

Oncimmune<sup>®</sup>



**Oncimmune**

Beating cancer, one test at a time

**Solebury Trout European  
Biotech Investor Day  
2019**



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A leader in the development and commercialisation of immunodiagnostics for the screening and detection of cancer.





## Company overview



- Proven autoantibody (AAb) derived cancer-detection methodology
- Simple blood tests transforming patient cancer care
  - Can detect cancer 4 years or more<sup>1,2</sup> before clinical diagnosis via standard care pathways
  - Helps guide critical clinical diagnostic and treatment decisions
  - ECLS trial reported positive top line results in June 2019. A phased population-based evaluation expected to deliver up to 200k commercial tests to commence later in 2019
- Leading immunodiagnostic cancer detection products
  - EarlyCDT® Lung
  - Over 155,000 commercial tests performed to date
  - Recent commercial distributor appointed in Russia for screening, key distributors in China and Europe
  - EarlyCDT® Liver

1 Zhong L, et al. Profiling tumour-associated antibodies for early detection of non-small cell lung cancer. J Thor Oncol 2006; 1:513-519.

2 Jett J, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. J Thor Oncol 2017; 12(11):S2170.



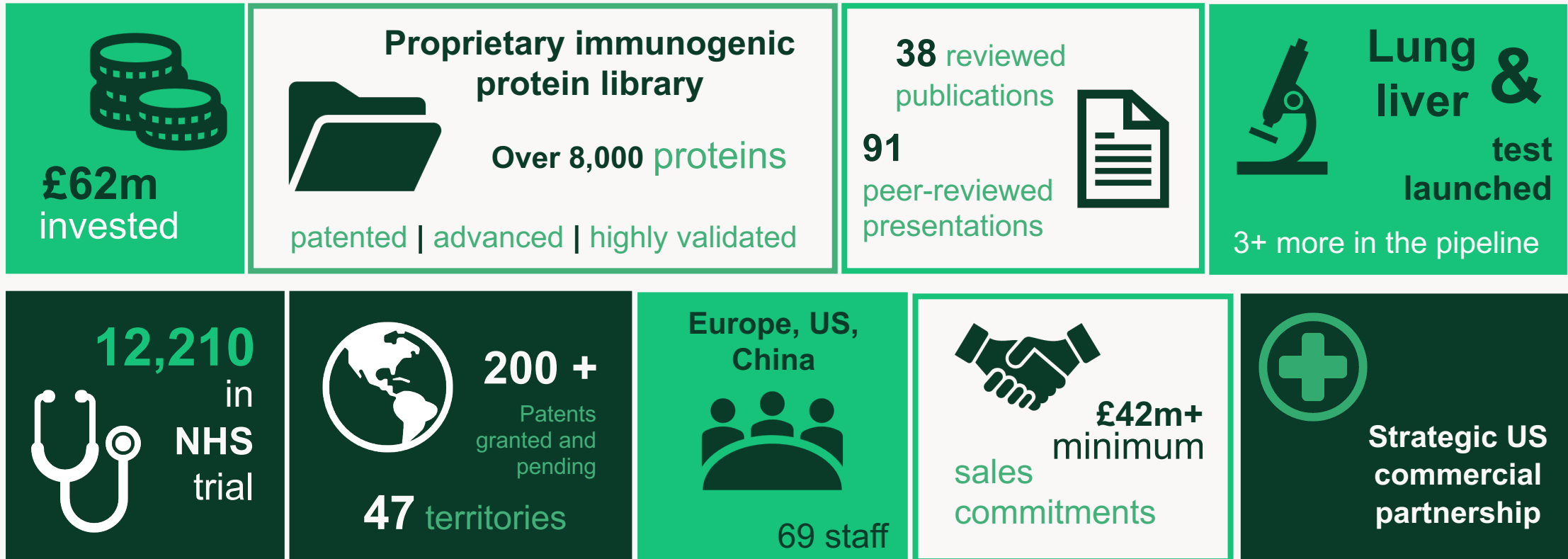
## Company overview

- Newly appointed management team that is already delivering on core strategic objectives
  - Maintaining focus on core business of developing and commercialising clinical tests for the early detection of single cancer types
  - Unlocking the existing technology platform through strategic partnerships and acquisitions
- Strategic partnership agreement with US-focused lung cancer specialist, Biodesix, Inc. for EarlyCDT Lung valued at up to \$28 million over next 5 years with product revenues, lump sum payments and direct cost savings
- Acquisition of Protagen Diagnostics AG (March 2019)
