



# Liquid Biopsies

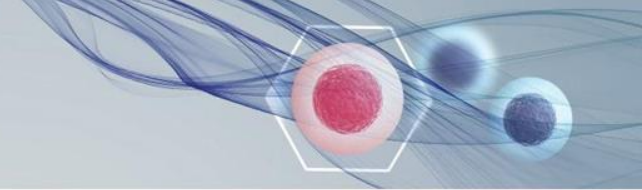
## **Next Generation Cancer Molecular Diagnostics**

William Annett

Chief Executive Officer

January 2016

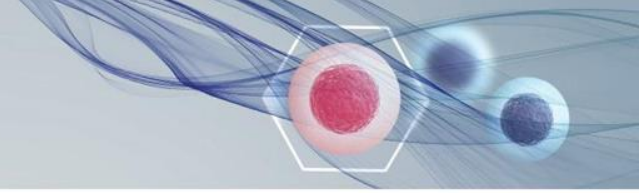
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Statements pertaining to future financial and/or operating results, future research, diagnostic tests and technology under development, clinical development of diagnostic tests, and potential opportunities for OncoCytte Corporation and the diagnostic tests it is developing, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute forward-looking statements. Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “may,” “believes,” “plans,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development, testing, marketing and/or commercialization of potential diagnostic tests, including developing or obtaining the resources and capabilities required to do so, uncertainty in the results of clinical trials, need and ability to obtain future capital, and maintenance of intellectual property rights, need to obtain approvals from federal and state regulatory agencies, and uncertainty as to reimbursements or coverage from third party payers such as Medicare, health insurance companies, and health maintenance organizations. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the business of OncoCytte, particularly those mentioned in the Risk Factors and other cautionary statements found in the registration statement on Form 10 and the Information Statement included therein as an exhibit, filed by OncoCytte with the Securities and Exchange Commission. OncoCytte disclaims any intent or obligation to update these forward-looking statements and/or this presentation, including but not limited to any changes resulting from changes in fact or circumstances.

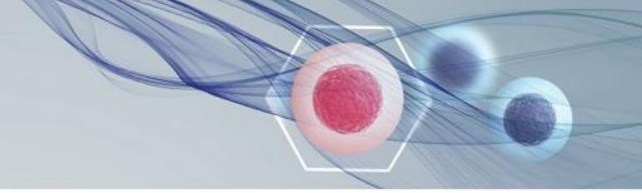
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# Investment Highlights



- Positioned to capitalize on standard of care moving to liquid biopsy
- Addresses large unmet needs for early, accurate diagnosis in multiple cancers
- Initial focus on lung, one of the largest markets and a national health priority
- Current lung cancer standard of care is inaccurate, risky, and expensive
- Strong clinical data potentially positions OncoCyte to develop standard of care
- Compelling value proposition for payers, physicians, and patients
- On track for first product launch
- Deep product pipeline leveraging core R&D competencies
- Experienced leadership team with background in commercialization

