

Enriching the quality of life for people everywhere.

# Earnings Conference Call 4<sup>th</sup> Quarter & Fiscal Year 2007

César M. García, CEO

Veronica O. Tarrant, Acting CFO

Thomas H. Adams, PhD CTO

Tom E. Warekois, President Iris Diagnostics



03.07.07

IRIS International, Inc.

## Safe Harbor Provision

This presentation contains forward-looking statements made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, the Company's views on future financial performance, market growth, capital requirements, new product introductions and acquisitions, and are generally identified by phrases such as "thinks," "anticipates," "believes," "estimates," "expects," "intends," "plans," and similar words. Forward-looking statements are not guarantees of future performance and are inherently subject to uncertainties and other factors which could cause actual results to differ materially from the forward-looking statement. These statements are based upon, among other things, assumptions made by, and information currently available to, management, including management's own knowledge and assessment of the Company's industry, R&D initiatives, competition and capital requirements. Other factors and uncertainties that could affect the Company's forward-looking statements include, among other things, the following: identification of feasible new product initiatives, management of R&D efforts and the resulting successful development of new products and product platforms; acceptance by customers of the Company's products; integration of acquired businesses; substantial expansion of international sales; reliance on key suppliers; the potential need for changes in long-term strategy in response to future developments; future advances in diagnostic testing methods and procedures; potential changes in government regulations and healthcare policies, both of which could adversely affect the economics of the diagnostic testing procedures automated by the Company's products; rapid technological change in the microelectronics and software industries; and competitive factors, including pricing pressures and the introduction by others of new products with similar or better functionality than our products. These and other risks are more fully described in the Company's filings with the Securities and Exchange Commission, including the Company's most recently filed Annual Report on Form 10-K and Quarterly Report on Form 10-Q, which should be read in conjunction herewith for a further discussion of important factors that could cause actual results to differ materially from those in the forward-looking statements. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



