



# **Molecular Cytology That Transforms Patient Care**

William Blair 35<sup>th</sup> Annual Growth Stock Conference  
June 9, 2015

# Forward-Looking Statements

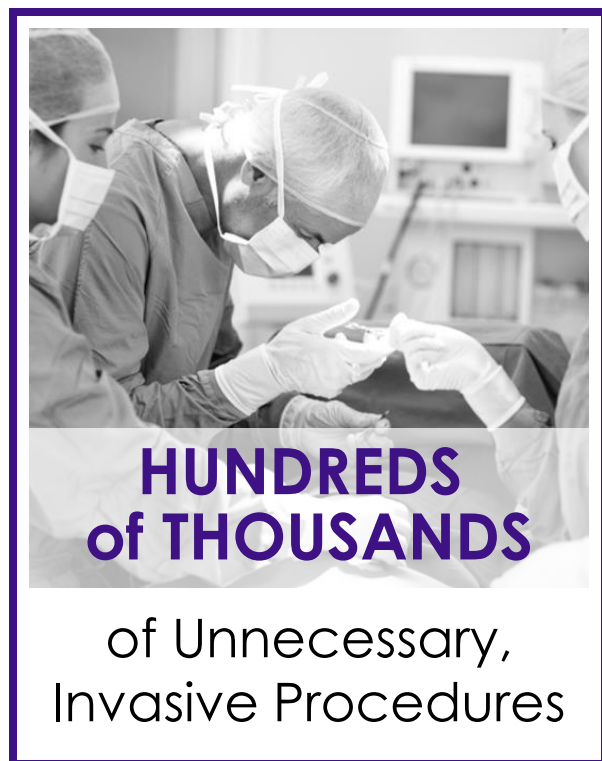
Various remarks that we make in this presentation that are not historical, including those about our business strategy and goals, future plans and prospects, growth opportunities, drivers of our business, the size of potential addressable markets, international expansion plans and future products and product pipeline, constitute forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: our limited operating history; our ability to increase usage of and reimbursement for Afirma and any future products we may develop or sell, including our Percepta™ bronchial genomic classifier for lung cancer; our dependence on a few payers for a significant portion of our revenue; risks associated with new laws and regulations, including regulation of our tests by the FDA; our ability to attract and retain key personnel; our ability to develop and commercialize new products and the timing of commercialization; the timing, results and applicability of clinical study results to actual outcomes; our ability to raise capital as needed; our ability to successfully commercialize our Percepta test; our ability to commercialize other pulmonology products and the other risks set forth under the heading “Risk Factors” in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. We disclaim any obligation to update these forward-looking statements.

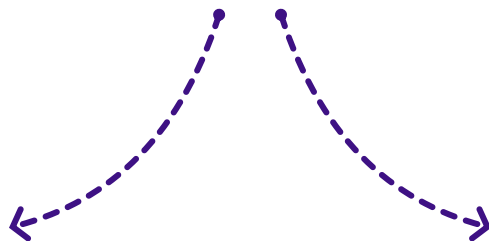
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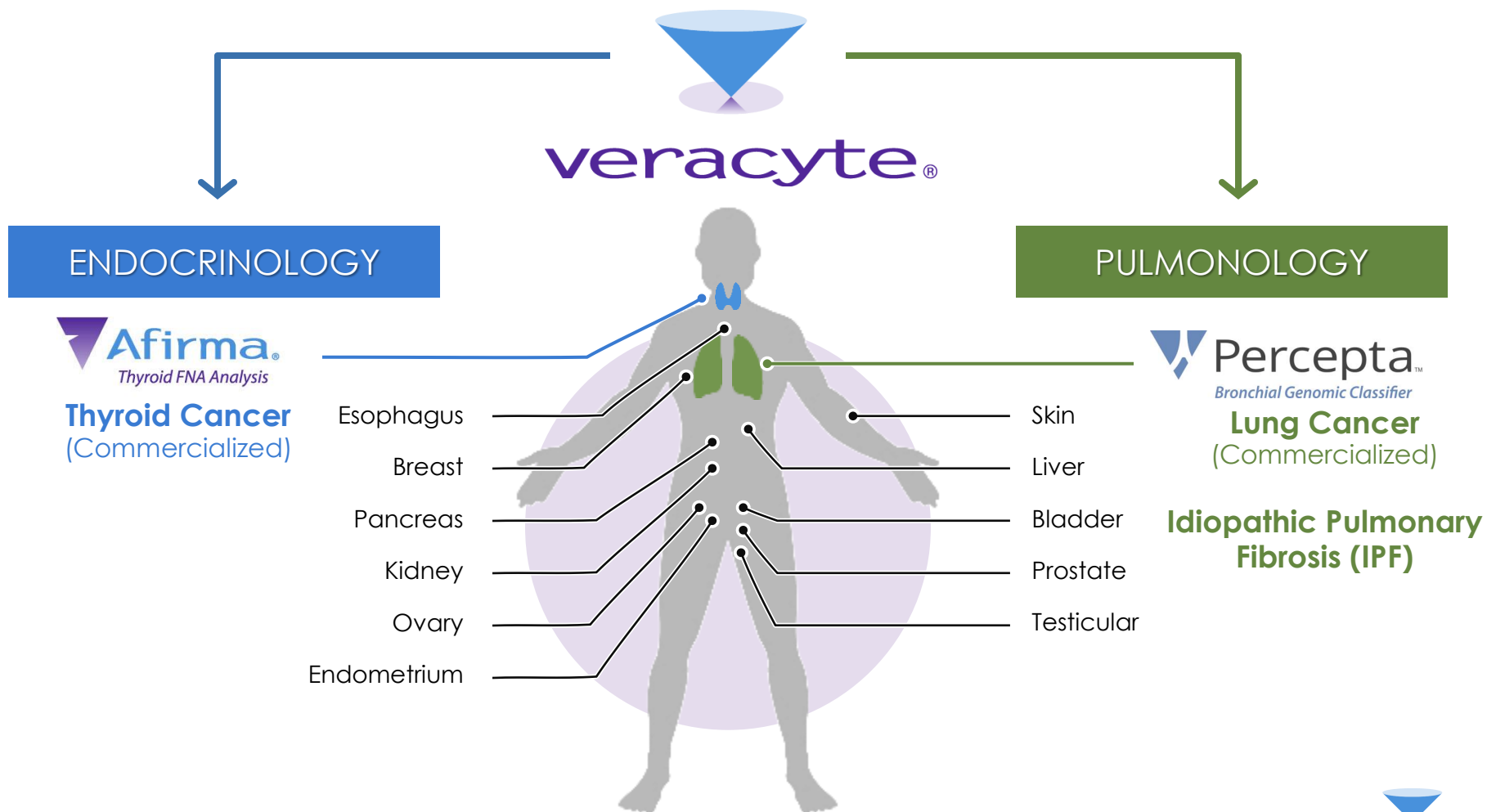
# Diagnostic Ambiguity: A Significant Healthcare Issue



