Liquid Biopsies

Advancing cancer diagnosis

William Annett
Chief Executive Officer

June 2017

OncoCyte™

Forward Looking Statements

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 OncoCyte 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 OncoCyte, particularly those mentioned in the Risk Factors and other cautionary statements found in OncoCyte’s latest Annual Report on Form 10-K and other Quarterly Reports and Current Reports filed by OncoCyte with the Securities and Exchange Commission. OncoCyte 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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OncoCyte™

Investment Highlights

- Focused on largest unmet needs for early, accurate cancer diagnosis
- Compelling value proposition for physicians, patients, and payers
- Lung confirmatory test launch planned second-half 2017
- Breast confirmatory test being developed as second product
- Experienced leadership team leveraging core Commercial and R&D capabilities

OncoCyte™

Oncocyte is focused on early diagnosis – the largest market segment with less competition

Prognosis	Diagnosis $15B	Companion Diagnostics $6.7B	Recurrence $6.9B
MYRIAD	OncoCyte, Vermillion, veracyte	GUARDANT HEALTH, FOUNDATION MEDICINE	genomic health

Source of revenue: The 2015 Liquid Biopsy Report Piper Jaffrey (September 2015).

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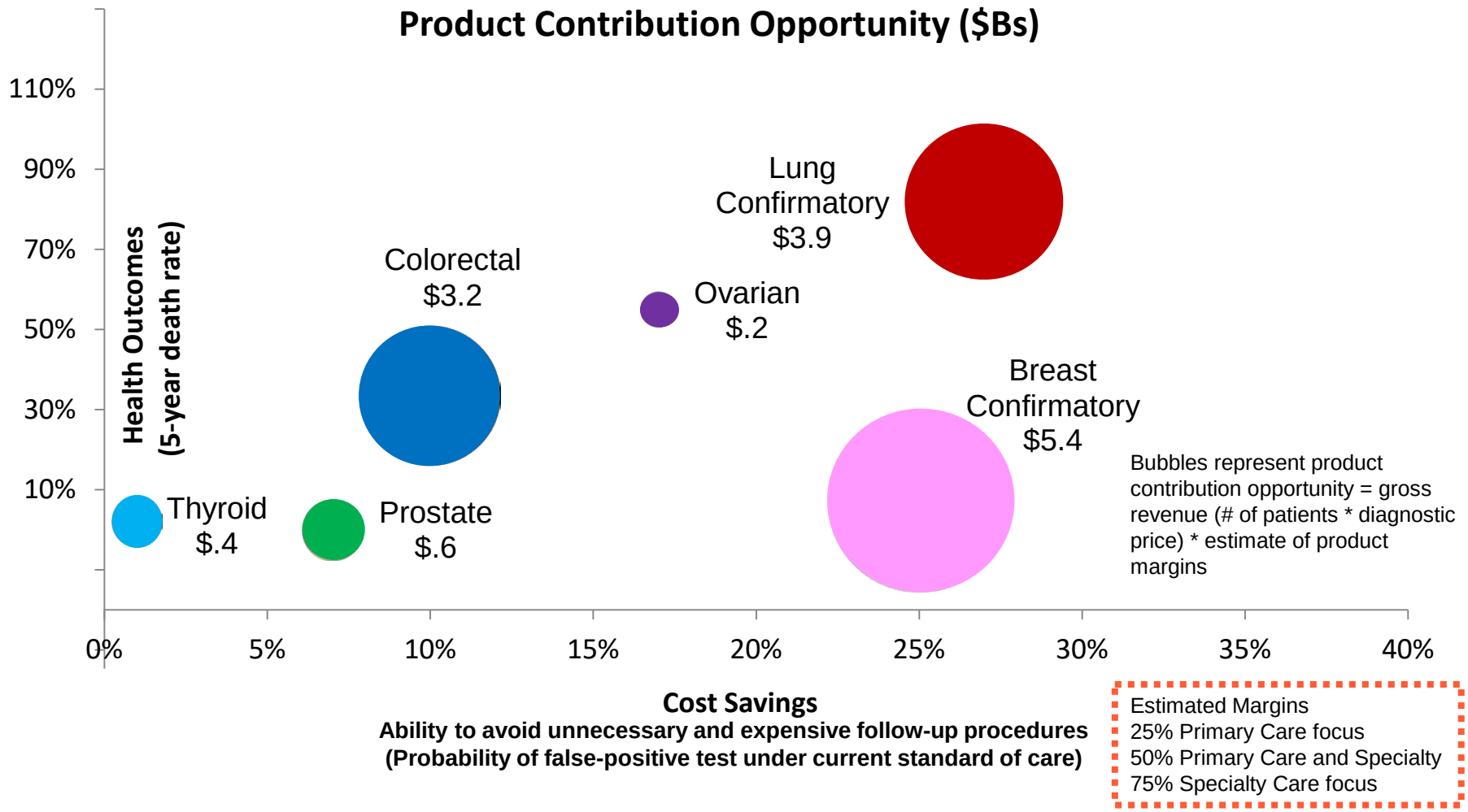
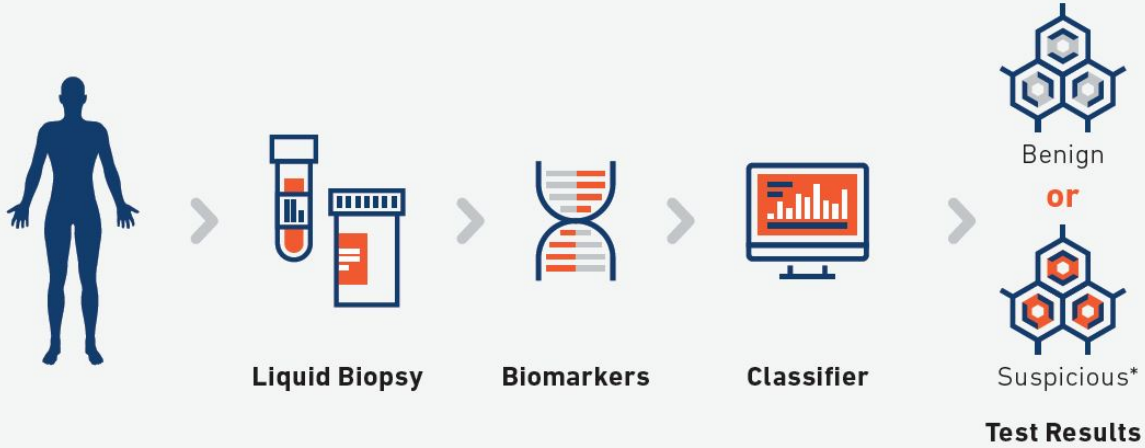
OncoCyte is focused on areas of greatest unmet need and most attractive margins



Health Outcomes is a proxy for clinician unmet need; Cost Savings is a proxy for payer unmet need.

Diagnostics based on gene expression classifier and binary call



OncoCyte's initial focus is on cancers with large patient populations and significant unmet need.

*Potentially malignant, clinician to determine follow up procedure.