# **Introduction of Thomas E. Warekois**

**Corporate VP, President Iris Diagnostics Business Unit**

**4<sup>th</sup> Quarter Earnings Conference Call**

**03.07.07**



# **Business Discussion**

**4<sup>th</sup> Quarter Earnings Conference Call  
03.07.07**



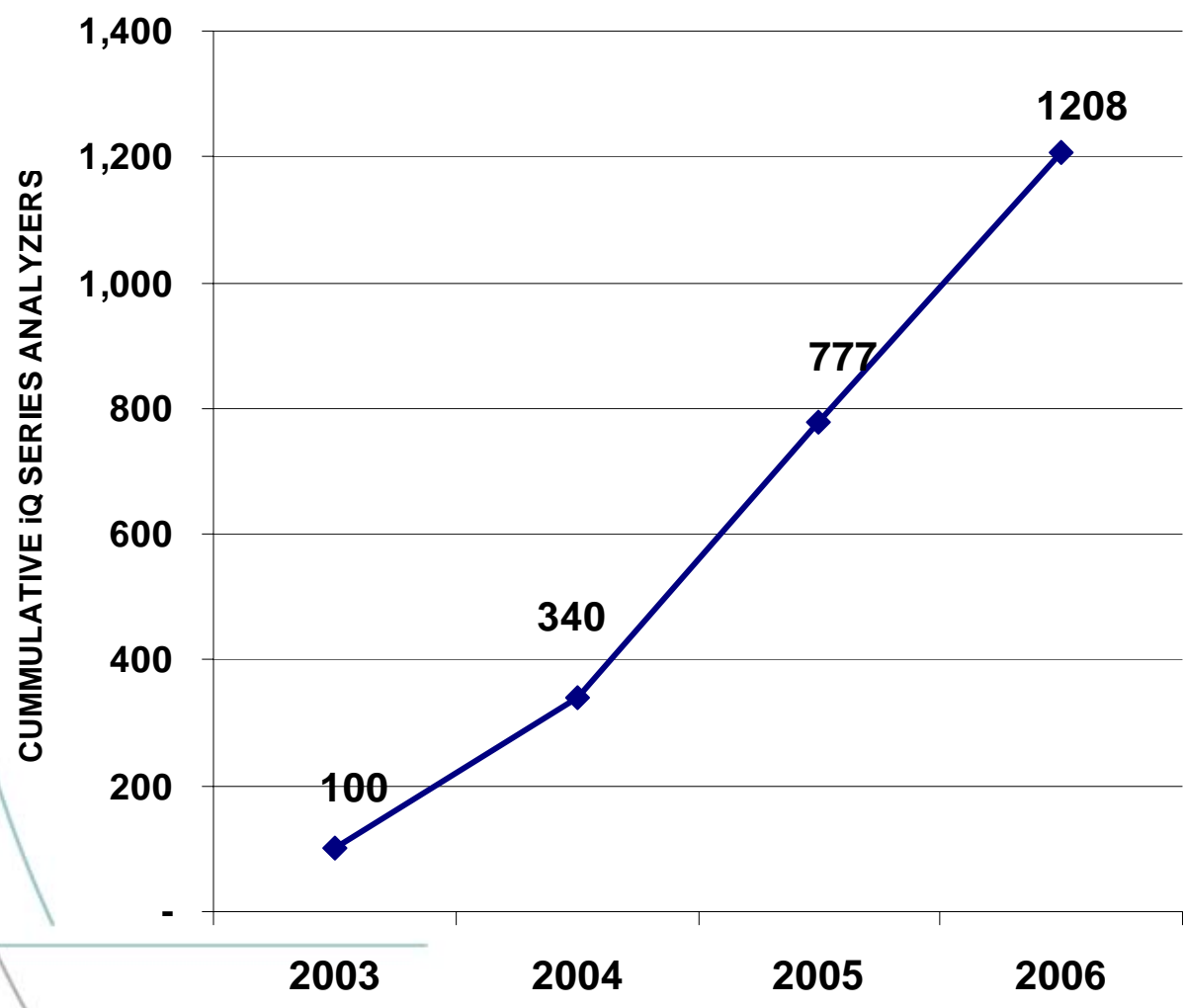
# Q4-06 Highlights

## Record Revenue!

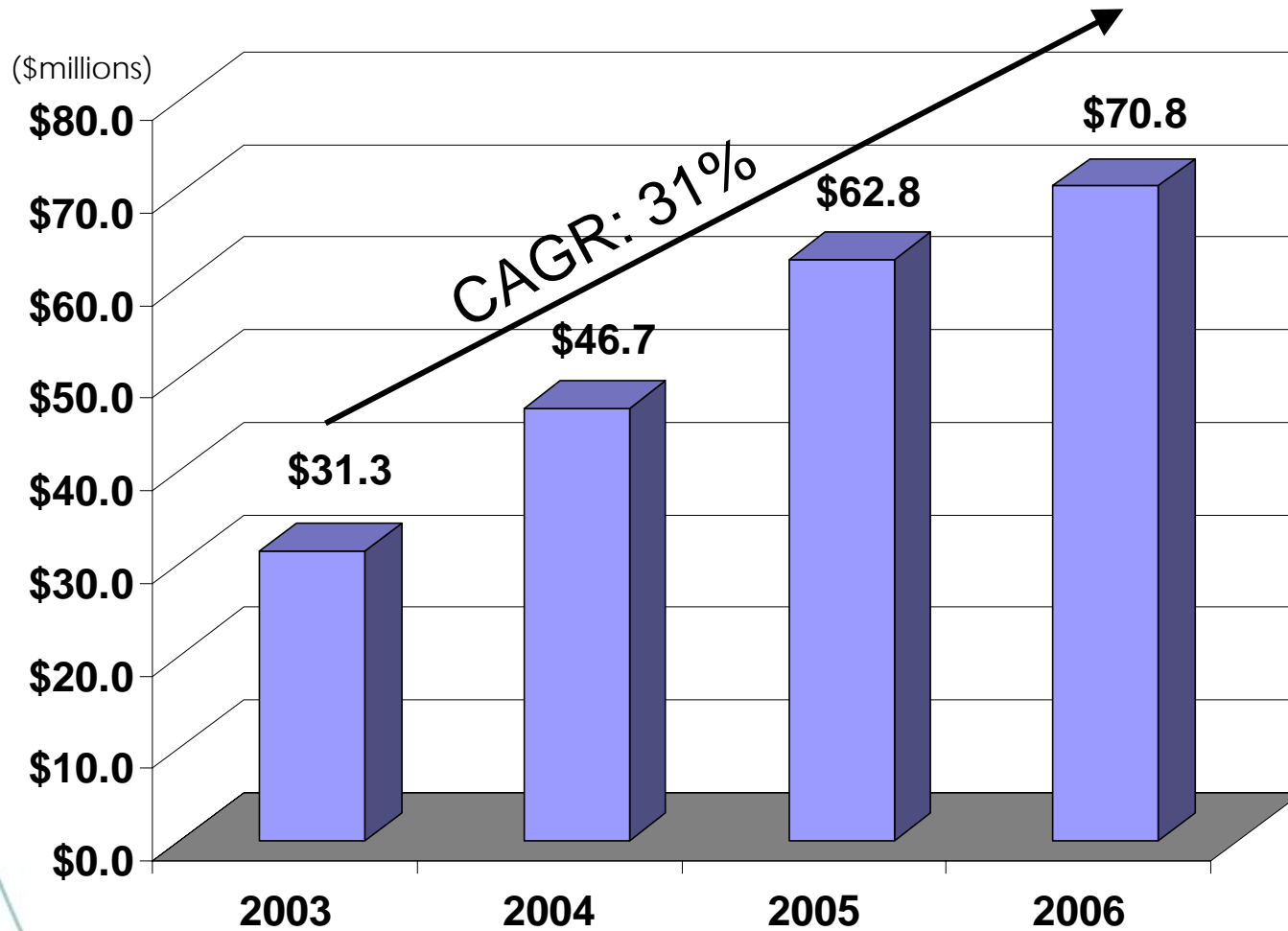
- **120 iQ200 & Sprint Analyzers Globally**
- **Domestic Growth**
  - Record instrument revenue quarter
  - Highest percentage of new business
  - Highest number of iQ<sup>®</sup>200 Sprints
  - Major contracts awarded in 2H-06:
    - LabCorp, Kaiser, Mayo Clinic
  - Strong pipeline for Q1-07
- **Consumables growth to accelerate during first half 2007**



