



# Empowering Oncology Decisions

DiagnoCure is a life sciences company commercializing high-value cancer diagnostic tests and lab services that increase clinician and patient confidence in making critical treatment decisions

BIOFINANCE, TORONTO  
APRIL 29, 2009

**Diagno**Cure

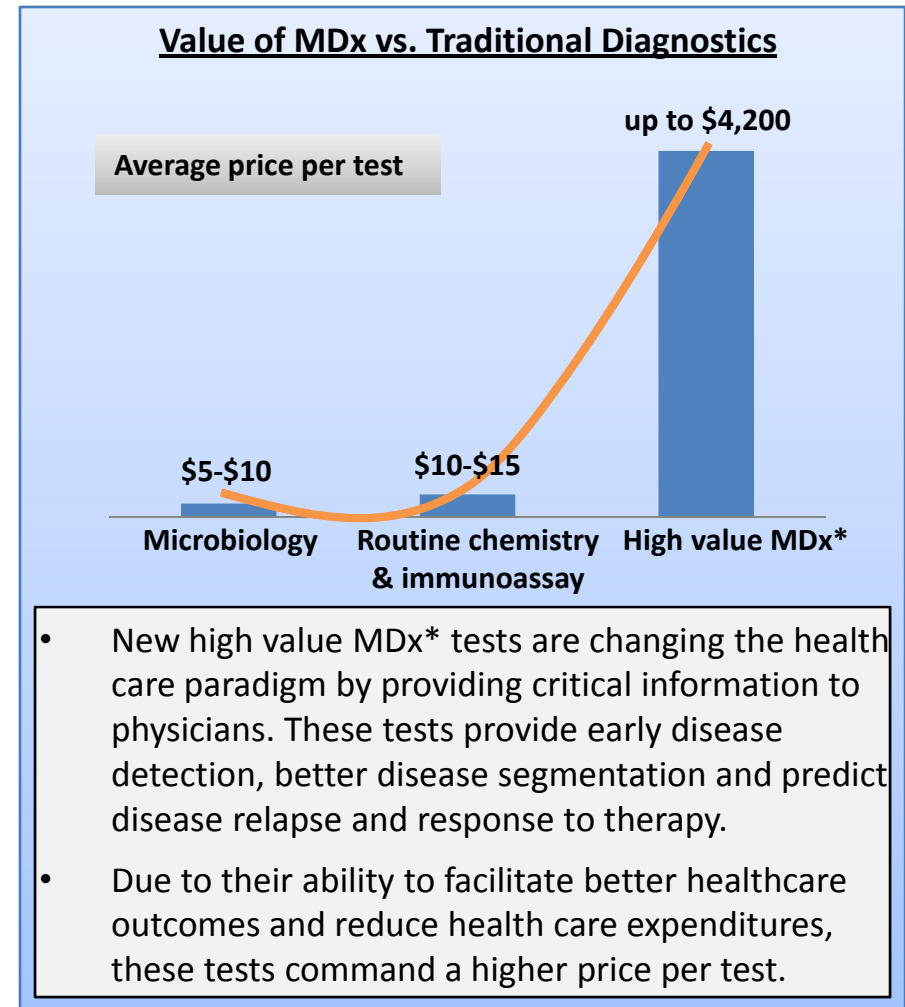
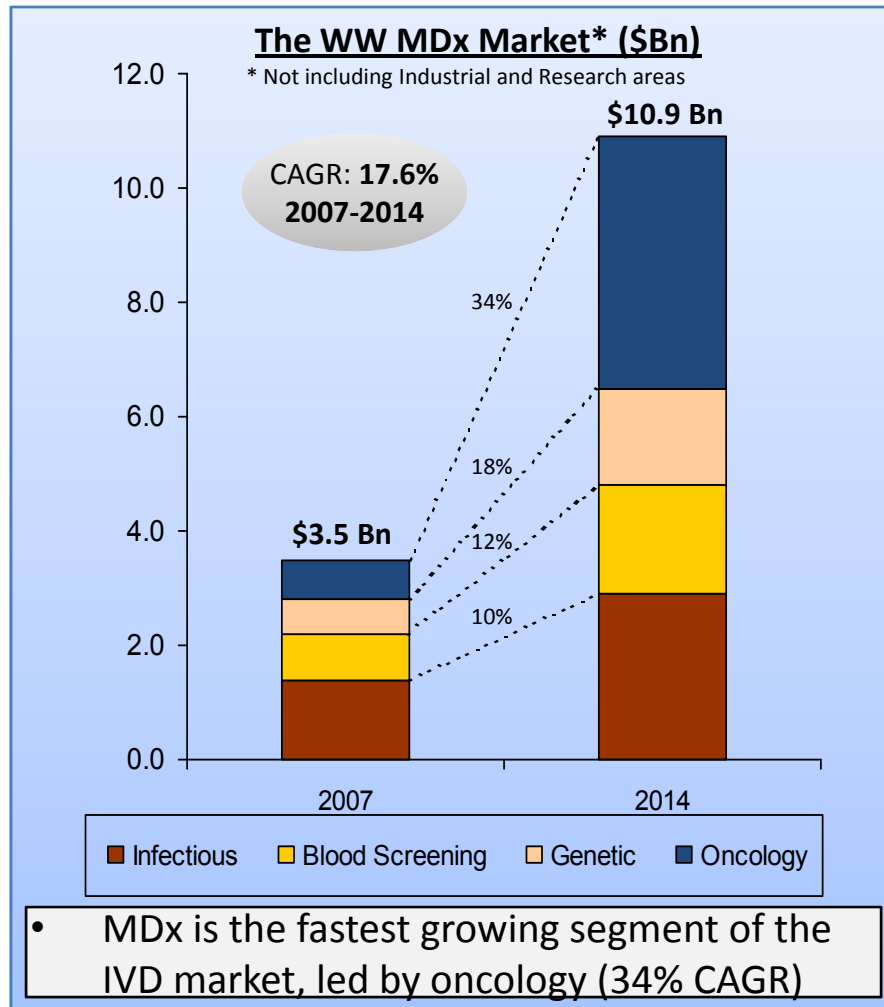
# SAFE HARBOUR STATEMENT

**The statements made in this presentation or in response to questions that are not historical facts are forward-looking statements that involve risks and uncertainties, including but not limited to: risks associated with the uncertainty of product development and commercialization; the impact of competitive products; intellectual property; the risk of unanticipated delays in research and development efforts; the risks and uncertainties associated with the regulation of our tests; our ability to obtain capital when needed; our history of operating losses; and other risks and uncertainties, including those detailed from time to time in periodic reports, including the Annual and Quarterly Reports filed by DiagnoCure with the Canadian Securities Regulatory Authorities.**