# Molecular diagnostics are evolving toward non-invasive liquid biopsies

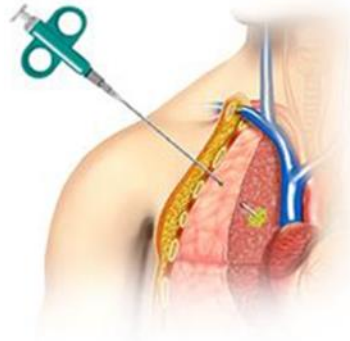


## IMAGING



Mammogram  
LDCT

## TISSUE BIOPSY

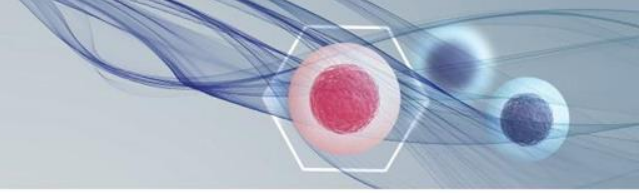


Veracyte  
Genomic Health

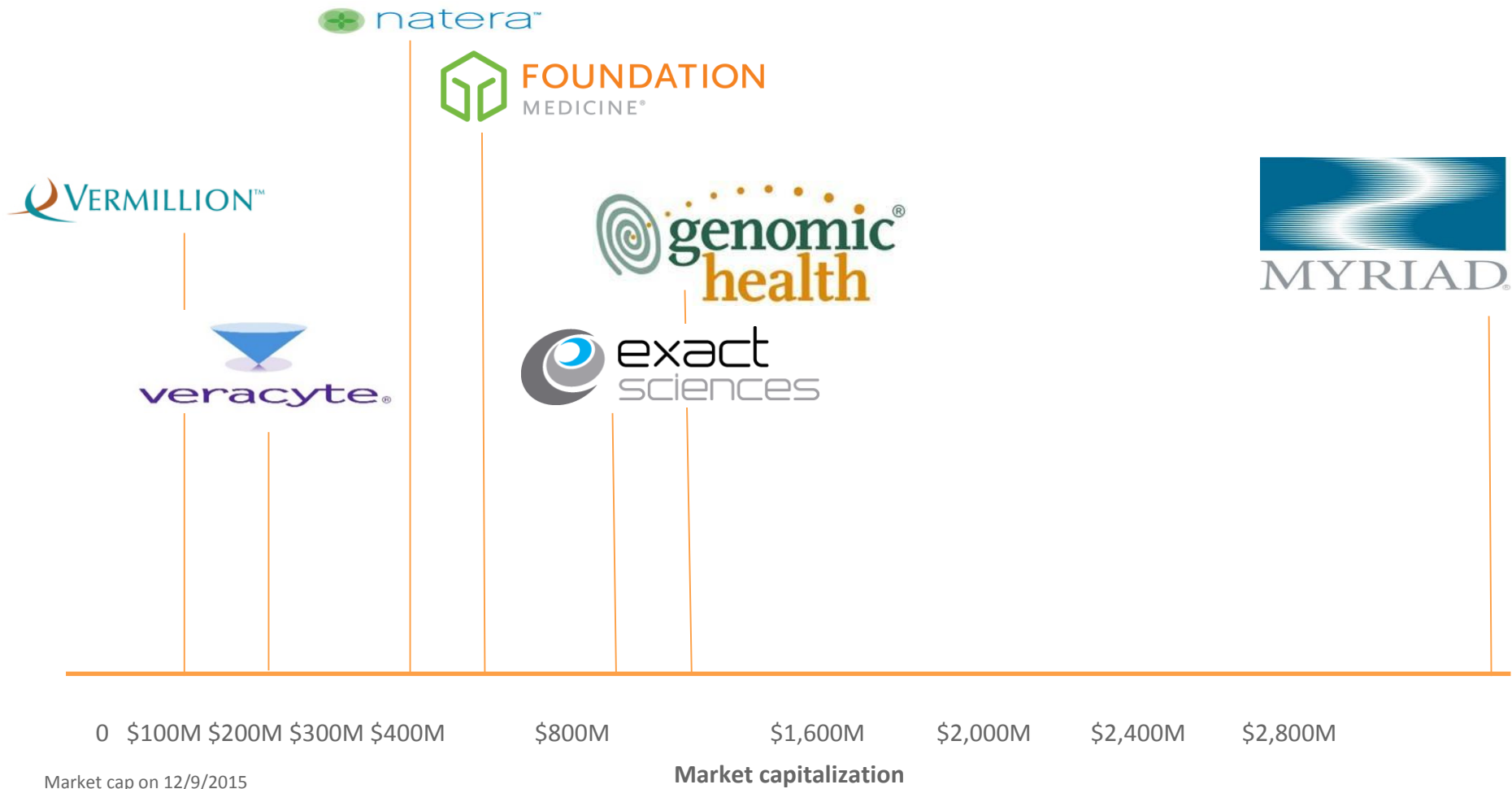
## LIQUID BIOPSY



# Some molecular diagnostics companies have substantial valuations

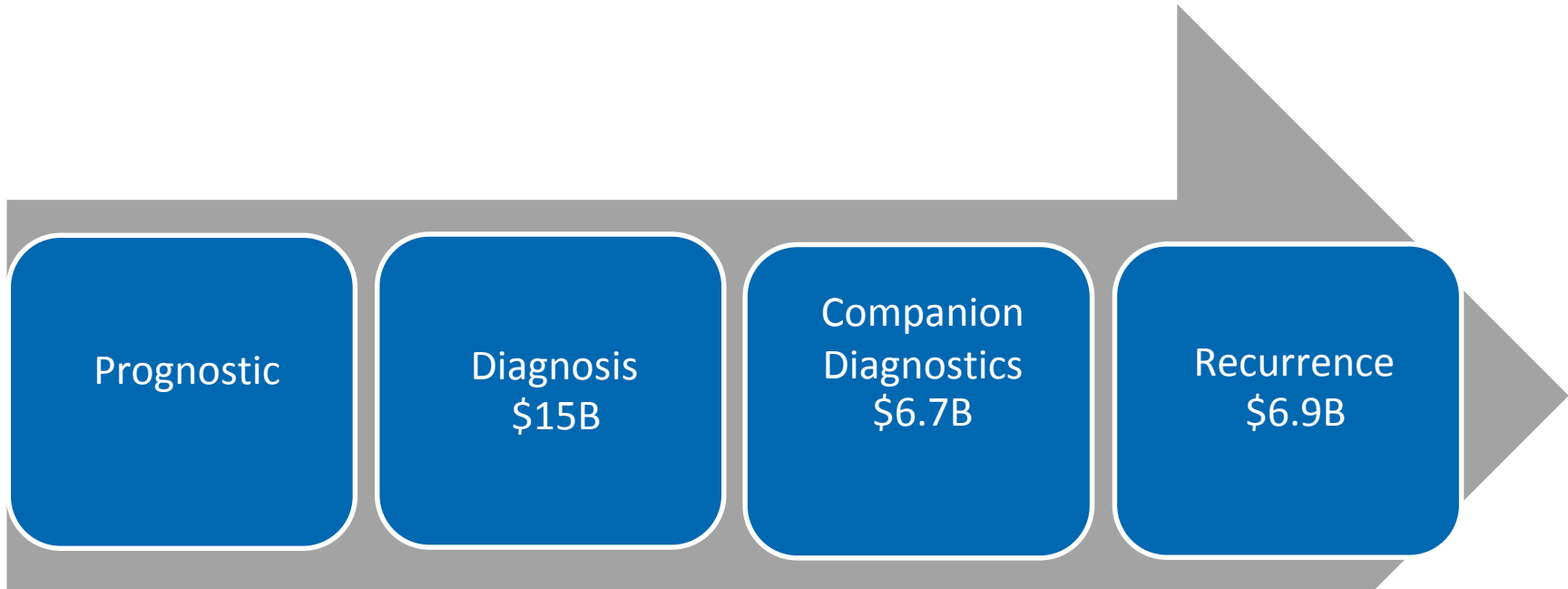
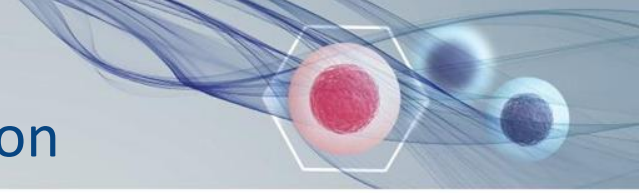


In some cases based on incremental improvements and/or small markets

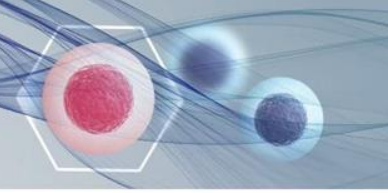


OncoCyte is focused on the largest segment and the biggest market opportunity

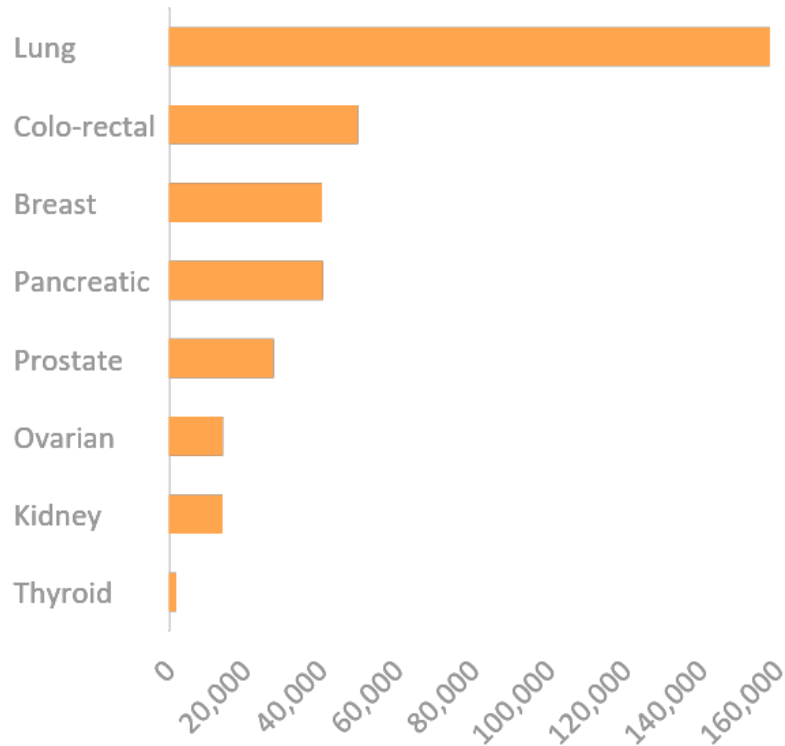
# OncoCyte is focused on early diagnosis – the largest market segment, but with low competition



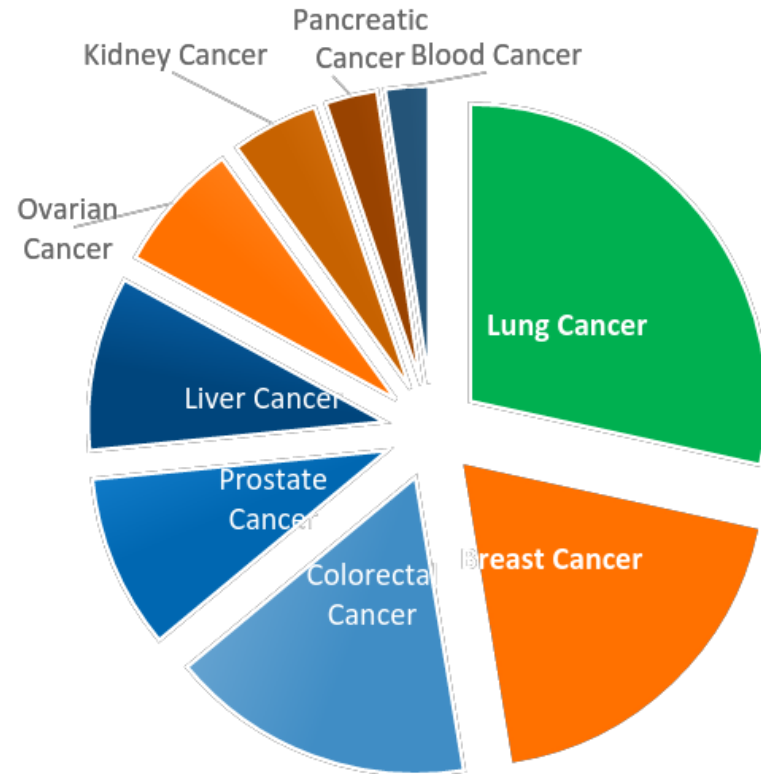
# Lung cancer is the largest market opportunity



Most cancer deaths each year in the U.S.



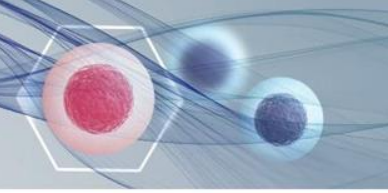
Largest % of global diagnostics revenue



Cancer Diagnostics Market: Global Industry Analysis, Size, Share, and Forecast 2014-2020, Transparency Market Research  
Diagnostics include both imaging and molecular diagnostics  
SEER Stat fact Sheet Estimated deaths 2015

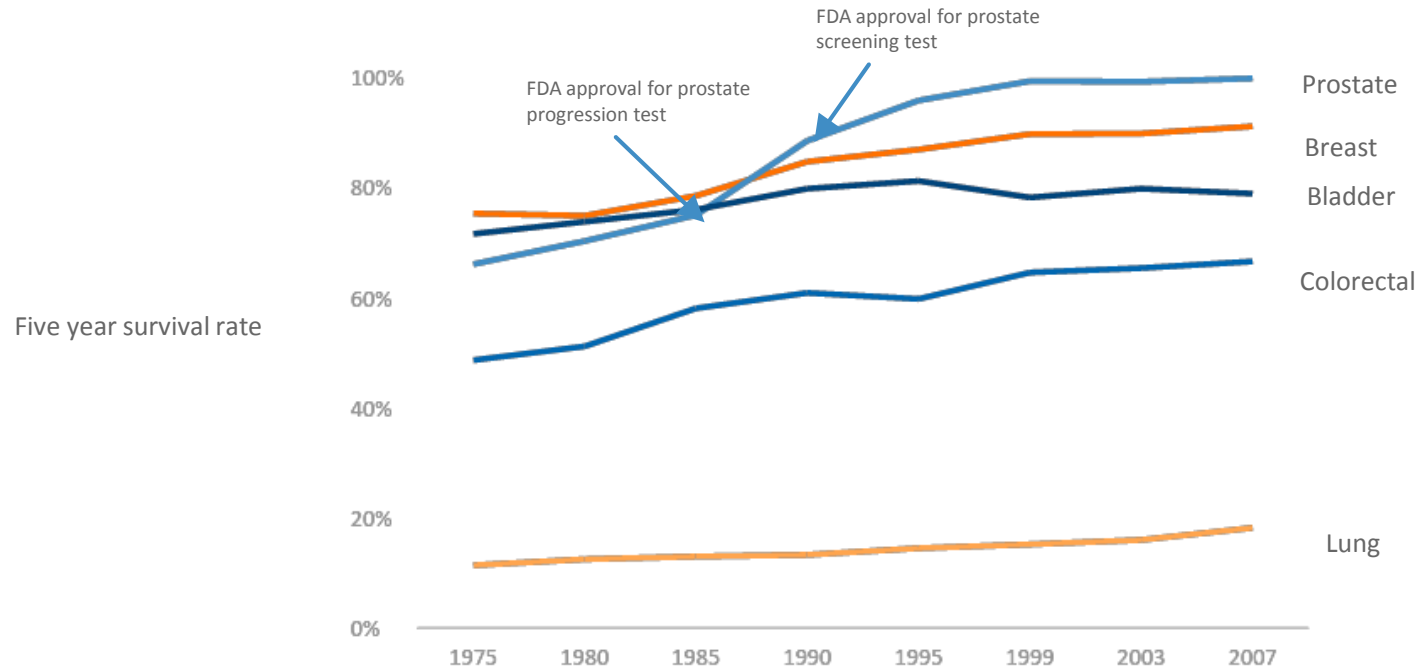


# Lung opportunity driven by poor outcomes with little improvement over the last 40 years



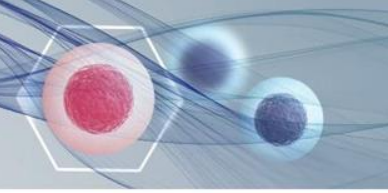
Lung cancer is typically diagnosed at later stages, limiting survival rates