Over 1200 Analyzers now sold.  
Over 1200 Analyzers now sold.

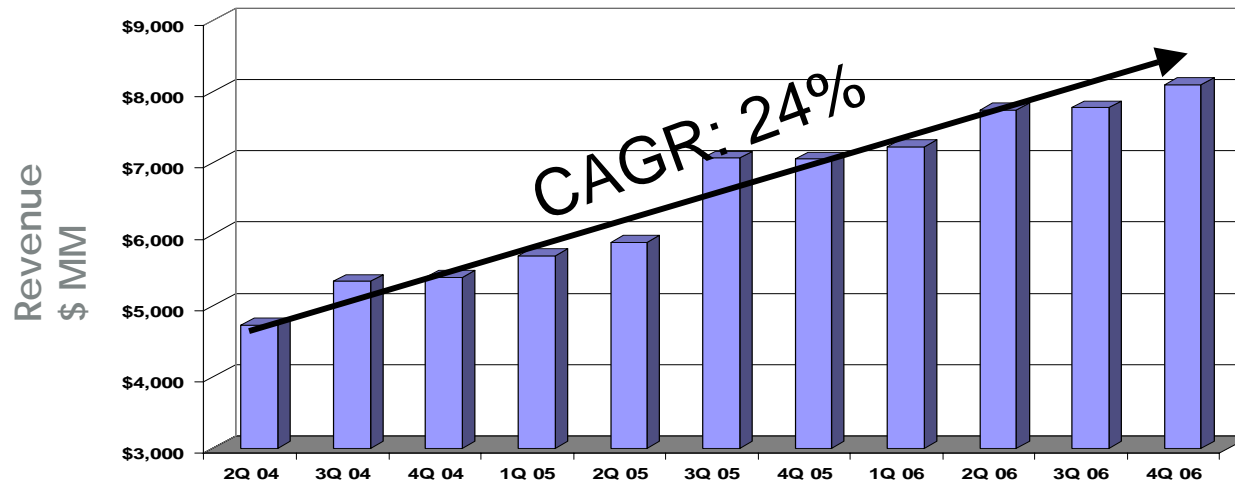


# Strong Revenue Growth



*Iris*<sup>®</sup>

# Consumables and Service High Growth



## Despite Transitional Factors:

- Slow Service Growth:
  - 15 month lag in Service Contracts and high % of installed based under warranty (On average, over 400 iQ Analyzers under warranty in 2006)
- Turkey: ~\$400K revenue loss in 2H-06 due reimbursement problems, now resolved
- 50% domestic replacement rate from 2003 – 2005
- Excellent reliability: lower international spare parts



# A Recurring Revenue Model

## Fully-Automated Segment

	US (Direct Sales)			Ex - US (Through Distribution)		
	Consumables	Service & Parts	Total Recurring Revenue	Consumables	Service & Parts	Total Recurring Revenue
iQ200 SPRINT System	\$42,000	\$14,000	\$56,000	N/A	-	
iQ200 & ELITE System	\$31,000	\$13,000	\$44,000	N/A	-	
iQ200 SPRINT Analyzer	\$28,000	\$10,000	\$38,000	\$15,000	\$4,000	\$19,000
iQ200 & ELITE Analyzer	\$18,000	\$8,000	\$26,000	\$8,500	\$3,000	\$11,500
Automated Chemistry	\$13,000	\$4,000	\$17,000	N/A	-	
Body Fluids	\$5,000		\$5,000	\$3,500		\$3,500
Recurring Revenue Range per Site	From \$ 17,000 to \$61,000			From \$ 11,500 to \$22,500		

*In 2006 Consumables and Service Sales Generated:*

- 44% Consolidated Revenue
- 52% Diagnostics Segment



# 2006 Challenges

- **Weak First Half – Strong Second Half**
- **Financing Major Investments in New Product Pipeline**
- **Lumpy International Consumable Revenues**
  - **Turkey – government temporarily eliminated reimbursement for outpatient testing**
    - Affected consumables in 2H-06
    - Reimbursement re-instituted Q4-06
  - **Inventory Reduction / Distributors purchasing practices**
- **Service Profitability**
  - High percentage of installed base under warranty:
    - No Service Revenue
  - Service contract revenue loss due to Legacy replacements