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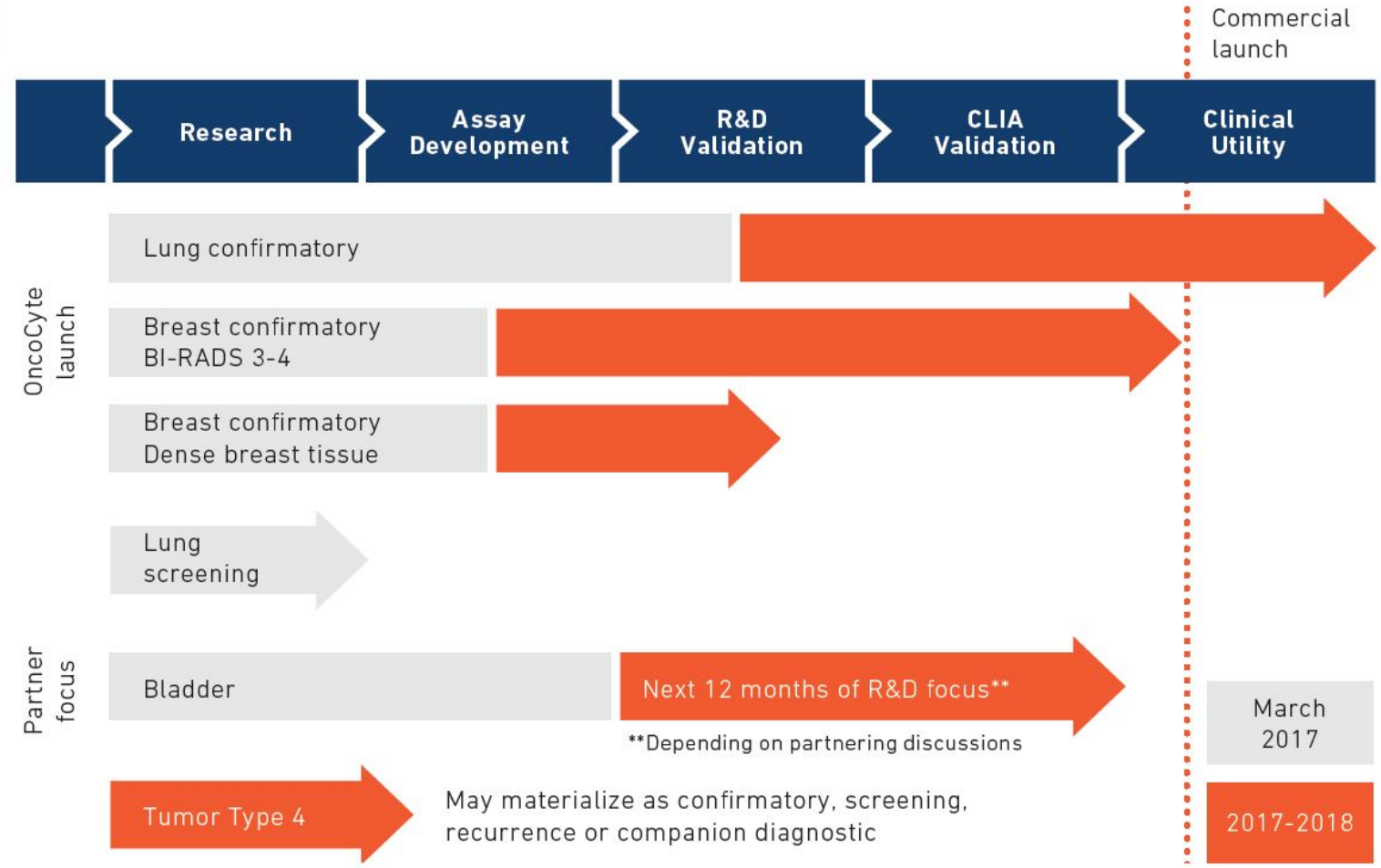
OncoCyte's deep product pipeline



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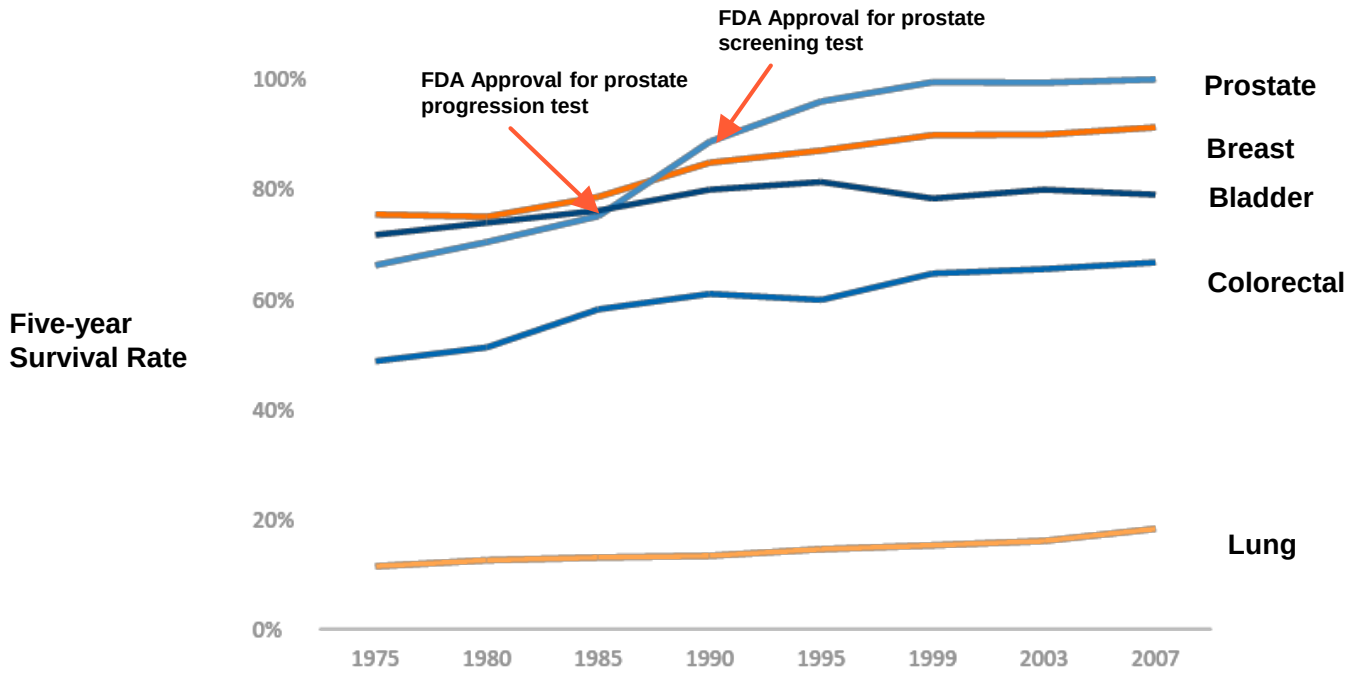
Lung opportunity driven by poor outcomes with little improvement over the last 40-years

Lung cancer is typically diagnosed at later stages, with 57% of diagnoses made in stage IV, limiting survival rates



Sources: Cancer SEER Stat Fact Sheets; NCCN Guidelines Lung Cancer Screening (February 2014); USPSTF Guidelines for Lung Cancer (December 2013).