## 57% of lung cancer diagnoses are made in stage IV

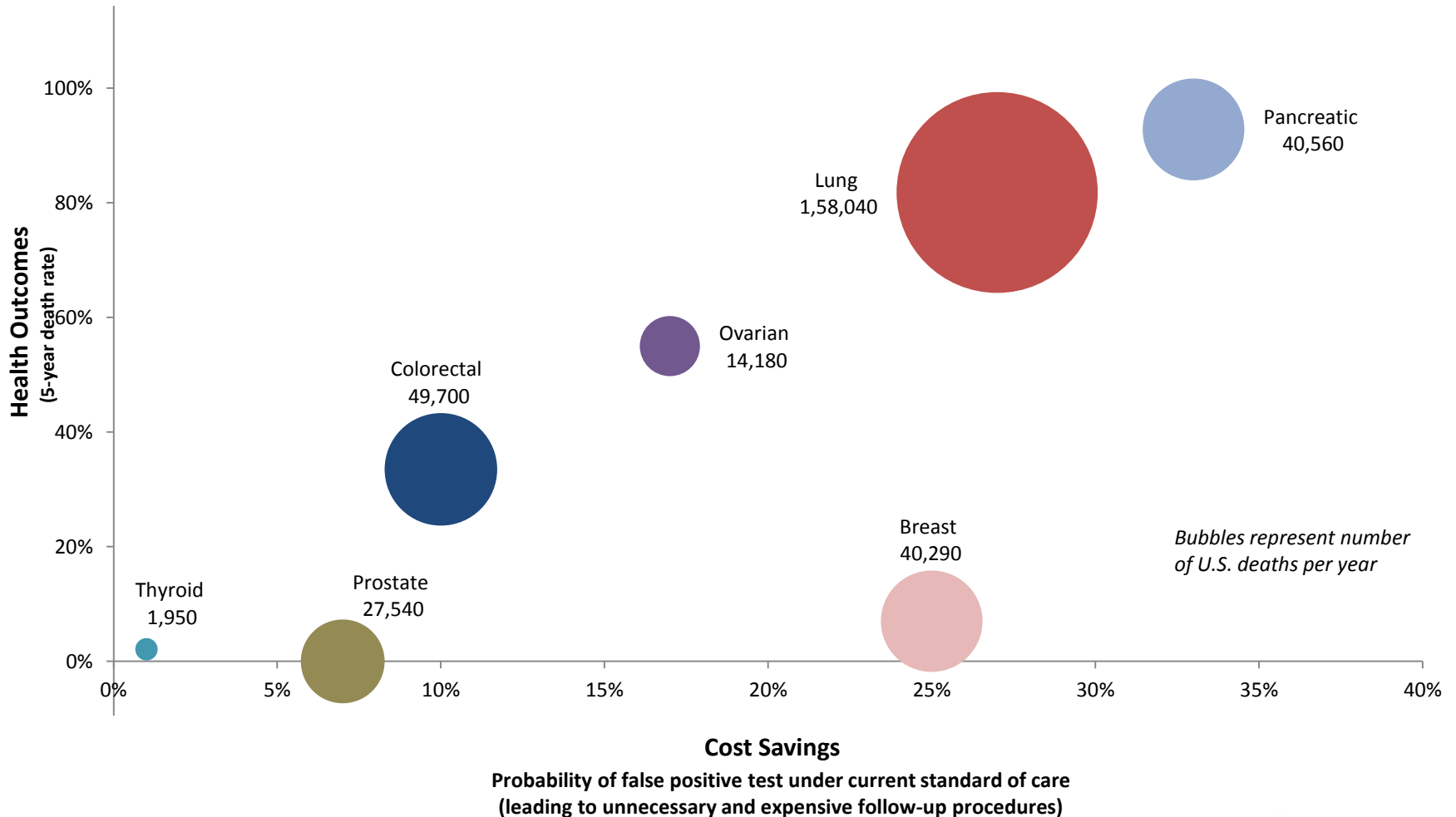




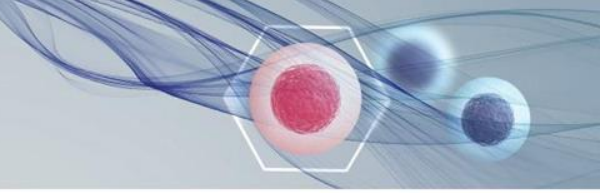
# Lung cancer diagnosis is the highest unmet need



The most lethal cancer with one of the worst survival rates, but one of the poorest standards of care



# Lung cancer is now a major U.S. health priority



Early detection of lung cancer is now a national health priority because it has the highest death rate

- Better diagnosis will increase the survival rate and save lives

December 2013

- USPSTF guidelines recommend annual LDCTs for patients with 30 pack-year history
- 7-10M Americans

February 2015

- CMS announces Medicare coverage of LDCTs

However LDCT has a high rate of false positives

- 25% of all LDCTs are indeterminate, requiring additional procedures
- But **96% of indeterminate LDCTs turn out to be benign** – false alarms
- So 96% of follow up procedures are unnecessary



# Current standard of care is risky and expensive

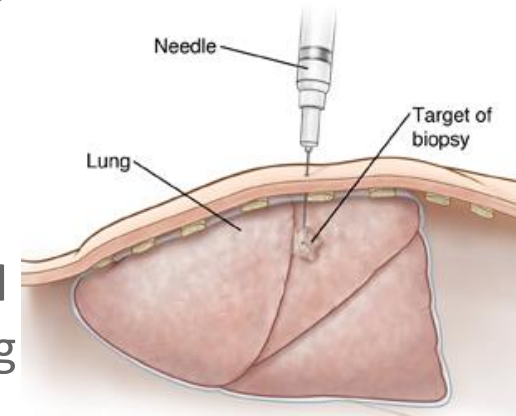
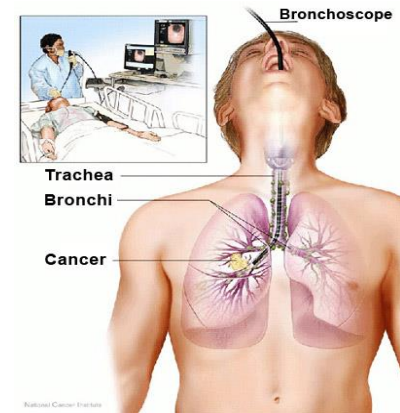
Follow up procedures are also expensive

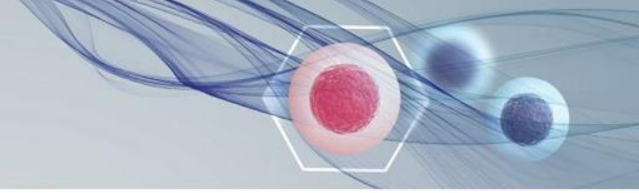
- Biopsies via bronchoscopies, surgery, needle biopsy
- Frequent follow up LDCTs (radiation exposure)

Lung biopsies are much riskier than other types of biopsies, and deaths could be avoided:

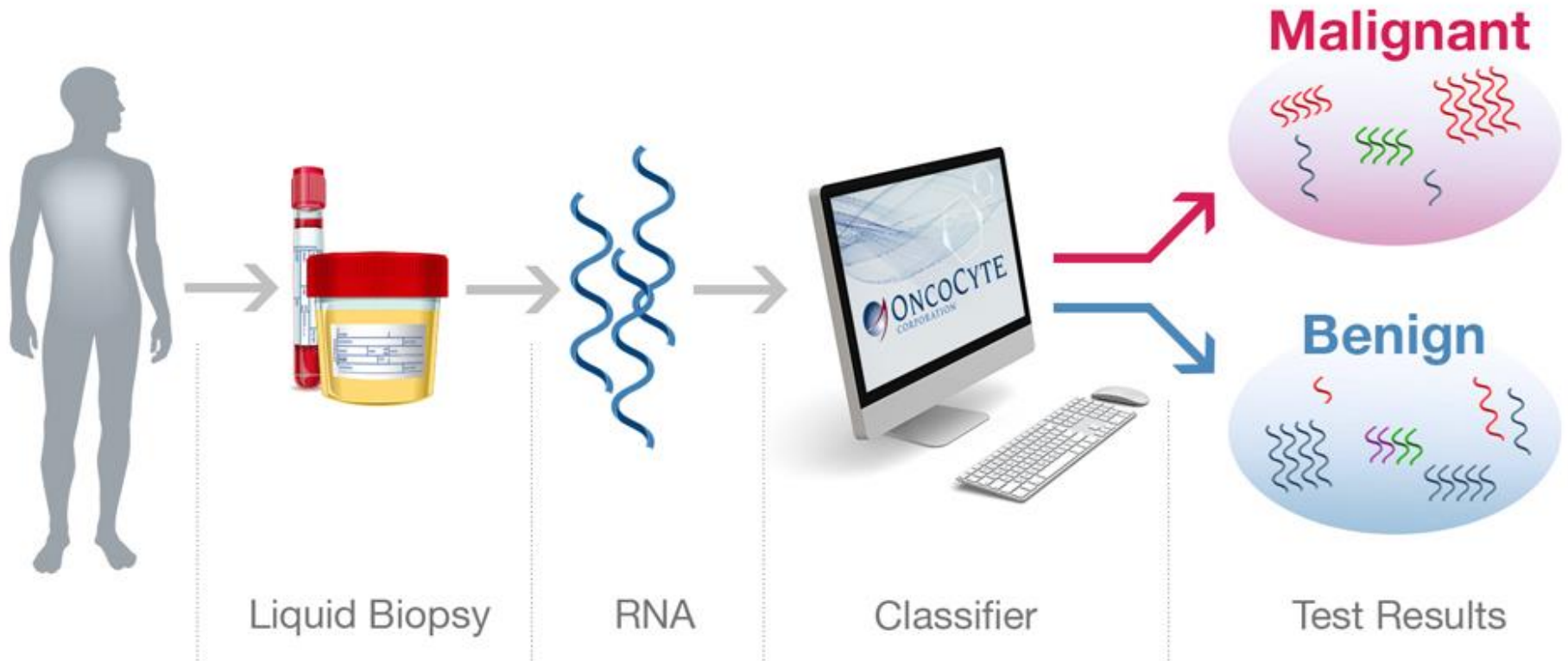
- 0.5 to 1% mortality (600 to 1,300 annual deaths averted)
- 4-20% major complications (5,000 to 26,000 fewer events annually)
- 2-15% collapsed lung (2,600 to 20,000 fewer events annually )

For an average patient a lung biopsy has a **higher likelihood of leading to a serious complication** than of confirming lung cancer

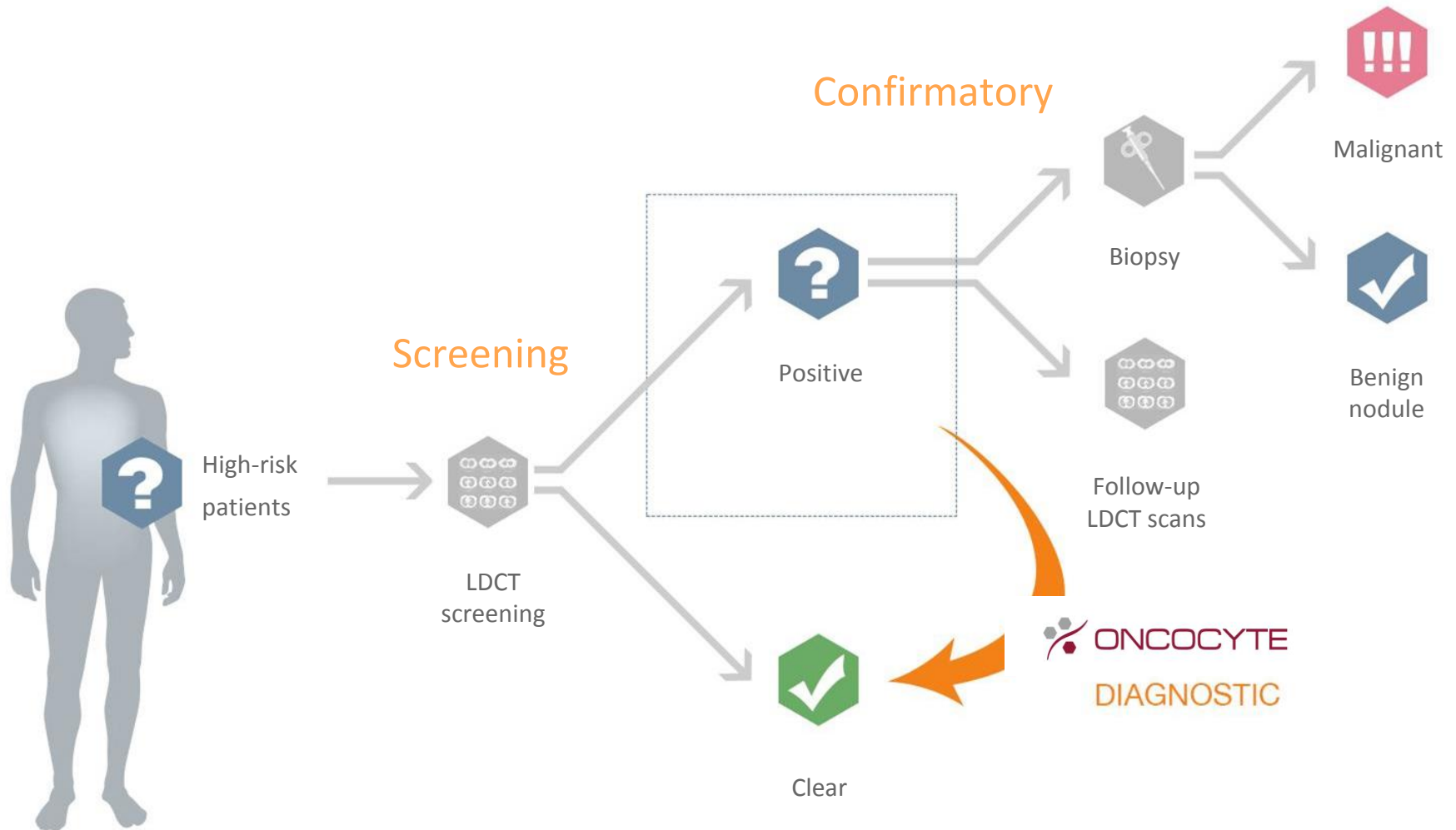
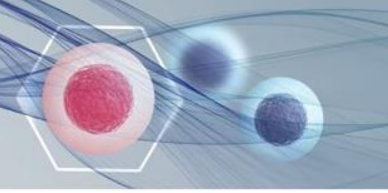




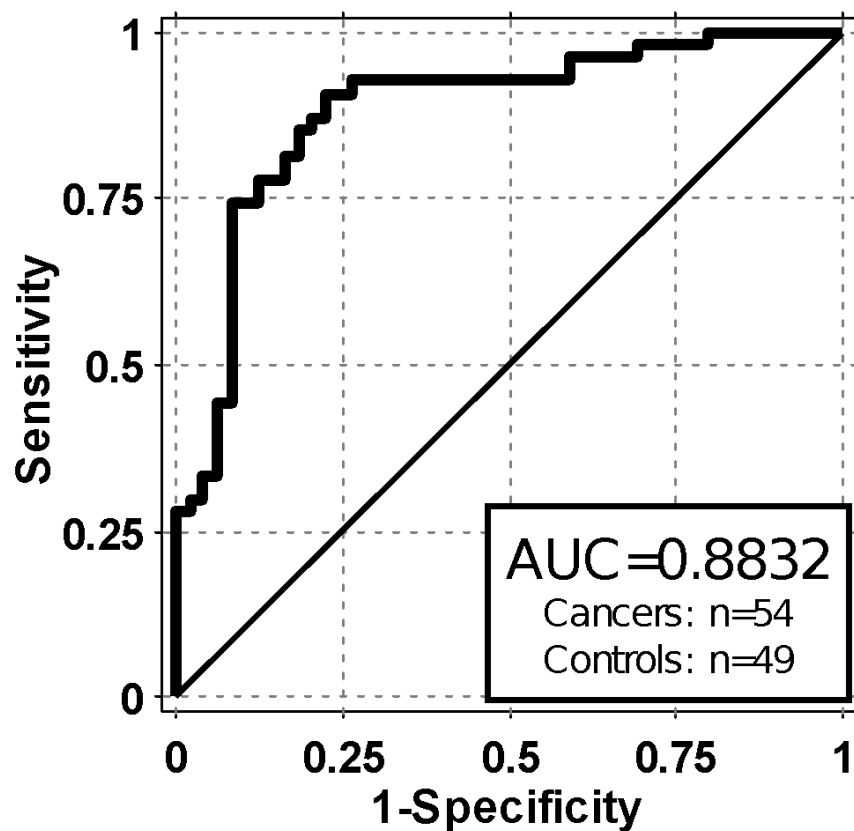
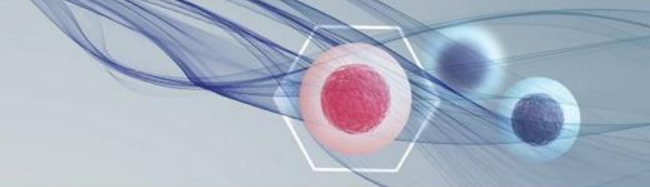
## Diagnostic Strategy