# Company Overview

- **TSX-listed company with U.S.-based commercial operations; Canadian head office/development lab**
  - 50 employees (1/3 in U.S.)
- **Proprietary oncology molecular diagnostic portfolio**
  - 25 issued patents; 67 pending applications
- **Royalty-generating partnership with Gen-Probe**
  - Progen<sup>®</sup> PCA3 Assay for prostate cancer
- **Recently launched Previstage™ GCC colorectal cancer staging test from own CLIA lab**
- **Experienced senior management team**
  - Abbott, Becton Dickinson, Baxter
- **Depressed valuation at a value-inflection point**

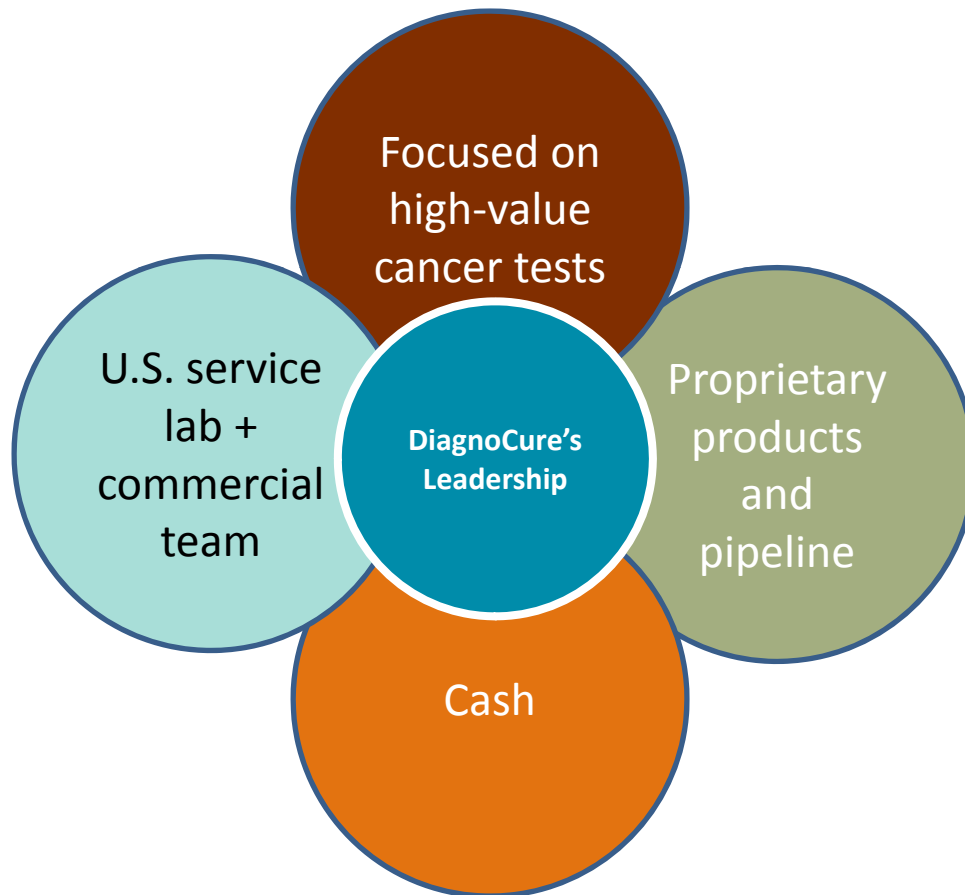
# Our Space



Source: TSG Partners; Scientia Advisors

**CONFIDENTIAL**

# Our Model



## Who else has this model?

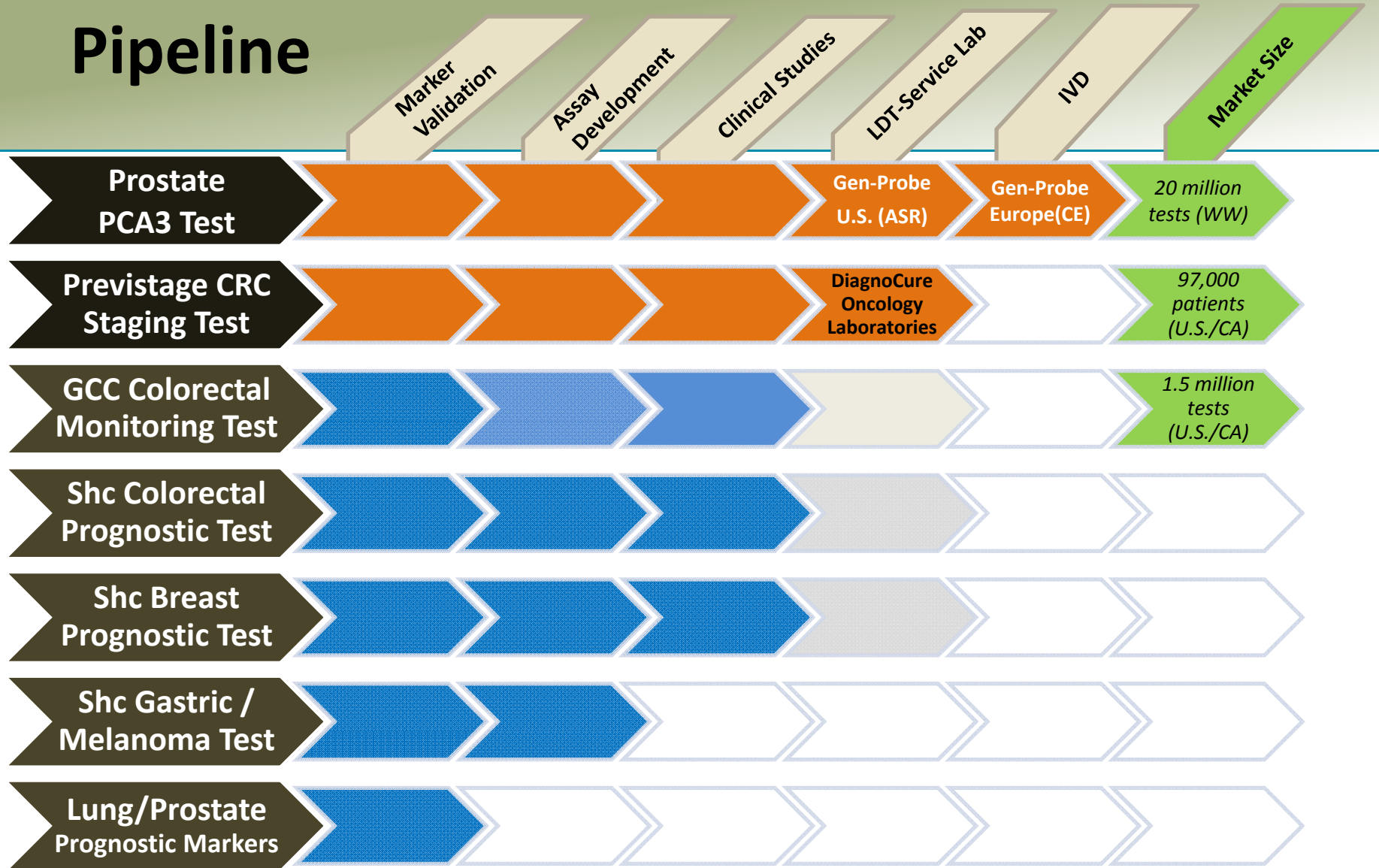
### Established companies:

- Myriad Genetics
  - BRACAnalysis®
- Genomic Health
  - Oncotype DX®

### Emerging companies:

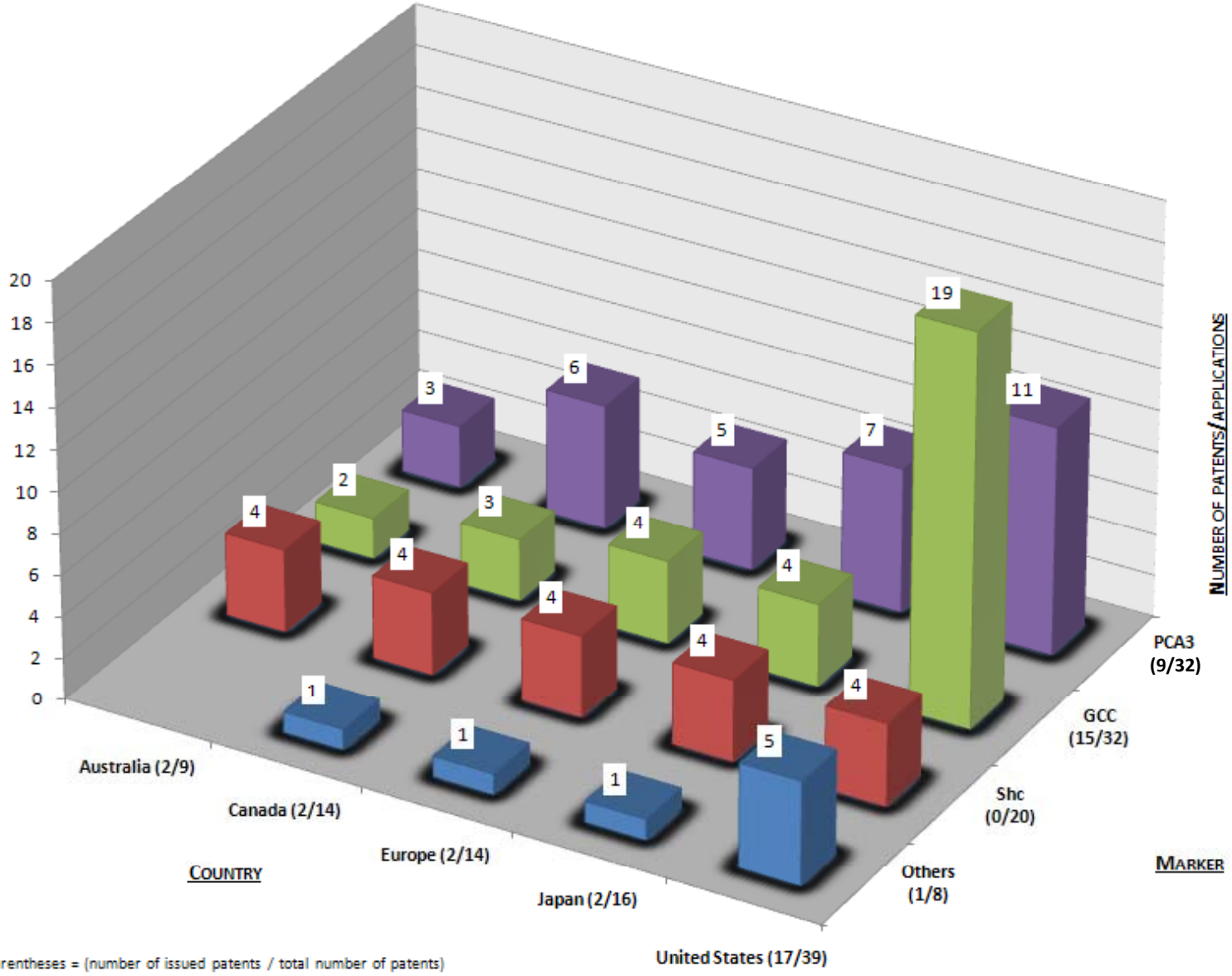
- XDx
  - AlloMap® Molecular Expression Testing
- Agendia
  - MammaPrint®
- Pathwork Diagnostics
  - Pathwork® Tissue of Origin Test

# Pipeline



Marketed products plus a strong and balanced pipeline with short-, mid-, and long-term opportunities

# Patent Portfolio



Parentheses = (number of issued patents / total number of patents)

CONFIDENTIAL



**PCA3**  
**for Prostate Cancer**  
**Licensed to Gen-Probe Inc.**

# The Prostate Cancer Dilemma

## Serum PSA: a standard test for diagnosing Prostate Cancer, but not Prostate Cancer-specific

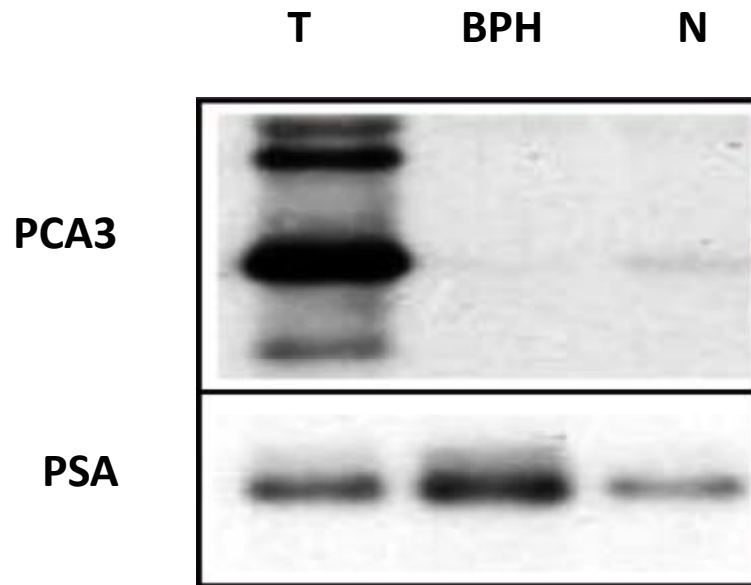
- PSA levels increase due to benign conditions
- PSA levels increase with prostate size
- PSA levels do not reflect the size of the tumor
- With cut-off = 4 ng/mL, PSA misses significant prostate cancer
- PSA is not useful in “**PSA biopsy dilemma**” population:
  - Men with chronically elevated PSA and  $\geq 1$  negative biopsy

## Summary Dilemma

- Biopsy is costly and can be associated with considerable anxiety, discomfort, pain and complications
- PPV of Digital Rectal Exam (<20%) and PSA (<25-30%) far from optimal
- High percentage of initial biopsies is negative (PSA false-positives)
- A large population of men with falsely elevated PSA has emerged over the years
- There is need for accurate diagnostic tests that:
  - detect the development of clinically significant Prostate Cancer
  - reduce the number of unnecessary biopsies

# PCA3 (Prostate Cancer Gene 3)

Prostate-specific, non-coding RNA<sup>1</sup>



PCA3 Assay:  
Direct detection of PCA3 in urine



<sup>1</sup>Bussemakers, et al (1999) Canc Res 59:5975-5979

# The PCA3 Solution

- PCA3 provides a new method for accurate PCa detection in the problematic serum PSA “false-positive” population<sup>1,2</sup>.
- The PCA3 Score is superior to serum PSA in predicting repeat biopsy outcome<sup>3</sup>.
- The PCA3 Score correlates with the probability of a positive biopsy, but not with prostate gland volume<sup>2,3</sup>.
- Men with high volume/high grade cancers have significantly higher urine PCA3 Scores<sup>4</sup>.
- Currently available in Europe and as an ASR in U.S.