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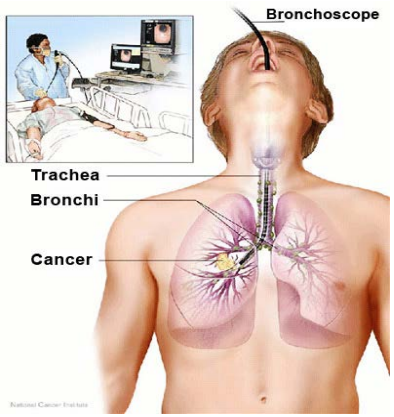
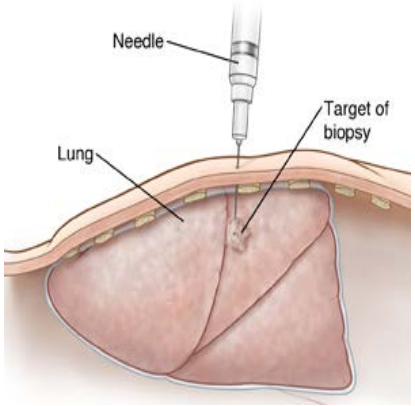
Post-LDCT biopsies are risky and expensive

- Lung biopsies – via needle, bronchoscopy or surgery – are much riskier than other biopsies

Incidence (%)	Complication	Annual Events (~#)
0.5–1%	Mortality	600–1,300
4–20%	Major complications (including collapsed lung)	5,000–26,000

- Mean cost of $14,634 per biopsy
- Frequent LDCTs expose patients to potentially unnecessary radiation





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

Sources: Gould, MK et al. Evaluation of Individuals with Pulmonary Nodules: When is it lung cancer? *CHEST* 2013; 143(5)(*Suppl*):e93S-120S; OncoCyte absolute number estimated using TAM 10M and 65% specificity; Lokhandwala, T et al. Costs of Diagnostic Workup for Lung Cancer – A Medicare Claims Analysis. ASTRO Abstract presented Thursday, October 20, 2014.

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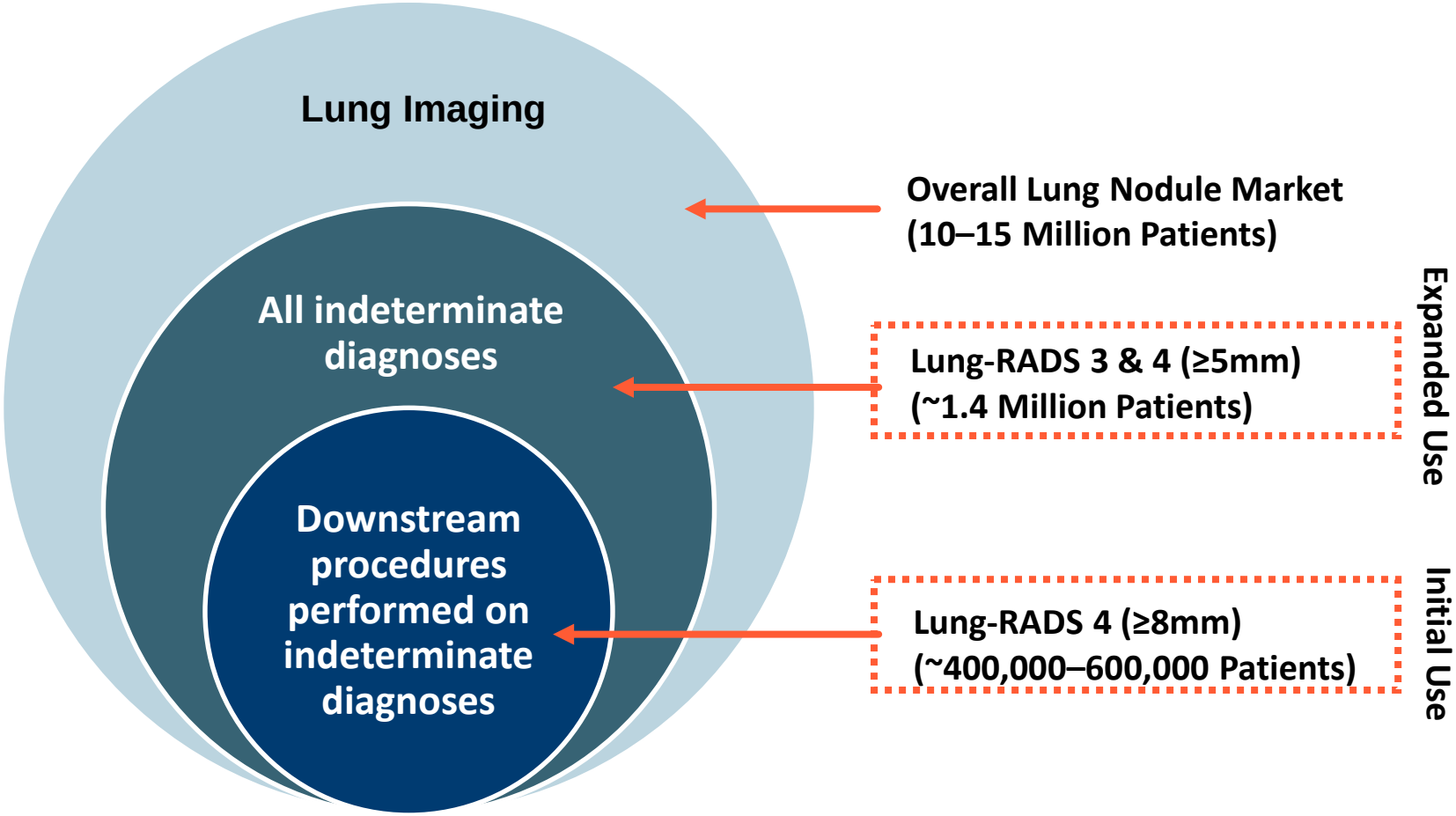
Large market opportunity for lung tests



TAM Numbers based on company estimates and secondary data: 7–10 Million screening patients (Source: USPSTF, NCI); 4.9 Million patients with incidental nodules (Source: Gould, MK. Et al. *Am J Respir Crit Care Med* 2015 Nov 15; 192 (10):1208-1214.)

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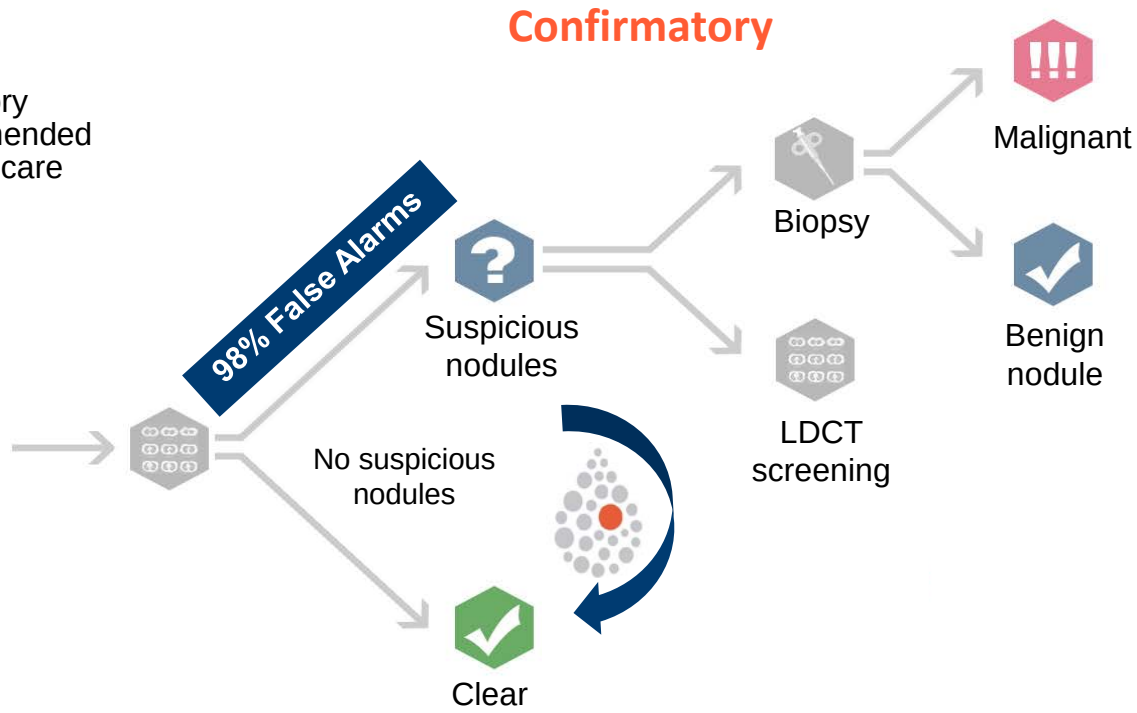
Oncocyte's initial focus is on a confirmatory diagnostic solution

