

# **Advancing Cancer Diagnosis**

Improving patient outcomes while lowering health care costs

September 2018 NYSE AMERICAN: OCX

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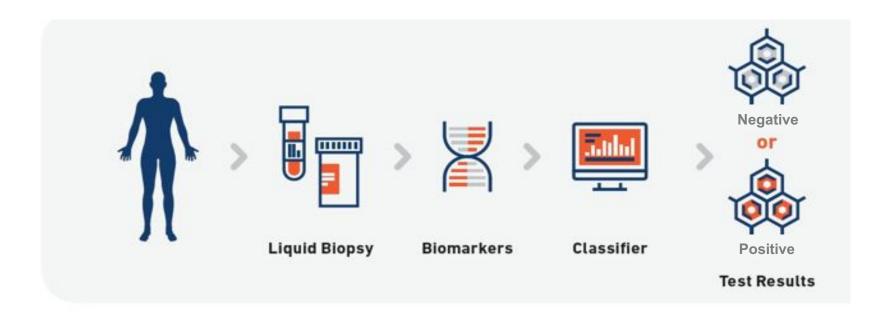
## **Investment Highlights**

- Oncology diagnostics company targeting lung cancer highest mortality rate
- DetermaVu<sup>™</sup> lung test can reduce the number of expensive, risky, unnecessary biopsies, saving lives while lowering costs
- Compelling value proposition for physicians, patients, and payers
- Very large Total Addressable Market with high margin potential
- Rapid pathway to key results (Q4 2018) and commercialization (2H 2019)