  - Established revenue-generating company with existing partnerships with leading pharmaceutical multinationals
  - Will accelerate Oncimmune's biomarker discovery process
  - Stratification tools will support drug development, improve treatment strategies and patient management
- Strong Intellectual Property (over 200 patents granted and pending patents)
- Regulatory progress: local regulatory approvals – CLIA laboratory, 510k De Novo<sup>3</sup>; CE marked kit in EU; CFDA application progressing
- Listed on London Stock Exchange AIM market (ONC:LN)
- Offices in London (UK); Nottingham (UK); Dortmund (Germany); Kansas City (USA); and a partner representative office in Shanghai (China)

<sup>3</sup> De Novo classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This process provides a pathway to Class I or Class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.



## Foundation for success





## Core scientific principle

Early cancer detection based on autoantibodies

- Autoantibodies produced early in tumour formation – can be detected years ahead of clinical diagnosis<sup>4,5</sup>
- Absent or low concentrations in healthy & benign groups
- Patients with lung cancer can mount an immune response with autoantibodies providing an early measurable signal

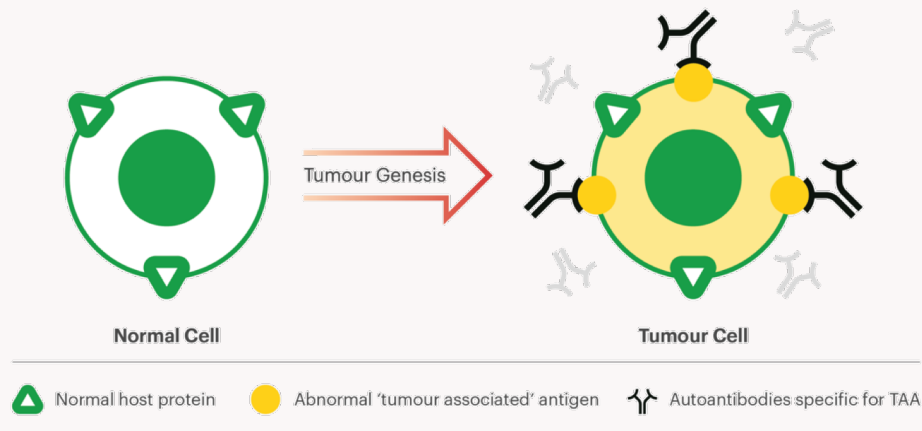
Proven cancer detection methodology

## Antibody capture technology

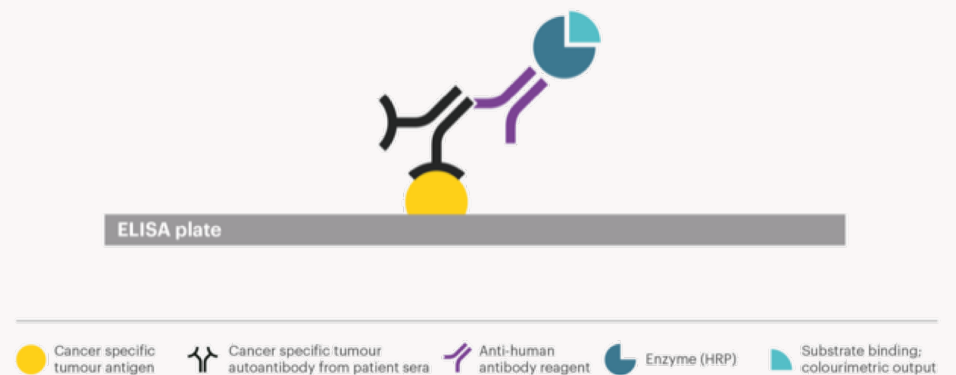
Proprietary immunogenic protein library

- Over 8,000 immunogenic proteins
- Enzyme-Linked ImmunoSorbent Assay (ELISA)
- Multi-analyte panels developed to cover disease heterogeneity
- Cut-offs established to return a positive result on single analyte

### Core Scientific Principle



### Oncimmune's Autoantibody ELISA



<sup>4</sup> Zhong L, et al. Profiling tumour-associated antibodies for early detection of non-small cell lung cancer. *J Thor Oncol* 2006; 1:513-519.

