



# biodesix<sup>®</sup>

## Corporate Presentation

Biodesix is a blood-based lung diagnostic company addressing a large unmet need with limited competition

4Q24



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# Third Quarter 2024 Highlights

Estimated 5 million patients with lung nodules annually in the US

5 blood-based Lung Diagnostic Tests with Medicare coverage

Deep test discovery and development expertise

Total revenue grew 35% YoY



Strong gross margins at 77.0%

Reiterated FY24 Revenue Guidance of \$70-72M

Expecting Adj. EBITDA\* profitability in 2H25

# Two revenue growth drivers



## Lung Diagnostic Tests

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Focused on early diagnosis of lung cancer and personalized cancer treatment with best-in-class turn around times

## Biopharmaceutical and Diagnostic Services

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Biomarker discovery, assay design and development, clinical trial testing and support, companion diagnostic and IVD test development and commercialization for various tumor types and diseases



# Biodesix operates **two** certified, high-complexity laboratories



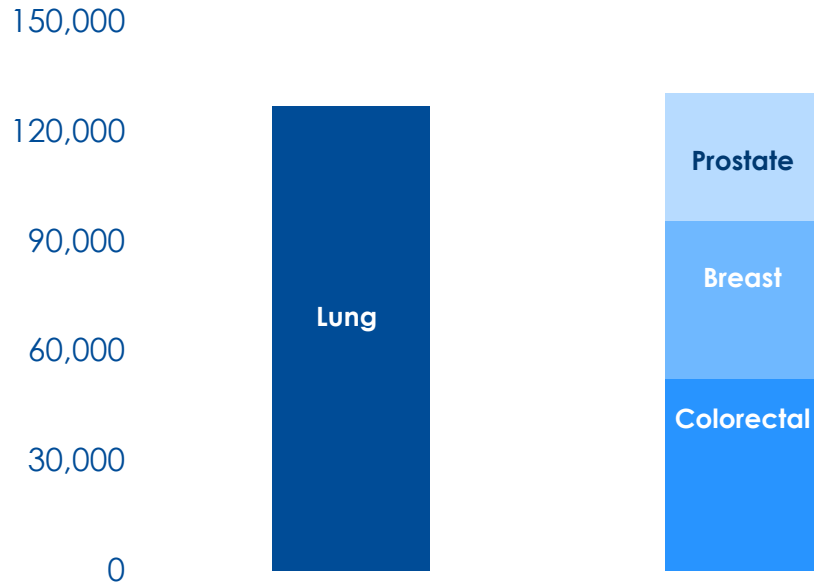
- ✓ **CLIA** certified to perform high-complexity testing
- ✓ **CAP** accredited
- ✓ **NYS CLEP** approved: Clinical Chemistry (limited to soluble tumor markers), Oncology - Molecular & Cellular Tumor Markers
- ✓ **ISO 13485** certified



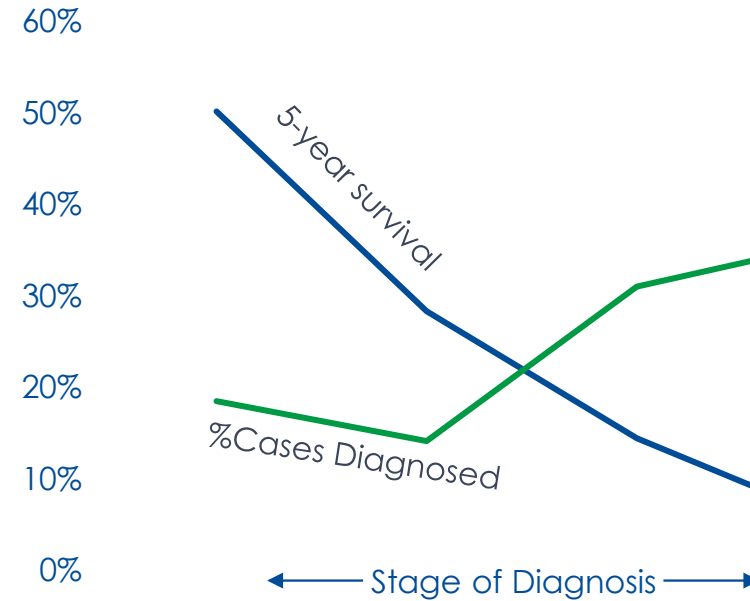
- ✓ **CLIA** certified to perform high-complexity testing
- ✓ **CAP** accredited
- ✓ **NYS CLEP** approved: Clinical Chemistry (limited to soluble tumor markers), Diagnostic Immunology – Diagnostic Services Serology
- ✓ **ISO 13485** certified