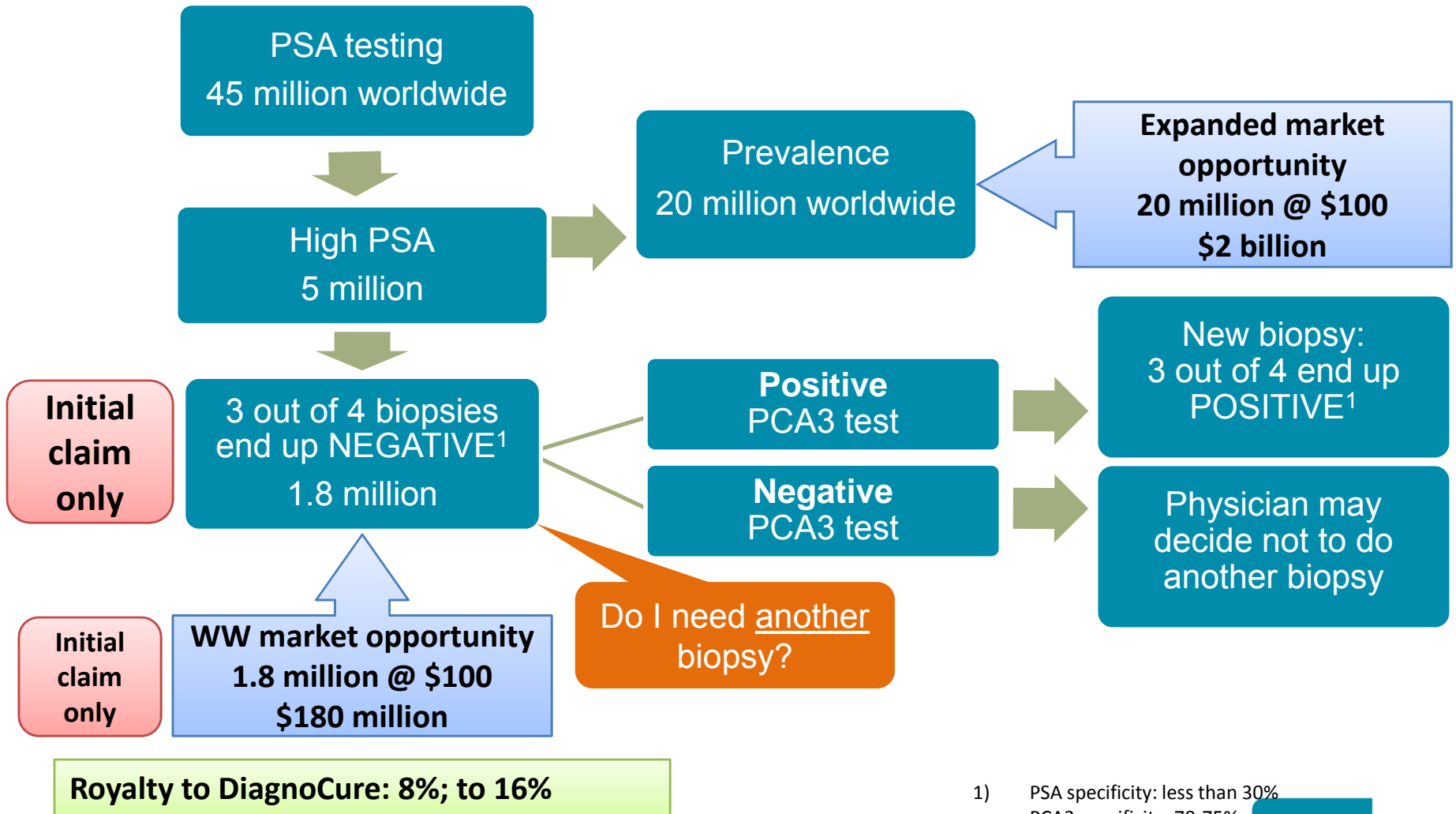
<sup>1</sup>Marks et al., Urology 69 (2007) 532-535

<sup>2</sup>Deras et al., Journal of Urology 179 (2008) 1587-1592

<sup>3</sup>Haese et al., European Urology 54 (2008) 1081-1088

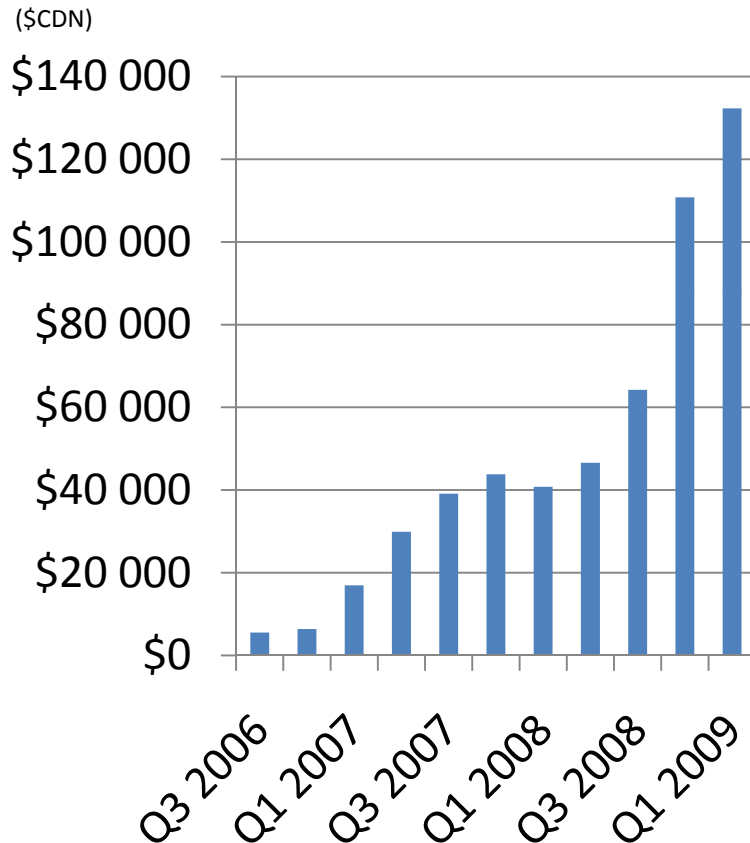
<sup>4</sup>Whitman et al., Journal of Urology 180 (2008) 1975-1979