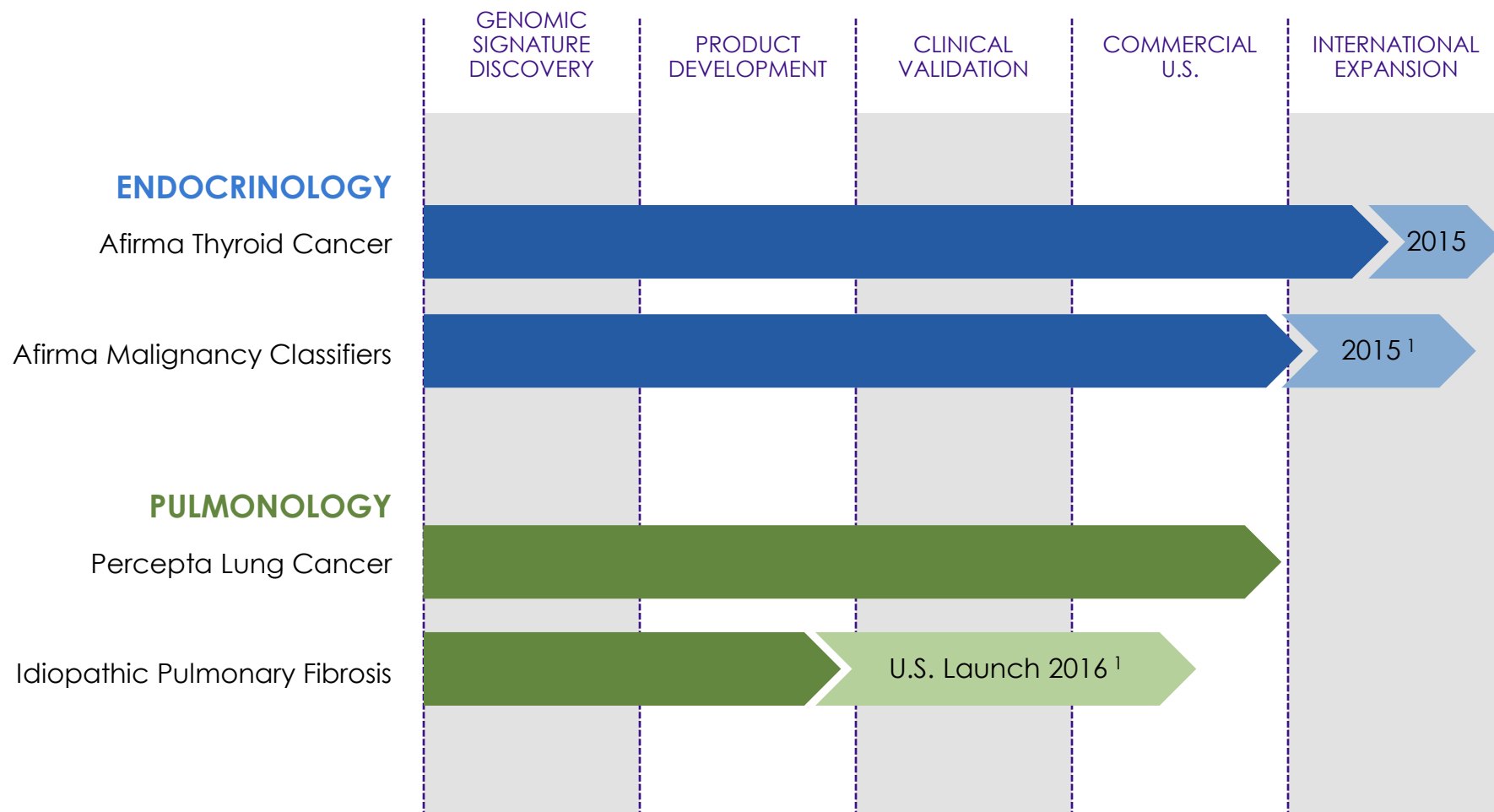
**AMBIGUOUS  
DIAGNOSIS**



# Veracyte: Using Molecular Cytology to Resolve Diagnostic Ambiguity



# Deep Pipeline with Multiple Near-Term Milestones

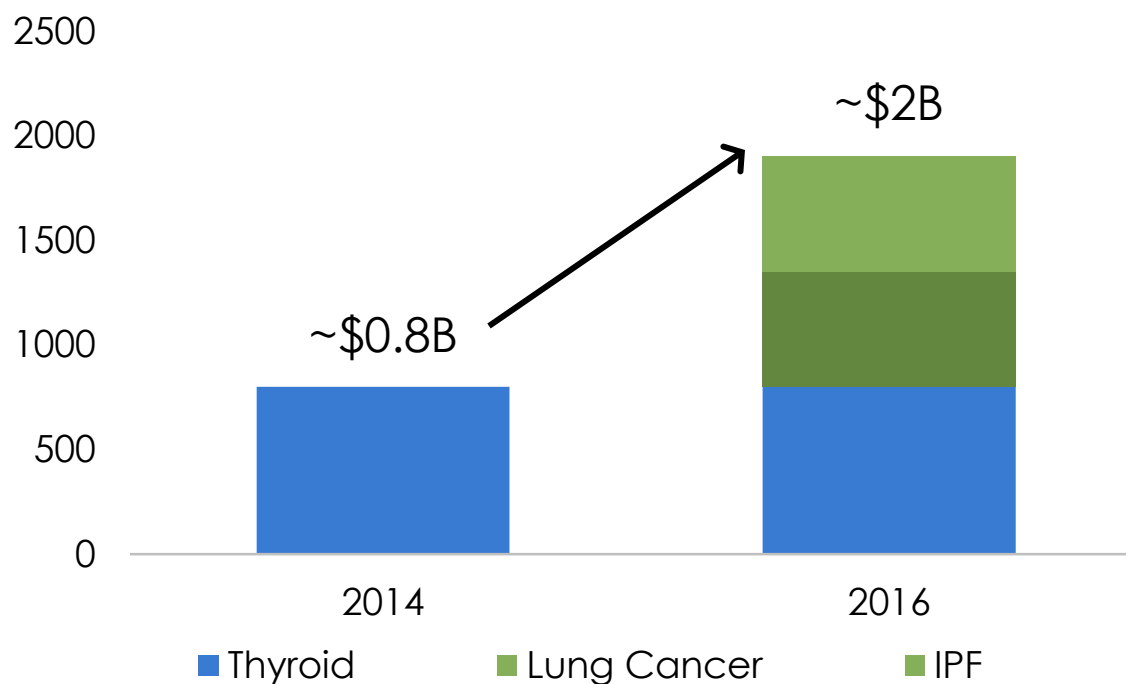


<sup>1</sup> Estimated

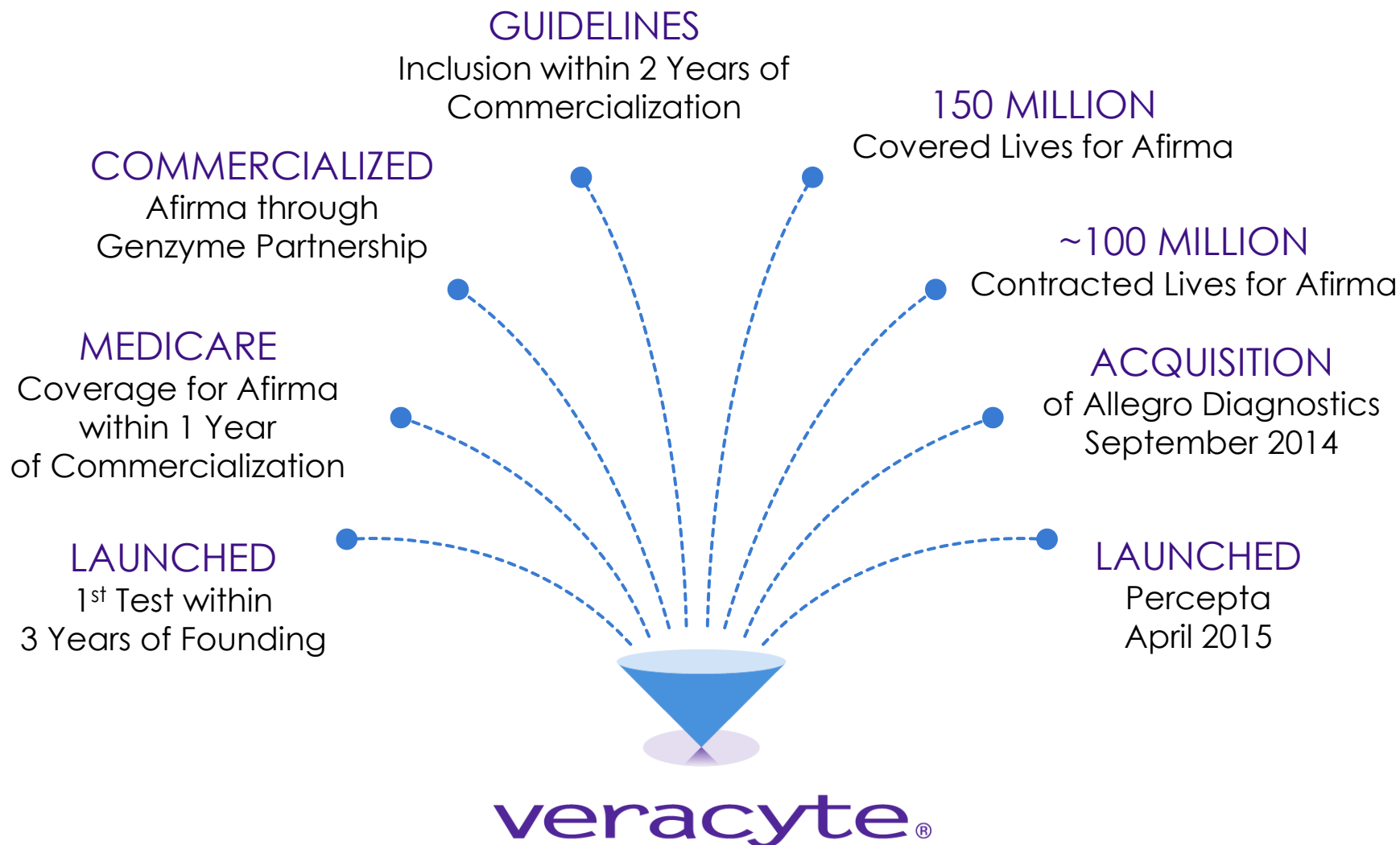
# Large, Expanding Addressable Genomic Testing Markets