# Lung cancer is the **leading cause of cancer deaths**, but early detection saves lives

Lung cancer deaths versus colorectal, breast, and prostate combined<sup>1</sup>



Few patients are diagnosed early when survival is up to 10x greater



Only 5.8% of those eligible were screened

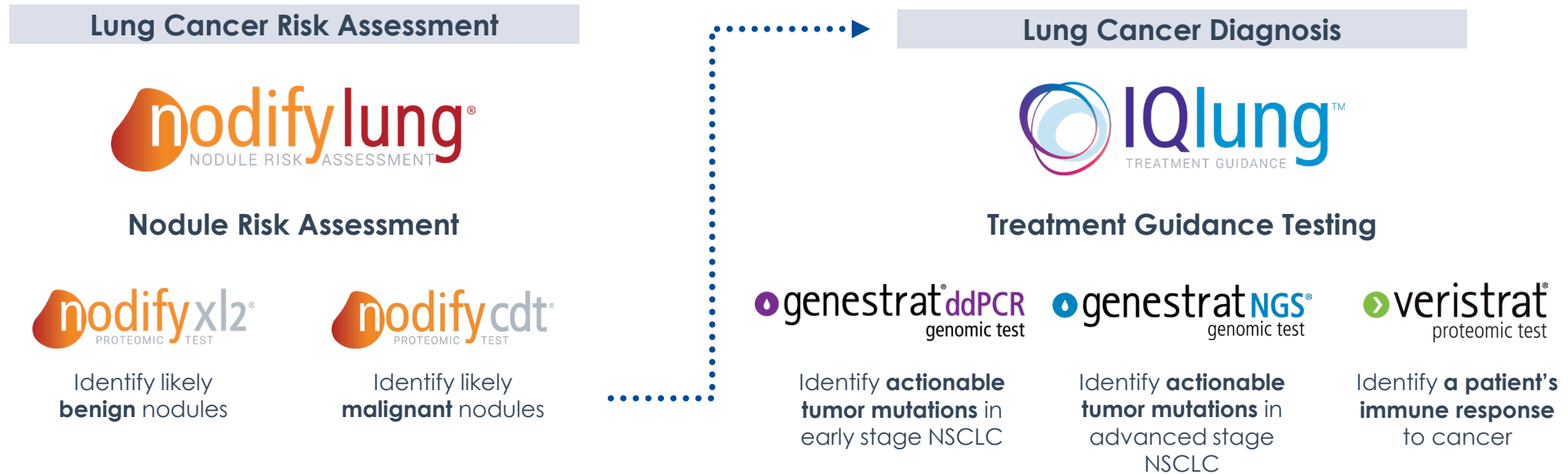
1 in 16 people will be diagnosed with lung cancer in their lifetime

