



**THIRD WAVE  
TECHNOLOGIES**

# **Third Wave Technologies, Inc. Investor Day**

**September 20, 2007**

# Safe Harbor Statement

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# Agenda

- 8:20-9:15am**      **Introductions / Corporate Overview**
- 9:15-9:45am**      **The HPV Market & Third Wave's Offering**
- 9:45-10:15am**      **Presentation by Dr. Juan Felix**  
                                 **- Clinical Testing for HPV**
- 10:15-10:30am**      **Break**
- 10:30-11:15am**      **Presentation by Jamie Golleher**  
                                 **- The Customer's Experience with Third Wave's HPV Offering**
- 11:15am-12pm**      **Third Wave's Long-Term Strategy & Future Growth Drivers**
- 12:00-12:10pm**      **Financial Performance**
- 12:10-1:30pm**      **Informal Lunch and Q&A with Third Wave Management**



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# Corporate Overview

**Kevin Conroy, President & CEO**

# Third Wave's Management Team

- > **Kevin Conroy**
  - President & Chief Executive Officer
- > **Cindy Ahn**
  - Vice President, General Counsel & Secretary
- > **Maneesh Arora**
  - Senior Vice President & Chief Financial Officer
- > **John Bellano**
  - Vice President, Sales
- > **Jorge Garces, Ph.D.**
  - Vice President, Research & Development
- > **Greg Hamilton**
  - Vice President, Finance & Operations
- > **Mauro Scimia**
  - Third Wave Europe
- > **Ivan Trifunovich, Ph.D.**
  - Senior Vice President; President, Third Wave Japan

# About Third Wave Technologies

- > **Emerging leader in molecular diagnostics**
  - 190 US lab customers; developing EU network
- > **Strong growth from current product range**
  - 24% y/y clinical revenue growth in Q2; 74% margins
- > **Substantial near-term HPV opportunity**
  - \$1B addressable market
- > **Proprietary Invader® chemistry**
  - Easy-to-use platform for sustained expansion

# Third Wave: Molecular Diagnostics Pure Play

- > High performance, proprietary chemistry for DNA and RNA testing



# Third Wave's Vision & Mission

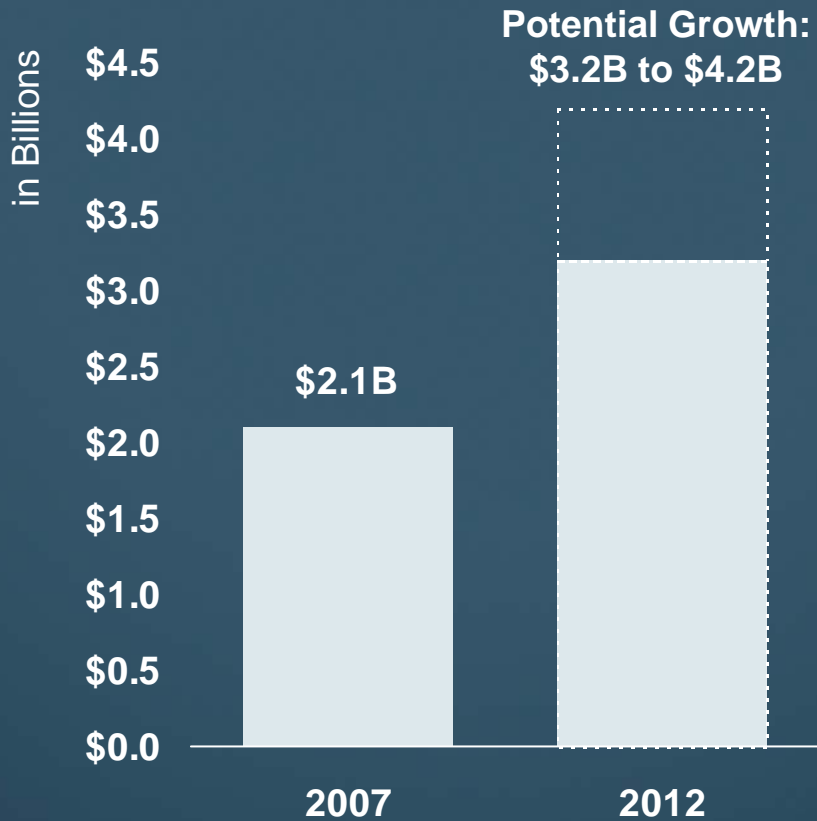
## > Vision

- To be the most innovative global leader in molecular diagnostics

## > Mission

- To be the fastest growing, most profitable molecular diagnostics company by:
  - > Leading the market in HPV testing
  - > Broadly serving the hospital lab segment of the market

# Molecular Diagnostics Set For Rapid Expansion

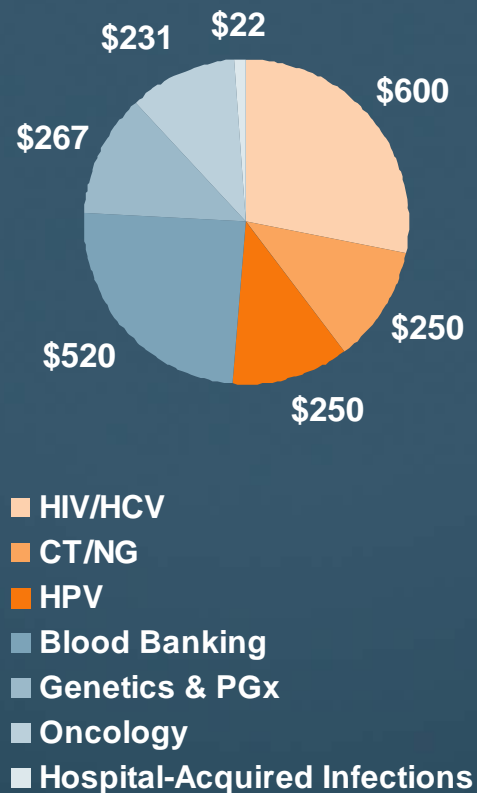


- > Global Diagnostics Market \$29B — 5-6% CAGR\*
- > Fastest growing segment Molecular = 10-15% CAGR\*

*\*Estimated growth rates from 2007 – 2012  
Source: AdvaMed, G2 Reports, Company Estimates*

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# Molecular Diagnostics: Market Overview



- > **Total Global Market in 2007**
  - \$2.1B
  - 10-15% CAGR
- > **HPV is the largest driver of molecular diagnostic market growth**
- > **Hospital Acquired Infection testing is modest but rapidly growing area of MDx testing**