# OncoCyte's confirmatory diagnostic solution



# OncoCyte's preliminary test shows strong performance

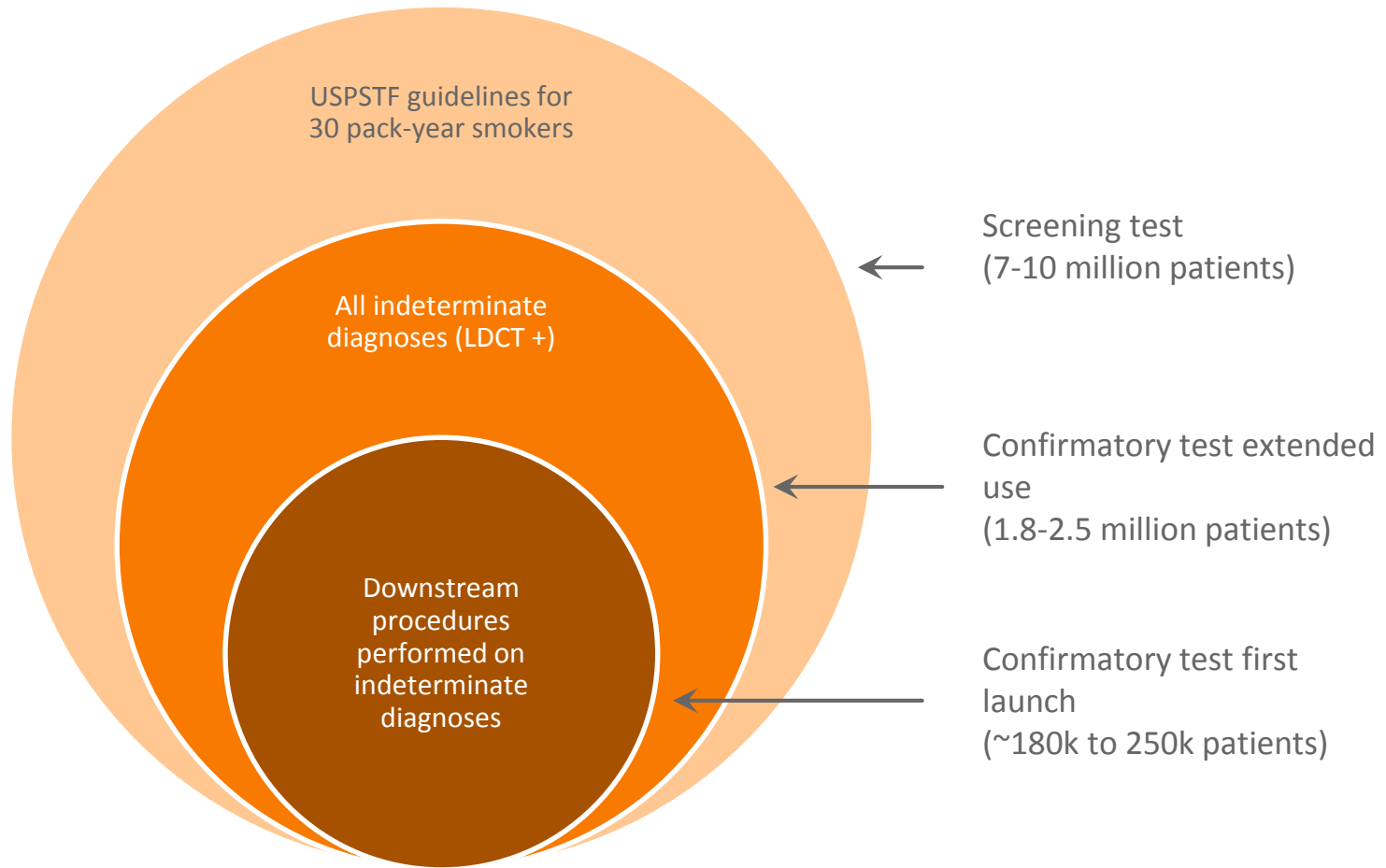
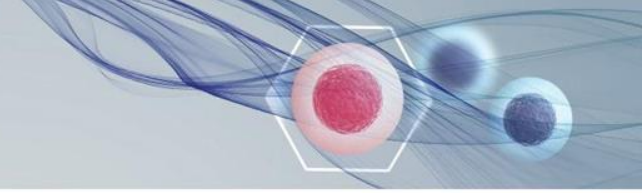


- Bioinformatics lab of Dr. Louise C. Showe
- 8+ years of developing blood-based tests for lung cancer
- Significant sample access (>2000 samples and ongoing collection)
- OncoCyte exclusive options and ongoing SRA
- Finalizing the licensing agreement
- Pivotal trial underway

- Prototype classifier presented at American Thoracic Society in 2015
- Sensitivity: 76%
- Specificity: 88%



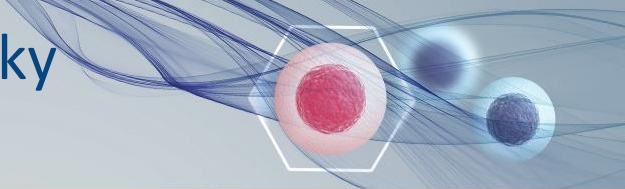
# Large market opportunity for lung tests



TAM numbers based on company estimates and secondary data



# High clinical utility – the potential for fewer risky procedures and significant cost savings



## OncoCyte's test could result in \$1.4B to \$4.0B in annual U.S. cost savings

### Current Standard of Care

USPSTF Guidelines 30-pack year smokers (8-10M patients)

Nodules Found  
(2-2.5M patients)

Referred to follow-up  
~230k (Use 1\*)  
~620K (Use 1-2\*\*)

Complications  
34K

### OncoCyte's Test as part of Standard of Care

USPSTF Guidelines 30 pack year smokers (8-10M patients)

Nodules found  
(2-2.5M nodules patients)

Avoided procedures  
~140k (Use 1\*)  
~380K (Use 1-2\*\*)

Avoided complications  
9-26k

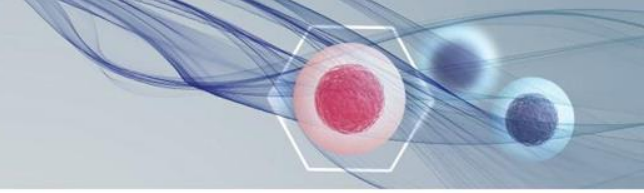
140,000 to 380,000 fewer procedures annually  
9,000 to 26,000 fewer hospitalizations annually

\*Use 1 – Confirmatory test first launch, Lung RADS 3 and 4 (see slide 15)

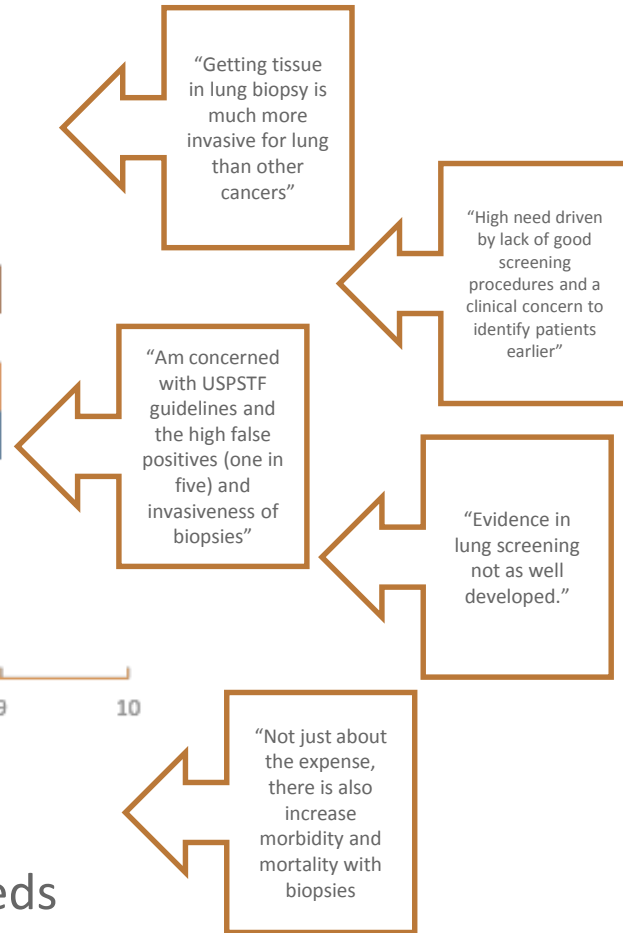
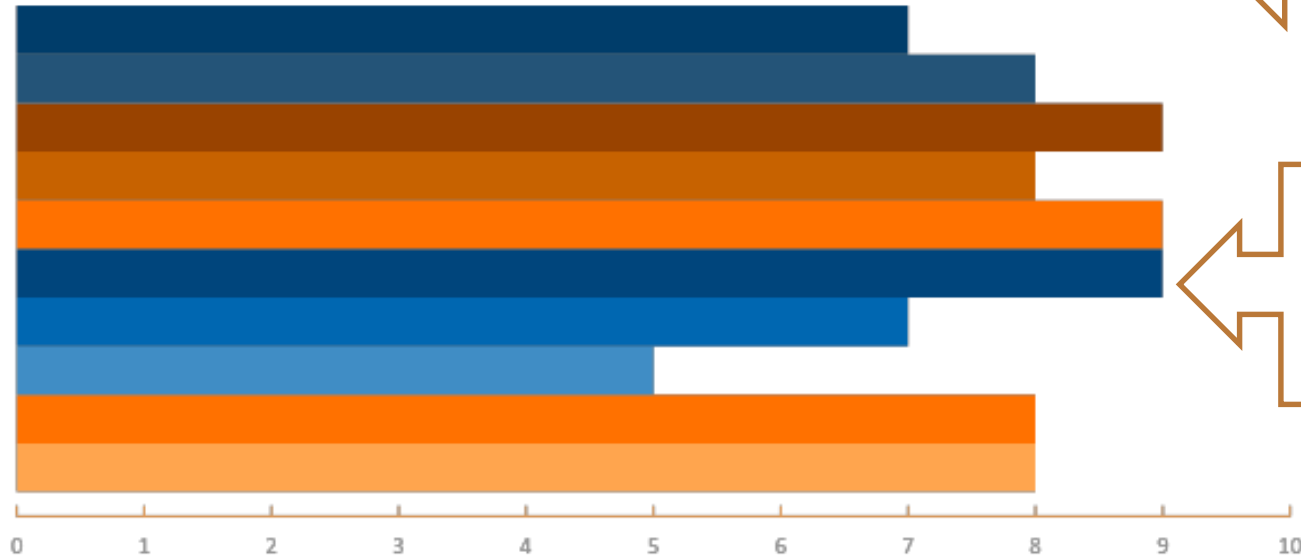
\*\*Use 1 and 2 – Confirmatory test first launch and expanded use, Lung RADS 2,3 and 4 (see slide 15)