5-year survival for metastatic cancer is only 6%

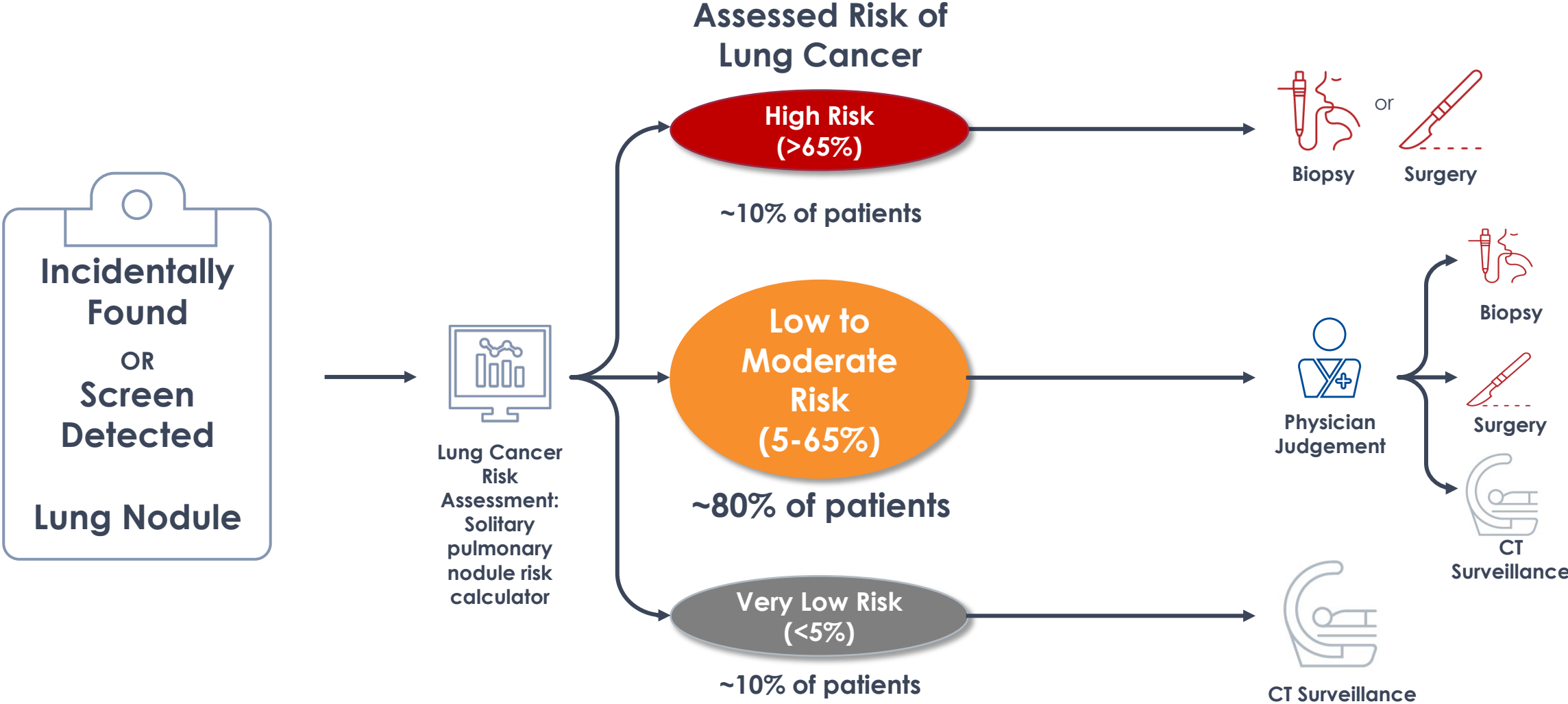
Deadliest of all cancers

# Five blood-based Medicare covered tests for the same patient population with best-in-class turnaround times

## **biodesix**<sup>®</sup> Lung Diagnostic Testing Portfolio



# Standard of care: **Guideline directed lung nodule management**<sup>1</sup>




<sup>1</sup>ACCP Guidelines: Evaluation of Individuals With Pulmonary Nodules – CHEST May 2013




# Standard lung cancer risk assessment has led to **over- and under-treatment of patients**

**62%** 

of patients receiving biopsy as the sole diagnostic procedure were benign<sup>1</sup>