**MORE THAN DOUBLING**

with New Product Launches over Next Two Years

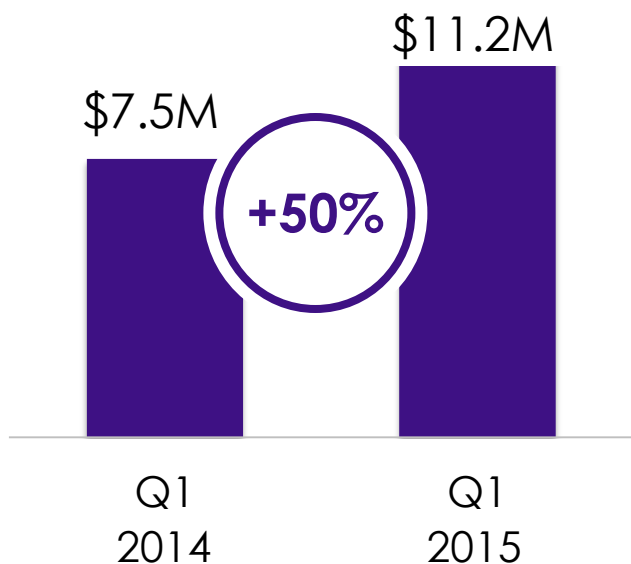


# We're Setting New Standards

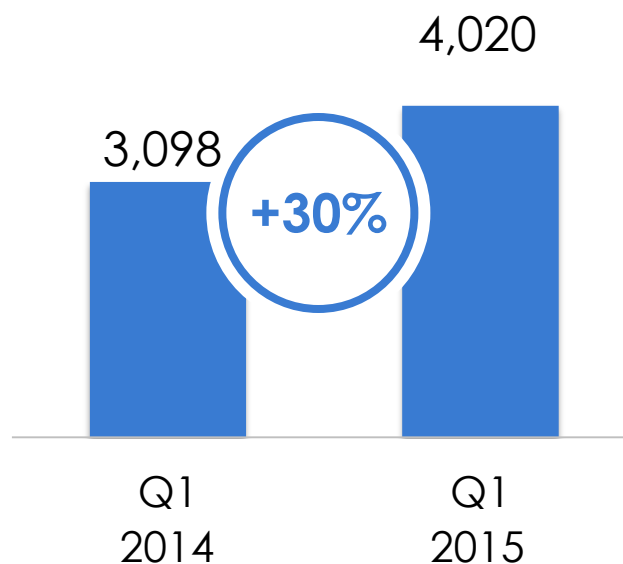


# Continued Afirma Revenue and GEC Test Volume Growth

Revenue



Afirma GEC Test Volume



## SIGNIFICANT IN-NETWORK CONTRACTS



Medicare



Cigna®



UnitedHealthcare®



# An Attractive Investment Thesis

## LARGE MARKETS



Near Term \$2B Opportunity in  
Multiple Specialty Markets

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## PROVEN MODEL



Unique Molecular Cytology Model  
Focused on Delivering Clinical Utility

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## GROWING FRANCHISE



Successful Execution in Thyroid;  
Expanding into Lung

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## ATTRACTIVE FINANCIALS



Efficient Commercialization and Reimbursement,  
Growing Revenue and Margins

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## STRONG TEAM



Deep Expertise in R&D, Commercialization,  
and Reimbursement

# Proven Model for Efficiently Building Additional Franchises

## DIFFERENTIATED STRATEGY

Inform a Specific, Relevant Question at the Right Point in the Clinical Pathway

## PROPRIETARY SCIENCE

Uniquely Apply Whole Genome Biomarker Discovery and Algorithms to Cytology Samples

## CLEAR VALUE

Clinical Utility and Economic Value that Changes the Standard of Care

## SUCCESSFUL REIMBURSEMENT

Published Evidence Drives Clinical Guidelines and Positive Coverage



veracyte®



## Thyroid Diagnostic Solutions

### COMMERCIALIZED

Gene Expression  
Classifier (GEC)

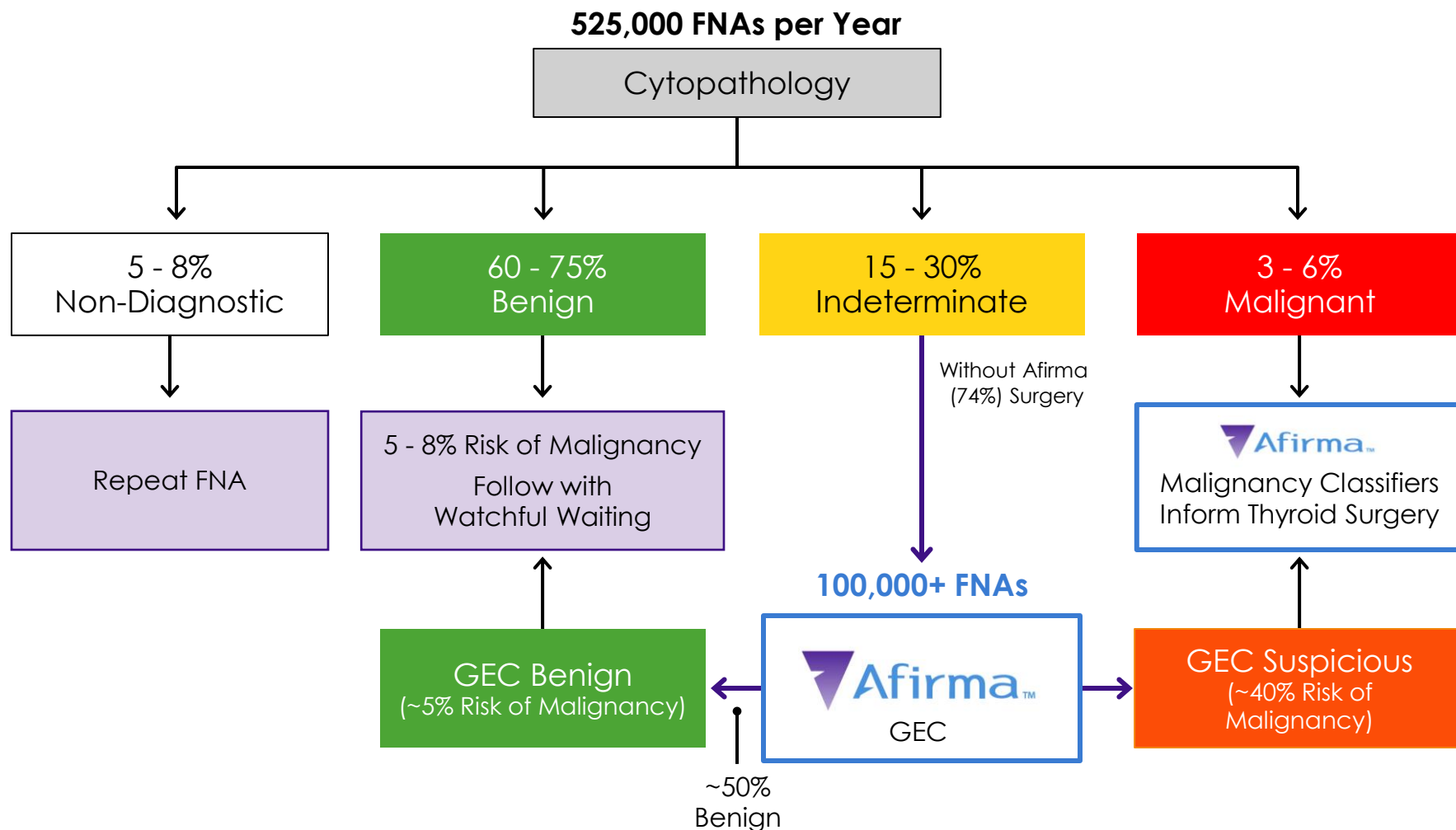
Reducing Unnecessary  
Thyroid Surgeries and  
Lowering Healthcare Costs

### LAUNCHED MAY 2014

Malignancy Classifiers  
(MTC and BRAF)