Source: G2 Reports, VPG, Company Estimates

# The Invader® Chemistry



- > **Signal amplification – with or without PCR**
- > **Fluorescence detection**
- > **Probe-based technology that directly detects specific nucleic acid sequences**
- > **Highly specific**

# Best-in-Class Invader® Chemistry



- > **Easy to Use**
  - Less hands-on time
  - Fewer liquid-handling steps
  - Easy to automate
- > **Broad compatibility with standard equipment**
- > **Proprietary**
  - 50 patents, 170 pending
- > **100% specificity with FDA-cleared test**

# Product Offerings & Submissions

- > Track record of innovative products
- > High-quality, easy-to-use products drive customer adoption

## 2001-03

- Coagulation and Cardio markers
  - Factor V Leiden
  - Factor II
  - MTHFR
  - ApoE
- Early version Cystic fibrosis

## 2004

- HCVg

## 2005

- HPV ASRs
- CFTR InPlex™
- Invader Plus™
- UGT1A1 IVD

## 2006

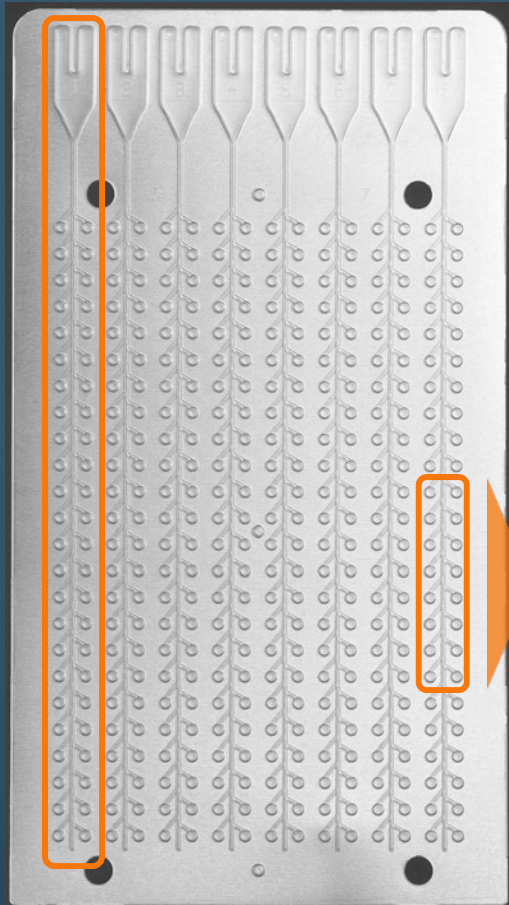
- HPV clinical trial
- Universal Invader™
- CFTR InPlex™ FDA submission
- Warfarin sensitivity

## 2007

- HPV submissions
  - FDA
  - CE
  - Health Canada
- CFTR InPlex™ FDA clearance
- Warfarin sensitivity ASRs

*Unless otherwise noted, all products are Analyte Specific Reagents. Analytical and performance characteristics are not established.*

# Current Menu Growth Driver: CFTR



A sample lane



Close up view of reaction chambers

## > CFTR InPlex ASRs

- Innovative new solution for complex CF testing
- Market share growth from 10% in 2006 to >15% 2007
- Ease of use enabling new customers and displacing competitors

*Analyte Specific Reagent. Analytical and performance characteristics are not established.*

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# Expanded Product & Service Offerings

## > Pharmacogenetics

### – UGT1A1

- > FDA cleared in August 2005
- > Recent study reinforces importance of genetic testing for patients receiving higher doses of irinotecan

### – Warfarin

- > ASRs launched earlier in 2007
- > Relabeling completed August 2007
- > FDA submission – anticipated 1H08

### – LabCorp / ARCA Collaboration

- > Genetic test in conjunction with next-generation beta blocker – first genetically-targeted cardiovascular drug
- > Two genetic variations in 45% of population positively affect drug's efficacy

*Analyte Specific Reagent. Analytical and performance characteristics are not established.*

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# Expanded Product & Service Offerings

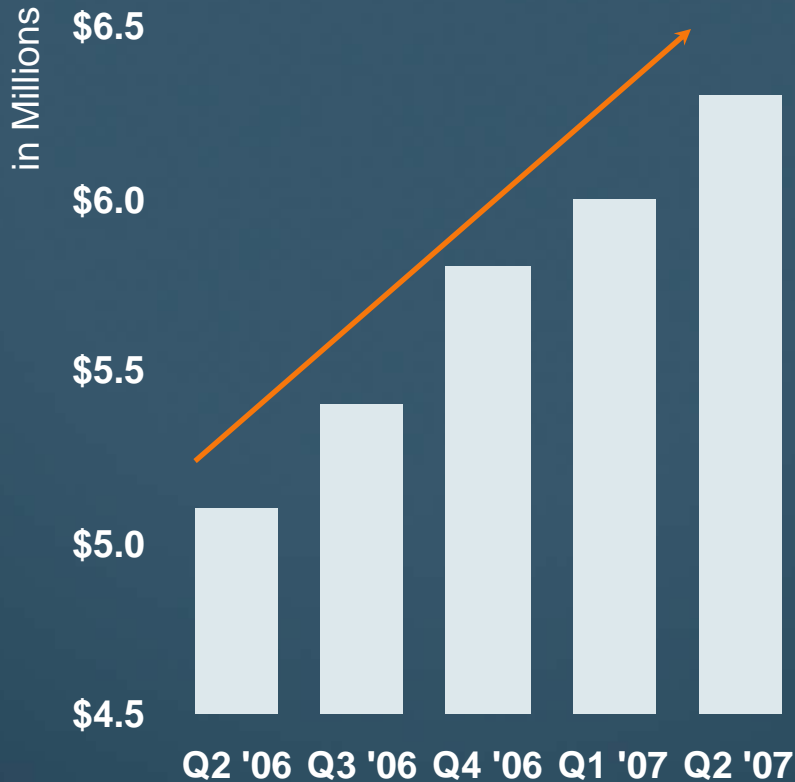
## > Third Wave Japan

- Mitsubishi Corp. Joint Venture
  - > Strong brand recognition in Japanese market of over \$100M
  - > Developing panel of molecular tests
  - > 3 labs control 90% of market
  - > BML to adopt tests as approved by Japanese regulators
  - > Leverage other Asian markets

## > Third Wave Europe

- HPV is a strong emerging growth driver in EU MDx market
- Finalizing distribution partnerships in EU
- Building direct infrastructure

# Delivering Growth



- > 7 consecutive quarters of clinical revenue growth
- > Clinical revenue up 24% y/y
- > Gross margins expanded to 74%
- > \$47.8M cash
- > 7 quarters expanding customer base