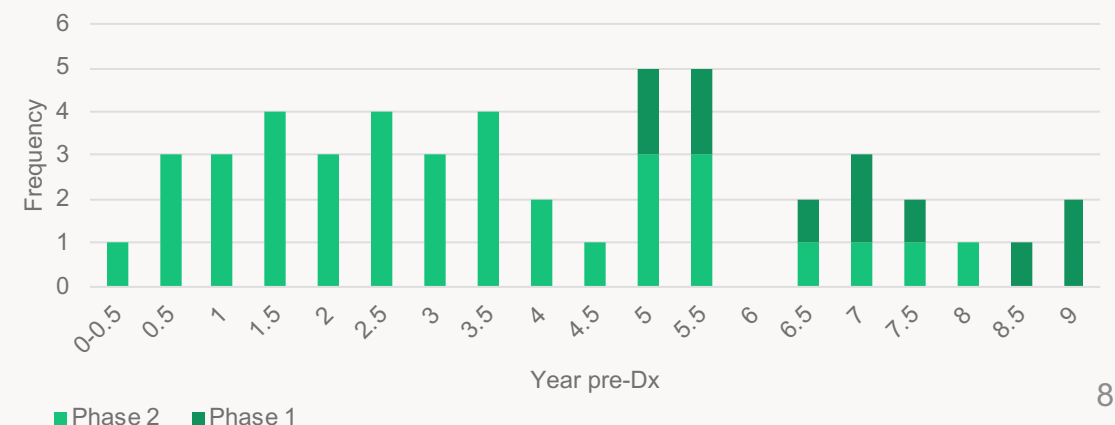
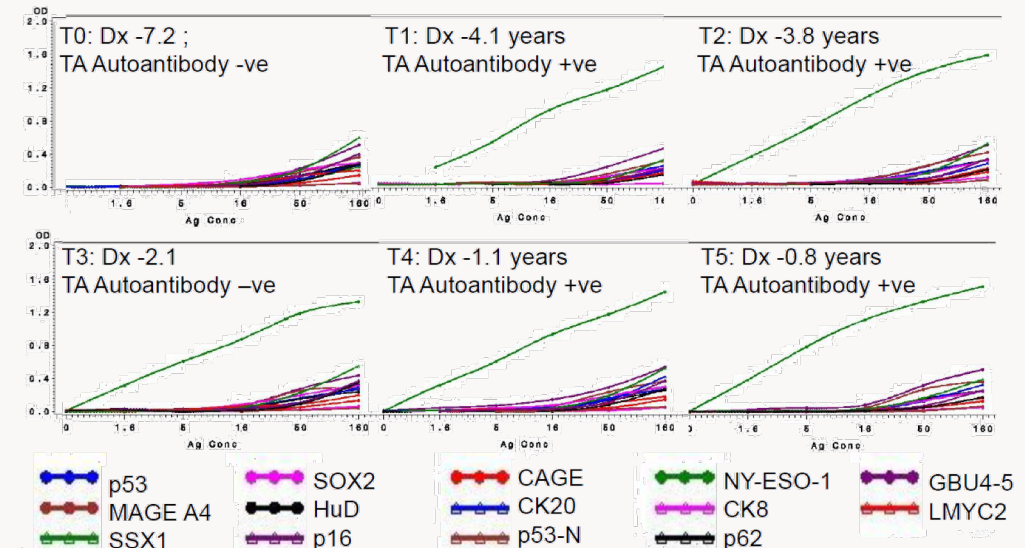
<sup>5</sup> Jett J, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. *J Thor Oncol* 2017; 12(11):S2170.



## EarlyCDT – scientifically proven earlier detection technology

Longitudinal study of autoantibody detection lead time

- 202,000 women followed for 14 years (UKCTOCS)
- 142 lung cancer cases with longitudinal sampling up to 10 years prior to diagnosis
- Median detection of lung cancer by EarlyCDT Lung 4 years before standard diagnosis