# Advancing the Standard of Cancer Diagnosis

## IP Protected gene expression classifier with binary call

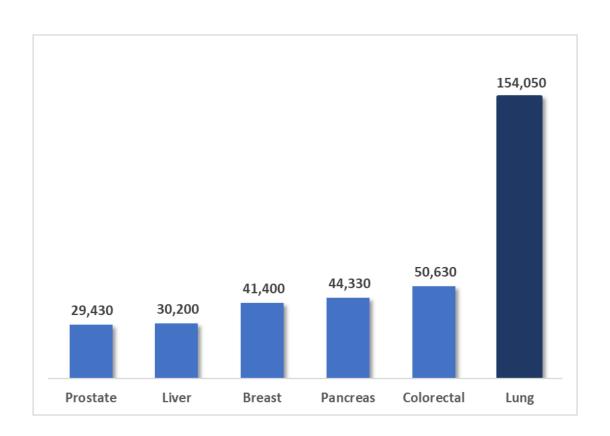




# Lung Cancer: Highest Mortality Rate

**234,030**New diagnoses

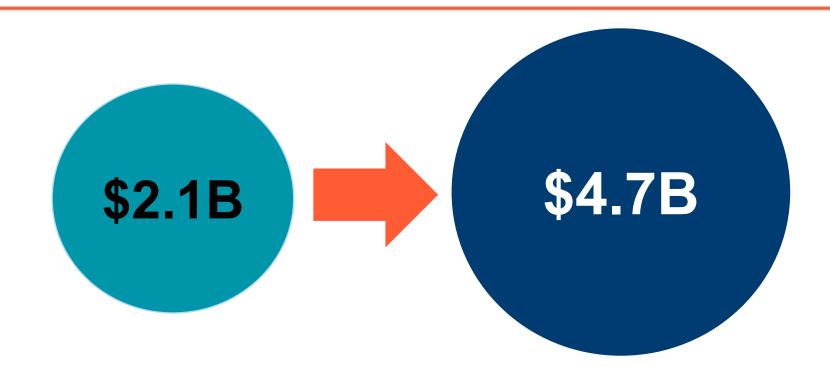
154,050
Deaths



**Annual Cancer Deaths** 



## Lung is One of Largest US Market Opportunities



## **Initial use**

400,000–600,000 Patients with large nodules

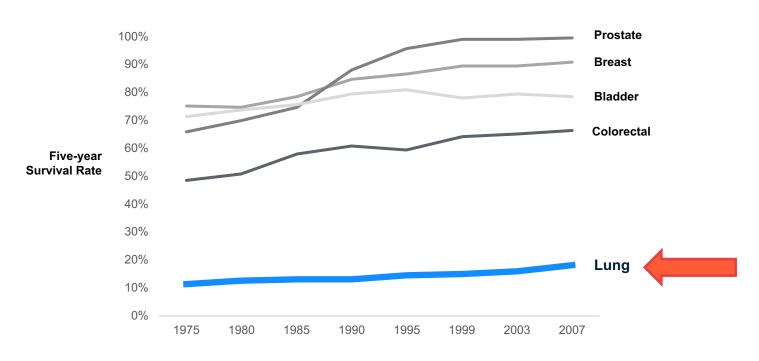
## **Expanded use**

1.4 Million Patients with medium to large nodules



# Detecting Lung Cancer Early is Critical

# Lung cancer is typically diagnosed in Stage IV, resulting in grim 5-year survival



But detection in Stage I gives 5-year survival comparable to other major cancers

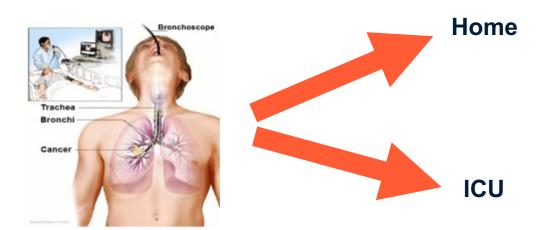


## **Lung Cancer Detection Process**



10 – 15M smokers should get annual Low Dose CT scans

If medium/large nodules are found, biopsy carried out





## Lung Biopsies are Risky and Expensive

- Lung biopsies are much riskier than other cancer biopsies
  - Up to 1% result in death
  - Up to 20% result in serious complications
- Mean U.S. cost is \$14,634 per biopsy
  - Average cost of a lung biopsy with complications is \$37,745

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



# DetermaVu™ is Designed to Reduce Biopsies

## Potential for\*:

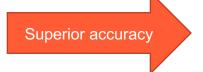
- 165,000 to 350,000 fewer procedures
- 25,000 to 55,000 fewer hospitalizations
- 2,000 to 5,000 lives saved
- Over \$4B annual U.S. cost savings



# Test Accuracy Exceeds Physician Requirements

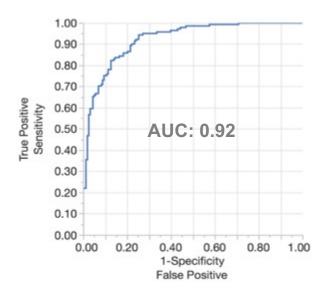
### Physicians require

>85% Sensitivity >35% Specificity



### DetermaVu

95% Sensitivity 73% Specificity

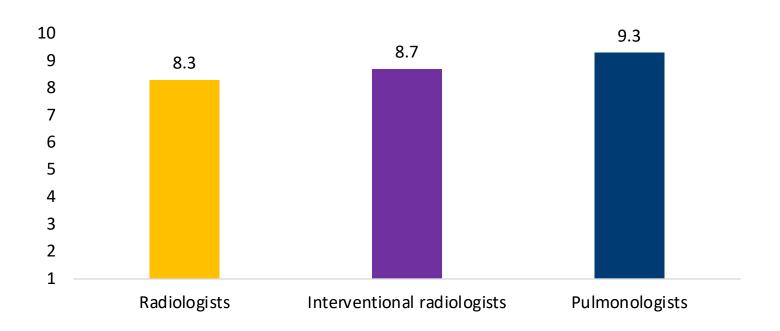




This data from Vachani, A et al. American Thoracic Society and CHEST 2017, 299 patient clinical study Performance on new assay and algorithm not available until completion of R&D Validation study



# Strong Physician Interest in DetermaVu™



## Reasons physicians rated DetermaVu™ highly:

- Useful for smaller nodules with high-risk factors
- Provides additional accuracy and benefit
- Avoids unnecessary biopsies
- Non-invasive blood test
- Provides clinical utility



## Near-Term Milestones to Commercialization



## **Key milestones:**

- Critical data Q4 2018
- Commercialization in 2H 2019



## R&D Validation Data in Q4

- Study results should be indicative of final test performance
- Physicians require a minimum of 35% specificity with 85% sensitivity (market survey)
- > At 65% specificity, annual potential for:
  - 165,000 to 350,000 fewer procedures
  - 25,000 to 55,000 fewer hospitalizations
  - 2,000 to 5,000 lives saved
  - Over \$4B annual U.S. cost savings
- R&D Validation will give specificity findings accurate to about +/- 8%



## Capital-Efficient Commercialization Plan

- Capital on hand is sufficient to reach commercialization
- Efficient and focused sales and marketing plan
  - Low number of chest physicians, can be covered with a small specialty sales force
- Targeting both high gross margin and high net margin



# Commercialization Strategy Addresses All Key Stakeholders



- Determinate diagnosis
- High accuracy
- Reduce unnecessary biopsies



- Earlier diagnosis
- Improved outcomes
- Reduce

   anxiety over
   indeterminate
   findings



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



**Benefits** 

# Payers View DetermaVu<sup>™</sup> Very Favorably

- Previewed intended use and clinical development plan with medical directors from 10 public and commercial payers
  - Included: Medicare, private Medicaid plans, United Healthcare, Aetna, Cigna, Anthem, and Humana
  - 77M covered lives
- All recognized the large unmet medical need addressed by DetermaVu
- Expressed strong support for DetermaVu's clinical development plan, saying it was robust and addressed appropriate clinical endpoints
- Indicated high level of interest in giving DetermaVu a positive coverage policy if it meets clinical endpoints of the planned studies