7–10M Americans

High-risk, 30 Pack-year history
USPSTF Guidelines recommended screening – covered by Medicare

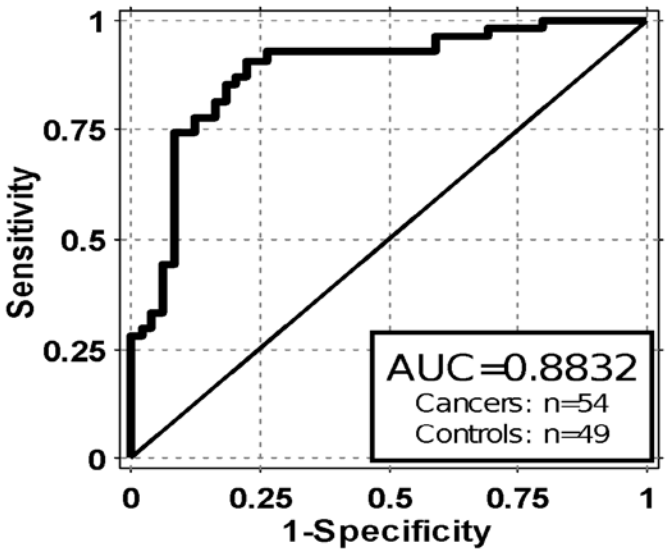


5M Americans

Incidentally detected nodules

OncoCyte's preliminary test shows strong performance

- Prototype classifier presented at the **American Thoracic Society (ATS) 2015 International Conference**
  - Sensitivity 76%
  - Specificity 88%



- Proof of concept for confirmatory, screening diagnostic

THE WISTAR INSTITUTE

- Bioinformatics lab of Dr. Louise C. Showe
- 9+ years developing blood-based tests for lung cancer
- Significant sample set (3,000 samples and ongoing collection)
- OncoCyte exclusive global licensing agreement

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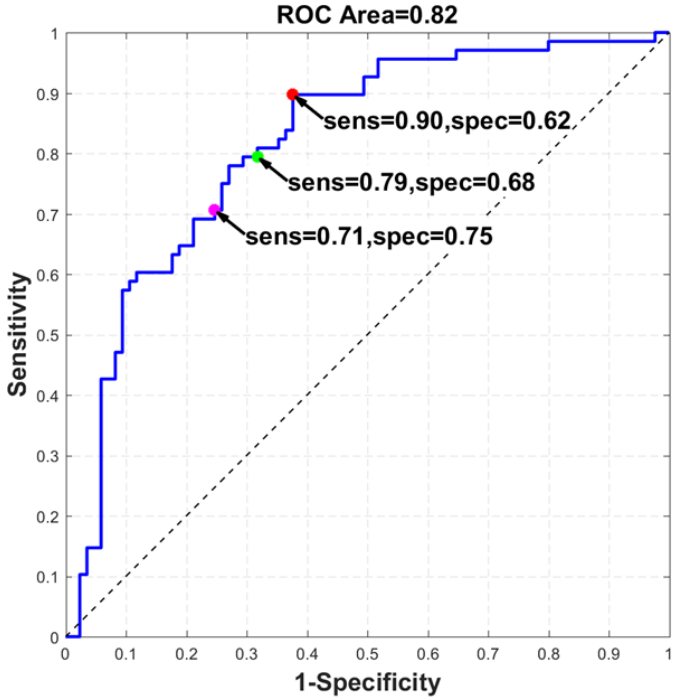
Wistar validation suggests commercially attractive diagnostic

- Validated results from a large (n=610) sample analysis, biomarkers only presented at the **CHEST 2016 Annual Meeting**

- Validated results show comparable findings to previous study
  - Sensitivity 90%
  - Specificity 62%

100 Gene Model



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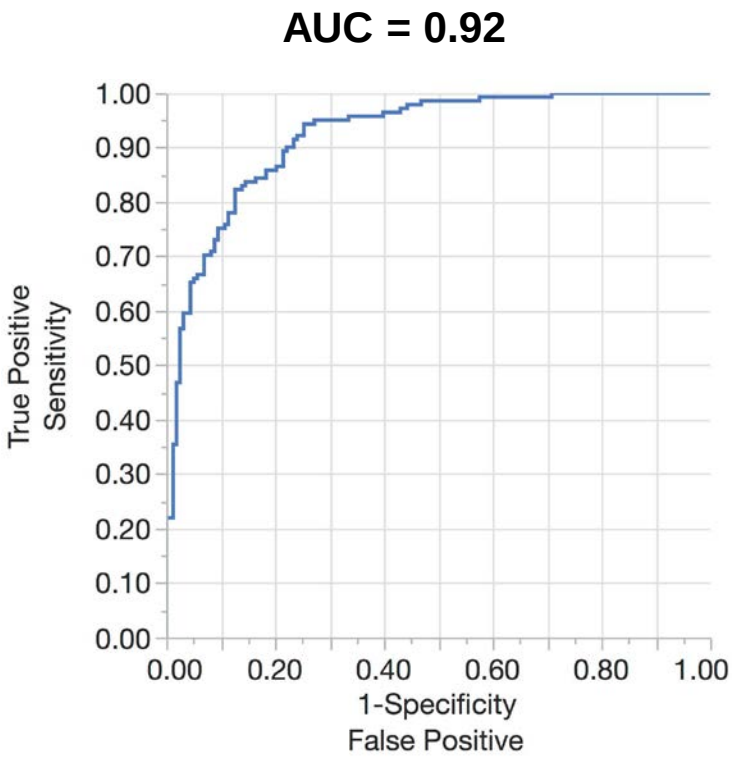
OncoCyte validation study confirmed Wistar results

Findings suggest assay could significantly improve standard of care

- Validated results from a large (n=299) sample analysis of prospectively collected samples presented at **ATS 2017**

- Validated results show comparable findings to previous study
  - Sensitivity 95%
  - Specificity 73%



Next Steps

- Application for CLIA Certification (completed)
- OncoCyte Clinical Validation Study (2H 2017)
- Commercial Launch (2H 2017)
- Clinical Utility Studies (Post-launch)

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

OncoCyte's test could result in $2.2B to $4.7B in annual US cost offsets

Current Standard of Care

USPSTF Guidelines and Incidentally Detected Nodules
(7–15M Patients)

Nodules Found
(0.9–2.0M Patients)

Referred to Follow-up
(630–1,400K Patients)

Complications
(203K Patients)

OncoCyte's Test as part of Standard of Care

USPSTF Guidelines and Incidentally Detected Nodules
(7–15M Patients)

Nodules Found
(0.9–2.0M Patients)

Avoided Procedures
(164–352K Patients)

Avoided Complications
(24–53K Patients)

Annual Estimates

164,000–352,000 Fewer procedures
24,000–53,000 Fewer hospitalizations
2,000–5,000 Lives saved

Intended use – Confirmatory test first launch, Lung-RADS 3&4

Assumptions: 15M patients screened, 13% positive results, molecular diagnostic with 65% specificity (OncoCyte test may have higher or lower specificity); all Lung RADS 3-4 referred to downstream procedures including repeat LDCTs, PET scans, bronchoscopies, surgical biopsies, with 15% complications and associated hospitalization costs. 65% physician compliance with test results.
Cost offsets does not reflect cost of diagnostic.