Assumptions: 10M patients screened, 25% positive results, molecular diagnostic with 65% specificity (OncoCyte test may have higher or lower specificity); for Use 1 and 2 all positive screens referred to downstream procedures including repeat LDCTs, PET scans, bronchoscopies, surgical biopsies, with 15% complications and associated hospitalization costs

# Compelling proposition for payers



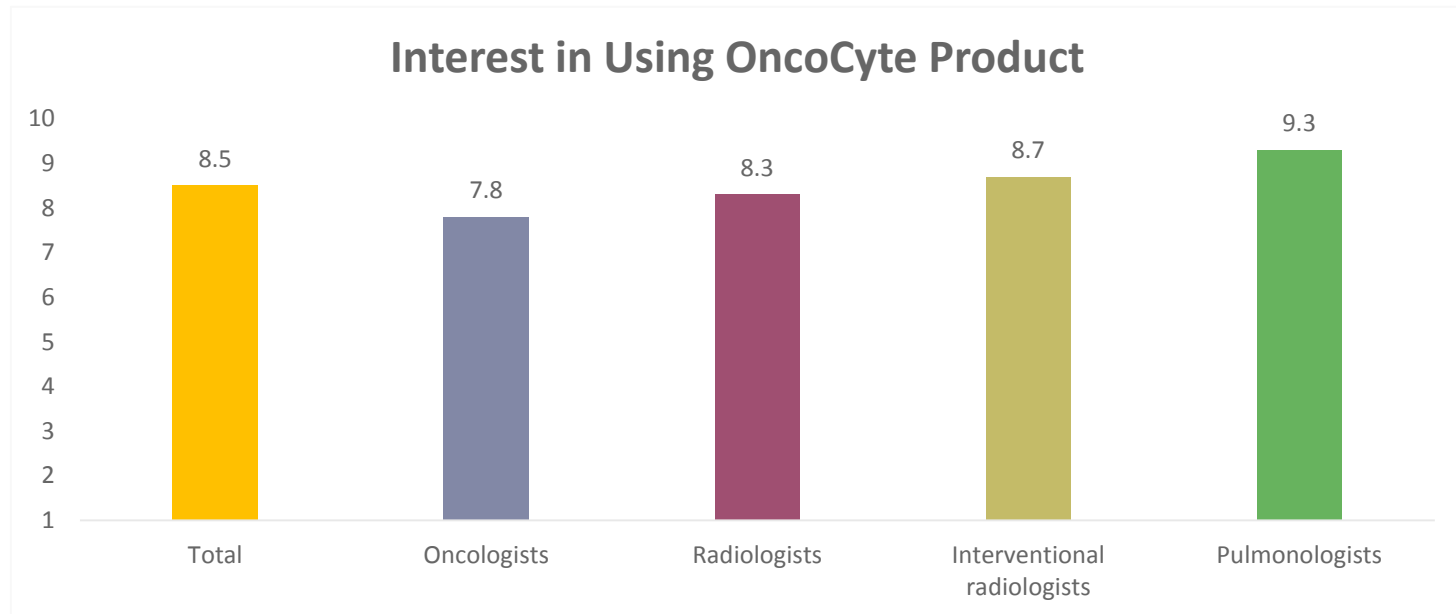
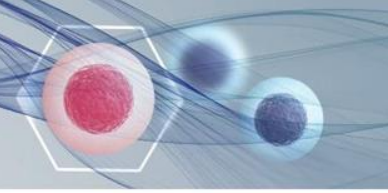
Ratings by Payer for Lung Diagnostic Unmet Need



- Payers gave diagnostic high ratings for unmet needs
- Pricing and TPP discussion with payers very positive

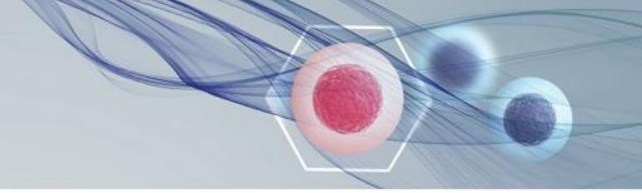
Asked of 10 Commercial, Managed Medicaid and Managed Medicare payers representing 20M covered lives  
Q8: Now I would like to ask what is your perception of the overall unmet need for certain oncology screening diagnostics or procedures.  
On a scale of 1 to 10 where 1 is no unmet need and 10 is significant unmet need for an improved screening procedure/diagnostic

# Compelling proposition for prescribers



- Interest in using the OncoCyte test is very high with a mean rating of 8.5 out of 10
- Pulmonologists expressed highest interest at 9.3, followed by interventional radiologists at 8.7
- Reasons provided for high ratings:
  - Useful for smaller nodules with high risk factors
  - Provides additional accuracy and benefit
  - Avoid biopsies
  - Non-invasive blood test
  - Provides clinical utility

# Commercialization strategy addresses all key stakeholders



## Benefits

### Provider

- Determinate diagnosis
- High sensitivity
- High specificity
- Reduce unnecessary procedures

### Patient

- Earlier detection
- Improved outcomes
- Reduce anxiety over indeterminate finding

### Payer

- Improved health outcomes
- Fewer unnecessary procedures
- Reduce overall costs

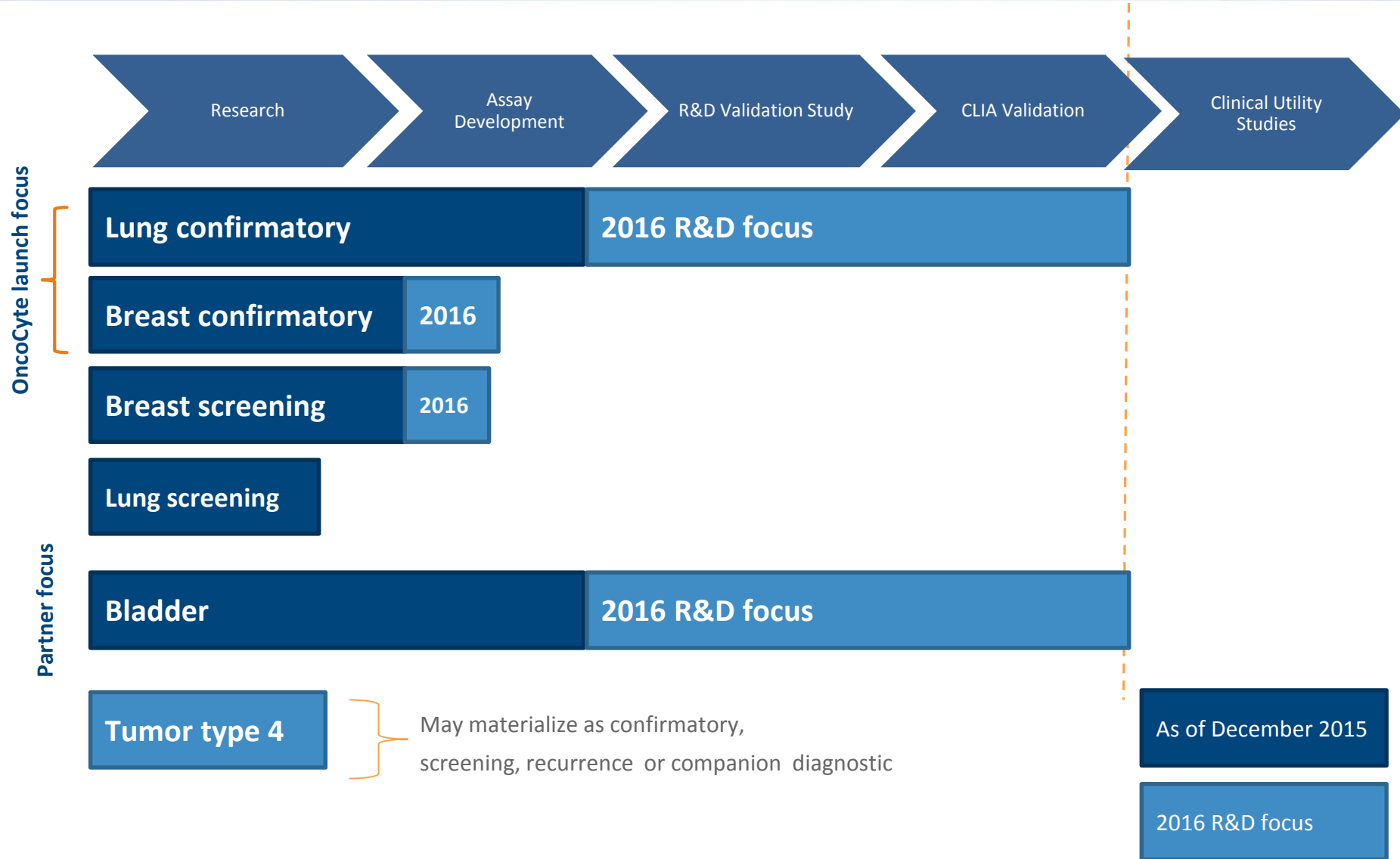
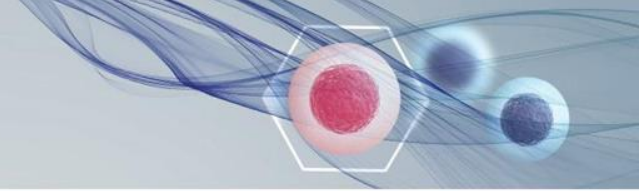
## Marketing Strategy