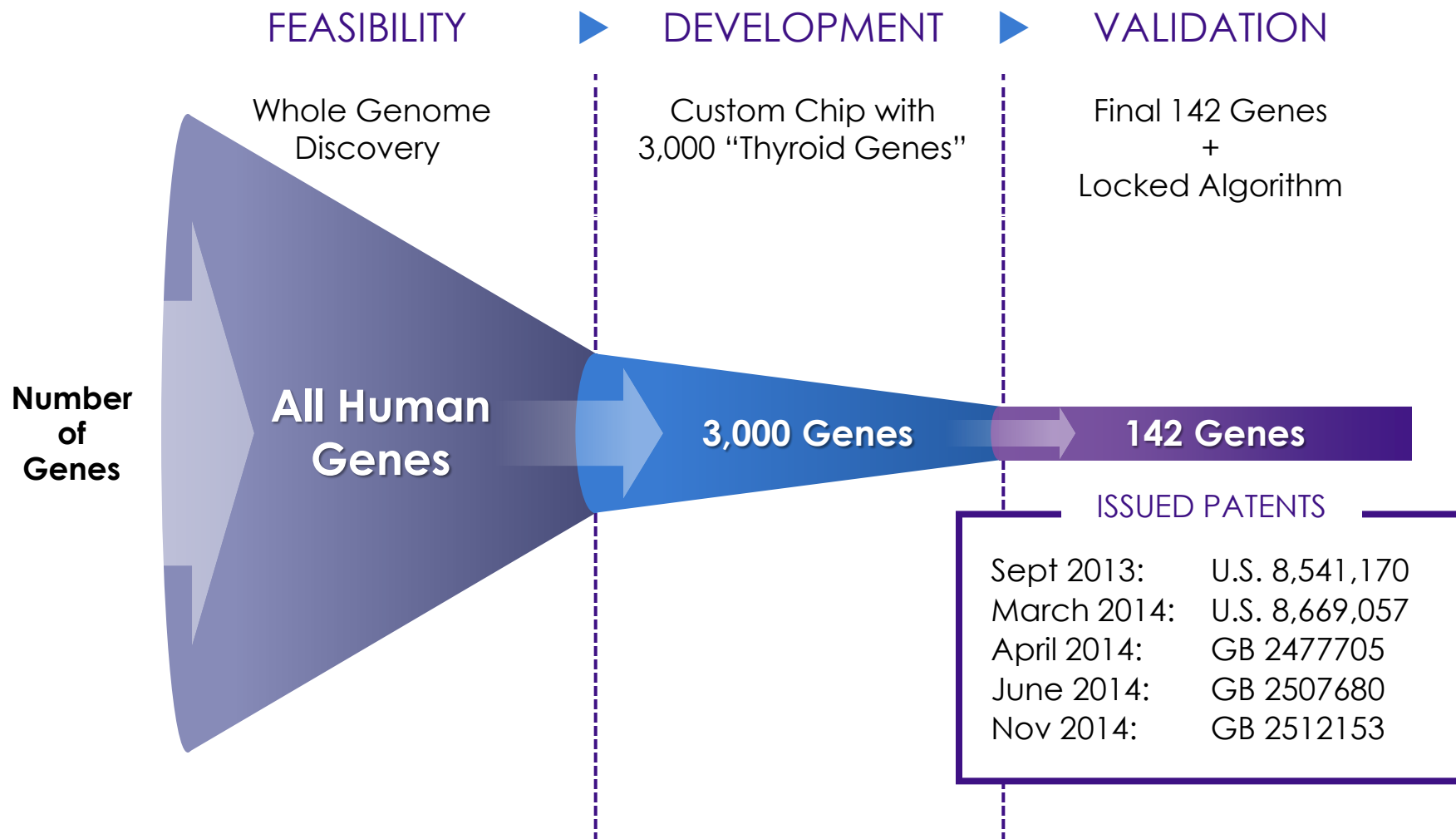
Pre-Operatively Informing  
the Choice of Thyroid  
Surgery When Surgery  
Is Needed

# DIFFERENTIATED STRATEGY: Focused on the Right Point in the Clinical Pathway for Thyroid Nodule Assessment



# PROPRIETARY SCIENCE:

## Entire Genome Explored to Identify Gene Signature



# PROPRIETARY SCIENCE: Proven Clinical Validity

## AFIRMA GEC

- Clinical Validation Study Published in *The New England Journal of Medicine* (August 2012)
- Prospective, Multi-Center, Double-Blinded Study
  - 49 Sites, 4,812 FNAs
- >94% NPV When It Identifies Benign Nodules Among Those Deemed Indeterminate by Cytopathology

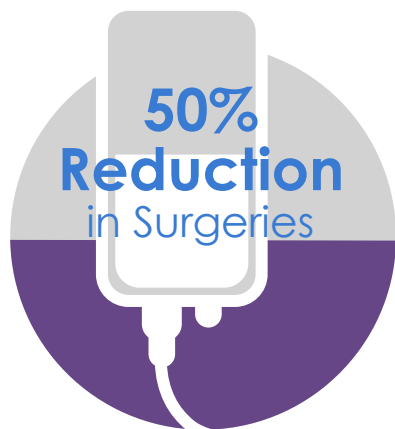


## CONCLUSION

Findings May Enable Physicians to Replace Surgery with Routine Monitoring for Patients with a Benign Afirma GEC Result

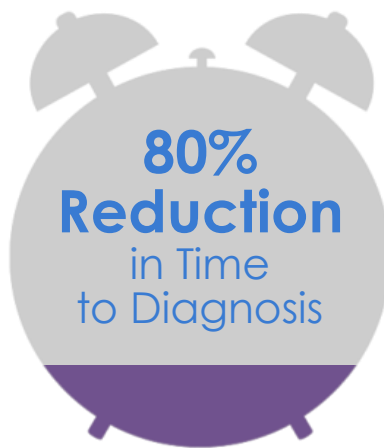
# CLEAR VALUE: Afirma Delivers Strong Clinical Utility and Measureable Economic Value