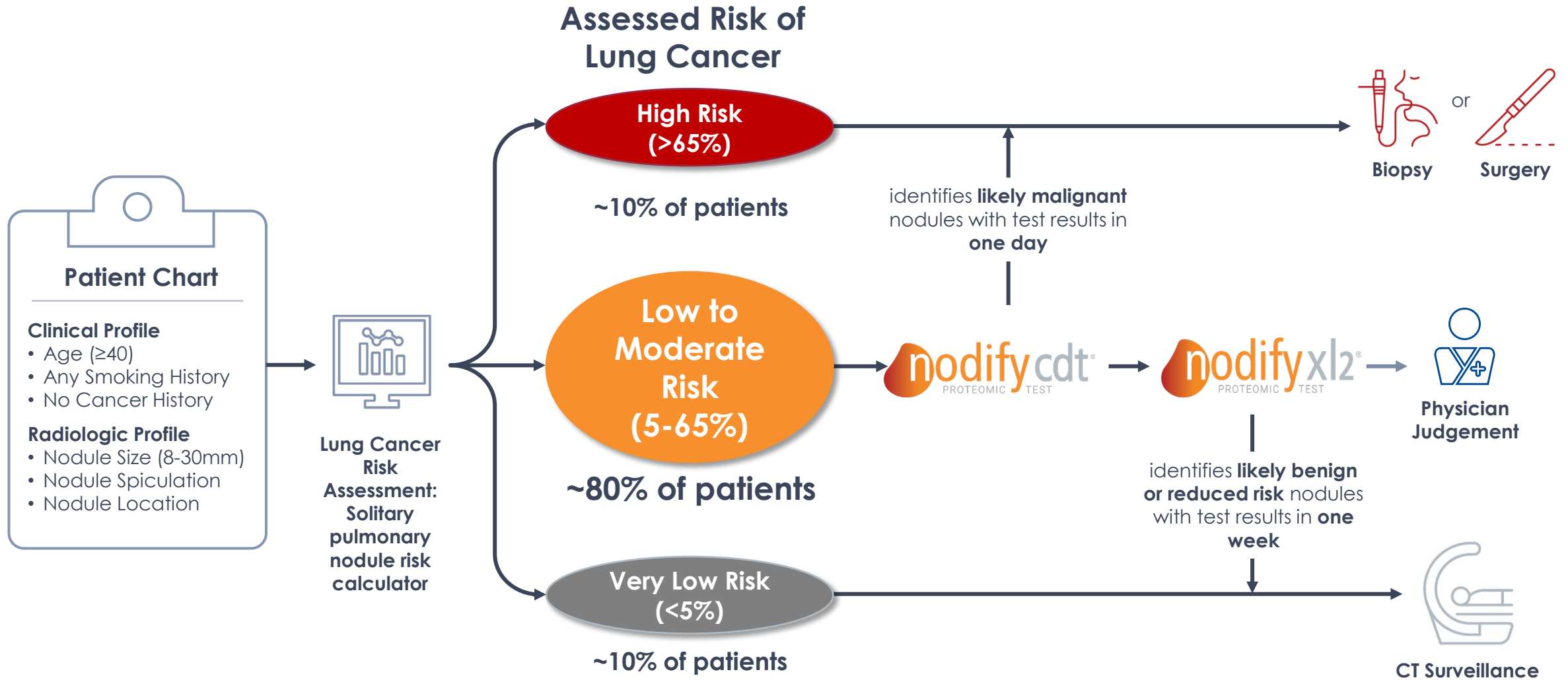
**35%** 

of patients who underwent surgery had benign nodules<sup>1</sup>

**17%** 

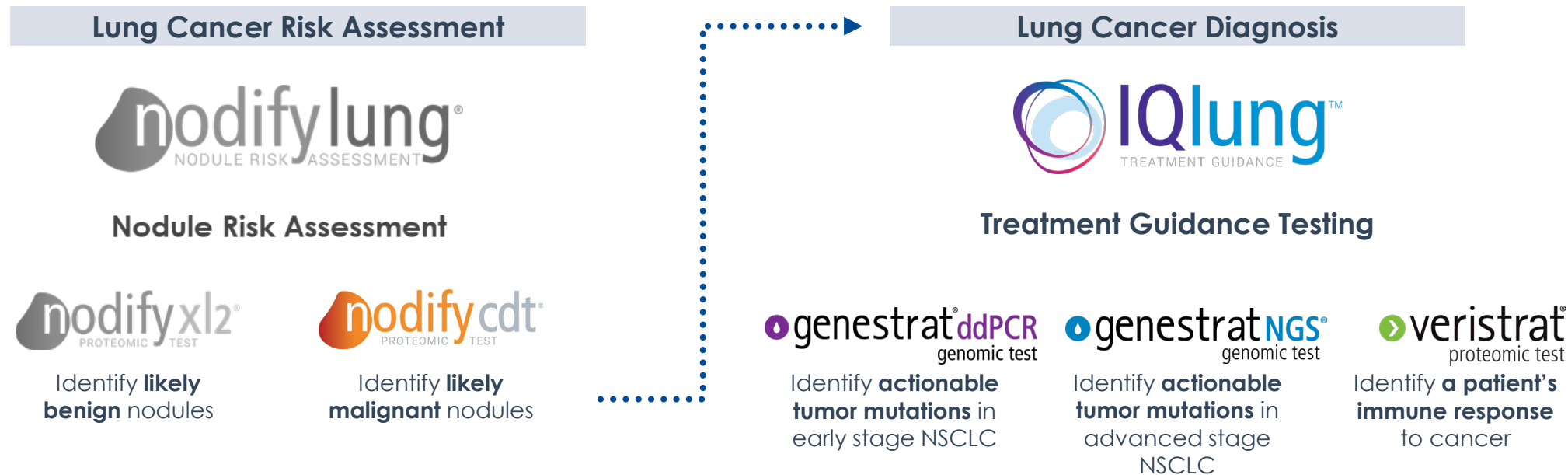
of patients sent to CT surveillance have malignant nodules<sup>2</sup>

# One blood draw, two tests to reclassify risk to help reduce uncertainty in lung nodule management



# Five Medicare covered tests for the same patient population with best-in-class turnaround times

## **biodesix**<sup>®</sup> Lung Diagnostic Testing Portfolio



# Testing helps guide the **right treatment to the right patient** as quickly as possible

~ **235k** 