- Specialty sales force
- TPP refinement via market research
- Practice guidelines
- Peer review journals
- KOL influence

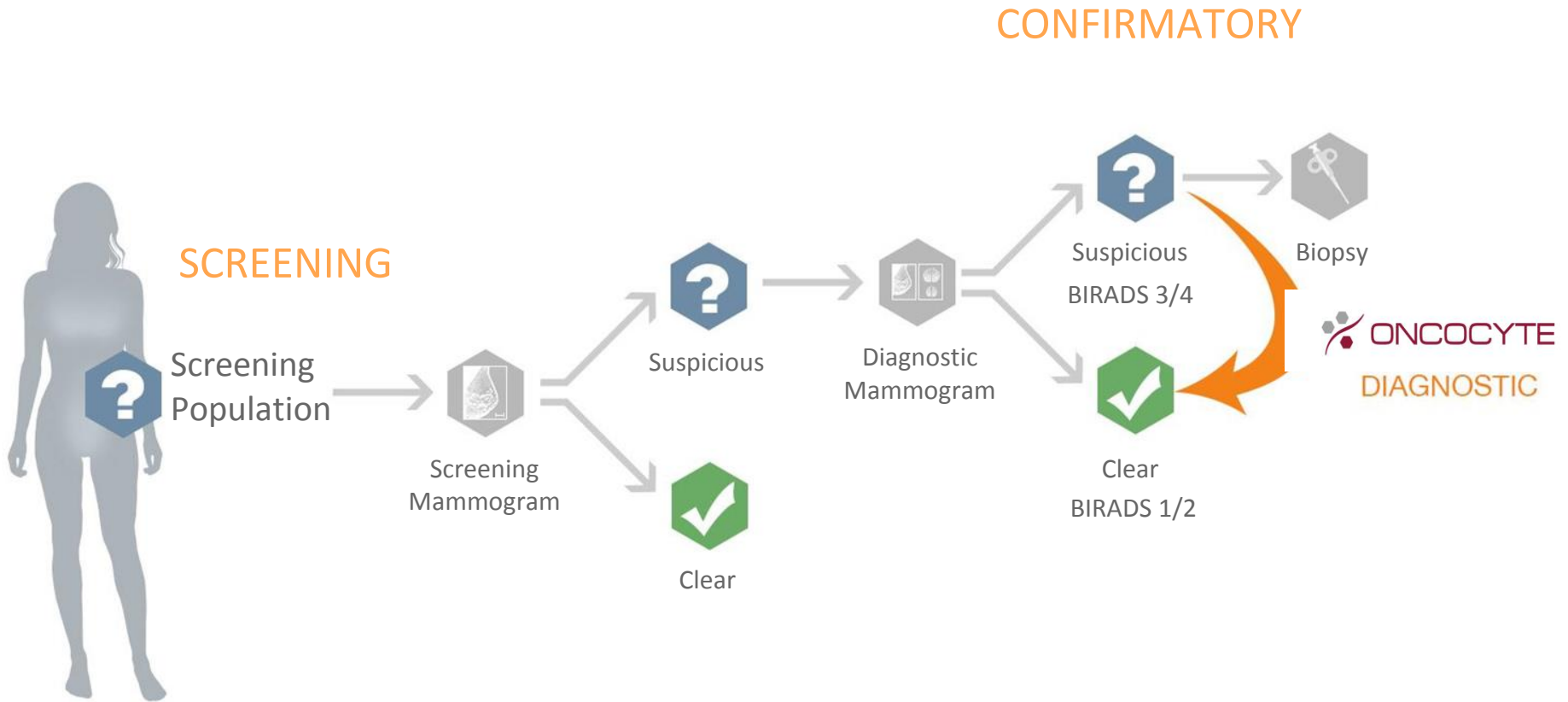
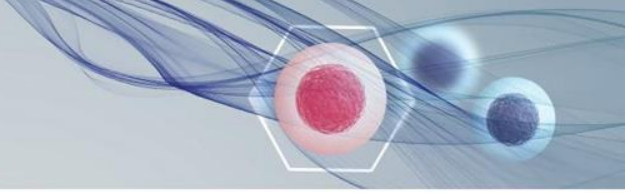
- Reimbursement support out of pocket
- Increase awareness to increase LDCT uptake
- Patient friendly test report

- Pricing vs comparator
- RWE clinical utility studies
- CMS 1<sup>st</sup> coverage focus
- 5 Large health plans

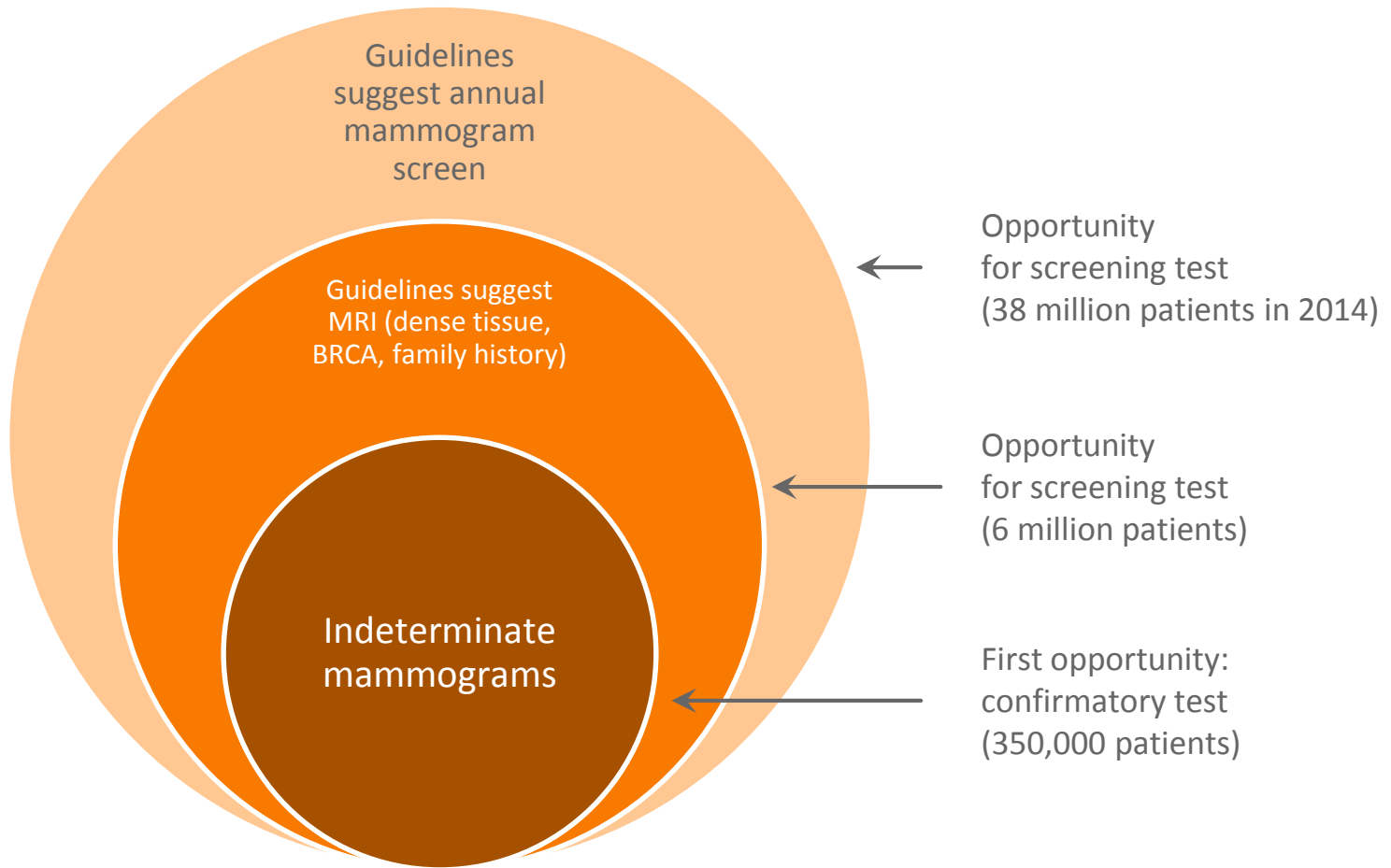
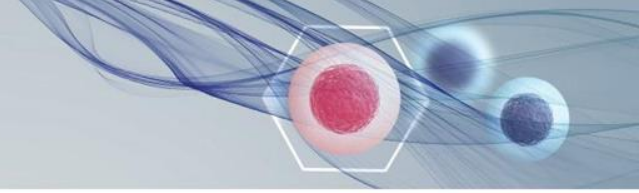
# OncoCyte's deep product pipeline