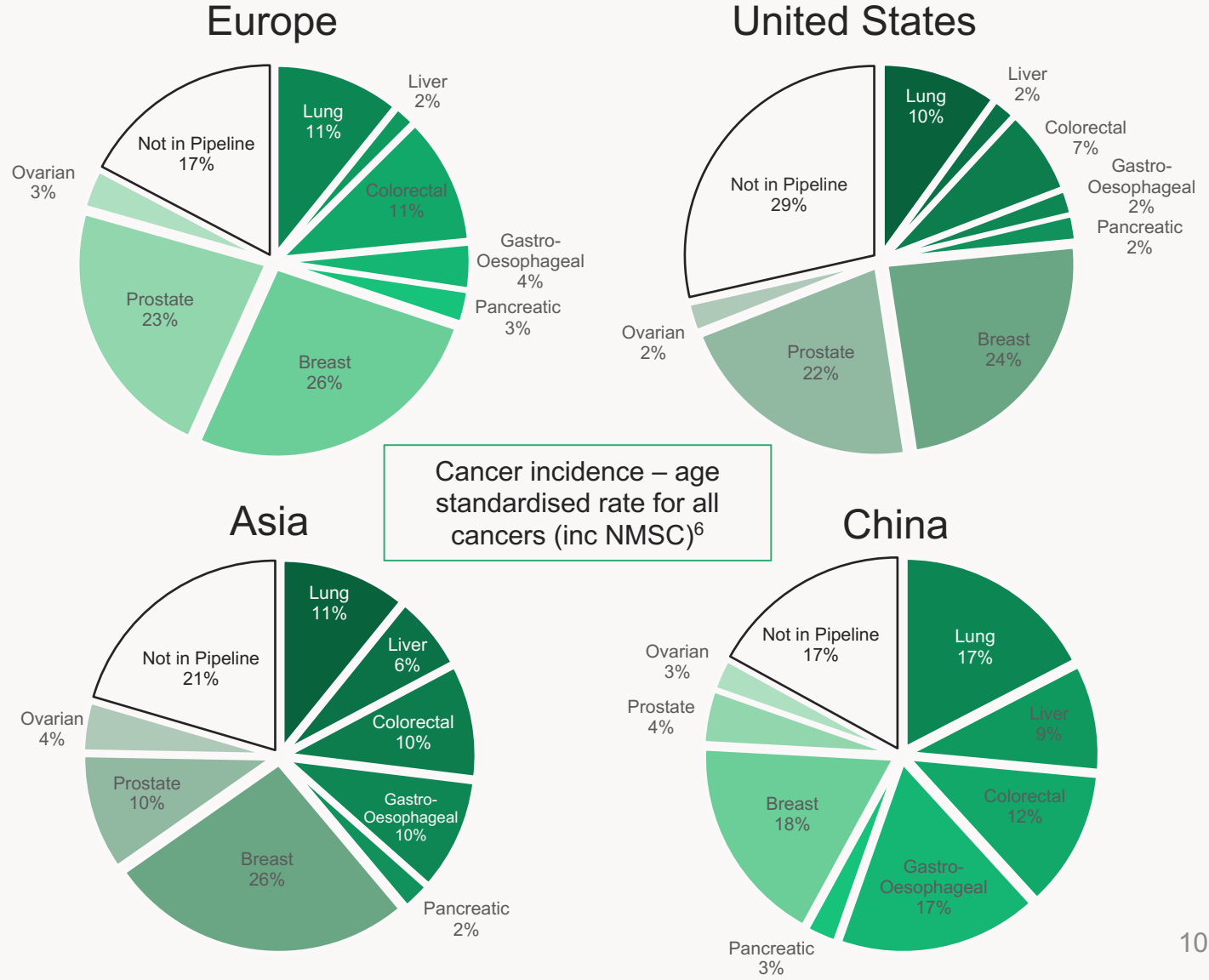


**Market overview &  
corporate strategy**



## Portfolio and pipeline designed to address many cancer types

2,100,000 lung  
&  
840,000 liver  
new cancer cases  
annually



<sup>6</sup> International Agency for Research on Cancer, WHO; The Global Cancer Observatory, Globocan 2018 <https://gco.iarc.fr/today/home>



## EarlyCDT clinical test portfolio & roadmap

	Preclinical exploratory	Clinical assay and validation	Retrospective longitudinal	Prospective screening	Cancer control <sup>7</sup>	
Commercialised clinical tests	Lung					Launched 2012 Commercial delivery – deepening market access
	Liver					Launched 2018 Initiating commercial delivery
Clinical tests in development	Ovarian		Sub-screening application launch			Performance validated
	Breast					Data generated
	Prostate					Data generated
	Colorectal					Proof of concept – panel discovery
	Gastro Oesophageal					Proof of concept – panel discovery
	Pancreatic					
				Screening application launch		