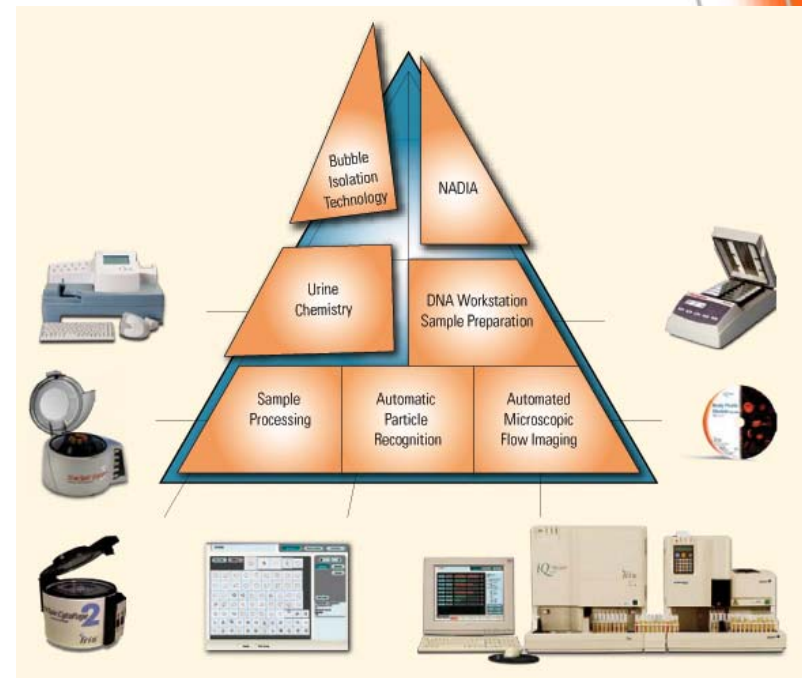
# Consumable & Service Margin

- C & S Margin is a blend of proprietary consumables, distributed consumables, instruments service and under-utilized capacity in our Marburg urine strips chemistry plant:
  - Blended margins of all consumables continue to be high
  - Service margins are low due to high percentage of installed base under warranty and other operational inefficiencies
  - Include approximately \$1.0 million in under-utilized capacity (under-absorbed overhead)
- Margins are forecasted to improve in 2007:
  - Increased installed base of iQ200 Systems and Analyzers
  - Higher number of SPRINTS: LabCorp, Kaiser & Sonic Labs
  - Operational improvements in Service and lower percentage of installed base under warranty
  - iChem 100 / vChem global launch



# New Product Initiatives All On Schedule

- Market Segmentation Initiative
- iChem 100
- Automated urine chemistry analyzer
- MrPSA



*Iris*<sup>®</sup>

# Market Segmentation Initiative

- Fully automated systems (ELITE & SPRINT) are the “Customer Choice” in the US and developed countries
- iQ200 SPRINT represented 23% of 2006 analyzer orders
- The iQ200 SELECT System is forecasted to increase the number of instruments placements in 2007 with minimal cannibalization in core product line
- Almost doubled US sales force

**iQ<sup>®</sup><sub>200</sub> SPRINT**



101 Samples per Hour

**iQ<sup>®</sup><sub>200</sub> ELITE**



70 Samples per Hour

**iQ<sup>®</sup><sub>200</sub> SELECT**



40 Samples per Hour

**Iris<sup>®</sup>**

# Iris Chemistry Plan Market Overview

*~\$350MM Incremental Market Opportunity*

Products	%	\$ MM/ Year				Iris Market Share 2005	
		End-User	Mfg'r Level	USA	EX - US	USA	EX-US
Fully Automated	22%	\$110	\$83	\$28	\$55	44%	
Semi-Automated	21%	\$107	\$80	\$27	\$54		2%
Small CLIA Waived	10%	\$50	\$37	\$12	\$25		
Visual	47%	\$234	\$176	\$59	\$117		1%
		\$501	\$375	\$125	\$250		

IRIS is the market leader in automated urine chemistry in the US



# Iris Urine Chemistry Plan

## Strategic Objectives

- Establish Iris as a complete provider of ALL urine chemistry products globally by early 2008
  - Add another significant, high margin, recurring revenue stream
  - Goal is to achieve 25% CAGR 2008 -2011 in the urine chemistry segment
- Building on the domestic success of **The Complete Urinalysis Solution** (integrated Chemistry & microscopy) to competitively strengthen our global strategic position



# What Iris is Doing to Meet Objectives?

- Iris is developing new products, adding distribution channels, and launching new marketing programs to significantly penetrate all segments of the global chemistry market
  - Introducing state of the art, patented technology
    - Automated urine chemistry analyzer
    - iChem100 semi-automated urine chemistry analyzer with iConnect - released
    - CLIA-waived portable urine chemistry analyzer for the decentralized UA market (POL market, ER, etc.)
  - New US and Int'l distribution partners to cover market segments other than the hospital core lab
  - Sales and marketing programs for all segments