# The PCA3 Market Potential



1) PSA specificity: less than 30%  
PCA3 specificity: 70-75%

# PCA3 Royalties (Quarterly)



## PCA3 royalty revenue growing\*

- U.S.: available in all major labs using ASR<sup>1</sup> produced by Gen-Probe
- Europe: Progensis™ PCA3 available in 30 testing centers
- Current royalty 8%; moving to 16%

## Gen-Probe's initiatives announced\*

- Strengthening of European sales team in 2008 with ~30 employees expected in Europe in 2009
- Employees to be based in key markets of Germany, UK, France, Italy
- Continued acquisition efforts in 2009 to strengthen global market penetration

(1) ASR: analyte specific reagents

\*Source: Gen-Probe 2008-11-07

# GCC Previstage™ for Colorectal Cancer Staging



The Previstage™ GCC Colorectal Cancer Staging Test is a laboratory-developed test, and its performance characteristics have been validated and determined by DiagnoCure Oncology Laboratories. DiagnoCure Oncology Laboratories is certified under CLIA regulation as high-complexity laboratory.

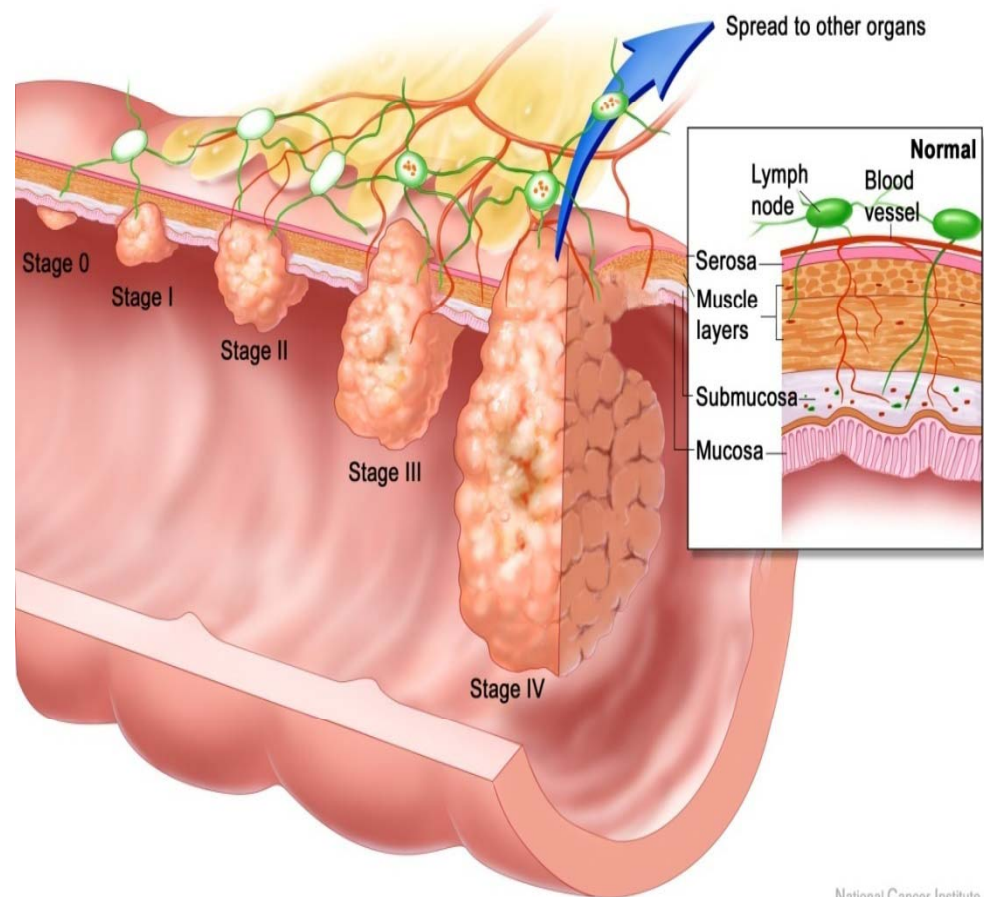
# Clinical Dilemma

- Presence of metastatic tumor cells in lymph nodes (LN) is the single most important prognostic factor in treatment decision making
- Despite LN being identified as “free of tumor cells” by histopathology (pN0), 20%-30% of pN0 patients develop recurrent disease
- Those patients with apparently localized disease, in fact, harbor occult metastases undetected by current pathological examination
- Histopathology alone is inadequate for accurately staging LN negative Colorectal Cancer (CRC)

*Nicastro et al. J. Mol. Diag 2007;9:563-571.*

# Colorectal Cancer Staging

- Stage I and II vs III and IV
- Is disease contained within the intestine or has it escaped into extra-intestinal tissues?
- **Stage determines prognosis and adjuvant chemotherapy**

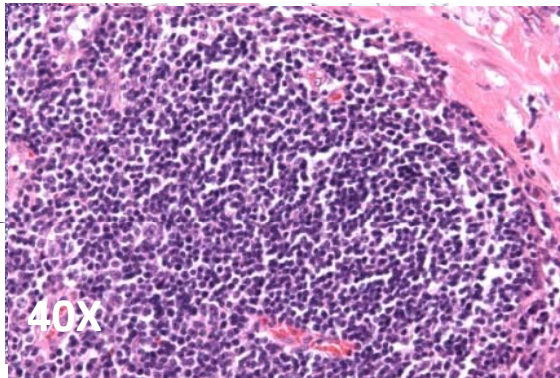


National Cancer Institute

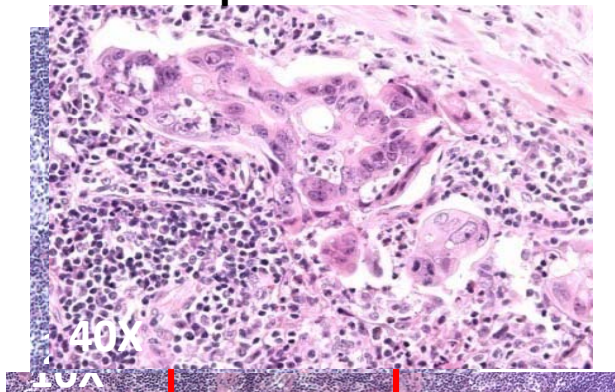
# Current Staging Paradigms Have Significant Limitations

## Original Section of a CRC LN

Diagnosis: metastasis free



Occult metastasis found on a subsequent section



- Insufficient number of lymph nodes (LN) used for staging
- Histopathology analysis of only a small volume of individual lymph node tissue is inadequate for accurately staging LN positive CRC
  - Sampling error may account for up to 15% of false-negative
- Low sensitivity of standard histopathology which detects only 1 cancer cell in 200 normal cells.