# Human Papillomavirus (HPV) Testing

- > **Most common sexually-acquired virus**
- > **14 “high-risk” types cause 99.9% of cervical cancer cases**
- > **HPV types 16 and 18**
  - Cause 70% of cervical cancer cases
  - Most persistent
  - Most carcinogenic
- > **Almost 500K new cases worldwide, 275K deaths a year**
- > **Most treatable form of cancer**

*Source: NCI*

# HPV Market Opportunity



- > HPV testing market growing very rapidly
- > Significantly underpenetrated global market
  - Less than 15% penetrated

# HPV FDA Submissions

- > **Two Third Wave HPV products**
  - High-risk HPV Screen (14 types)
  - HPV type 16/18 discrimination
  
- > **Addressing unmet customer needs**
  - Performance
  - Ease of use / Workflow

HPV Timeline

Q3: Complete Enrollment



Q4: FDA Submissions

# Third Wave Today

## Technology

- Flexible
  - Inherently adaptable to large array of test types
- Simple
  - Straightforward protocol run successfully with minimal training
- Broad compatibility with standard equipment
  - Runs on thermal cycler and plate reader

## Products and Services

- Genetic Testing
  - Factor II, Factor V
  - MTHFR
  - ApoE
  - CFTR
- Infectious Disease
  - HPV
  - HCV
- Pharmacogenetics
  - UGT1A1
  - Warfarin sensitivity

## Current Customers

- National Reference Labs
- Regional Reference Labs
- University Hospitals
- Community Hospitals
- Public Health Labs
- Pathology Labs

*Analyte Specific Reagent. Analytical and performance characteristics are not established.*

# Third Wave Tomorrow

## HPV Instrument

- High-throughput
- Automated Solution

## Hospital Instrument

- Minimal User Steps

## Relevant Menu

- Sexually transmitted diseases
- Hospital-acquired infections
- Infectious disease
- Pharmacogenetics

# Summary of Third Wave Strategy

- > HPV market leadership across all customer segments with FDA-approved products and instruments
- > Take leadership position in hospital lab segment by leveraging the easy-to-use instrument and bundled assay menu

*Building sustainable competitive advantage*

# Best Suited For Strategy Execution

- > **Uniqueness of Invader® Chemistry**
  - Access to high-value HPV market
  - Ease of use advantages for customers
  - Flexibility in product development
- > **Ability to deliver a broad menu on a single platform**
- > **Commitment to Customers**
  - Strategy built on unmet customer needs
  - Dedicated, experienced team



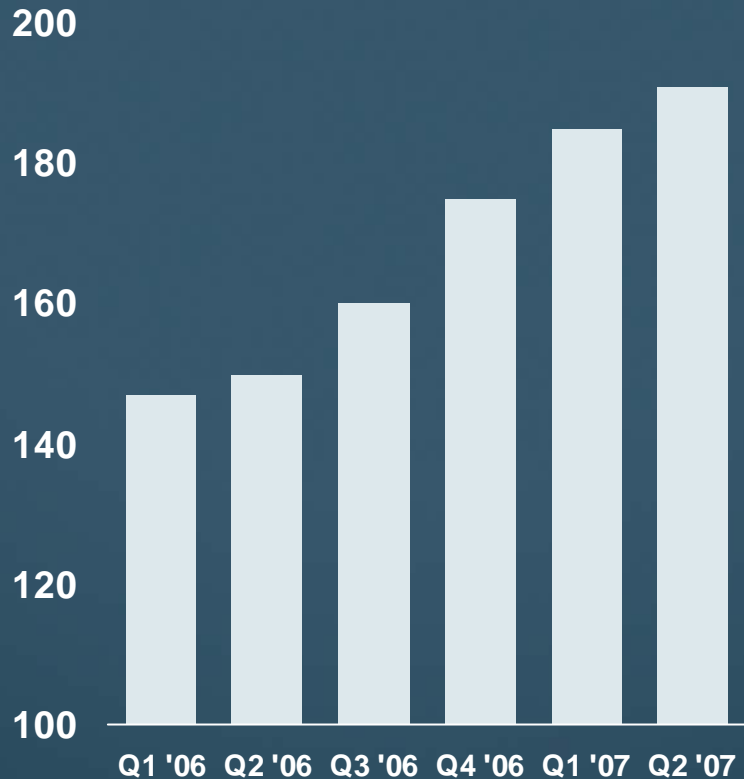
# The HPV Market & Third Wave's Offering

**John Bellano, Vice President, Sales**

**Mauro Scimia, Third Wave Europe**

**Jorge Garces, PhD, Vice President, R&D**

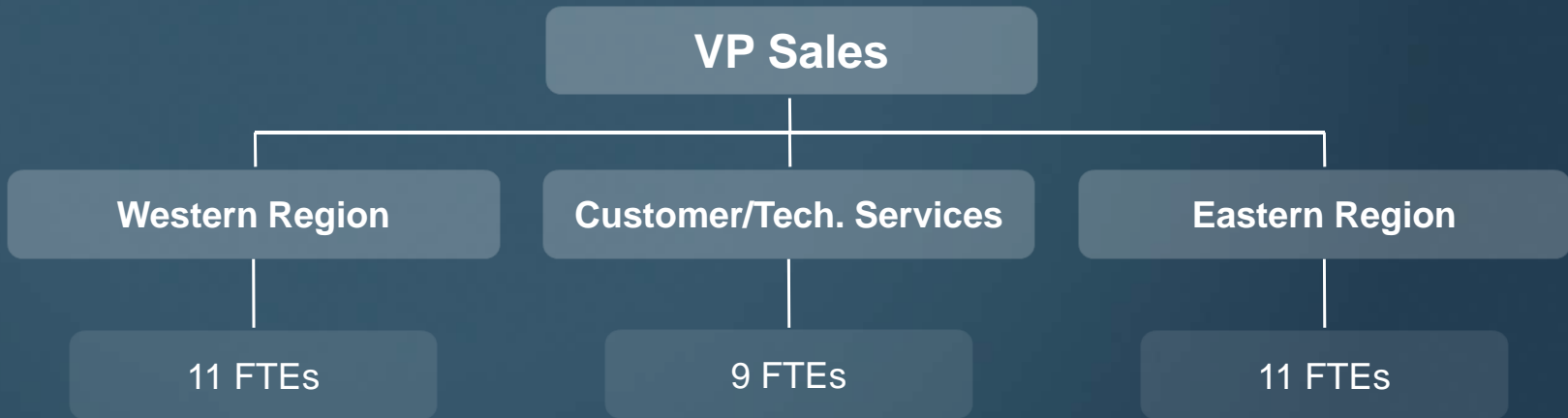
# Growth From Current Menu



## > Current customers include

- National Reference Labs
- Regional Reference Labs
- University Hospitals
- Community Hospitals
- Public Health Labs
- Pathology Labs