# Automated Urine Chemistry Analyzer

- Design progressing per plan
- Facility expansion completed December 2006
- Pre-production pilots in process
- CE-mark & 510(k) submission mid -2007



# Why did we buy Leucadia?

- Bubble Isolation Technology to enable urine culture screening product (bacteria program)
- NADIA to enable rare cell detection
- World-class chemistry group
  - iQ NEXT: Expand iQ200 morphology applications
  - Synergies with other IVD programs
  - Increased capability / probability of success



# **NADIA & Bubble Isolation Implementation Plans**

**Thomas Adams, PhD.**

**4<sup>th</sup> Quarter Earnings Conference Call**

**03.07.07**



# NADIA

## (Nucleic Acid Detection Immuno Assay)

- NADIA is a technology platform—not a product
- NADIA is used for the ultra-sensitive detection of proteins
- NADIA can be used to develop many products

# Ultra-sensitive Detection of Proteins

- Most proteins in serum are at undetectable levels
- Sano and Cantor invented Immuno-PCR (I-PCR) (Science Journal 1992)
- I-PCR took two days to process and it was too complicated for the reference lab
- NADIA is a significantly improved version of this arduous research procedure that is practical for a reference lab
- NADIA and I-PCR have similar sensitivity (1fg/ml)

# Ultra-sensitive Detection Nomenclature

- No standard definition of “ultra-sensitive”
  - Milligram =  $1/1,000\text{g}$
  - Microgram =  $1/1,000,000\text{g}$
  - Nanogram =  $1/1,000,000,000\text{g}$
  - Picogram =  $1/1,000,000,000,000\text{g}$
  - Femtogram =  $1/1,000,000,000,000,000\text{g}$

# Ultra-sensitive assays

- No standard definition of "ultra-sensitive"
- The best commercially available immunoassays can measure concentrations as low as 2,000 -10,000 fg/ml
- Most are in the 30,000-200,000 fg/ml range
- NADIA has measured 1 fg/ml concentrations
- NADIA range of measurement: from 1 to millions fg
- NADIA complexity is scalable to reach the sensitivity required

# Plans for NADIA PSA

- 510k submitted February 2007
  - Expect regulatory process to take up to 6 months
- Intended use is monitoring prostate cancer patients
- Complete a reverse outcome study for prostate cancer patients in 2007
- NADIA Awareness Campaign
  - Publications & presentations at CLAS, IFCC, AACCC, Oakridge Conf
- Early commercialization – second half 2007



# Bubble Isolation Technology Platform

- Antibody coated bubbles can be used to isolate many different types of cells
- Bacteria
- Tumor cells
- Different types of blood cells

# Bubble Isolation - Bacteria

- Isolation for all major bacteria types in urine
- Already demonstrated capability to isolate & concentrate gram negative bacteria
- Proprietary micro-bubbles used to isolate and concentrate bacteria in urine
- Target Completion of Feasibility Studies - Summer 2007
- Initiate joint-development program with IRIS instrumentation group
- Market Potential: \$300MM/yr