## Diagnostic Clarity WITHOUT SURGERY



### PATIENTS

Reduce Unnecessary Surgeries



### PHYSICIANS

Make More Informed Treatment Decisions, Earlier



### PAYERS

Lower Healthcare Costs

**~50,000**

Surgeries Potentially Avoided Annually

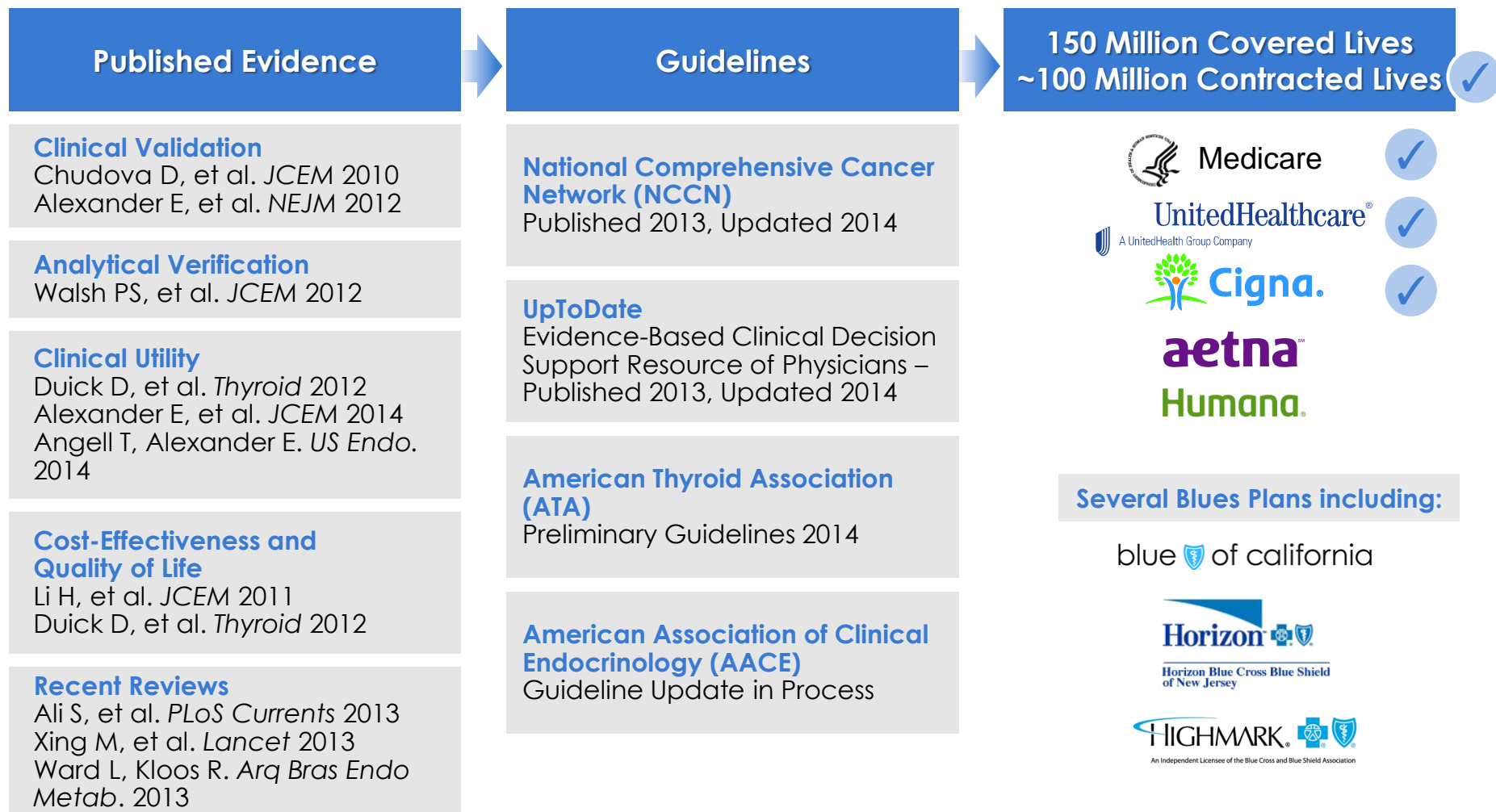
**14 Days**

Instead of 60-90 Days

**\$500 Million**

in Direct Medical Savings Over 5 Years

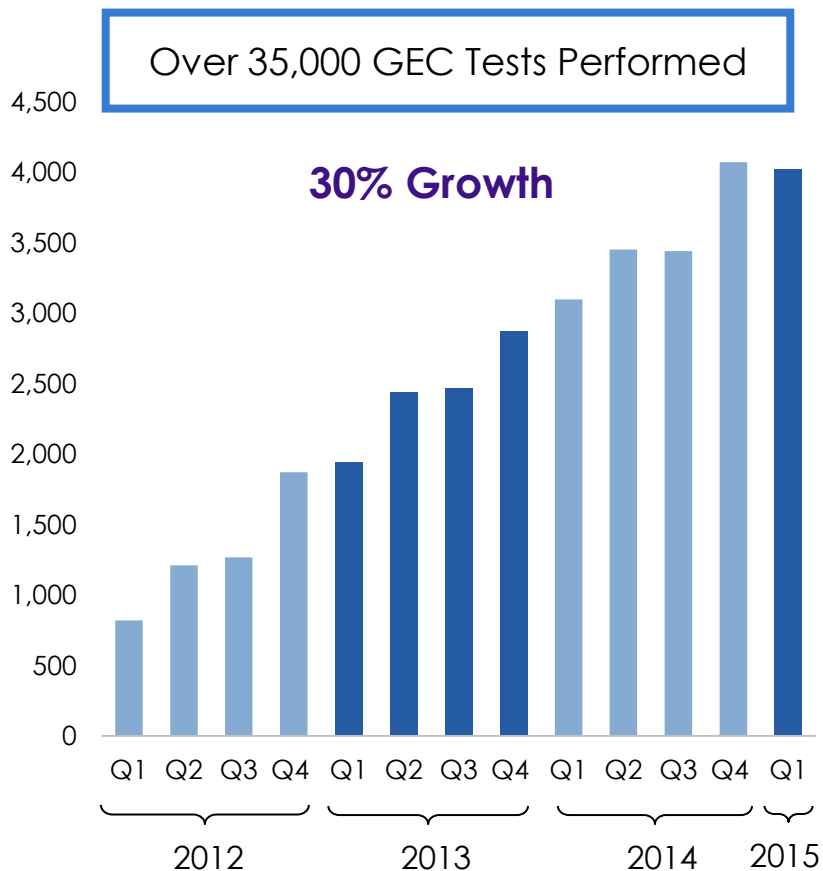
# SUCCESSFUL REIMBURSEMENT: Published Evidence Drives Guidelines and Positive Coverage



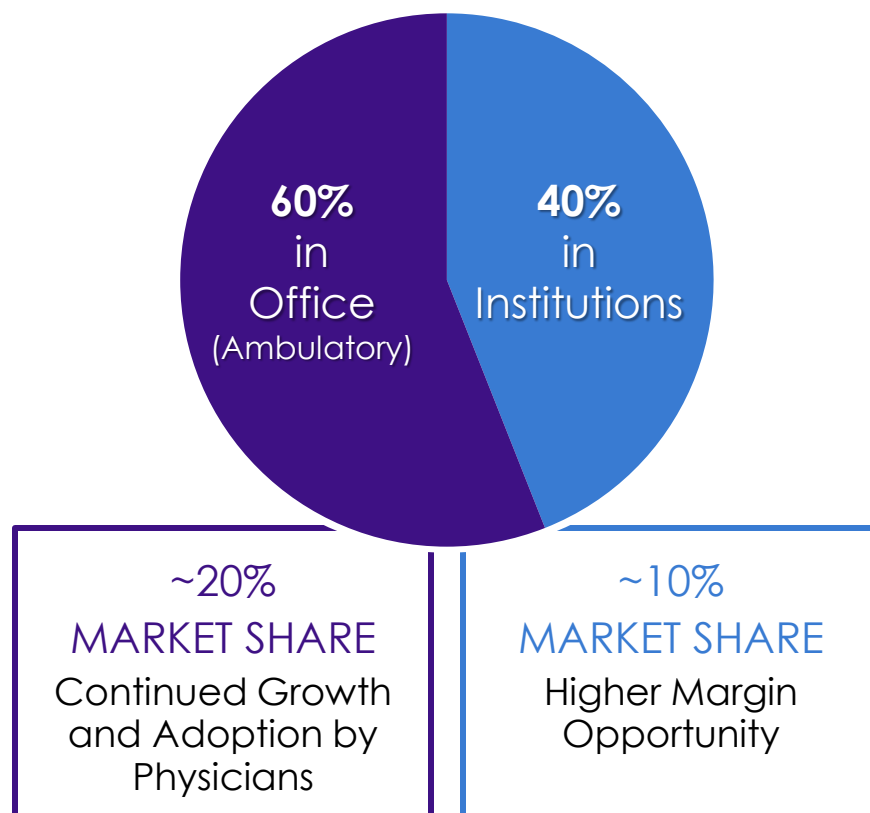


# Continued Afirma GEC Volume Growth: Attractive Opportunities in the Institutional Segment

## Afirma GEC Test Volume



## FNAs Performed Annually (U.S.)



# Sales Force Is Positioned for Continued Afirma Growth

## SCALE

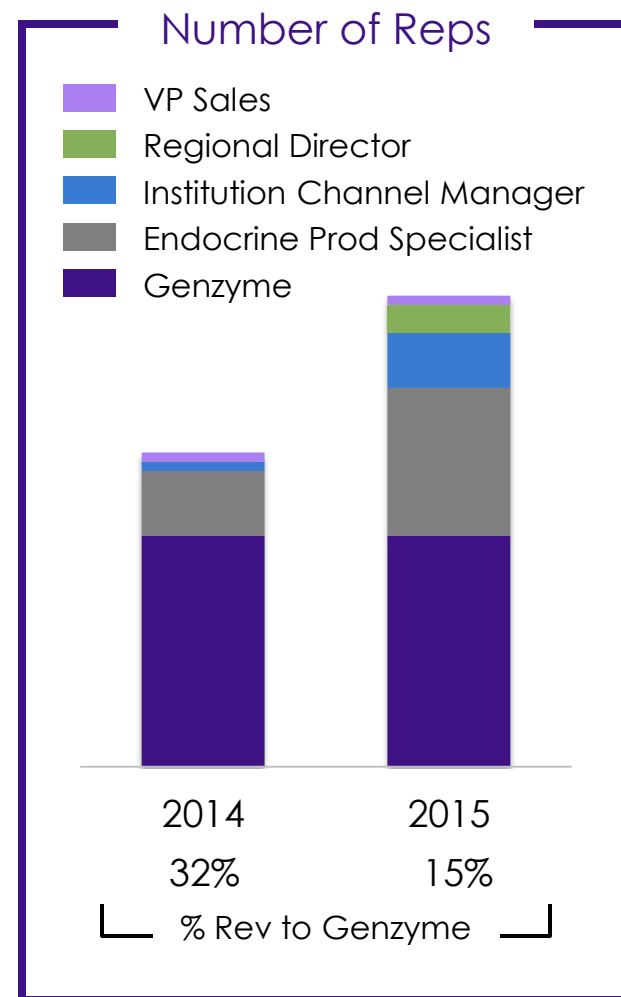
- Grew Veracyte Sales Force from 8 to 26 in 2014
- Continued Leverage with Genzyme Sales Force
- Expanded Marketing Campaigns, Physician and Patient Awareness Initiatives