patients diagnosed annually with NSCLC in the US<sup>1</sup>

**10.5 months** 

median overall survival of patients with advanced stage NSCLC<sup>2</sup>

**26 days** 

Length of time for turnaround for tissue testing<sup>3</sup>

*>60 treatments and combinations recommended by NCCN for patients with lung cancer<sup>4</sup>*

# Treatment guidance tests for all stages of lung cancer

## Early stage Lung Cancer

 **veristrat**  
proteomic test      Immune profiling test

 **genestrat** **ddPCR**  
genomic test

## Advanced, metastatic, or recurrent Lung Cancer

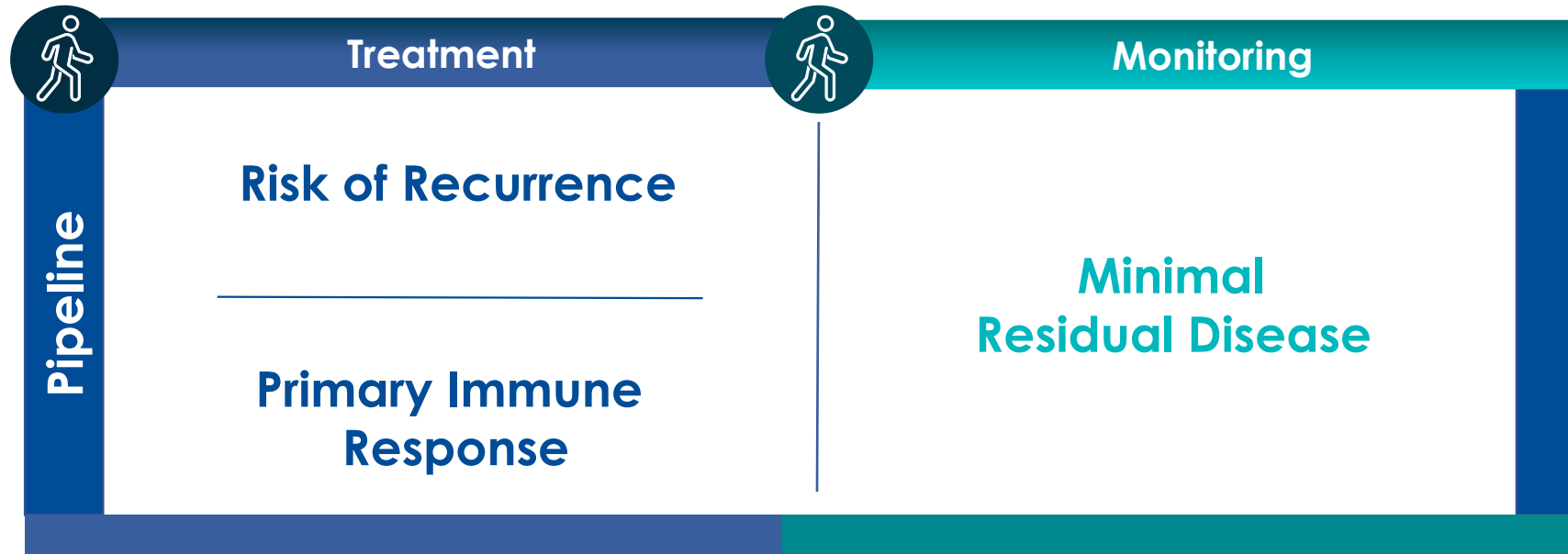
 **veristrat**  
proteomic test      Immune profiling test