## Extensive Leadership Experience

#### Management

William Annett	President, Chief Executive Officer and Board Member	
Al Parker	Chief Operating Officer	
Mitch Levine	Chief Financial Officer	
Lyndal Hesterberg, PhD	SVP, Research and Development	
William Haack	VP, Market Access and Business Operations	

#### **Board of Directors**

Cavan Redmond	Chairman
Ronnie Andrews, Jr.	Board member
Andy Arno	Board member
Andrew Last	Board member
Adi Mohanty	Board member
Alfred Kingsley	Board member





























# **Financial Summary**

Ticker / exchange	OCX (NYSE American)	
Recent close (8/28)	\$2.25	
Shares outstanding	40.7mn	
Market cap	~\$91mn	
52-week range	\$1.10-\$7.64	
Average daily trading volume	~100,000	
Cash*	\$10.3mn (6/30/18)	
*Cash excludes \$3.3mn (net) raised in July via registered direct equity offering led by management and the Board		
Covering research analysts	3*	

<sup>\*</sup> Benchmark (Bruce D. Jackson), Chardan Capital Markets (Keay Nakae, CFA), Janney Capital Markets (Paul Knight, CFA)



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# **Advancing Cancer Diagnosis**

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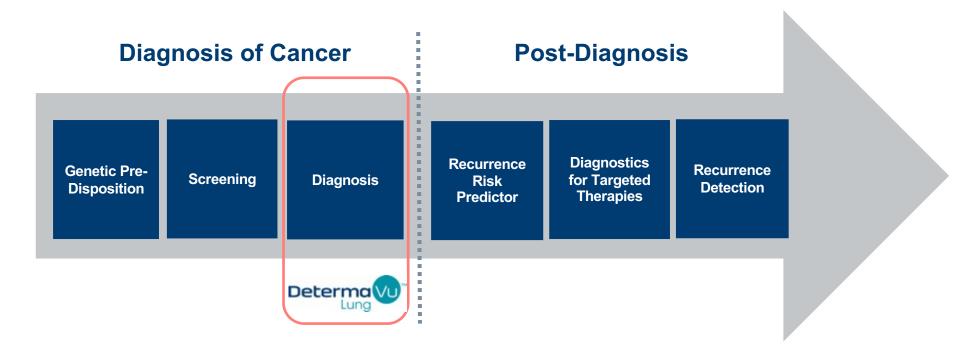