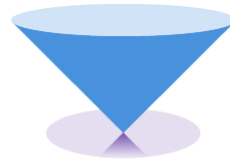
## FOCUS

- Fully Dedicated Team, Transaction Oriented Process
- Positioned to Target the Institutional Opportunity
- Genzyme Will Focus Efforts on Lead Development and Account Maintenance

## EFFICIENCY

- Continued New Account Penetration
- Deeper Selling into Institutions
- Growth in GEC Test Volume





veracyte®

## Pulmonary Diagnostic Solutions



U.S. LAUNCH APRIL 2015



Improving  
the Diagnosis of Lung Cancer  
without Surgery



U.S. LAUNCH 2016<sup>1</sup>

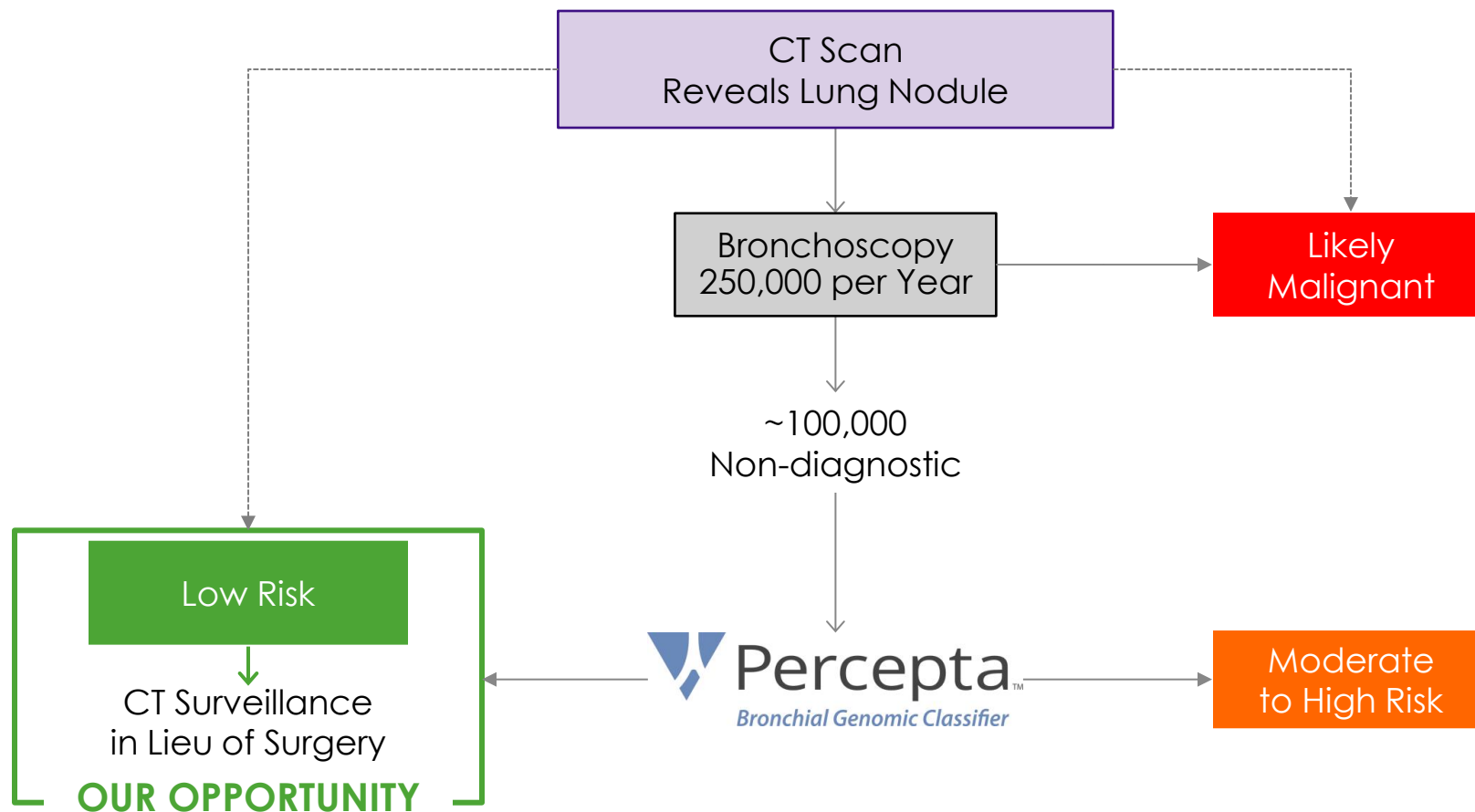
Interstitial Lung Diseases

Improving  
the Diagnosis of IPF  
without Surgery

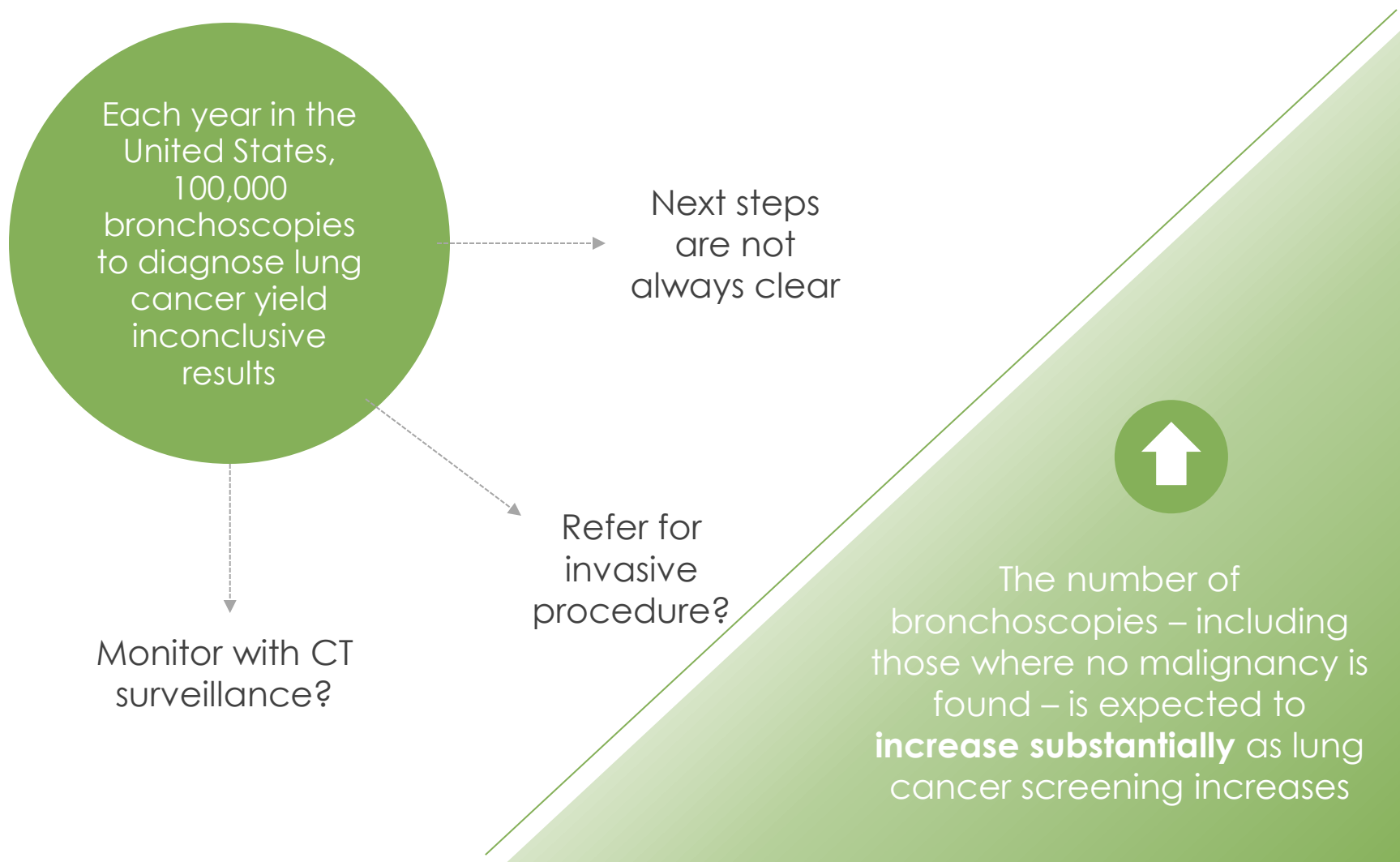
<sup>1</sup> Estimated



# DIFFERENTIATED STRATEGY: Focused on the Right Point in the Clinical Pathway for Lung Cancer



# Clinical Dilemma



# PROPRIETARY SCIENCE: Innovative “Field of Injury” Genomic Technology



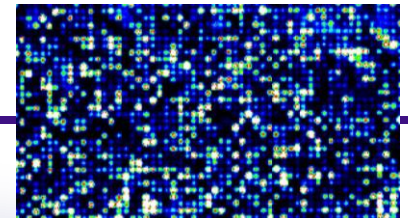
Peripheral Lung Nodules Are Difficult to Biopsy, Yielding High Rates of Non-Diagnostic Bronchoscopies