 **genestrat** **NGS**  
genomic test      52-gene test

**Average turnaround time of 3 business days**



# Robust pipeline to address additional clinical needs for the same patient population



# Biopharmaceutical and Diagnostic Services partnerships

providing research, discovery, new test development, and clinical study testing

**\$11.1 M in Biopharma Services under contract but not yet recognized**

## Select Highlights

**Top Proteomics Company<sup>1</sup>**

Life Sciences Review

Developed  
**>30 custom tests**  
(Genomic and  
Proteomics)

**>20 New York State CLEP  
approvals**

## Research Partners

**ThermoFisher**  
SCIENTIFIC

**BIO-RAD**



Memorial Sloan Kettering  
Cancer Center

**STRECK**

## Biopharma Partnerships

**60+**

biopharma customers and  
academic partners

Partnerships with

**9 of the Top 12**  
largest pharma companies  
by 2023 revenue

Select publicly-disclosed biopharma customers

AstraZeneca

**GSK**

**Genentech**

**Pfizer**

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# Extensive knowledge and experience in diagnostics & reimbursement

**Scott Hutton**  
CEO



**Spectranetics**  
Always Reaching Farther  
**Medtronic**

**Robin Harper Cowie**  
CFO



**Precision Therapeutics**  
The Science of Biodesigning Cancer Therapy  
**UPMC**  
LIFE CHANGING MEDICINE

**Gary Pestano**  
CDO (PhD)




**Roche** **VENTANA**  
**HARVARD** **Dana-Farber**  
MEDICAL SCHOOL Cancer Institute

**Kieran O'Kane**  
CCO




**nanoString**  
**Eisai** **Bristol-Myers Squibb** **Roche**

**Chris Vazquez**  
CAO




**Sprint** **KPMG**

**Niki Givens**  
VP Clin Dev




**TERUMOBCT**  
Unlocking the Potential of Blood  
**CU**  
University of Colorado

**Mark DeBlock**  
VP Sales




**spiration**  
**HOLOGIC**

**Steven Springmeyer**  
CMO (MD)



**Indi** **SPRINT**  
Integrated Diagnostics, Inc. **SPRINT**

**James Jeff**  
CMO (MD)



**Oncimmune** **MAYO CLINIC**  
**UPMC** **UPMC**  
LIFE CHANGING MEDICINE

**Brianna Phillips**  
VP Qual & Reg



**Medtronic** **COVIDIEN**



# Thank you!





# Appendix





### Blood-Based Nodule Risk Assessment



Ordered together - Run in sequence



Identifies patients with lung nodules that are **likely malignant**



**Autoantibodies** on an **ELISA platform** from **blood**  
P53 | CAGE | NY-ESO-1 | GBU4-5 | MAGE A4 | SOX2 | HuD



**78% PPV, 98% specificity** & 28% sensitivity



**1 business day** turnaround time



**Medicare and new Private Payer coverage**  
with a unique CPT code & ADLT status (\$649)



Identifies patients with lung nodules that are **likely benign**



**Proteins** on an **LC-MS platform** from **blood**  
*Proteins:* LG3BP | C163A  
*Clinical Profile:* Age | Smoking History | Cancer History  
*Radiologic Profile:* Nodule Size | Location | Spiculation