## Autoantibodies are advancing liquid biopsy early cancer detection

### Autoantibodies

Complementary approaches: sDNA, ctDNA, miRNA, CTC

Required blood volume	0.15mL	80 mL – (ctDNA) or Stool (sDNA)
Sample stability	Industry standard, processing and shipping	Special care needed (all)
Result turnaround	4hrs	7 day (ctDNA)
Required equipment	Kit test run on common lab equipment	Costly specialised equipment required (all)
Sensitivity as a standalone	>40%	92% (sDNA)
Specificity as a standalone	>90%	87% (sDNA)
Stage shift vs SOC	50% to stage I and II (lung)	No evidence of stage shift benefit (sDNA)
Proven cancer coverage	Applied commercially in lung and liver, method applicable in potentially all solid tumor types	Applied commercially in CRC



## Autoantibodies have the highest level of evidence in detection of lung cancer

Biomarkers for detection of lung cancer and validation stages<sup>8</sup>

		Phase #1 Preclinical exploratory	Phase #2 Clinical assay & validation	Phase #3 Retrospective longitudinal	Phase #4 Prospective screening	Phase #5 Cancer control
Serum/plasma	Autoantibodies	x	x	x	x	2019 to 2021
	MALDI TOF MS profiling	x	x	x		
	Specific antigens /proteins	x	x	ongoing		
	miRNA	x	x	ongoing		
	DNA methylation (blood)	x	x			
	ctDNA	x				
Tumour/ airway epithelium	Preinvasive histo/cytology	x	x	x		
	DNA methylation	x	x	x		
	RNA airway signature	x	x	ongoing	ongoing	
	MALDI MS profiling	x	x			
	Chromosome aberrations	x	x			
Sputum/ EBC	DNA methylation sputum	x	x	x		
	DNA CN -FISH	x	x			
	VOCs	x	x			



## EarlyCDT Lung performance



	Accuracy	PPV
EarlyCDT Lung (High)	97%	1 in 4
EarlyCDT Lung (High & Moderate)	92%	1 in 8
CT screening (annual)	73%	1 in 25
Mammography	89%	1 in 23
PSA	86%	1 in 18

- A simple blood test that requires <150µl of serum
- ELISA measurement of a panel of 7 autoantibodies associated with lung cancer:
  - p53, NY-ESO-1, CAGE, MAGE A4, GBU 4-5, SOX2, HuD
- Detects all types and stages of lung cancer
- LDT performed under CLIA regulations in USA
- CE marked kit distributed outside USA
- Billed to Medicare & private insurance plans in USA

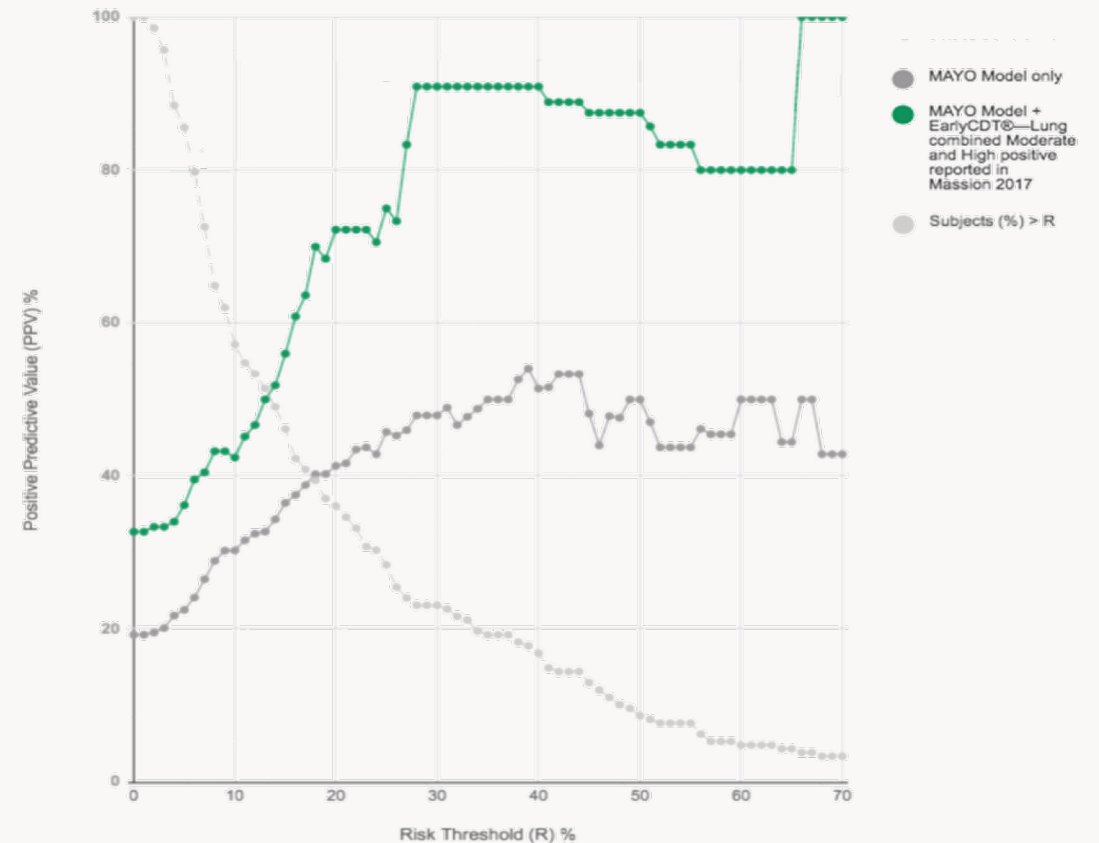
<sup>9</sup> Based on cancer/non-cancer positivity for the high positive stratum  
<sup>10</sup> After adjustment for occult cancers in the population