# Breast cancer confirmatory diagnostic in early stage development

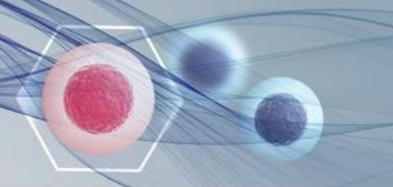


# Large market opportunity for iterative breast cancer diagnostic tests

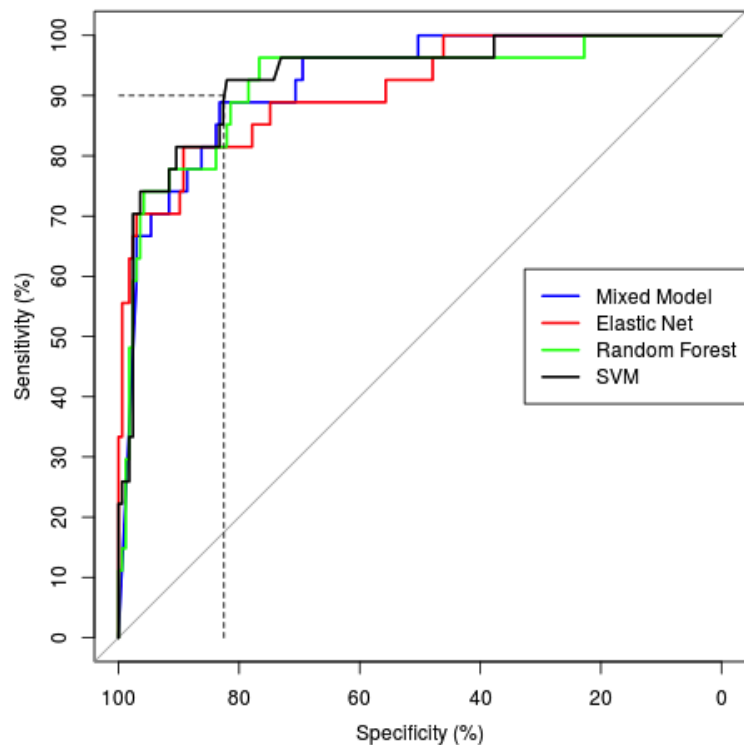


TAM numbers based on company estimates and secondary data





**Potential to partner** development and/or commercialization of bladder cancer test

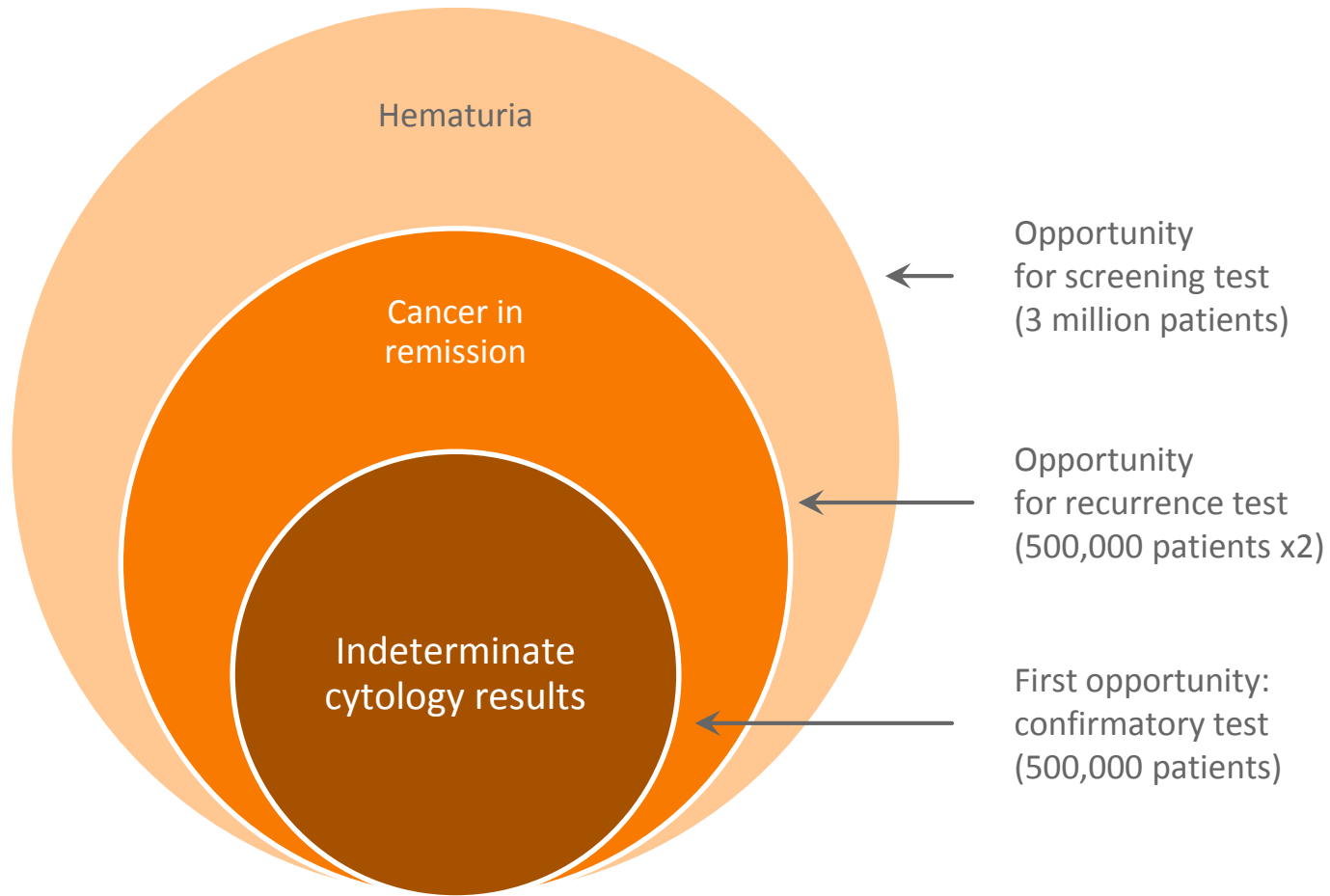
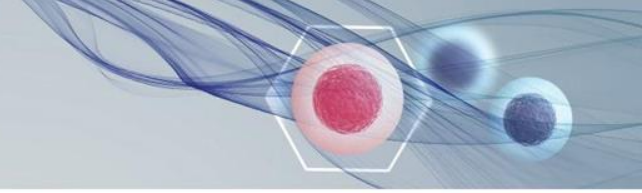


**ROC AUC = 0.91**

Sensitivity = 90%

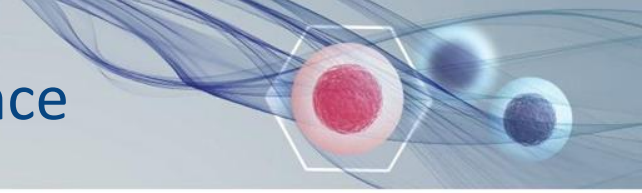
Specificity = 83%

# Large market opportunity for bladder cancer diagnostic tests



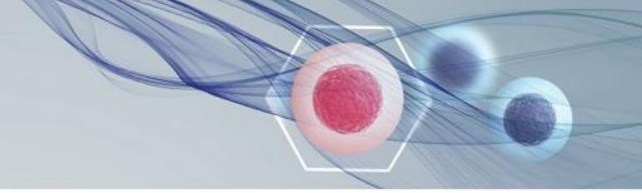
TAM numbers based on company estimates and secondary data

# Management team with commercial experience



	Position	Experience
William Annett	CEO	CEO BioFx Labs; CEO Corra Life Sciences; Managing Director Accenture Life Science; Led Commercial Strategy, Project Finance Genentech; Harvard MBA
Karen Chapman	VP Research	Advanced Cell Technology; Origen Therapeutics; Geron Corporation; Ph. D. Johns Hopkins University School of Medicine
Lyssa Friedman	VP Clinical and Regulatory Affairs	Veracyte VP Clinical Operations, Telomere Diagnostics, VP Clinical Development Carmenta Biosciences, McKesson Oncology Network, Oncology RN
Lyndal Hesterberg	VP Development	CEO BaroFold; Carmenta Biosciences; CTO Crescendo Biosciences; EVP Thermo BioStar; Senior Director SomaLogic
Kristine Mechem	VP Marketing	Business Analytics Abbott Labs, Market Planning Genentech, Managed Care Consulting, VP Marketing and Business Development Corra Life Sciences
William Seltzer	VP Clinical Services	Lab Director Veracyte, Illumina, Counsyl, Athena Diagnostics
Russell Skibsted	CFO	CFO BioTime; CFO Proove Biosciences; Managing Director and CFO RSL Ventures, CFO Aeolus Pharmaceuticals; CBO Hana Biosciences; Portfolio Management Partner Asset Management Company

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- Deep product pipeline leveraging core R&D competencies
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# Liquid Biopsies

## **Next Generation Cancer Molecular Diagnostics**

William Annett

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