**98% NPV, 97% sensitivity** & 44% specificity



**4-5 business days** turnaround time



**Medicare and new Private Payer coverage**  
with a unique CPT code & ADLT status (\$3,520)

**Two studies (ALTITUDE & CLARIFY) for combined lung nodule risk assessment and over 50 peer-reviewed publications, presentations & abstracts**

## Rapid Turn-Around Blood-Based Tumor & Immune Profiling

### **genestrat<sup>®</sup> ddPCR** genomic test



Identifies **blood-based, guideline recommended NSCLC** tumor mutations



BRAF, EGFR, KRAS, ALK



**91% sensitivity & 100% specificity**



**Average 2-3 business day** turnaround time



**Medicare and private payer coverage**  
Can be ordered multiple times per patient (~\$600 based on # genes ordered)

### **genestrat<sup>®</sup> NGS** genomic test



Identifies **blood-based, guideline recommended** tumor mutations



**52 genes** including somatic nucleotide variants, indels, copy number amplification and rearrangements



**95% sensitivity & 100% specificity**



**Average 2-3 business day** turnaround time



**Medicare and private payer coverage**  
One per patient per cancer per lifetime (\$2,919)

### **veristrat<sup>®</sup>** proteomic test



**Blood-based test** identifies a **chronic inflammatory disease state** associated with compromised immune system leading to poorer outcomes



**Proprietary proteomic signature** identified from **blood** by **MALDI-ToF Mass Spectrometry**



VeriStrat Good test result (**2x median overall survival**) vs. VeriStrat Poor test result



**Average 2-3 business day** turnaround time



**Medicare and private payer coverage** with a unique CPT code & ADLT status (\$2,871)

**5000 patients** enrolled in INSIGHT<sup>1</sup> prospective clinical utility study

# In-Office Blood Collection with Tasso+ Capillary Device



## Impact to Lung Nodule Patient Care

- Single-use blood lancing device intended for obtaining capillary whole blood samples from a patient's upper arm
- FDA Class II Lancet 510(k) cleared
- Improves patient access to Nodify Lung® testing in practices without convenient access to venous draw services
- Administered in minutes by any healthcare provider without need for venipuncture
- Virtually painless sample collection
- Improves care delivery by accelerating time to results and preventing patients from making a second trip to have blood drawn

“Oneida Health is a referral center serving patients in a wide geographical area. This device has allowed us to order Nodify Lung testing when patients are here for visits, ensuring that we get the critical information to inform the shared decision-making process quickly and accelerate the time to diagnosis.”

- Pedro Del Pino, MD, Oneida Health

# Intellectual property portfolio



**>100 issued patents**

US and foreign

## Patent Subject Matter:

- VeriStrat® and Nodify® tests and their uses in non-small cell lung and other diseases (e.g., breast cancer, prostate cancer, liver cancer, graft v. host disease)
- DeepMALDI mass spectrometry methods
- Classifier development using the Diagnostic Cortex® AI platform
- Pipeline tests using proteomic testing in immunotherapies
- Biodesix Blood Collection Device
- Proteomic drug-associated tests developed for our 3<sup>rd</sup> party partners



**25 unique registered and filed trademarks**

across 11 countries

## Exemplary Issued Marks:

- Biodesix
- Biodesix Lung Reflex
- VeriStrat
- GeneStrat
- DeepMALDI®
- Diagnostic Cortex
- ImmunoStrat
- Nodify
- Nodify Lung
- Nodify XL2
- Nodify CDT
- GeneStrat NGS

## Filed Marks:

- IQlung
- IQlung + Logo



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McKinsey  
&Company

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