# Bubble Isolation – Tumor Cells

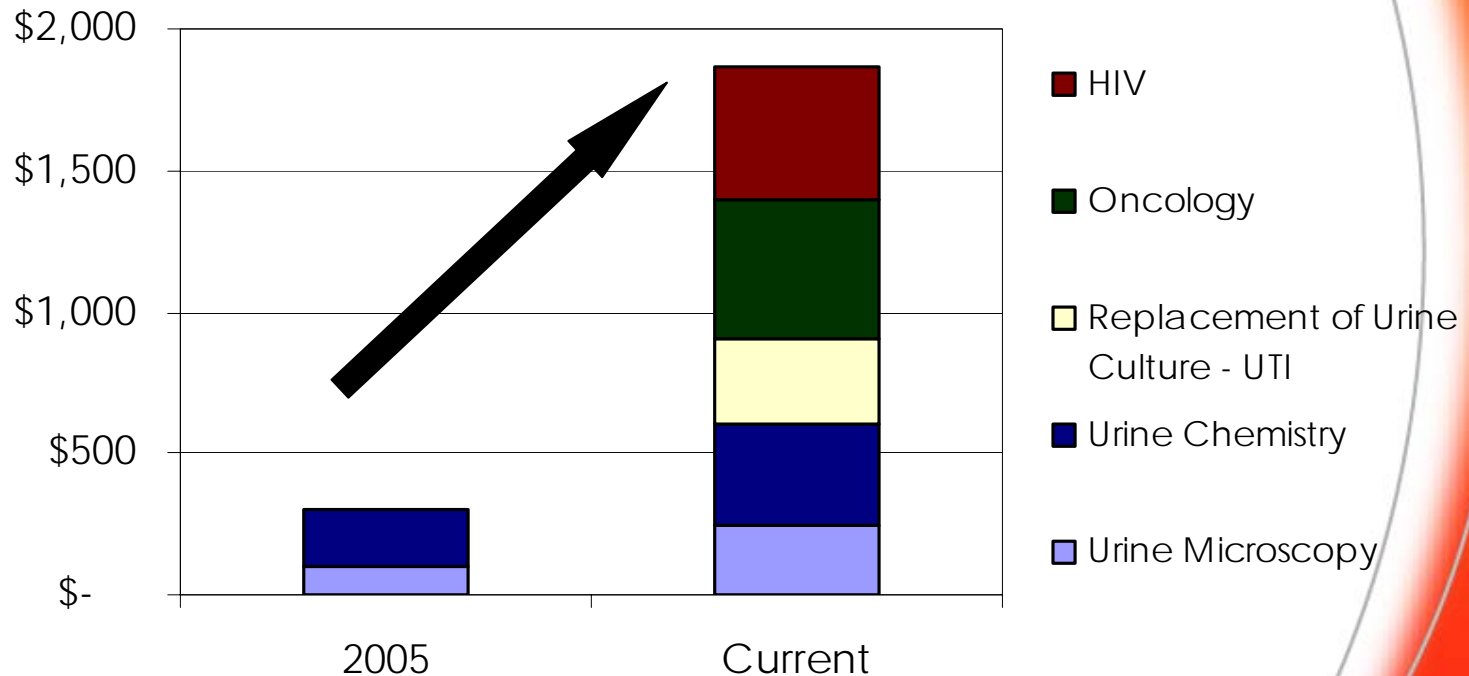
- All solid tumors are epithelial cell tumors
- Isolate circulating epithelial (tumor) cells
- Use to isolate and concentrate to phenotype cells
- Complete 2007

# NADIA - HIV

- Used to monitor HAART Therapy
  - Viral load tests measure amount of HIV RNA
  - Along with CD4 cell count, most valuable measure for predicting HIV disease progression
  - Current tests can measure viral load down to 50 copies/mL
- NADIA HIV p24 can provide detection down to the equivalent of 1 copy/mL
- Prototype high sensitivity assay in 2007
- Expected to file PMA in 2008
- HIV viral load testing was estimated to be approximately \$470 million in 2004

# Target Markets Approaching \$2.0 Billion

(\$ in millions)