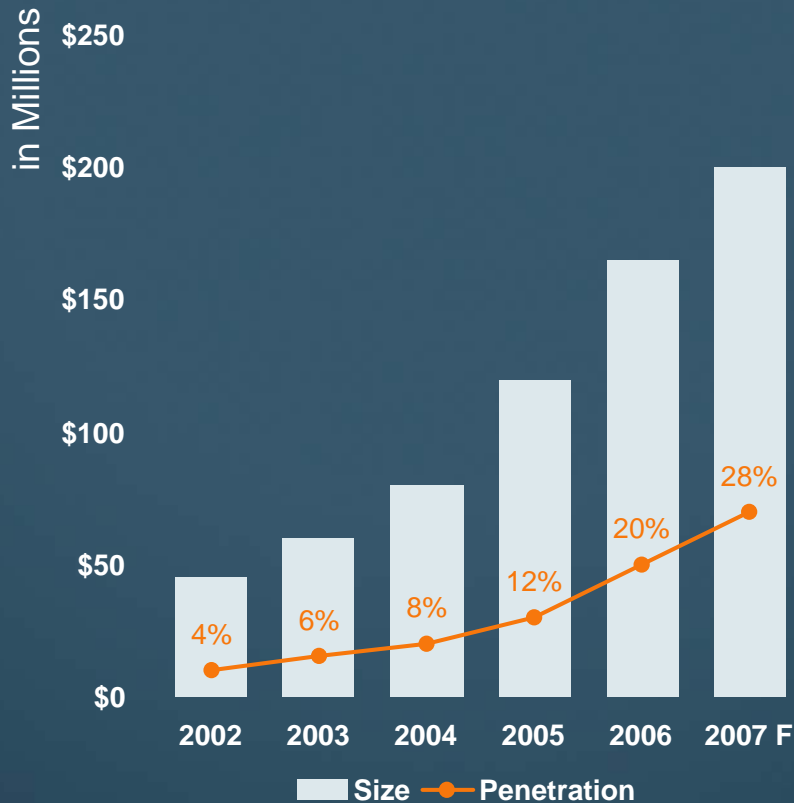
# Sales Structure



# US Sales & Customer Service

- > **32 employees in US sales and customer service**
  - Corporate account focus
  - Regional/Hospital lab focus
- > **Experience in diagnostics**
  - Average of 10 years in diagnostic sales and service
- > **Approximately \$1.5M revenue per rep with 18-20 accounts**
- > **Target of \$4.5M per rep with 30 accounts**

# HPV US Market Penetration



> **43% 5-year CAGR**

> **Growth Drivers**

- Well-established clinical utility
- Medical guidelines
- Consumer awareness driven by vaccines and DTC advertising

Source: Analyst and Company estimates

# European HPV Market

- > Market opportunity of over \$300M with limited penetration to date
- > Strong indicators promoting HPV testing
- > CE marking on track for 2H07
- > EU released Consensus Report indicating HPV viability as a primary screener and recommending initiation of pilot feasibility studies

## Italy

Nearly completed 5-year randomized study on 100,000 women proving HPV testing is better than conventional pap at detecting CIN2+ on women 35+ with acceptable specificity

## Germany

HPV test reimbursed for triage of ASC-US cytology tests

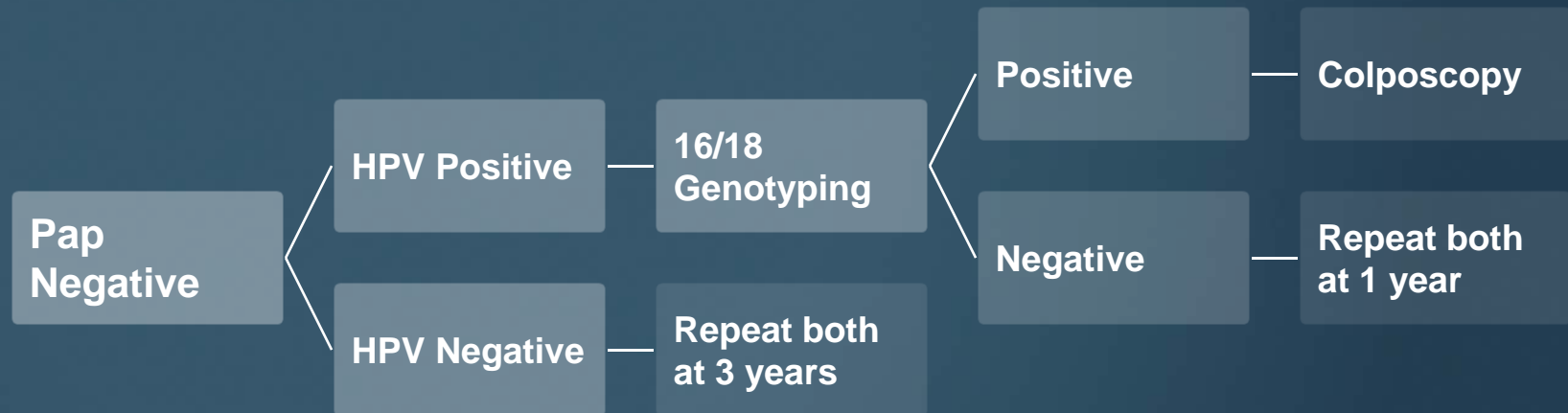
## Spain

Established guidelines for use of HPV testing

# Differentiated HPV Offerings

- > **Anticipating clinical trial will demonstrate:**
  - High-Risk 14
    - > Fewer false positives due to better specificity at appropriate sensitivity
    - > Enhance performance
      - Internal control
      - Built-in redundancy
      - Inclusion of HPV type 66
    - > Ability to process Quantity Not Sufficient (QNS) samples
    - > Better workflow and ease of use
  - 16/18 Genotyping
    - > Reflex from same sample as high risk
    - > Independent results for 16 and 18