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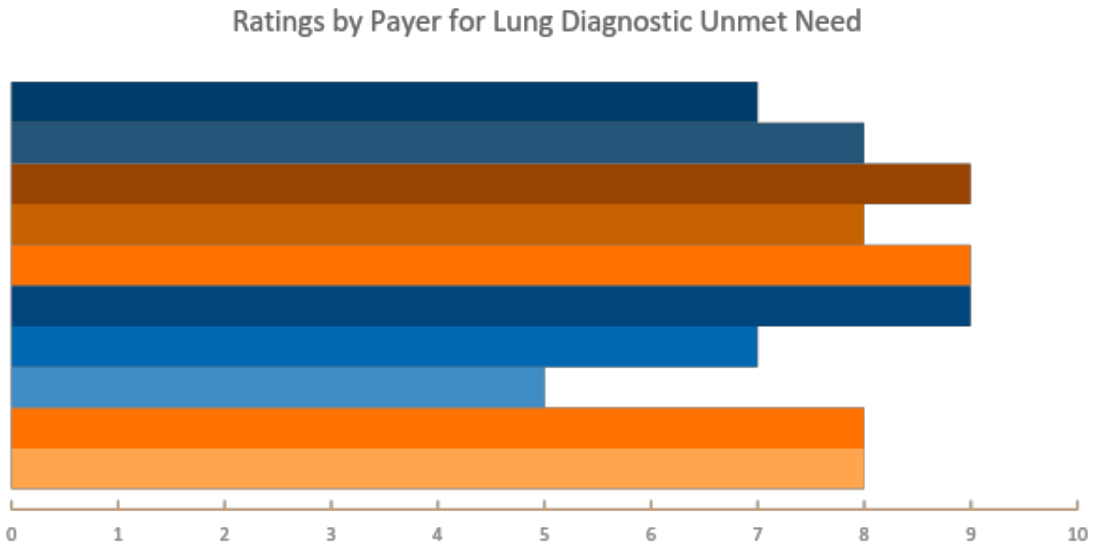
Lung is a compelling proposition for payers

High ratings for unmet needs and positive pricing and TPP feedback



"High need driven by lack of good screening procedures and a clinical concern to identify patients earlier"

"Not just about the expense, there is also increase morbidity and mortality with biopsies"

"Getting tissue in lung biopsy is much more invasive for lung than other cancers"

"Am concerned with USPSTF guidelines and the high false positives (one in five) and invasiveness of biopsies"

Survey of (10) Commercial, Managed Medicaid and Managed Medicare payers representing 20M covered lives.
Question asks: 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.

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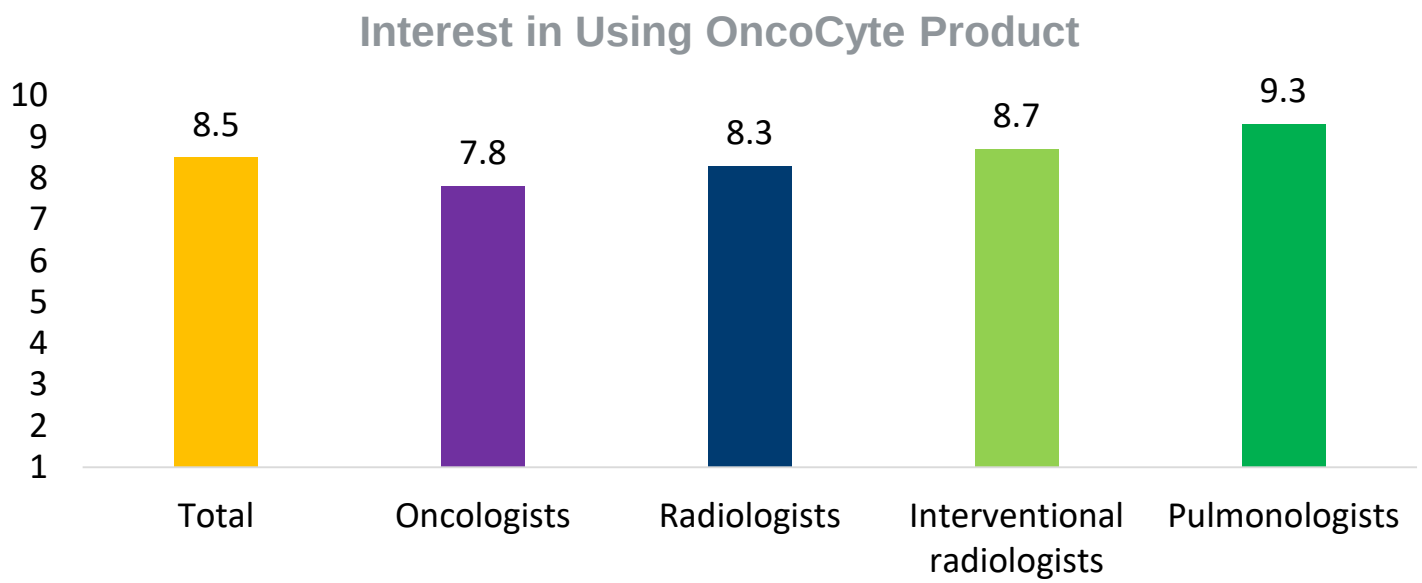
Physicians in target specialties express highest level of interest

OncoCyte's test is a compelling value proposition for physicians



- Reasons provided for high ratings:
  - useful for smaller nodules with high-risk factors
  - provides additional accuracy and benefit
  - avoids unnecessary biopsies
  - non-invasive blood test
  - provides clinical utility

Results of (30) in-depth, clinician interviews fielded in September/October 2015. Question asks: On a scale from 1-10 where 10 is very interested, how interested would you be in utilizing Test X?

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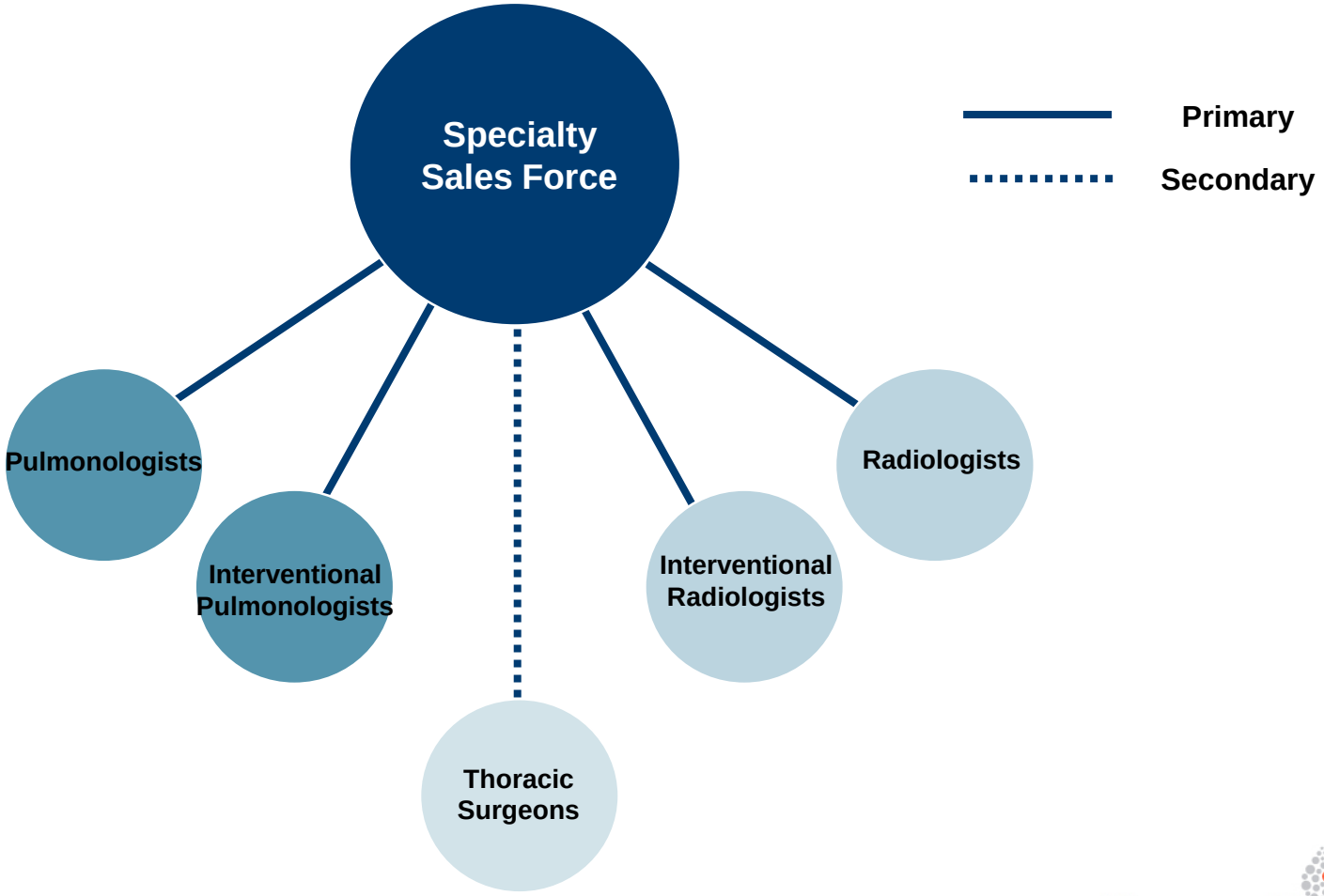
Commercialization strategy addresses key stakeholders