# **Financial Summary**

**4th Quarter & Fiscal Year 2007**

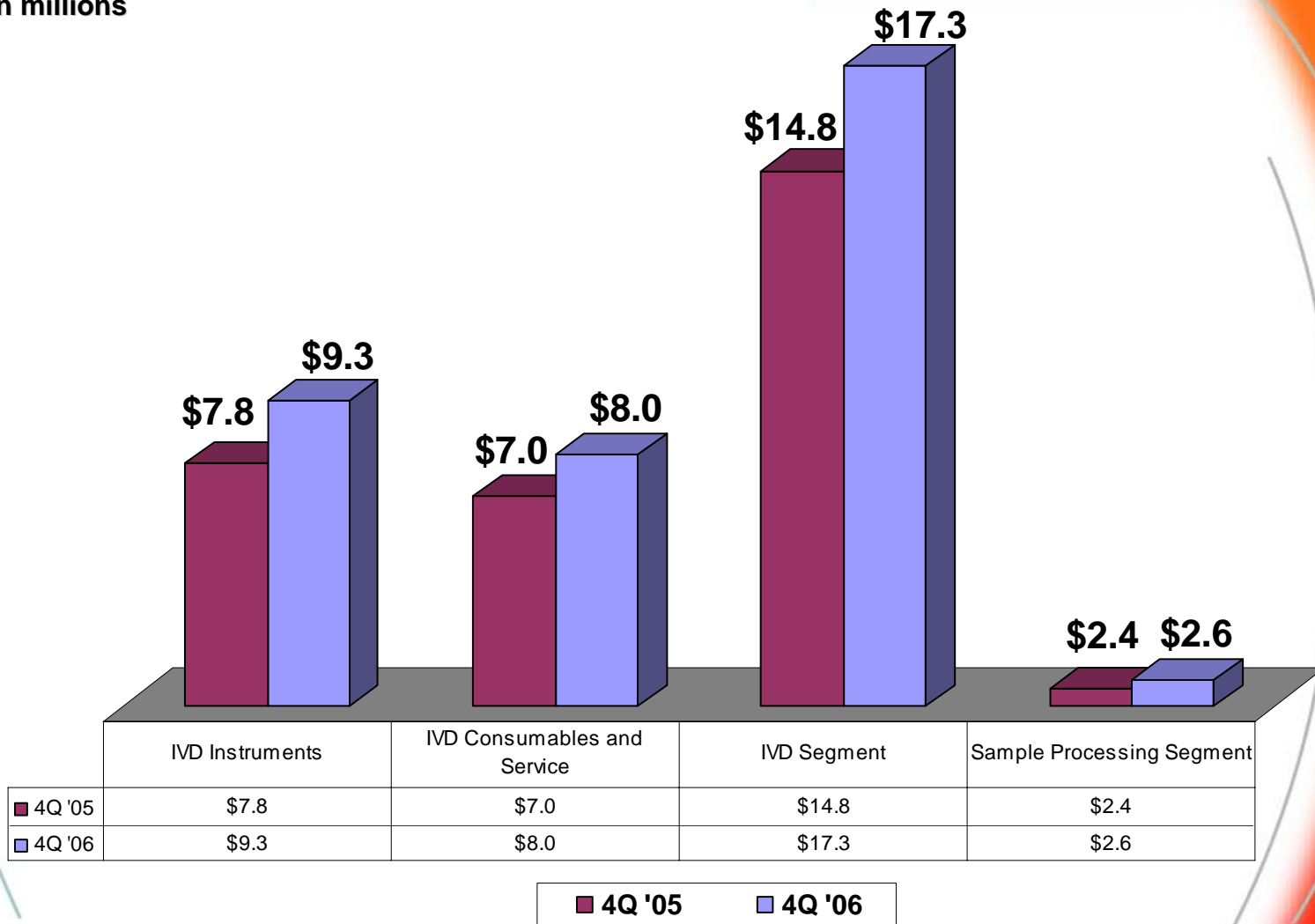
**Earnings Conference Call**

**03.07.07**



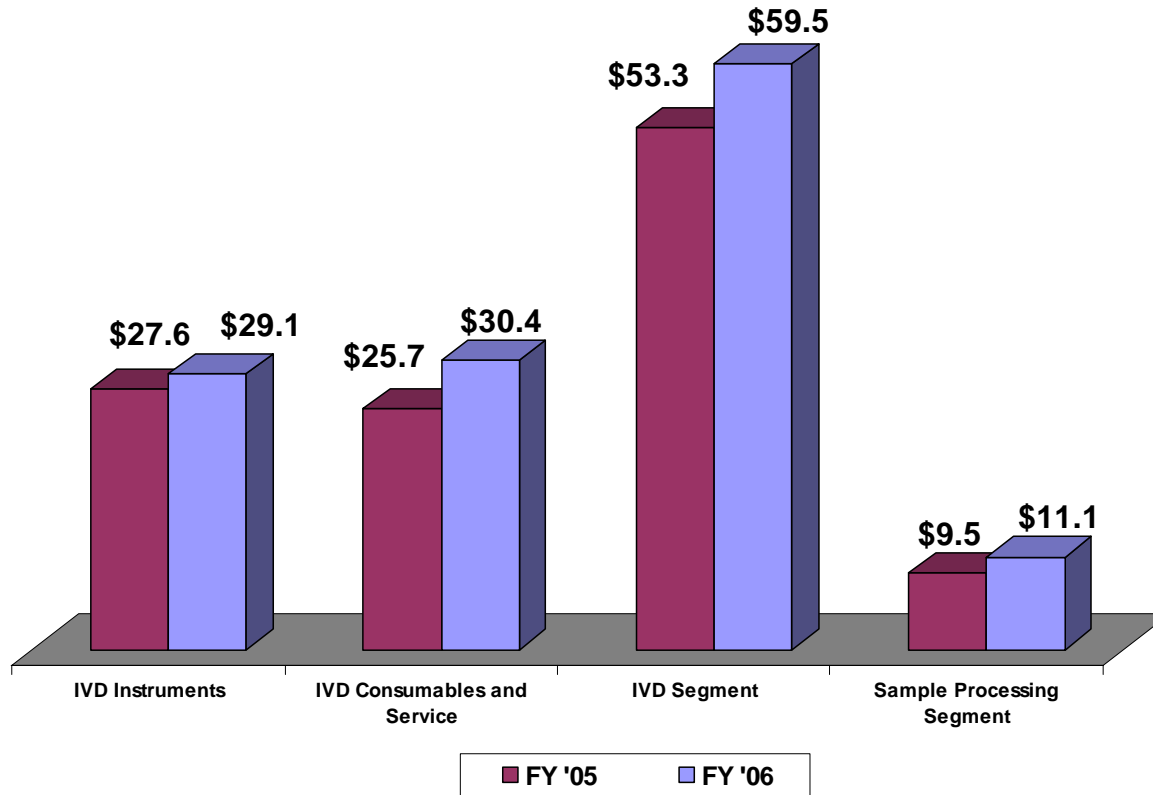
# Segment Revenues – 4th Quarter

\$ in millions



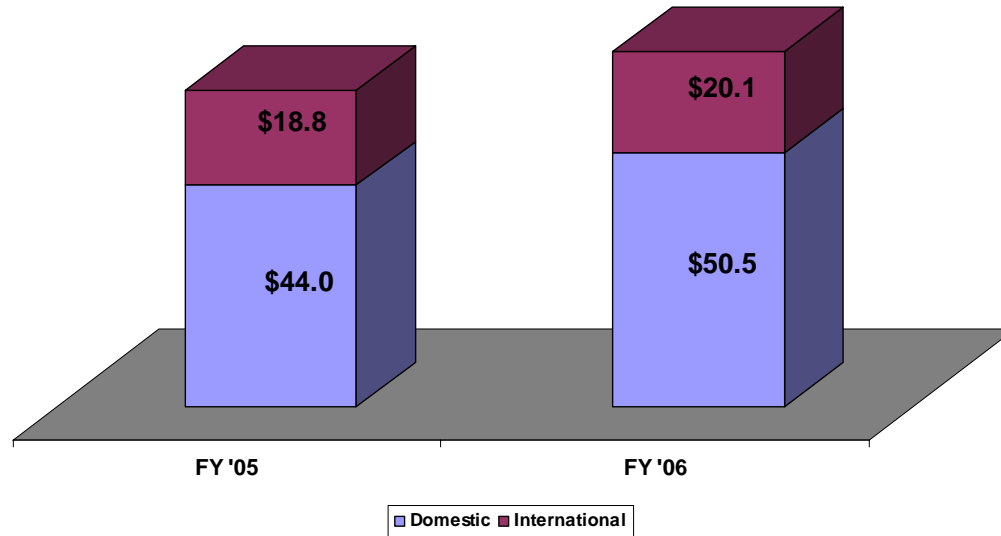
# Segment Revenues – FY 2006

\$ in millions



# Revenues By Geography – FY 2006

\$ in millions



# Special, Certain Large Items and 123R Charges

**FY 2006**

\$ in thousands

Adjustments	Cost of Sales	Operating Expenses	Income Taxes	Effect on Net Income	Effect on E.P.S.
(1) In-Process Research and Development Expense	\$ -	\$ (5,180)		\$ 5,180	\$ 0.28
(2) Bad Debt Expense		(350)	129	221	0.01
(3) CFO Transition Expense		(743)	275	468	0.02
(4) Incremental Stock Based Compensation Expense	(218)	(1,350)	580	988	0.06
	\$ (218)	\$ (7,623)	\$ 984	\$ 6,857	\$ 0.37

- (1) Represents the write-off of In-Process Research and Development assets acquired in the Leucadia Technologies acquisition.
- (2) Represent bad debt expense attributable to the default by an assignee of Company lease agreements.
- (3) Represents severance, recruiting and relocation expenses relating to the change in the Company's CFO.
- (4) Represents non-cash stock based compensation attributable to the adoption of SFAS 123R.



# Condensed Statement of Operations

2006 Adjusted versus 2005

\$ in thousands

	Three months ended December 31		Twelve months ended December 31	
	Adjusted 2006	2005	Adjusted 2006	2005