# HPV Genotyping



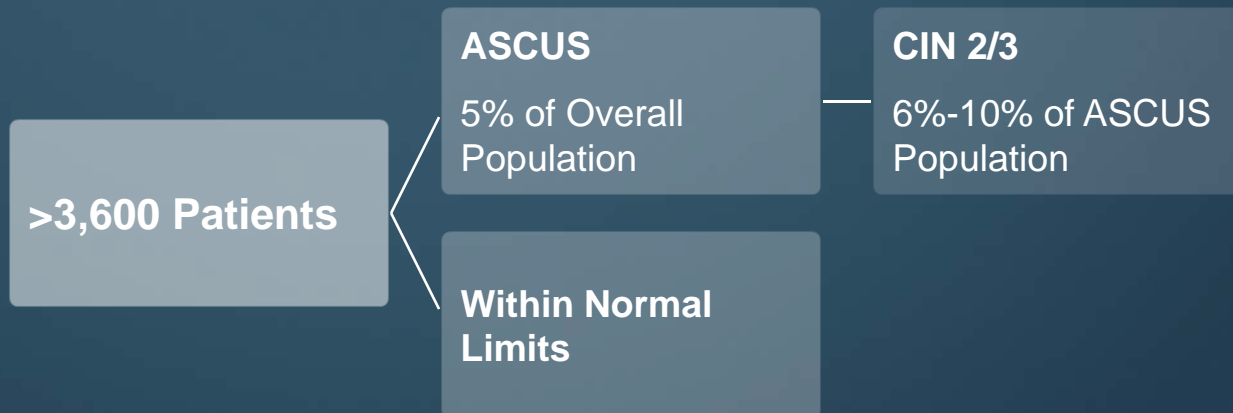
- > **Khan, et. al. (2005) in Journal of the National Cancer Institute**
  - HPV genotyping focuses ... “clinical attention on women at greatest risk [of cervical cancer]....”
  - HPV 16 and 18: 5½ times and 4½ times more likely to cause cancer than all others combined

# Clinical Trial Overview

## > Digene Package Insert

- Total subjects: 885
- Assay Positive Predictive Value = 17.2% (66/383)
- Assay Negative Predictive Value = 99.0% (497/502)

## > Third Wave Clinical Trial



# Third Wave HPV Instrument



- > Automated HPV instrument under development
- > Throughput: comparable to Rapid Capture
- > Walk away solution: load samples and go



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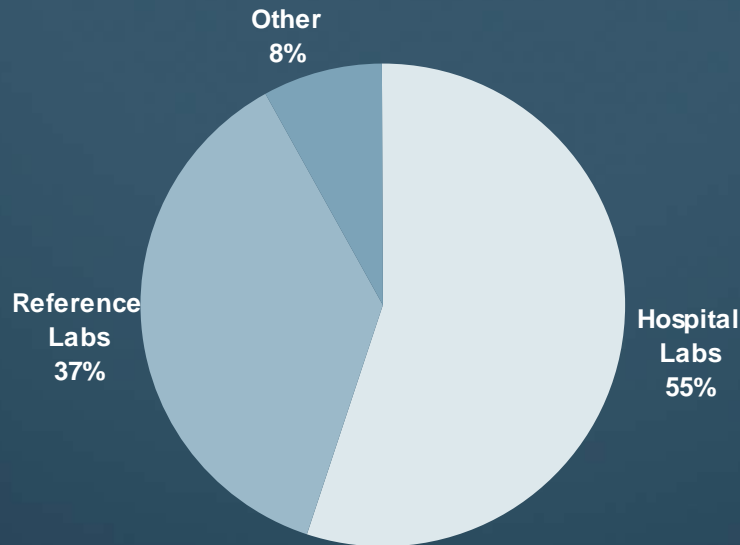
# Long-Term Strategy & Future Growth Drivers

Kevin Conroy, President & CEO

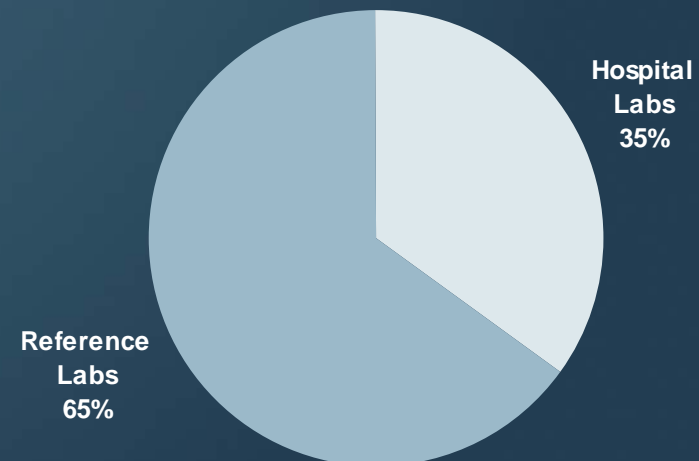
# Diagnostics Market Overview

- > Hospital labs comprise majority of global IVD market
- > Hospital labs smaller, but rapidly emerging segment of MDx market

