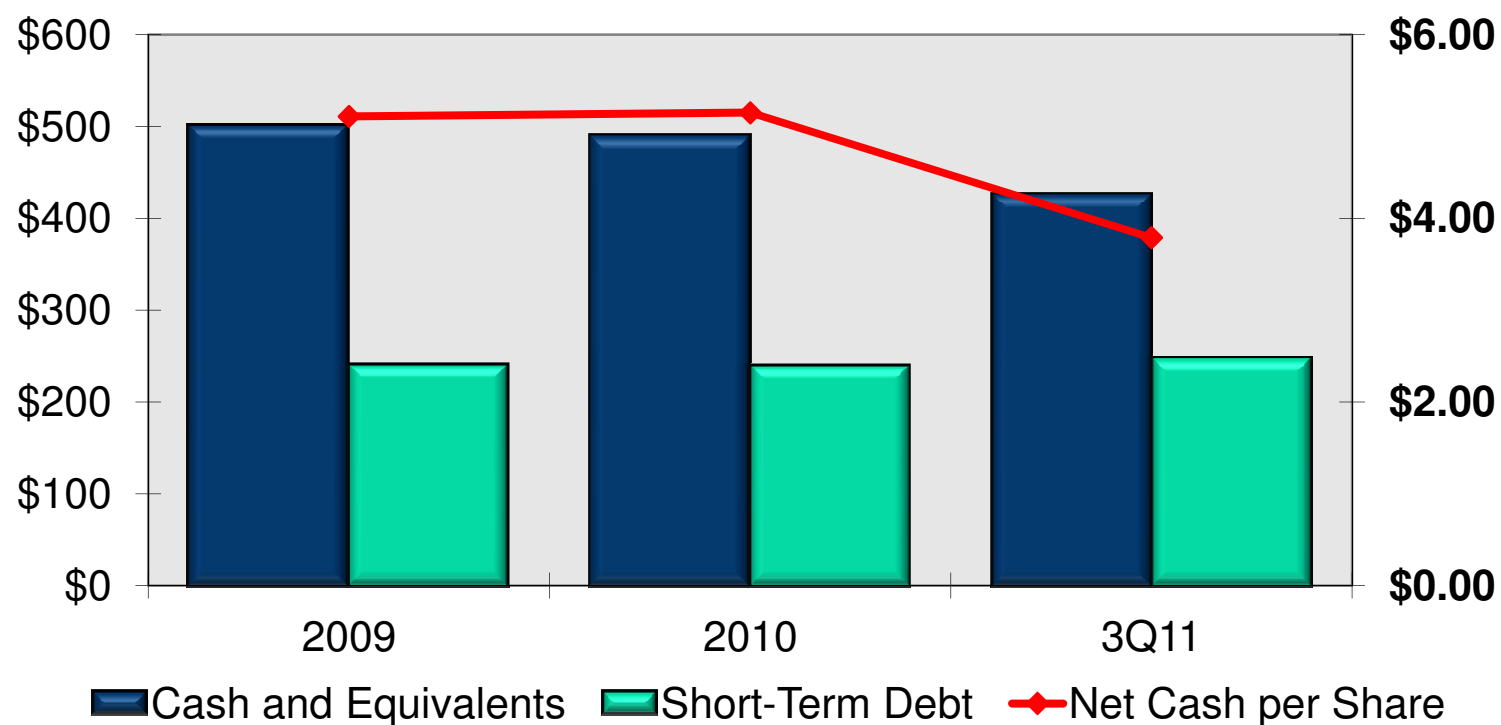
- Gen-Probe overview
- Markets and products
- **Financials and milestones**

## 2011 Financial Guidance (Non-GAAP)

	2011 Guidance	2010 Actuals
<b>Total Revenues</b>	\$575 to \$580 million	\$543.3 million
<b>Product Gross Margin</b>	69-70%	67.7%
<b>Operating Margin</b>	~ 27%	27.5%
<b>Tax Rate</b>	31-32%	32.3%
<b>Diluted Shares</b>	~ 48.5 million	49.0 million
<b>EPS</b>	\$2.28 - \$2.32	\$2.19

Note: Non-GAAP excludes non-cash impairment loss, transaction-related expenses, restructuring costs and contingent consideration adjustments. These totaled (\$0.01) in 2010 and are expected to total (\$1.06) in 2011. Percentages are of total revenues. Guidance provided by press release and 8-K on November 2, 2011. In compliance with SEC Reg. FD, Gen-Probe provides guidance only through broad, non-exclusionary means. Presentation here is not, and should not be construed as, re-affirmation of the guidance.