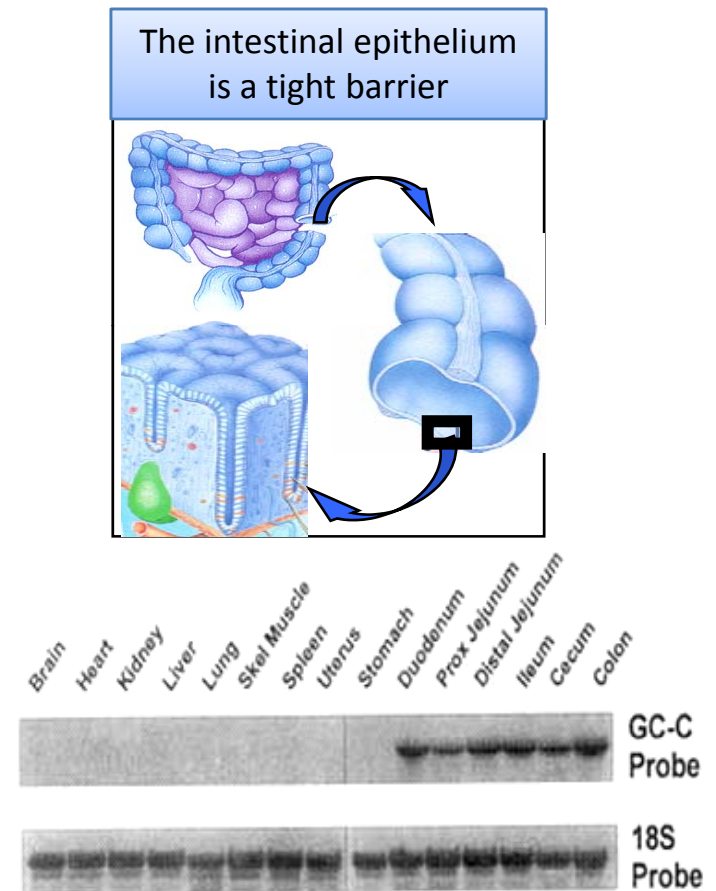
Bilimoria KY, et al. *J Natl Cancer* 2008;100:1310-1317

Iddings et al. *Ann Surg Oncol* 2006; 13:1386-92

Bilchik AJ, et al. *Ann Surg* 2007;246:568-577.

# Our Solution: GCC – a Molecular Marker for Colorectal Cancer

- Guanylyl Cyclase C (GUCY2C or GCC) is normally found only in intestine; from duodenum to rectum
- GCC is still expressed in colorectal tumors, but not in other cancers or normal tissue outside the GI tract
- Thus, GCC can be used clinically for the management of patients with colorectal cancer

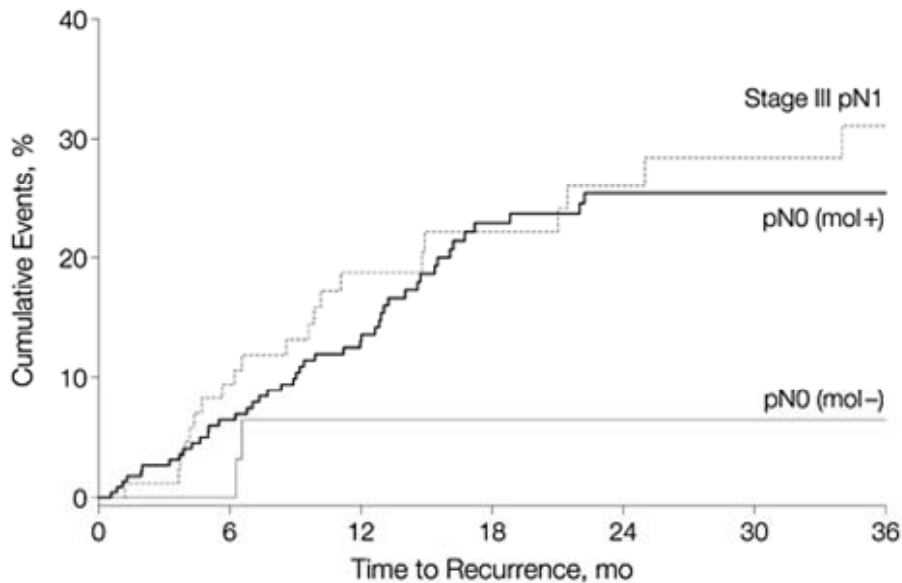


**GCC Northern Blot Analysis (mRNA)**

Swenson et al (1996) BBRC 225:1011

# GCC 5-Year Prospective Clinical Study

## Time to Recurrence in Patients With pN0 Colorectal Cancer Stratified by Occult Lymph Node Metastases



- Measuring GUCY2C mRNA expression in LN identify pN0 CRC patients at increased risk for recurrence
- Recurrence in pN0 (mol+) is identical to patients with histopathology positive LN (pN1) known to be at higher risk by standard pathology practice

**JAMA**<sup>®</sup>

### Association of GUCY2C Expression in Lymph Nodes With Time to Recurrence and Disease-Free Survival in pN0 Colorectal Cancer

Scott A. Waldman; Terry Hyslop; Stephanie Schulz; et al.

*JAMA*. 2009;301(7):745-752 (doi:10.1001/jama.2009.141)