Global IVD Market: \$29.0B

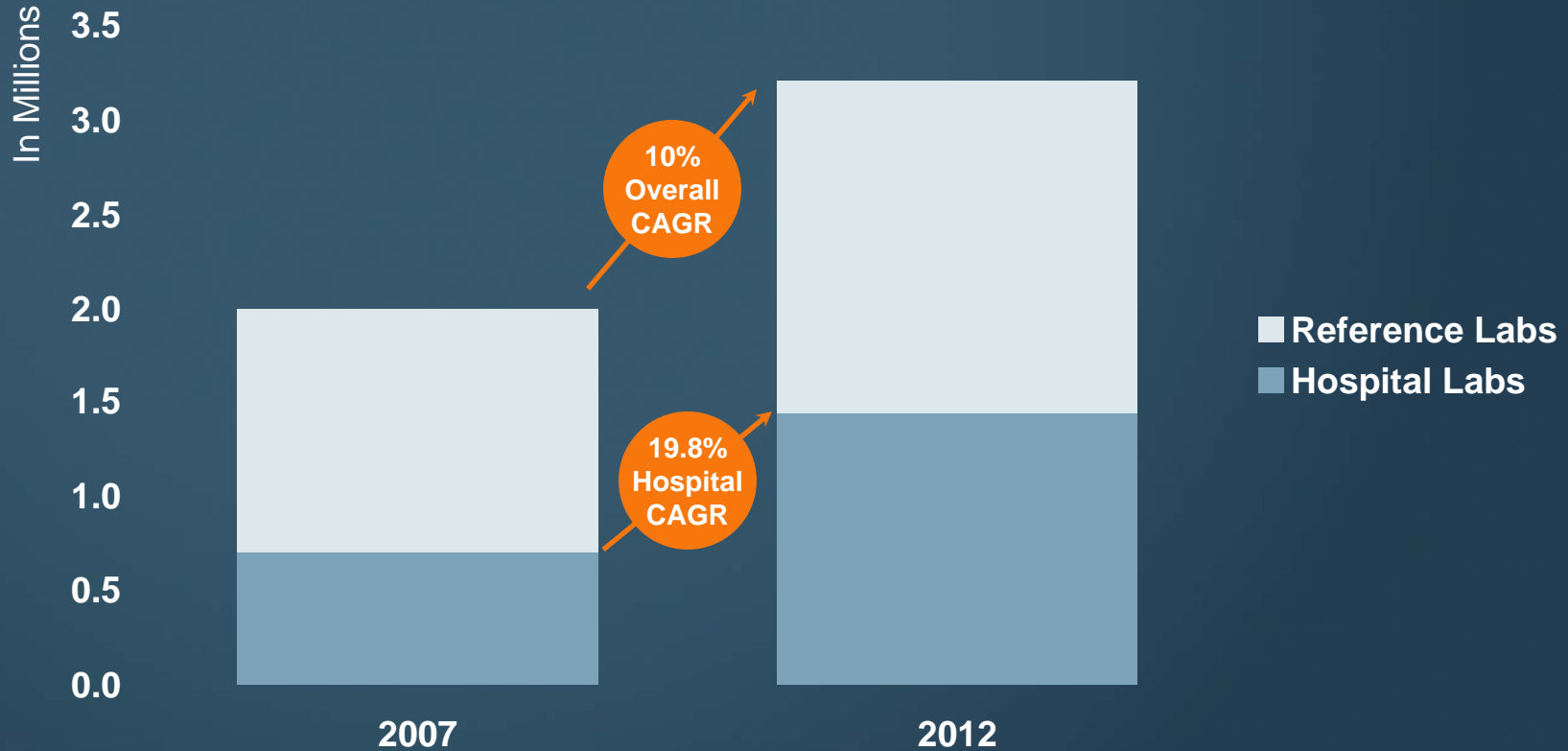


MDx Market: \$2.1B



Source: G2 reports, MedaCorp, Company estimates

# Projected Growth of Hospital Lab Market



Source: Company projections

# Drivers for MDx Market to Decentralize

- > **Development of cost-effective automated instrumentation will simplify testing and aid in future adoption**
- > **Physician adoption of molecular testing continues to grow**
- > **Core MDx test volumes are sufficient for hospitals to bring testing in house**
- > **Emerging tests like hospital-acquired infections (HAI) require faster turn-around times that only hospitals can provide**

# Third Wave Tomorrow

## HPV Instrument

- High-throughput
- Automated Solution

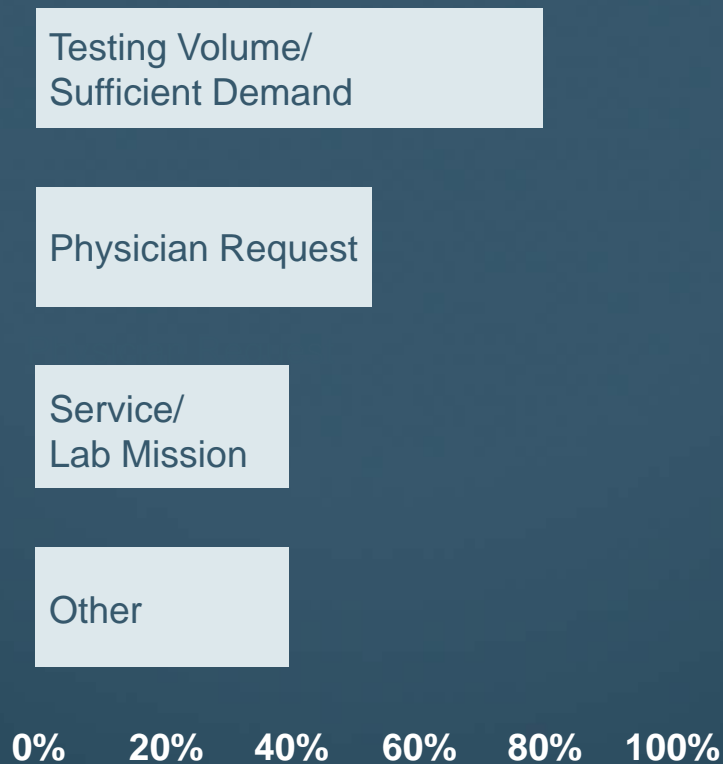
## Hospital Instrument

- Minimal User Steps

## Relevant Menu

- Sexually transmitted diseases
- Hospital-acquired infections
- Infectious disease
- Pharmacogenetics

# Hospital Market Testing Drivers



## > Hospital Lab Drivers for In-House Testing

“First you must remember that we’re not a business. This is a non-profit institution and **our first commitment is to providing quality care**. We believe that having [NAT] capability helps with that commitment.”

- Community Hospital Lab Director

Source: Company commissioned study of hospital laboratory market

# Hospital Segment Requirements

## Menu

Focused menu centered around core molecular tests

## Automation

Automate key process steps: Sample Prep, Analytics, Post-Analytics

## Batch Sizes

Batch sizes scaled efficiently to daily test volumes

## Turnaround Time

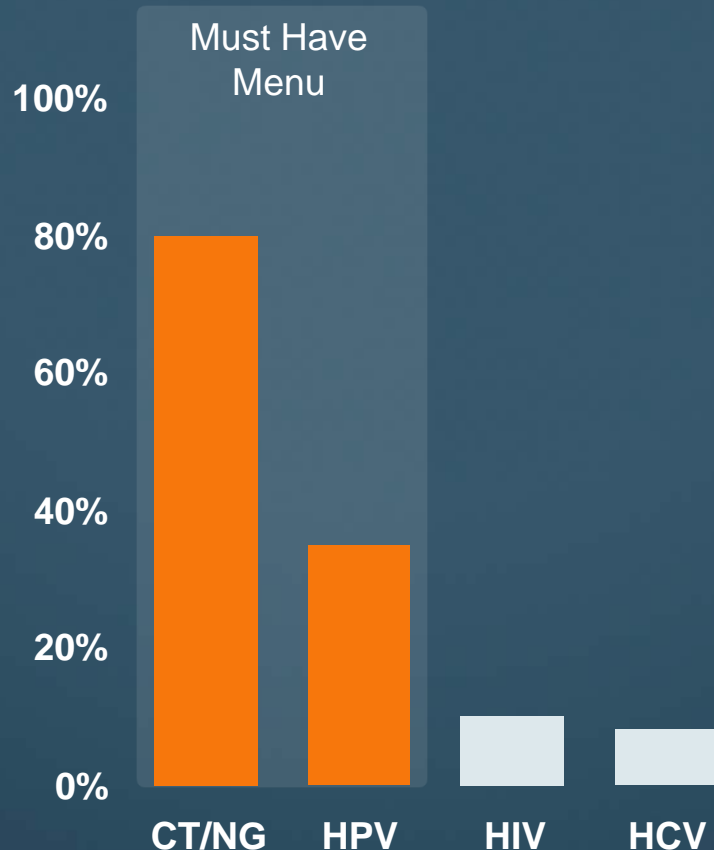
Allow testing in a single shift

## Physical Footprint

Benchtop installation

# Must Have Menu

## > Percentage of customers indicating must have test



“The volume of HPV is there to bring it in-house and our clinicians like to have results here to keep track of past test results.”