## EarlyCDT Lung vastly improves predictive risk of cancer

### Application one

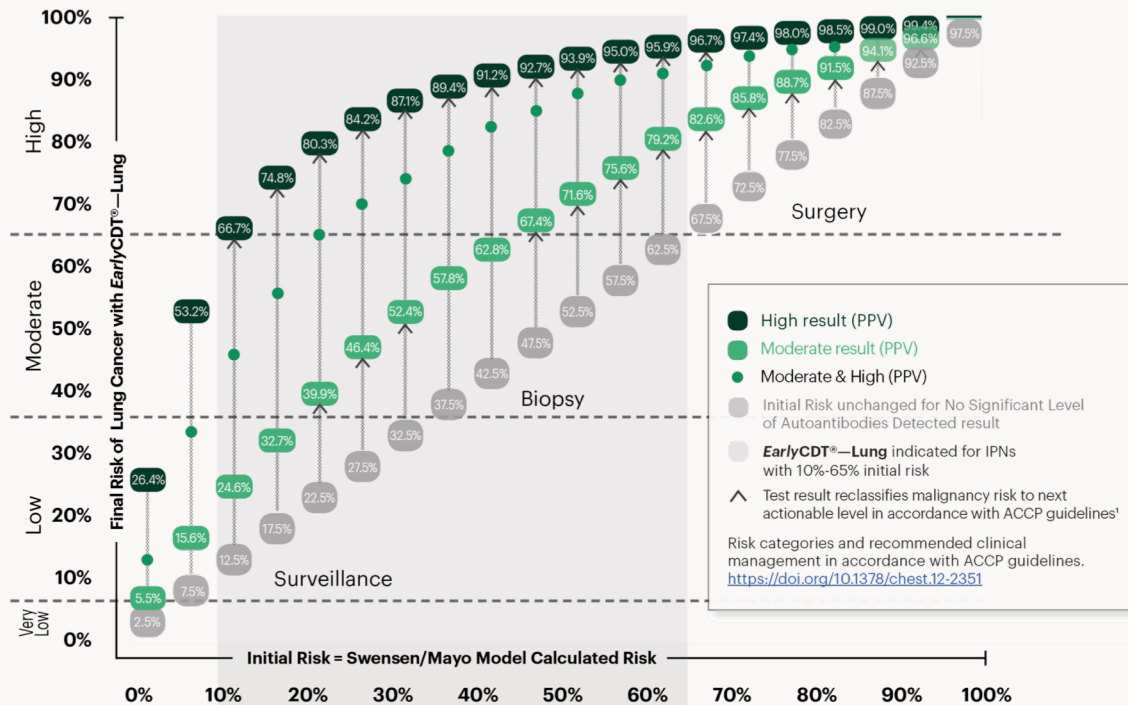
Improved diagnostic performance of MAYO CT risk model in combination with EarlyCDT Lung<sup>11</sup>





## Pulmonary nodule risk assessment with EarlyCDT Lung

**EarlyCDT®—Lung** Reclassifies Malignancy Risk  
in Nodules with 10%-65% Initial Risk



A nodule risk calculator combining the Swensen/Mayo model with **EarlyCDT®—Lung** is available at <http://oncimmune.com/nodule-calculator>  
1. Risk calculations: Healey GF, Macdonald IK, Reynolds C, et al. Tumor-Associated Autoantibodies: Re-Optimization of **EarlyCDT®—Lung** Diagnostic Performance and its Application to Indeterminate Pulmonary Nodules *J Cancer Ther.* 2017; 8:506-517.