# The GCC Solution

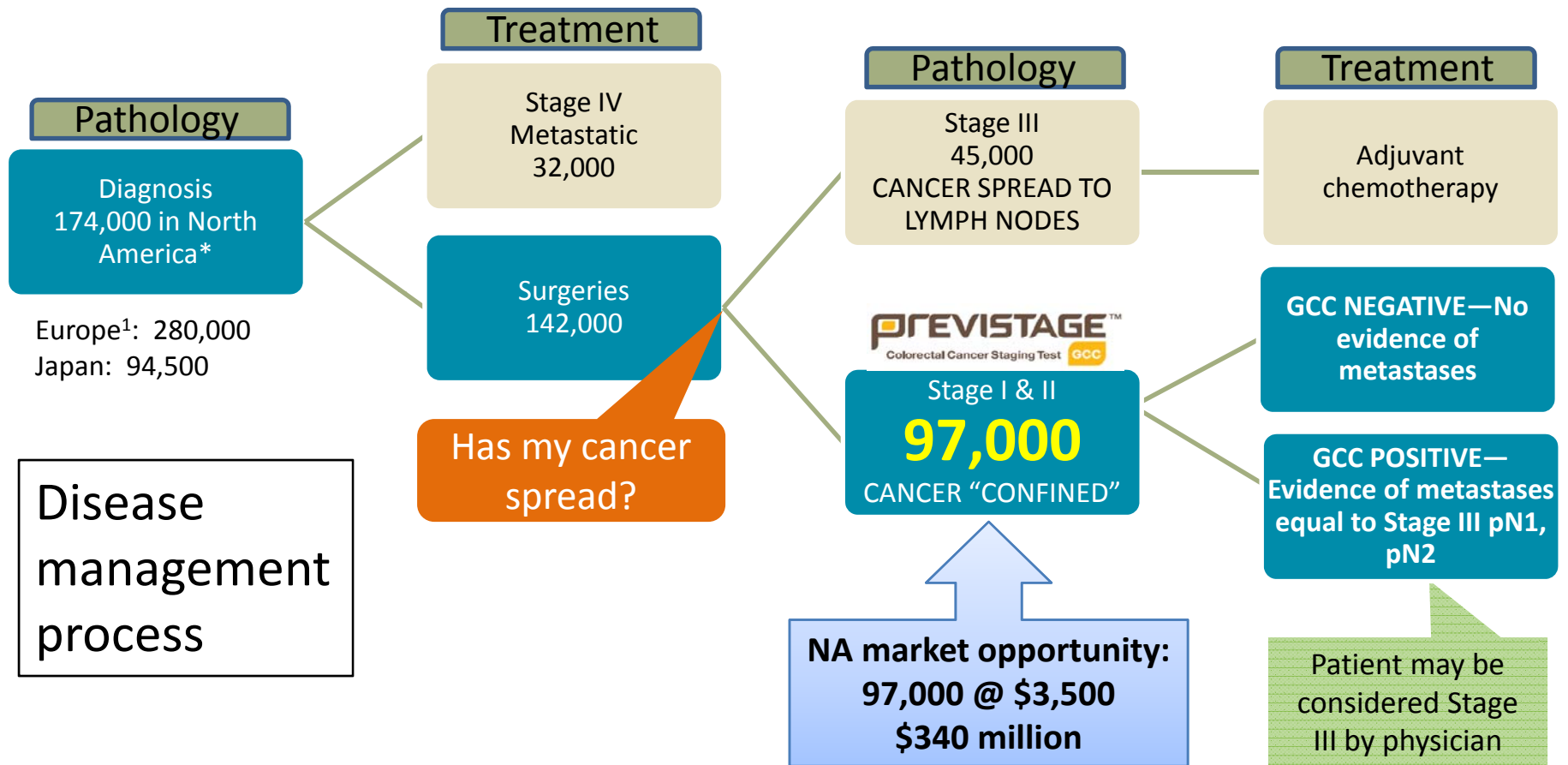
- Colorectal Cancer: 2<sup>nd</sup> leading cause of cancer death
- Current LN staging method inadequately stages node negative patients
- Using molecular methods (GCC qRT-PCR) can identify occult metastases in LNs that independently predict the risk of disease recurrence in pN0 CRC
- Previstage™ helps determine the correct stage of the disease

## Analytical Validation of Previstage™: Summary\*

- Analytical sensitivity of 92% in identifying patients with occult metastases vs. histopathology
- Analytical specificity of 98% in identifying patients without CRC
- Identified GCC mRNA in LNs of 22%-27% of pN0 CRC patients  
Classified as free of metastases by histopathology alone

\*Internal validation data

# Previstage™ Market Potential



\*Sources: Health Advances, various cancer societies, preliminary results on GCC testing study (Waldman et al.)

1. European Economic Union

# **GCC Blood Test for CRC Recurrence Monitoring**

# CRC Recurrence Monitoring

## The Unmet Need

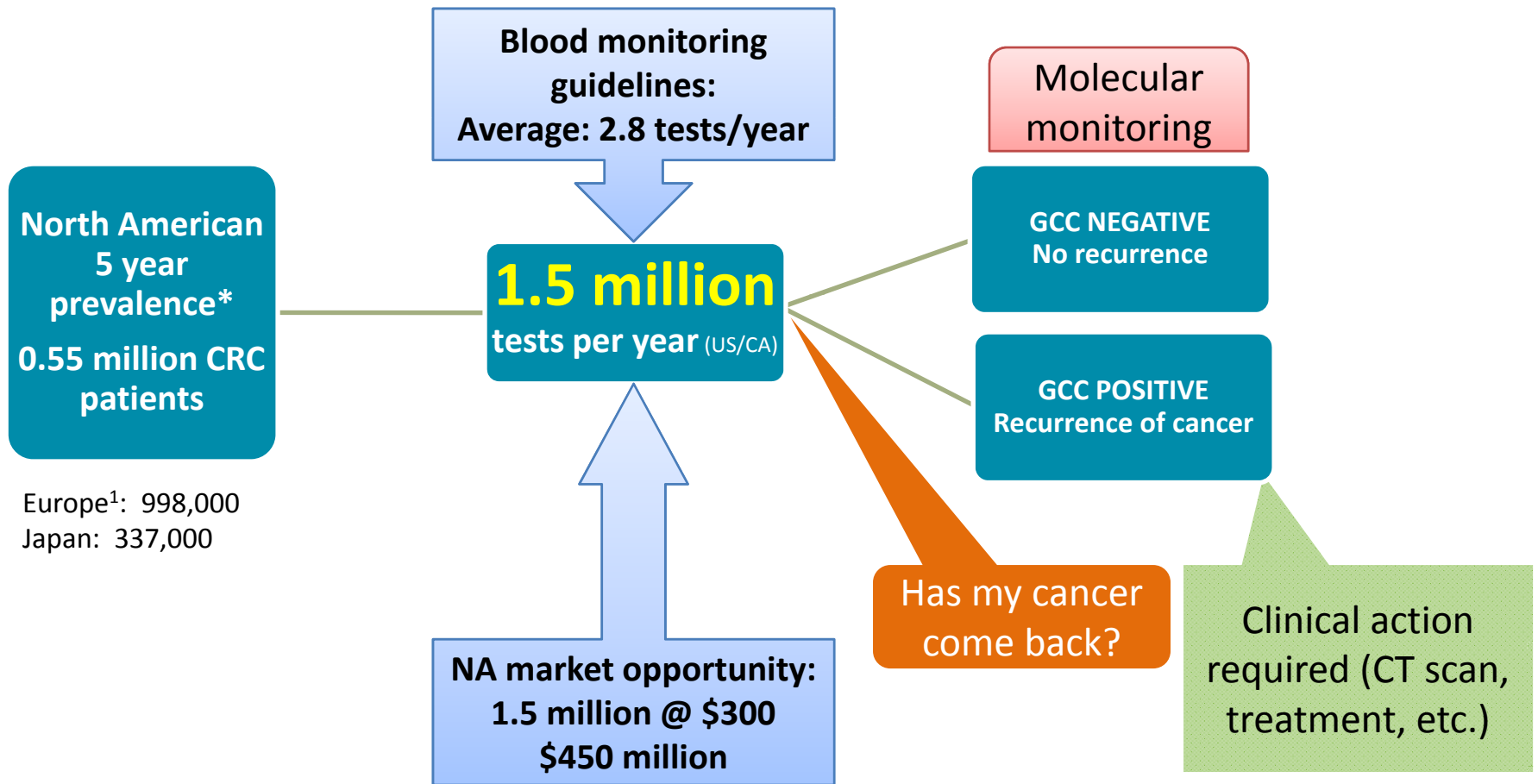
- There are no specific and sensitive markers to detect recurrent colorectal cancer following presumably curative surgery. CEA, the most frequently employed marker for postoperative surveillance, detects 60% of recurrences, most after development of terminal disease<sup>1</sup>.