– Hospital Lab Director

“With the volume [of samples] we receive for GC/Chlamydia, that’s probably the first test we’d want to perform in-house.”

– Hospital Lab Director

Source: Company commissioned study of hospital laboratory market

# Hospital-Acquired Infections

## > Background

- Kill nearly 100K in US each year
- Almost 2M patients treated
- Add \$5B to US health care costs

## > Growth Drivers

- Veterans Health Administration: all facilities to implement MRSA testing
- Medicare: no coverage for hospital-acquired infections
  - > HAI testing increases as hospitals test to establish infection status prior to admission

# Hospital Segment Requirements

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Focused menu centered around core molecular tests

## Automation

Automate key process steps: Sample Prep, Analytics, Post-Analytics

## Batch Sizes

Batch sizes scaled efficiently to daily test volumes

## Turnaround Time

Allow testing in a single shift

## Physical Footprint

Benchtop installation

# Hospital Instrument

## Today

- Advanced technology
- Standard off-the-shelf equipment
- Easy to use



## Tomorrow

- Increased automation
- Easier-to-use equipment
- Product aimed at relevant hospital menu
- Throughput 48 samples per day of multiple targets

# Future Product Menu

## > **Must Have**

- HPV
- CT/NG

## > **Hospital-Acquired Infections**

- MRSA
- VRE
- VRSA
- C. difficile

## > **Genetics / PGx**

- Coagulation (FVL, FII)
- CF
- Other PGx



**Common Platform**

# Future Growth Drivers

## Infectious Disease

- Expand hospital menu with lower volume assays
- HSV, Transplant viruses, Flu viruses, others

## PGx

- Targeted companion diagnostic deals
- Partner with pharma & labs (e.g. ARCA deal)

## Oncology

- License IP and develop clinical utility for cancer biomarkers

# Best Suited For Strategy Execution

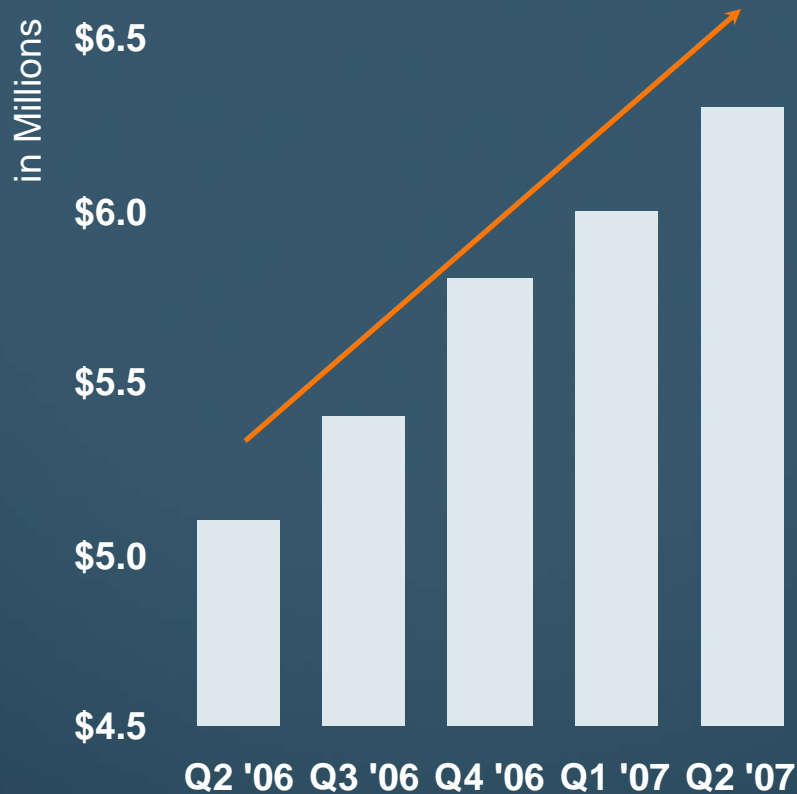
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# Financial Performance

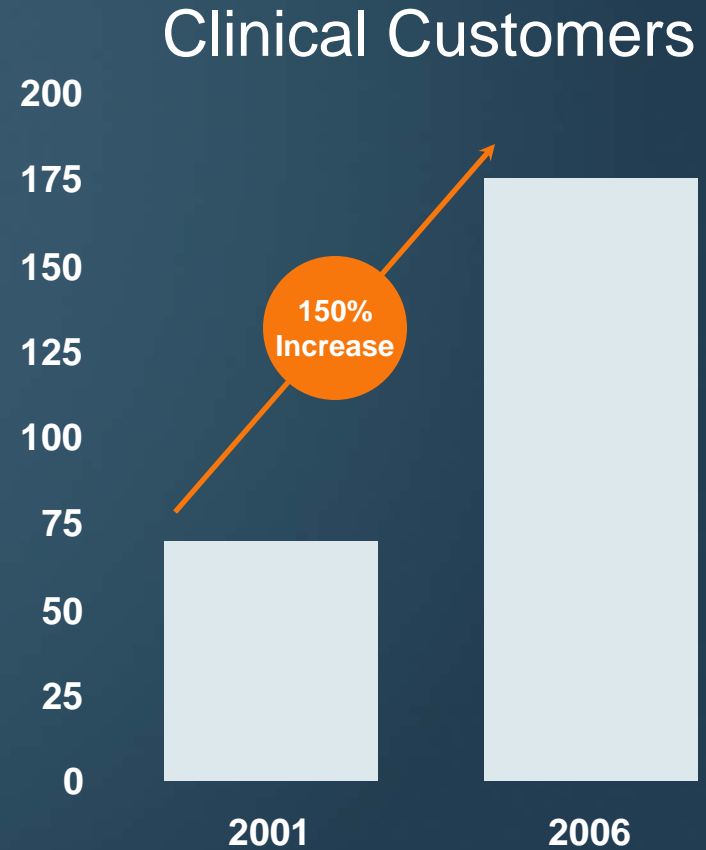
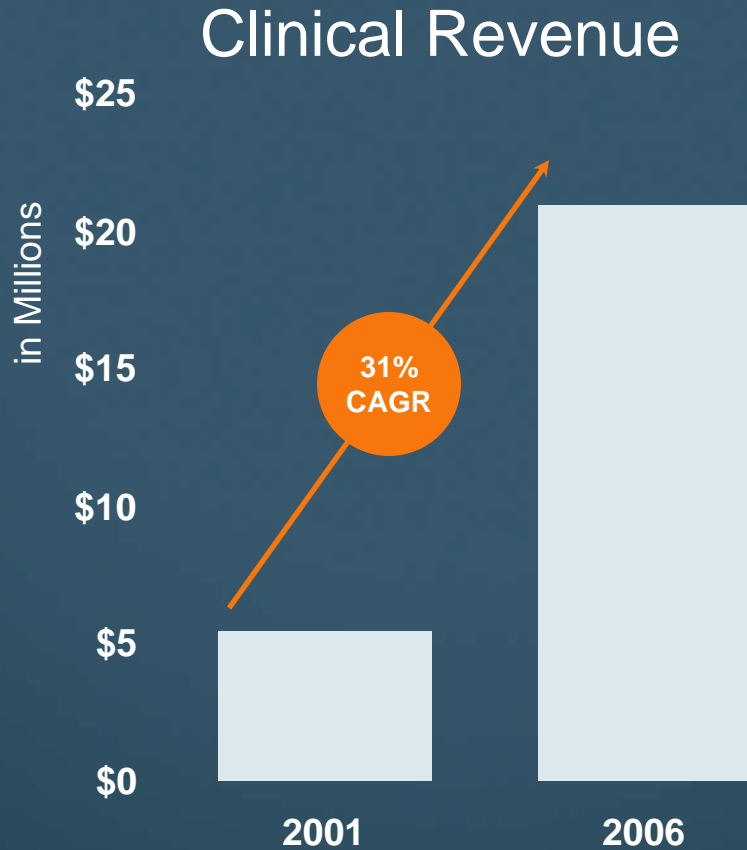
**Maneesh Arora, Senior Vice President & CFO**