	Physicians	Patients	Payers
Benefits	• Determinate diagnosis • High sensitivity, specificity • Reduce unnecessary biopsies	• Earlier detection • Improved outcomes • Reduce anxiety over indeterminate finding	• Improved health outcomes • Fewer unnecessary procedures • Reduce overall costs
Marketing Strategy	✓ Medical conferences exhibits and symposia ✓ Specialty sales force ✓ Speakers bureau ✓ Peer reviewed publications ✓ Practice Guidelines	✓ Increase awareness to increase LDCT uptake ✓ Patient friendly test report ✓ Patient assistance program	✓ Aim for highest level of evidence in clinical trials ✓ Contracting strategy aligned to value added pricing ✓ RWE Clinical utility studies ✓ CMS 1st Coverage focus

OncoCyte™

Sales strategy focused on targeted physician specialties

Small specialty sales force ramps-up in 2H 2017, additional hires as coverage is gained



OncoCyte™

Physician marketing focused on medical conferences and speakers bureau

CHEST Annual (International) Conference

October 28–November 1, 2017 in Toronto, ON, Canada

- Formal presence focused on market development including exhibit booth, educational seminars

OncoCyte Speaker's Bureau

2H2017 and 2018

- 6–8 National, regional key opinion leaders
- Peer-to-peer exchange sharing diagnostic clinical experience

American Thoracic Society International Conference

May 18–23, 2018 in San Diego, CA

- Formal presence focused on market development including exhibit booth, educational seminars

Patient marketing focused on increasing screening awareness and compliance

Patient Assistance Program

- To offset out-of-pocket expenses related to test

Screening Awareness and Education

- Syndicated, educational video airing during Lung Cancer Awareness Month (November)
- Collaboration with advocacy group(s) on a screening awareness campaign

Advocacy Group Conferences

- Participation in advocacy group research and educational conferences

Reimbursement strategy has three key components

Coding

- MAAA Ensured status allows value based pricing
- Pursue ADLT status
- Launch with unlisted code
- Obtain unique CPT code when CMS coverage is gained

Coverage

- MolDx has clear pathway to coverage
- Develop and implement a strong evidence and publication plan
- Clearly demonstrate analytical and clinical validation, clinical utility, and cost savings to healthcare systems
- Obtain CMS coverage 2 – 3 years after launch

Reimbursement

- List price at launch
- CMS Price set post-launch based on weighted average of commercial plans
- Pursue private payer strategy that leverages PAMA pricing guidelines
- Optimize rather than maximize in-network providers

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Successful trials should result in reimbursement

- Strong clinical validation and utility studies key to coverage
- OncoCyte's strategy is to provide the highest level (IA) of evidence
- Previewed study designs with payers
  - 10 Public/commercial payers
  - 77M Covered lives
  - Positively received
- Favorable recent Coverage with Data Development decisions
  - Preliminary Medicare coverage

MolDx Coverage Pathway

Coverage Probability

MolDx Level of Evidence	Clinical Trial Design Principal Study	Clinical Trial Design Secondary Study
Highest IA	Randomized, Prospective (PCT)	Randomized Prospective or Retrospective (PCT, PRT)
IB	PCT`	Prospective Observational Studies (POS) or Retrospective Data Modeling (RDM)
IIA	PRT	POS or RDM
IIB (minimum requirement)	POS	POS or RDM

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Focused reimbursement strategy supports value-based pricing

MAAA Creates value-based price

- OncoCyte test is MAAA
- Full list price for the first six months of Medicare coverage

Optimize contracting strategy

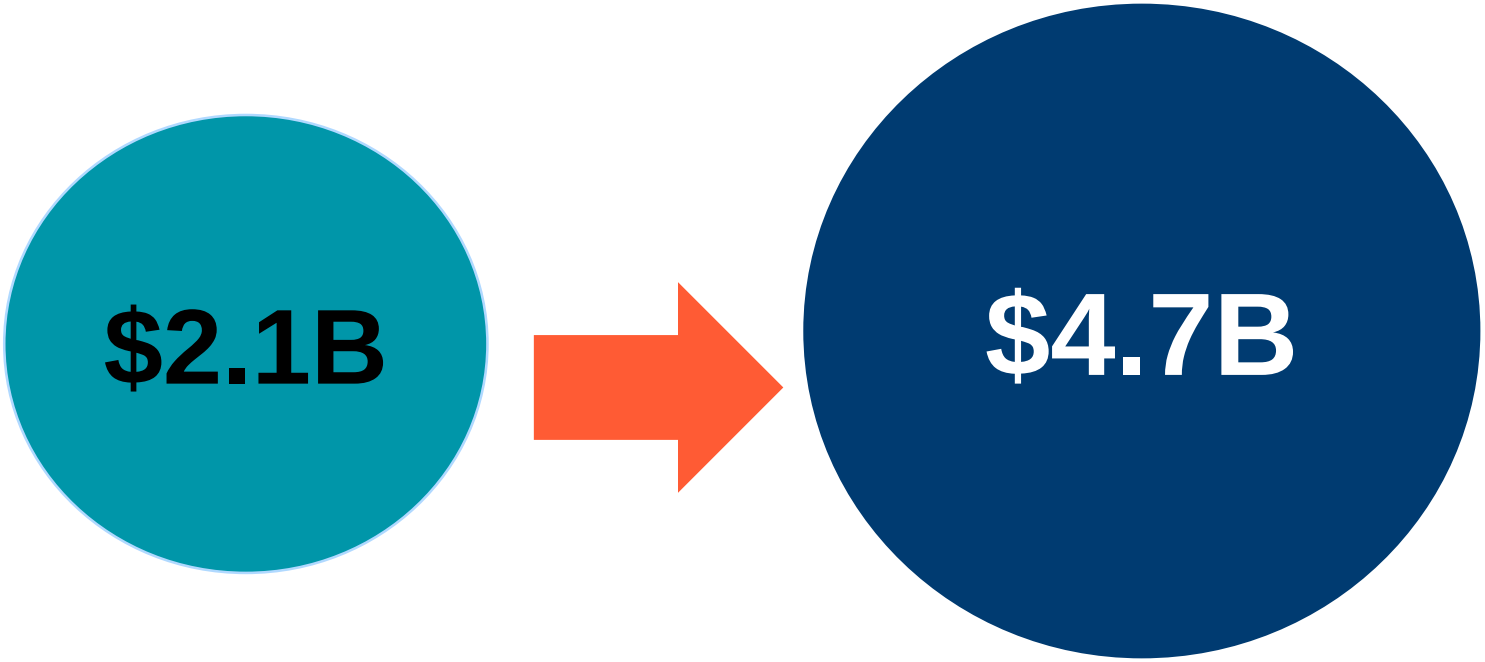
- Private payer contracting strategy maintains value-based pricing
- Patient assistance program reduces out-of-pocket