Revenues	\$ 19,915	\$ 17,237	\$ 70,636	\$ 62,780
Gross margin	9,802	8,547	34,804	31,145
<i>Gross margin %</i>	49.2%	49.6%	49.3%	49.6%
Research and development	1,740	1,674	7,518	5,037
S,G&A expense	5,185	4,859	18,397	17,167
Total operating expenses	6,925	6,533	25,915	22,204
Operating income	2,877	2,014	8,889	8,941
Interest income, net and other	299	215	1089	605
Pre tax income	3,176	2,229	9,978	9,546
Income tax	783	488	3,297	3,415
Net income	\$ 2,393	\$ 1,741	\$ 6,681	\$ 6,131

Iris®

# Earnings Per Share

	Three months ended December 31		Twelve months December 31	
	<u>2006</u>	<u>2005</u>	<u>2006</u>	<u>2005</u>
Fully Diluted EPS - GAAP	\$ 0.10	\$ 0.10	\$ (0.01)	\$ 0.35
Special and Nonrecurring Items and FAS 123R Expense	0.03		0.38	
Fully Diluted EPS - Pro Forma	<u>\$ 0.13</u>	<u>\$ 0.10</u>	<u>\$ 0.37</u>	<u>\$ 0.35</u>



# Cash Management

## Working Capital Management

- DSO's unchanged year over year at 68 days
- Significant improvement in inventory performance to 4.9 turns

## Investing Activity

- 2006 Facility Expansions and Upgrades (\$2.5 million)
- Leucadia Acquisition (\$3.6 million)

## Cash Position and Outlook

- \$23.2 million of cash, cash equivalents and marketable securities at December 31, 2006



# 2007 Guidance

As of 03.07.07

- Revenues: \$81.0 million - \$83.0 million
- R&D: 13% of revenue
- EPS: At least \$0.40\*

\* Includes \$0.05 per share of FAS123R items



# **Q & A**

**Thank you.**