Smoking Alters the Epithelial Cell Gene Expression throughout the Airway



A Gene Signature of a Cytology Sample Collected from the Airway Can Determine Cancer Risk in a Peripheral Lung Nodule



Determining Who Is at Low Risk of Cancer **WITHOUT** Surgery or a Sample From the Nodule or Lesion Directly



# PROPRIETARY SCIENCE: Thyroid Development Process Replicated for Lung Cancer Program

We Are Here

## Whole Genome Discovery and Algorithm Development

### BRONCHIAL BRUSHINGS

- Training Set n=299
- Affymetrix GeneST Array
- Supervised Learning Exploiting the **“Field of Injury”**
- 23 Genes
- Logistic Regression Classification Algorithm

## Two Clinical Validation Studies

- PROSPECTIVE Bronchial Brushing Samples
  - AEGIS I (n=298)
  - AEGIS II (n=341)
- Performance Shows High NPV >90%

## Support with Robust Clinical Evidence

- Published AEGIS I and II CLINICAL VALIDATION STUDIES
- Performed ANALYTICAL VERIFICATION Studies to Transfer Test to CLIA Lab
- Initiate CLINICAL UTILITY and COST - EFFECTIVENESS STUDIES

# PROVEN CLINICAL VALIDITY

## PERCEPTA BRONCHIAL GENOMIC CLASSIFIER

- Clinical Validation Studies Published May 2015
- Prospective, Multi-Center Studies
  - 28 Sites, 639 Patients (298 in AEGIS I and 341 in AEGIS II)
- 91% NPV in patients for whom there is the greatest uncertainty of cancer status\*
- 89% Sensitivity
- 47% Specificity
- Improves diagnostic performance of bronchoscopy for the detection of cancer

\* Assessed pre-bronchoscopy as intermediate risk (10-60%) patients



## CONCLUSION

Identifies Patients at Low Risk for Lung Cancer Following Inconclusive Bronchoscopy and Who Can Avoid Unnecessary Invasive Procedures



# The Roadmap to Percepta Coverage and Reimbursement

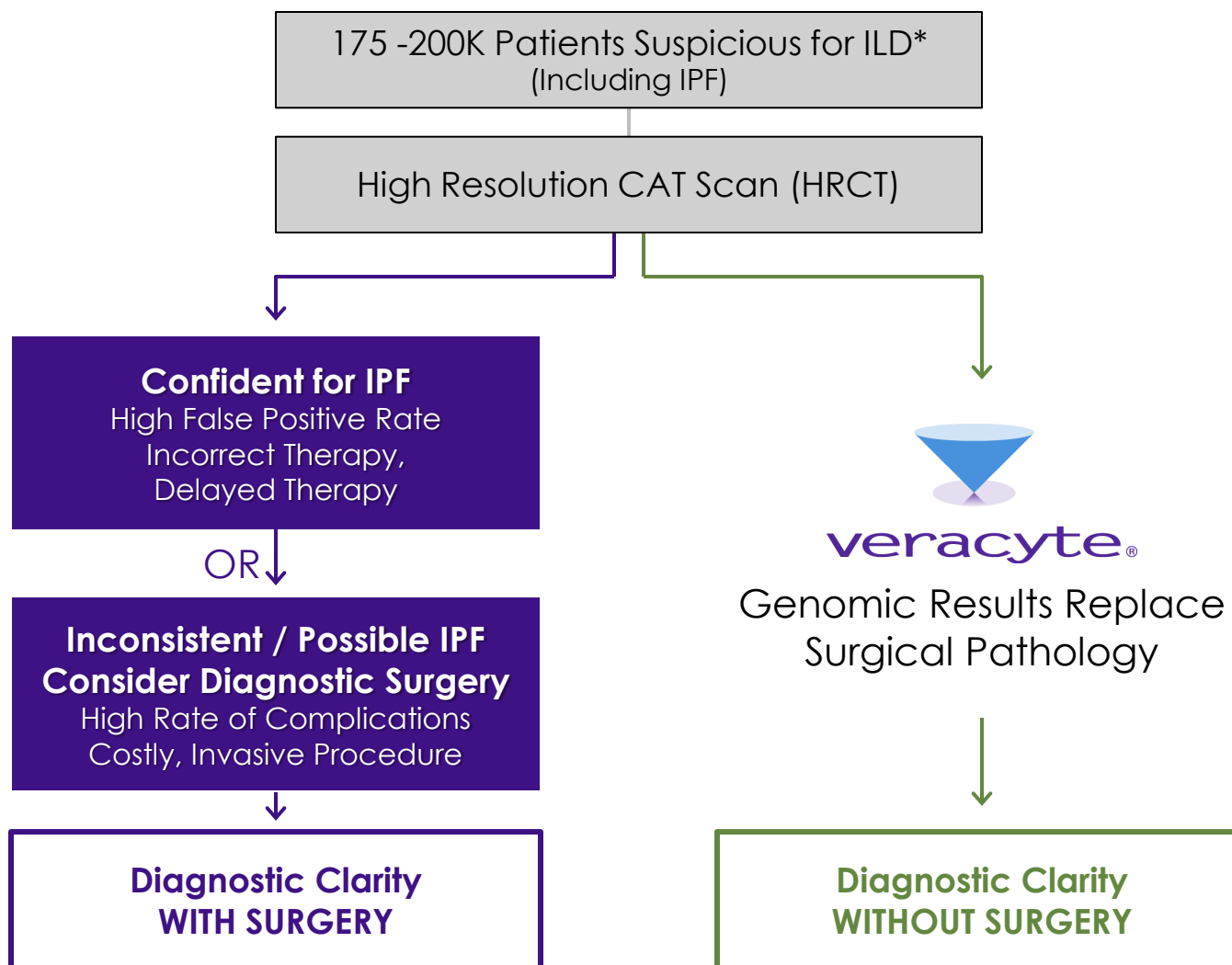
## On Track for Successful Commercialization

- ✓ Addressing a specific and compelling unmet clinical need
- ✓ Backed by proprietary and scientific foundation
- ✓ Analytical verification studies complete
- ✓ Two prospective, multi-center and blinded validation studies AEGIS I and II - published in *The New England Journal of Medicine*
- ✓ Study on Derivation of Percepta published in *BMC Medical Genomics*
- ✓ Early adoption with top thought-leaders in pulmonology

## Key Milestones Going Forward

- Additional published evidence including clinical utility and cost-effectiveness
- Coverage and reimbursement anticipated in 2016
- Broaden access to patients across the United States
- Meaningful revenue in 2017

# DIFFERENTIATED STRATEGY: Replacing Surgical Pathology with Transbronchial Biopsy Genomic Classifier



\*U.S. and Europe

# PROPRIETARY SCIENCE: Thyroid Development Process Replicated for IPF Program

**We Are Here**

## Whole Genome Discovery and Algorithm Development

### SURGICAL TISSUE

- Banked ILD Surgical Tissues (n = 309)
- Local Clinical Diagnosis and Some with Expert Surgical Pathology Review

### MACHINE LEARNING ALGORITHMS

- Microarray and Deep RNA Sequencing
- Support Vector Machines

## Product Development and Clinical Validation

- PROSPECTIVE Bronchoscopy Sample Collection
- >25 Sites in United States and Europe
- Diagnoses by Expert Pathologist and MULTI-DISCIPLINARY TEAM (MDT)
- Further Assay and Algorithm Development
- Lock Test and Algorithm