# **Appendix**

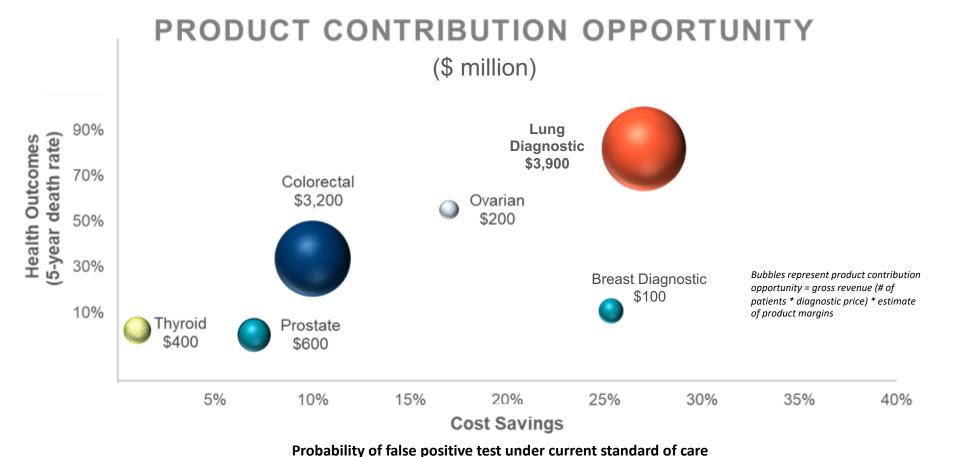


## Cancer Diagnostic Continuum





## Lung Cancer: the Largest Margin Opportunity

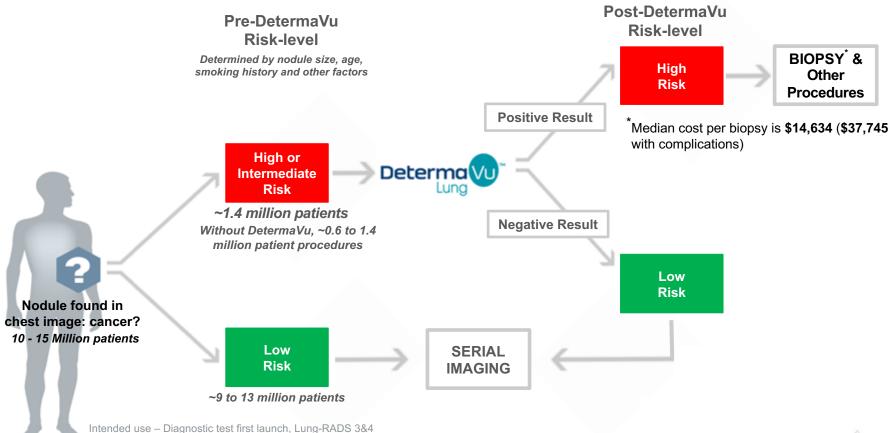


(leading to unnecessary and expensive follow-up procedures)



# DetermaVu<sup>™</sup> is Designed to Reduce Unnecessary Biopsies

- 165,000 to 350,000 fewer procedures
- 25,000 to 55,000 fewer hospitalizations
- 2,000 to 5,000 lives saved



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. Based on average cost of lung biopsy of \$15,000, compared to \$3,500 for lung assay.



## Validation Pathway for DetermaVu™



### **R&D Validation**

Confirms algorithm performance on a blinded sample set in an R&D setting

## **Analytical Validation**

Establishes the performance characteristics of the assay system to be validated in the CLIA laboratory

#### **CLIA Validation**

Confirms that the assay has been successfully transferred to the CLIA laboratory

### **Clinical Validation**

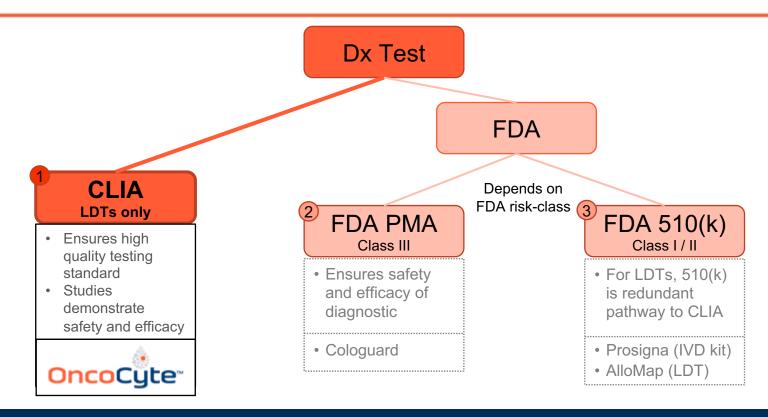
Establishes the product performance claims in an independent, blinded data set

## **Clinical Utility**

Demonstrates a net improvement in patient outcomes or similar outcomes at a lower price



## CLIA Regulatory Pathway in Place



- CLIA offers the quickest and least-risk path to commercial availability
- For our tests, FDA offers no commercial advantages, either for adoption or reimbursement
- OncoCyte's laboratory received CA CLIA certification August 2017



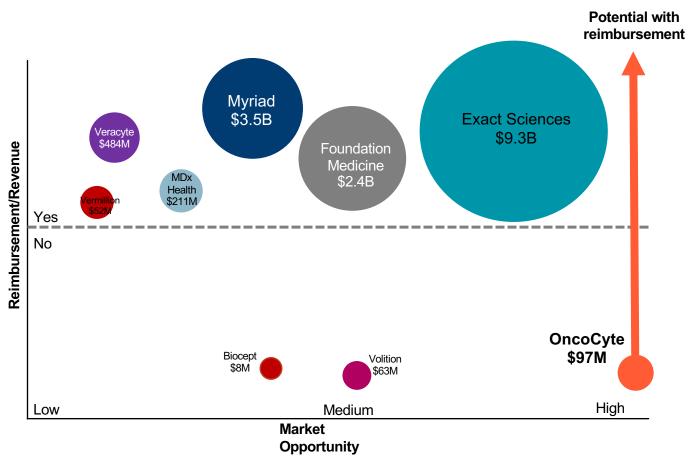
# Reimbursement is Driven by Strong Clinical Trial Results

- Strong clinical validation and utility studies are key to coverage
- Planning for a "gold standard" Clinical Utility Study randomized, prospective
- OncoCyte's strategy is to provide the highest level of evidence to increase probability of both Medicare and private payer coverage

Robust clinical trial evidence plan will drive payer reimbursement



# Valuation Driven by Market Opportunity and Reimbursement



Market capitalizations as of 8/30