PAMA Maintains value-based pricing

- Medicare price based on weighted commercial median
- Reviewed every 12–36 months

OncoCyte™

One of largest US Market opportunities



Initial Use

400,000–600,000 Patients

Expanded Use

1.4 Million Patients

Company estimates based on LungRADS guidelines and NLST data, list price comparable to existing molecular diagnostics with algorithm Percepta list price $4,875, Affirma CMS reimbursement $3,100.

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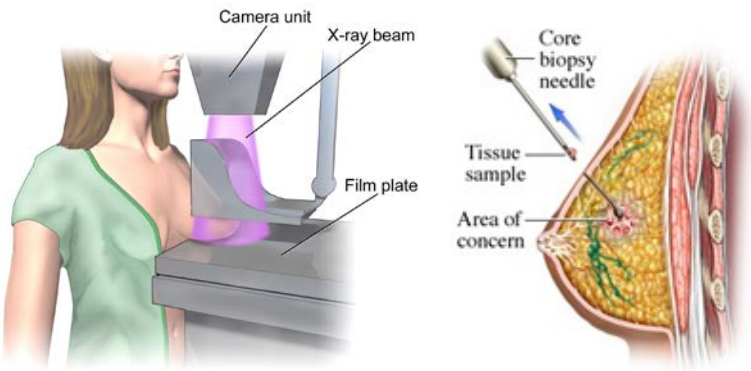
Current standard of care is not meeting the needs of many women

- High-number of unnecessary biopsies
  - ~1.7M Biopsies performed annually
  - ~$2.8B Annual cost associated with false-positive mammograms



Mammogram

- Mammograms perform poorly for one out of every six women resulting in follow-up MRIs
  - Dense breast tissue
  - Family history
  - BRCA Mutation positive
    - "Angelina Jolie" effect prophylactic mastectomies

WOMEN'S HEALTH

False alarm mammograms affect women for years

By Karen Rowan · Publish

REUTERS

HEALTH

Thu Feb 9, 2017 | 2:18 PM EST

False alarms delay future mammograms, linked to later diagnosis

By Gene Emery

(Reuters Health) - Women who are told that their suspicious mammogram was a false alarm are more likely to delay their next scheduled mammogram, or possibly not show up for their next screening at all.

The finding, in a study of 261,767 Chicago-area women in the journal Cancer Epidemiology, Biomarkers and Prevention, highlights an unintended consequence of such false alarms, known as false positives.

In cases where a mammogram was recommended every year, women who had an unfounded scare tended to delay their next test by an additional 13 months compared to a three- to six-month delay for women whose tests had come out negative.

That, in turn, can affect a woman's chances of survival if breast cancer is subsequently diagnosed.

A radiologist examines breast X-

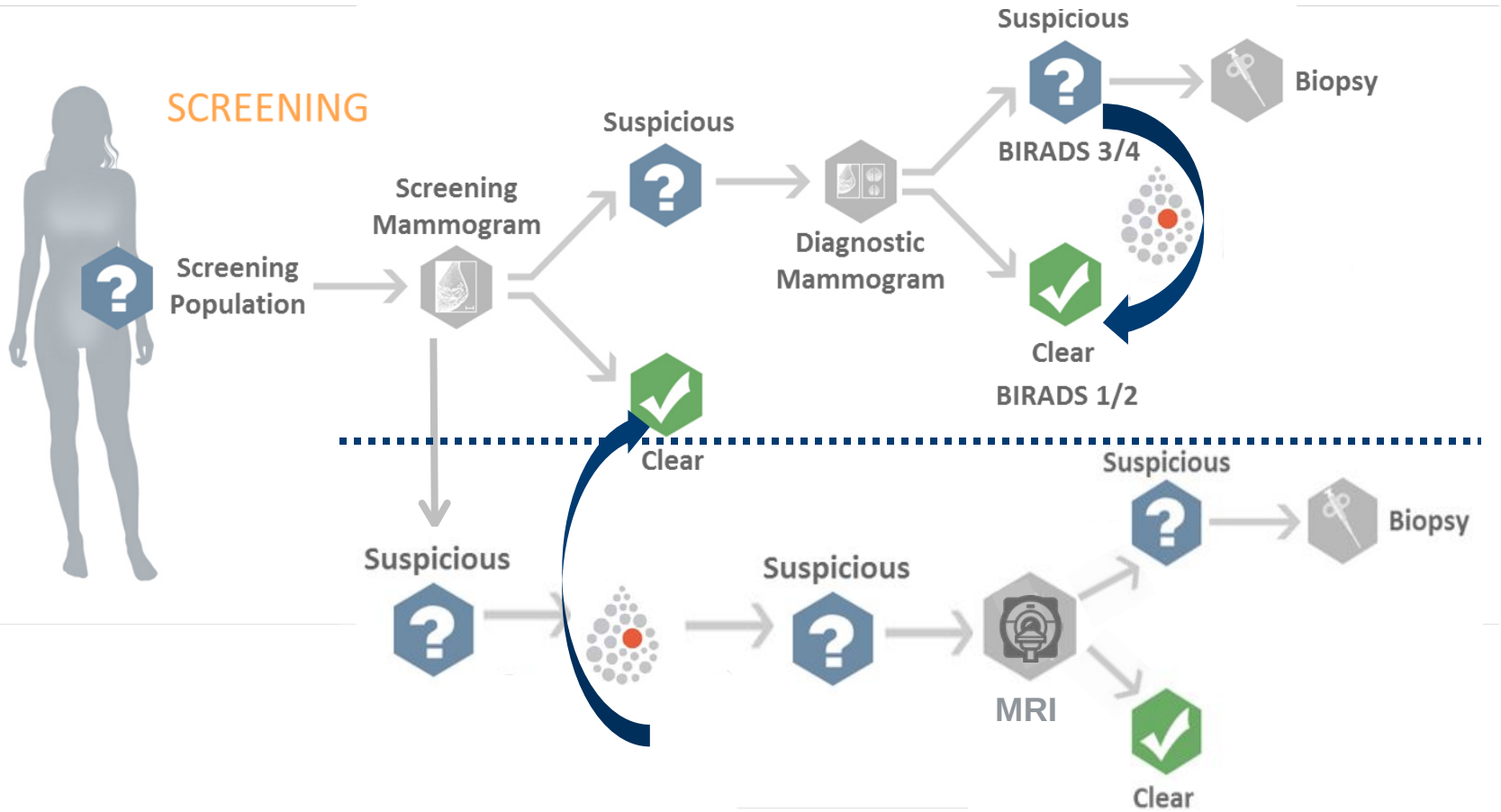
Women who receive ba
difficulties — regardless
cancer, a new study fro

Source: ACOG Guidelines; ACOG Committee Opinion March Number 625 (March 2015); Journal Health Affairs (April 2015).