## Support with Robust Clinical Evidence

- ANALYTICAL Verification
- Prospective, Multi-Center CLINICAL VALIDATION
- CLINICAL UTILITY and COST-EFFECTIVENESS Studies

# Financial Highlights

## Afirma Commercial Success

Strong Revenue, FNA and GEC Volume Growth

## Positioned to Achieve Afirma Profitability

Reimbursement Rate Expansion  
Increase in Institutional Volume and Penetration

## Upside Potential

from Percepta and Franchise Expansion

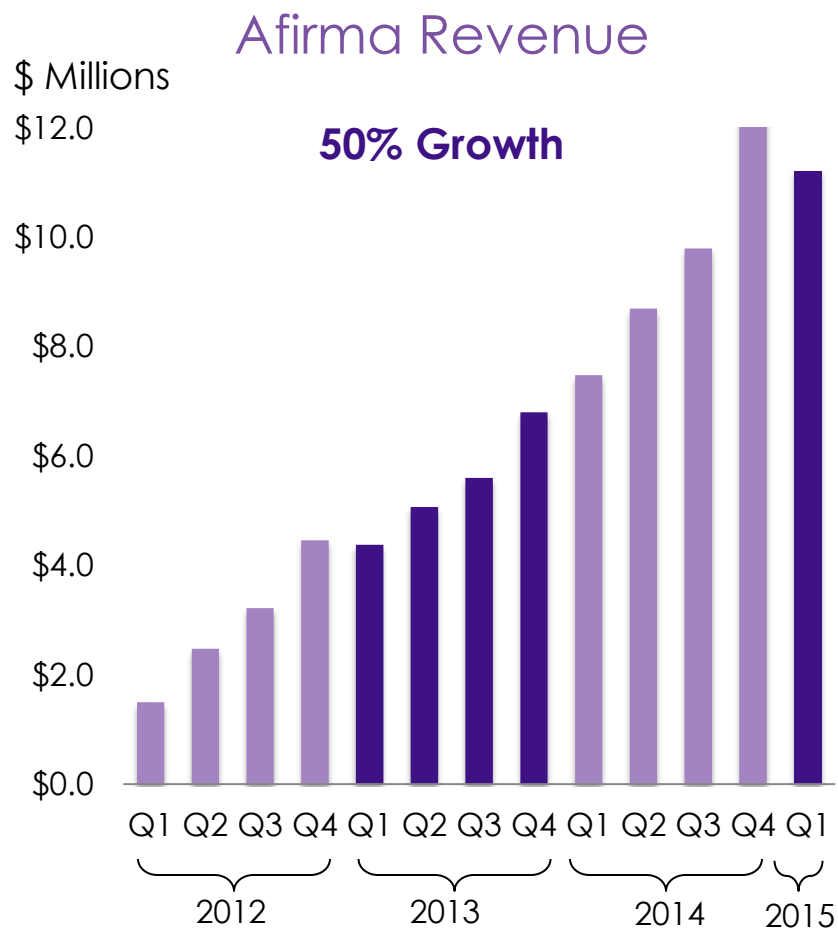
## Strong Financial Position

Over \$65M Cash as of March 31, 2015 (pro forma for PIPE). Can Substantially Progress All 3 Products



CONTINUED  
SUCCESSFUL  
EXECUTION

# Strong Revenue and Volume Trends



## Afirma GEC Test Volume



# Experienced Team with Track Record of Success

BONNIE ANDERSON

President and  
Chief Executive Officer



SHELLY GUYER

Chief Financial Officer

J.P.Morgan HAMBRECHT & QUIST

JULIE A. BROOKS

EVP, General Counsel  
and Secretary



CHRISTOPHER M. HALL

Chief Operating Officer



GIULIA C. KENNEDY, PHD

Chief Scientific Officer



RICHARD T. KLOOS, MD

Senior Medical Director,  
Endocrinology



J.A. THORSON

EVP, Corporate Strategy and  
Business Development



# Execution for 2015: Corporate Milestones

## Afirma Market Penetration

- ~50% YoY GEC Test Volume Growth
- ~30% YoY FNA Samples Received Growth
- Publication of Final ATA Guidelines Expected in 2015
- AACE Guidelines Expected in 2015

## Additional Positive Coverage Decisions and In-Network Contracts

- Focus on Blues

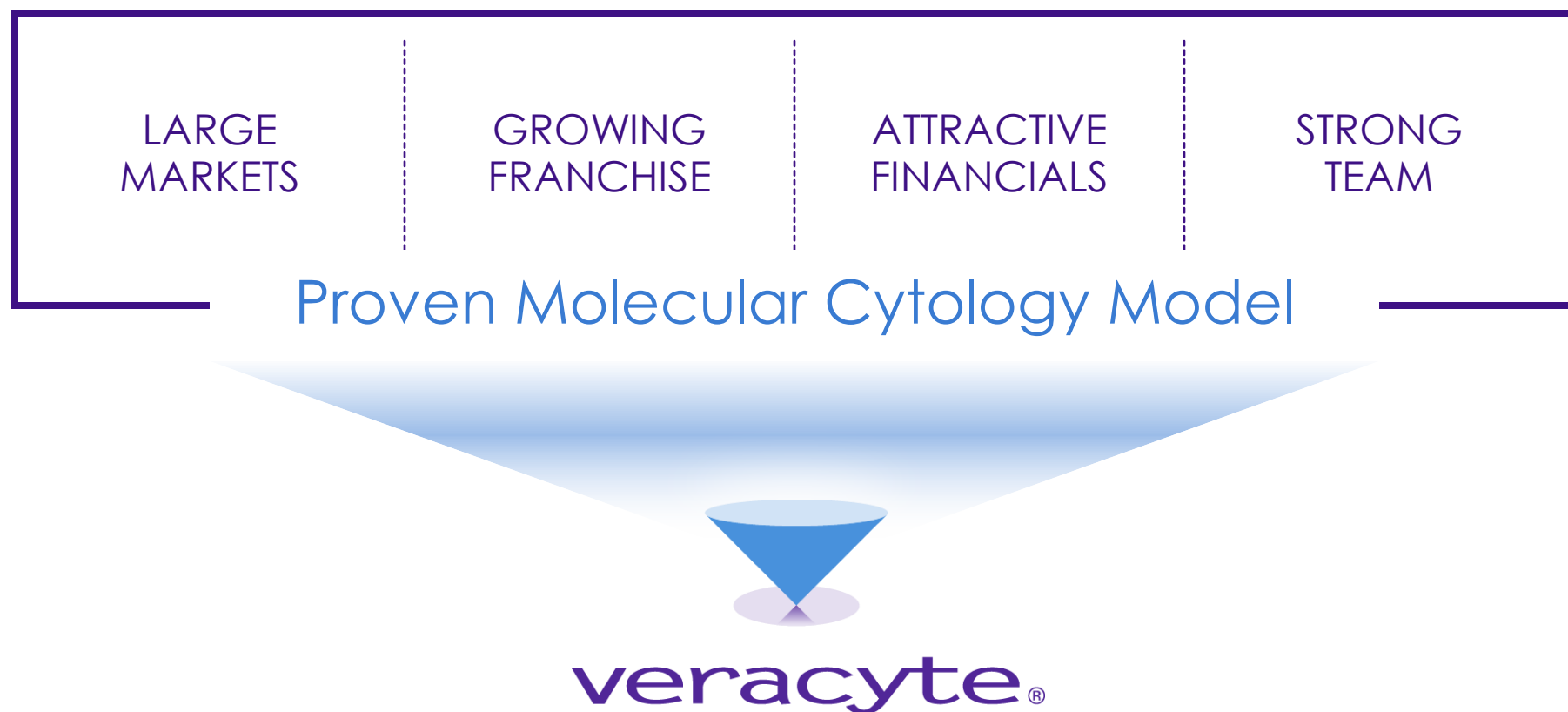
## Mid Year Commercial Launch of Lung Cancer Test

- ✓ Publication of Two Validation Studies Including AEGIS I and II (*New England Journal Medicine*)
- ✓ AEGIS Data Presentation at May ATS Meeting
- Publication of Analytical Verification Studies
- ✓ Commencement of Patient Testing in CLIA-Certified Laboratory (April 2015)
- ✓ Initiation of Clinical Utility Studies

## Advance IPF Program

- ✓ Presentation of IPF Data on Bronchoscopy Biopsies at May ATS Meeting

# Veracyte







**Molecular Cytology That Transforms Patient Care**