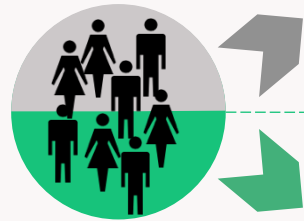
- “High level” result:
  - Shifts the risk of intermediate risk nodules up
  - Alters recommended course of action to intervention
- “Moderate level” result:
  - Adds more than 25% risk
  - Most patients will be moved to intervention



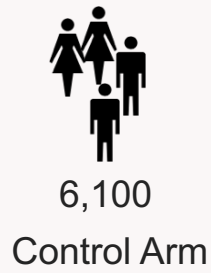
## ECLS<sup>12</sup> study in collaboration with NHS Scotland

### Application two

12,210 volunteers  
50-75 years  
20+ pack years



Glasgow



blood draw only

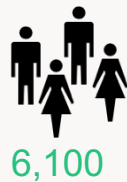


Standard of care (no screening)



Study Arm

blood draw and test run



+ *Early*CDT®—Lung



Positive result



CT scan every 6 months for 2 years

Negative result



Monitored by GP

- The ECLS study, conducted in Scotland with 12,210 patients, is believed to be the largest randomised controlled study using biomarkers for the detection of lung cancer
- It is estimated that 18.7% of the world's population will be smokers by 2028<sup>13</sup>; Scotland alone has over 800,000 smokers<sup>14</sup>
- We estimate early stage detection saves c.£40,000 in treatment costs per patient<sup>15</sup>

<sup>12</sup> ECLS: Early Cancer detection test – Lung cancer Scotland. Believed to be the largest

<sup>13</sup> Tobacco Free Initiative WHO; Global Report on trends in tobacco smoking 2000-2025 Trends, Second Edition

<sup>14</sup> Mid-year Population Estimates Scotland (Mid-2017); Fastfacts – Smoking in Scotland No.1 (published in October 2018 by Ash Scotland)

<sup>15</sup> NHS

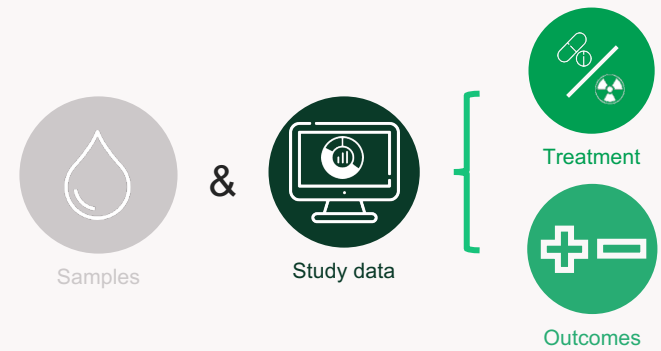


## ECLS – meets primary end-point

ECLS study primary endpoint: to assess the effectiveness of EarlyCDT Lung test in reducing incidence of patients with late-stage lung cancer at diagnosis, compared with standard clinical practice.

- A submission on the full ECLS study is being prepared for a leading peer-reviewed medical publication
- Preparations are underway for a phased evaluation in Scotland expected to recruit up to 200,000 patients each to be tested with EarlyCDT Lung to be supplied by Oncimmune on negotiated commercial terms

- Established partnership with NHS Scotland and study group – privileged access to:

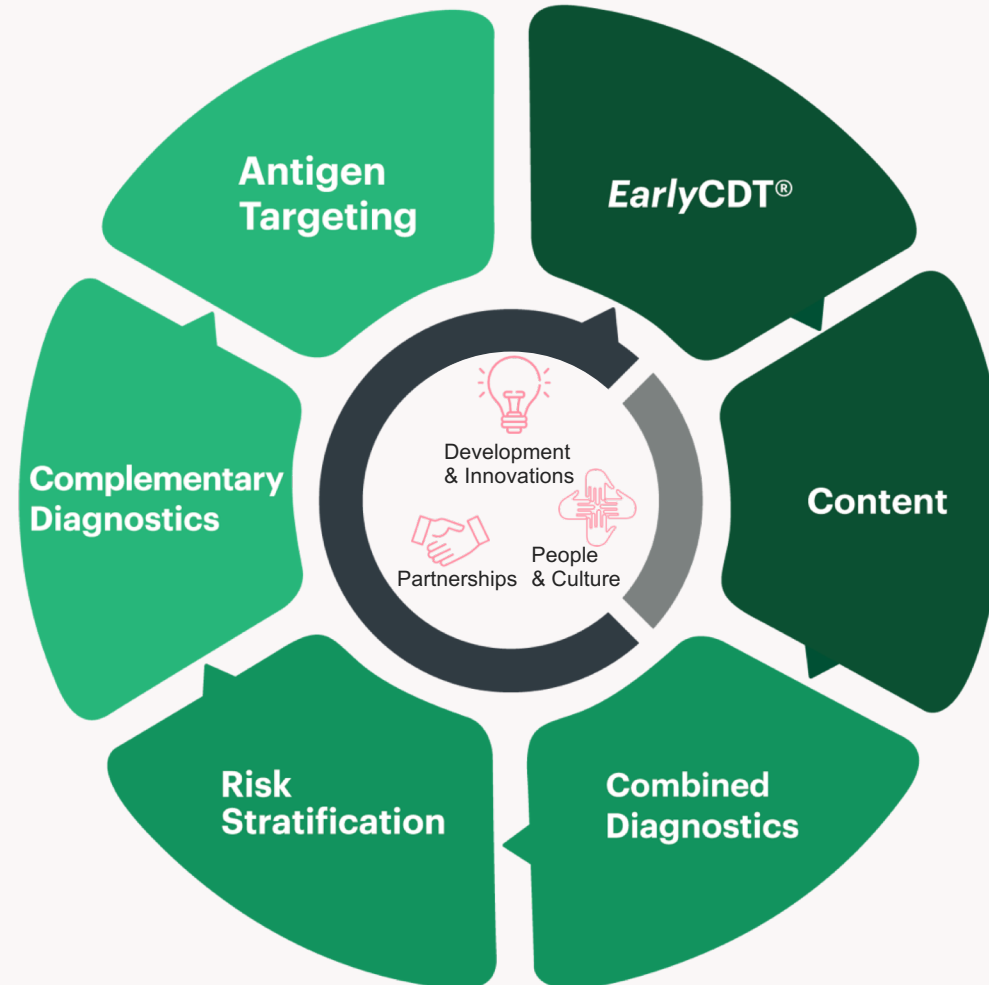




# Outlook and summary



## Unlocking the broad value of our technology through our core strengths





## Commercial update

- Currently distribution agreements in force across 18 countries globally, with minimum sale commitments of £42m+ over next 5 years – most require initial regulatory approvals – expect sales to build towards the end of these agreements
- Recently signed strategic commercial agreement for EarlyCDT Lung in the US with Biodesix – valued at up to \$28 million over next 5 years
- Recently signed distribution partnership with R-Pharm in Russia for use of EarlyCDT Lung in screening – valued at up to £5 million plus £3.5 million investment by R-Pharm
- Our Spanish distributor signs Quirónsalud Group, Spain's largest private hospital group – launched EarlyCDT Lung as a nodule and screening test



## Commercial update

- Gene Group agreement to sell EarlyCDT Lung in Hainan, China ahead of NMPA approval and product shipped
- Early stage of portfolio of distribution agreements means accurate forecasting remains difficult
  - Cash (c.£5m) at year end will be materially above expectations
  - Operating costs for FY2019 materially lower than expectations
- Protagen integration progressing well with the first commercial service contract since acquisition having been signed and a growing pipeline of opportunities
- Scottish phased population-based evaluation using EarlyCDT Lung in up to 200,000 patients expected to commence later this year (lasting 24 months) and deliver material revenues and profits



## Summary

- Landmark ECLS study proved EarlyCDT Lung was effective in reducing incidence of patients with late-stage lung cancer diagnosis; increasingly seen as potential screening test for health systems
- Two commercial tests launched, over £42m+ of sales commitments, strong IP with 200 granted and pending patents covering 47 territories, tumour-related antibody platform with proprietary 8,000+ immunogenic protein library at its core
- Outstanding delivery capability underpinned by a combination of leading development and innovation; growing pipeline of multi-industry partnerships and acquisitions – Biodesix and Protagen
- A high-potential platform with the capability to drive rapid revenue growth through supporting critical clinical decision making across the care pathway
- Strength of Oncimmune's platform and breadth of addressable cancer detection opportunities, means significant medium term potential to deliver value to shareholders
- Strong pipeline of early cancer detection tests across multiple cancers

Oncimmune<sup>®</sup>



**Oncimmune**

Beating cancer, one test at a time