OncoCyte™

Focused on eliminating unnecessary biopsies and MRIs

Intended Use Profile 1: CONFIRMATORY



Intended Use Profile 2: ADJUNCT for high-risk patients

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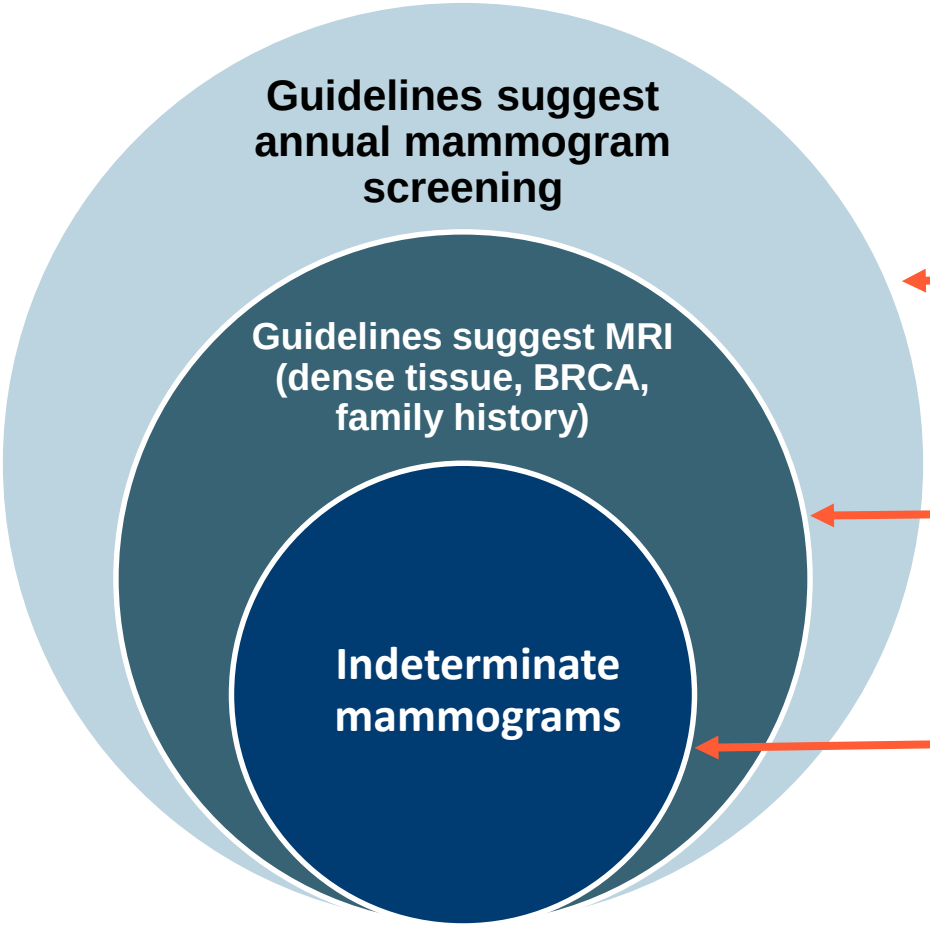
Large market opportunity for breast cancer diagnostic tests for specific patient profiles



Overall screening market
(39 Million Patients in 2016)

Supplemental screening test
(6 Million Patients)
and/or
Confirmatory test
(1.6–1.9 Million BI-RADS 3-4)

TAM Numbers based on company estimates and secondary data.

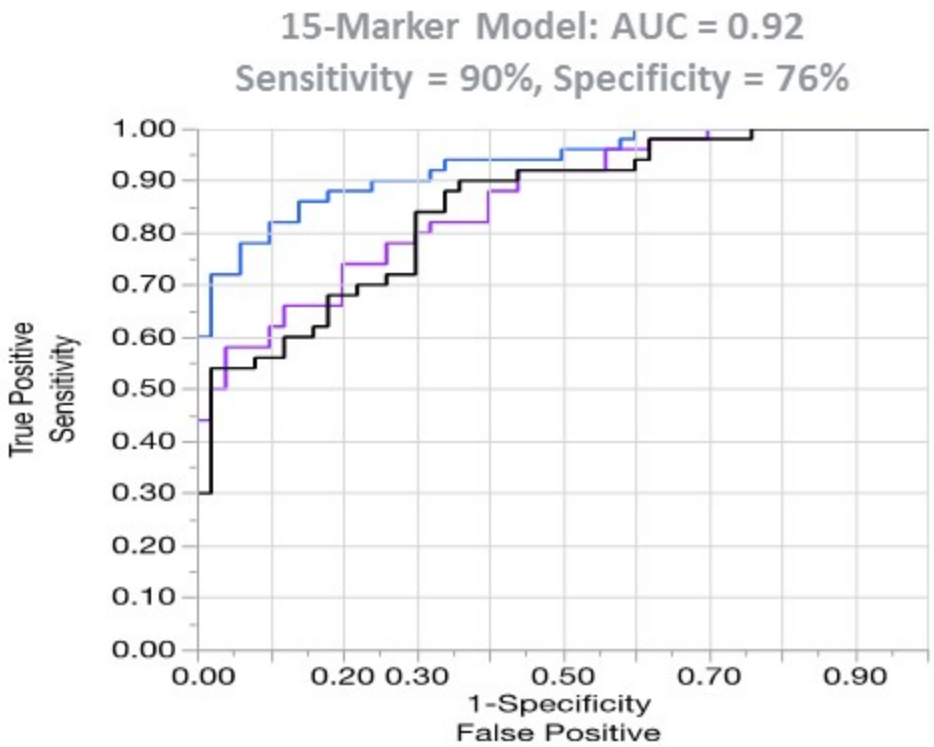
OncoCyte™

Compelling proof of concept presented at 2016 San Antonio Breast Cancer Symposium

Serum Biomarker Assay Research

Serum Samples → SomaScan 1.3K → Biomarker Identification

- Serum Samples: Patients undergoing biopsy
- SomaScan 1.3K: Screen 1,310 protein analytes in multiplexed format
- Biomarker Identification: Analysis and algorithm development



- Serum samples from 100 women with suspicious imaging results
- Pathology confirmed benign (50) and malignant (50)
- Malignancy detected in Stages I and II at 90% sensitivity, 76% specificity
- Proof of concept for non-invasive blood test which could help to avoid unnecessary biopsies
- OncoCyte is undertaking 300 patient study to confirm initial results

OncoCyte™

Management team with commercial experience

	Position	Experience
William Annett	President & CEO	CEO BioFx Labs; CEO Corra Life Sciences; Managing Director Accenture Life Science; Led Commercial Strategy, Project Finance Genentech; Harvard MBA
Lyssa Friedman	VP Clinical and Regulatory Affairs	Veracyte VP Clinical Operations; Telomere Diagnostics, VP Clinical Development; Carmenta Biosciences; McKesson Oncology Network; Oncology RN
William Haack	VP Market Access	VP Business Operations Invitae; VP EMEA, VP Global Operations and US Market Access Genomic Health; Sales Operations Genentech
Lyndal Hesterberg	SVP Research and Development	CEO BaroFold; Carmenta Biosciences; CTO Crescendo Biosciences; EVP Thermo BioStar; Senior Director SomaLogic. PhD University of St Louis
Kristine Mechem	VP Marketing and Planning	Business Analytics Abbott Labs; Market Planning Genentech; Managed Care Consulting; VP Marketing and Business Development Corra Life Sciences; PhD University of Chicago
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;

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Advancing cancer diagnosis

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