# Financial Highlights



- > 7 consecutive quarters of clinical revenue growth
- > Clinical revenue up 24% y/y
- > Gross margins expanded to 74%
- > \$47.8M cash
- > 7 quarters expanding customer base

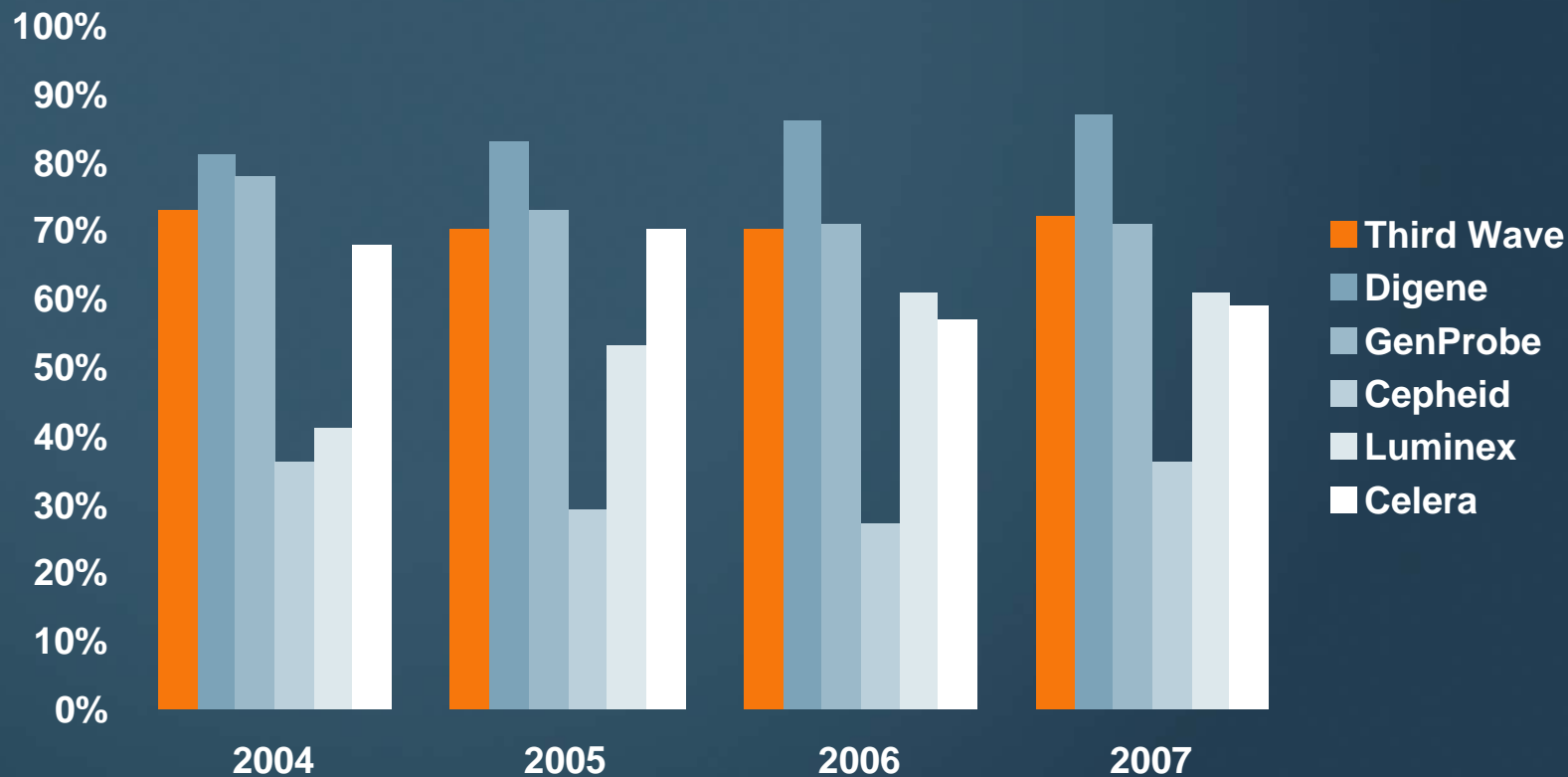
# Financial Performance: 2001-2006



# Financial Performance: 2001-2006



# Financial Comparison to Peers: Gross Margins



# Summary

- > **Emerging leader in molecular diagnostics**
  - 190 US lab customers; developing EU network
- > **Strong growth from current product range**
  - 24% y/y clinical revenue growth in Q2; 74% margins
- > **Substantial near-term HPV opportunity**
  - \$1B addressable market
- > **Proprietary Invader® chemistry**
  - Easy-to-use platform for sustained expansion