## The Solution

- Can GCC be used to detect CRC recurrence?
- An NIH-sponsored multi-center prospective study is in progress to answer the question. Interim data expected Q4 2009.

1. Moertel, C. G., Fleming, T. R., Macdonald, J. S., Haller, D. G., Laurie, J.A&Tangen, C. (1993) *J. Am. Med. Assoc.* **270**, 943–947.

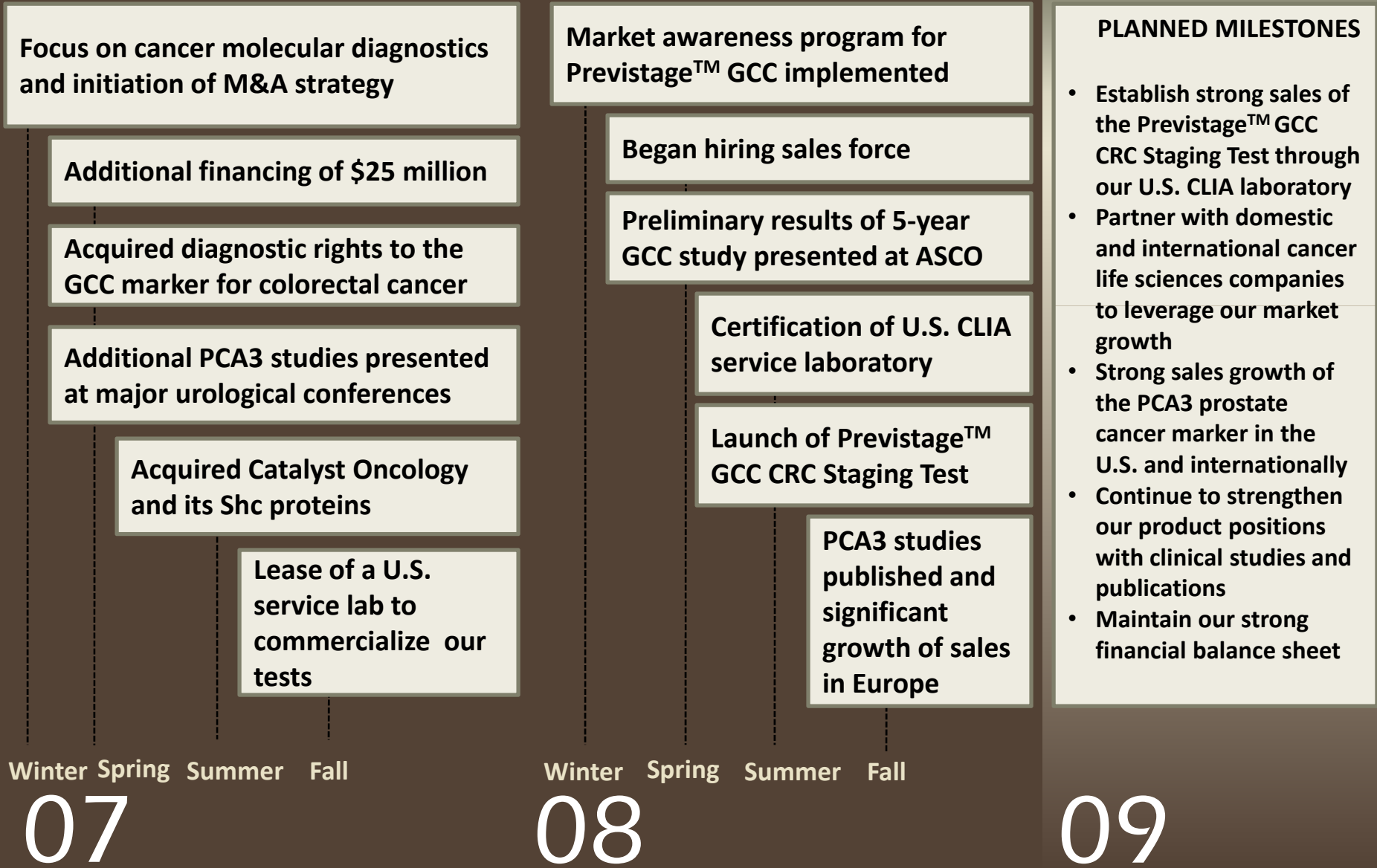
# GCC Blood Test Market Potential



\*Sources: SEER; Statistics Canada, various cancer societies,

1. European Economic Union

# Accomplishments and Milestones



# MANAGEMENT TEAM

## Independent Board Members

- **Alain Rhéaume**  
Chairman of the Board, DiagnoCure Inc.  
Managing Partner,  
Trio Capital
- **Alain G. Michel**  
Chairman of the Board,  
Cari-All Group
- **Mario Thomas, Ph.D.**  
Vice President,  
Gestion T2C2/Bio Inc.
- **Michel E. Côté**  
Corporate Director
- **Louise Proulx, Ph.D.**  
Vice President, Product Development,  
ViroChem Pharma
- **Vincent R. Zurawski, Jr., Ph.D.**  
President and CEO, Varinel, Inc.  
and Executive Chairman of the Board of  
Varinel LDC, Inc.
- **Paul Gobeil, FCA**  
Vice Chairman of the Board, Metro Inc.
- **Neil J. Campbell \*\***  
President and Chief Executive Officer  
The Mosaigen Corporation

## Management Team

- **John C. Schafer \***  
President and CEO
- **J.F. Bureau, CFA**  
Senior Vice President and  
Chief Financial Officer
- **Tim Holzer, Ph.D.**  
Vice President and  
Chief Scientific Officer
- **Yves Fradet, M.D., FRCS(c) \***  
Senior Vice President and  
Chief Medical Officer
- **Paule De Blois, MBA**  
Vice President,  
Corporate Affairs
- **Phil Wells**  
Vice President,  
Marketing and National Sales
- **Richard Gauthier, MBA**  
Vice President,  
Business Development
- **Michel Houde, Ph.D.**  
Vice President,  
Research & Development

\* Board Member

\*\* Delegated Director



# EMPOWERING ONCOLOGY DECISIONS

DiagnoCure Inc.  
2050 René-Lévesque Blvd W., 6th floor  
Québec (QC) G1V 2K8 Canada  
(418) 527-6100 / (888) 900-6626