## Our Balance Sheet Remains Strong ...

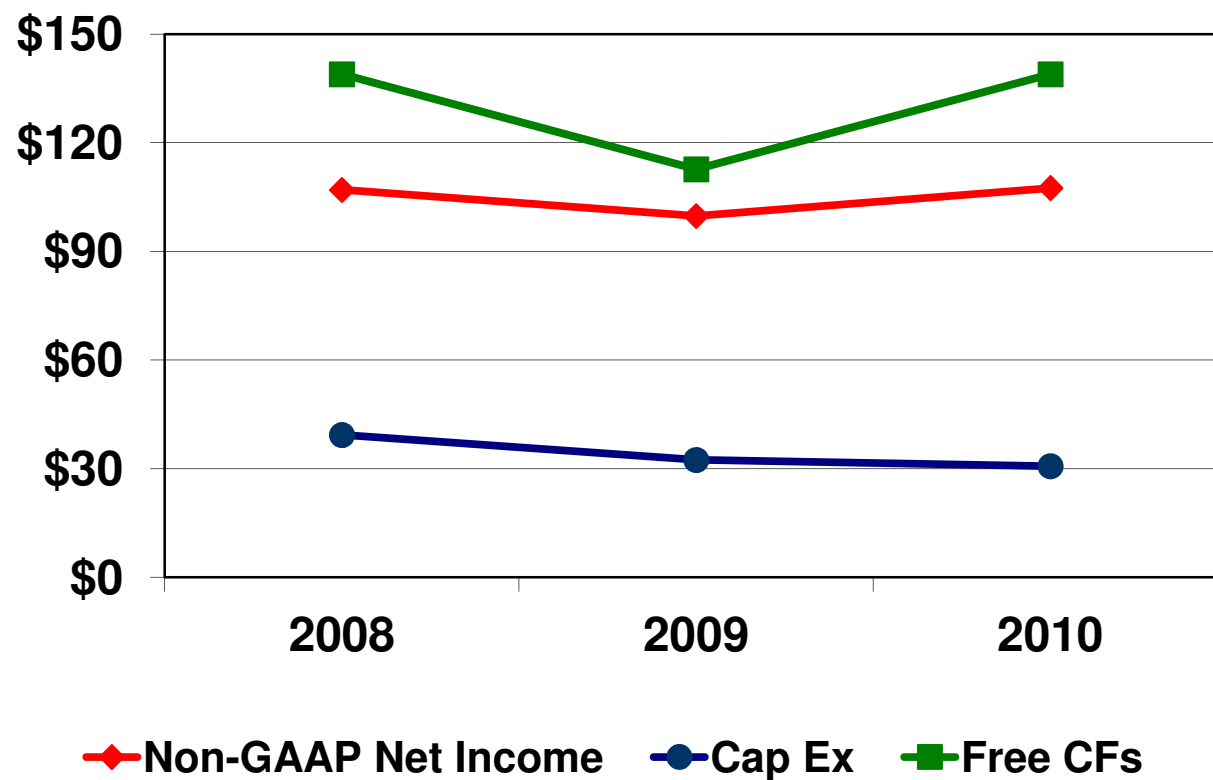


Note: 2008-10 data are as of year-end. Company pays interest on this debt at 1-month LIBOR + 0.6%

## ... Even as We Have Redeployed Capital Aggressively

Action	Investment	Timing
Acquired Tepnel	\$137 million	2Q09
Acquired Prodesse	\$70 million	4Q09
Acquired GTI	\$53 million	4Q10
Share buybacks	\$600 million	3Q08-4Q11
<b>Total</b>	<b>\$860 million</b>	

## Cash Flows Remain Robust



Note: All figures are for full years. \$ in millions.

# Multiple Drivers for Double-Digit Growth in 2012

- **Continued growth from STD, transplant and blood screening businesses**
- **Several new products in launch phase**
  - APTIMA Trichomonas assay on TIGRIS system
    - Added almost 1% to product sales growth in 3Q11, a few months after launch
  - APTIMA HPV assay on TIGRIS system
    - Strong early customer interest, recorded first sales
  - European expansion, driven by APTIMA COMBO 2 assay and PANTHER system
    - Achieved 2011 PANTHER placement goal, assay sales now ramping
  - PANTHER system with APTIMA COMBO 2 assay in US
    - Filed 510(k) application in 2011
  - PROGENSA PCA3 assay for prostate cancer
    - Under FDA review; no advisory panel





# **An Innovative Growth Company in Molecular Diagnostics**

**For more information:  
Michael Watts, VP of IR  
(858) 410-8673  
[michael.watts@gen-probe.com](mailto:michael.watts@gen-probe.com)**