



Leading early cancer detection

## Interim Results

For the half year ended  
30 November 2016

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## Oncimmune – leading early cancer detection

- Pioneering approach to cancer detection
- Extensively validated, highly regarded science
- Over 150,000 *EarlyCDT*<sup>®</sup>-**Lung** tests sold, mainly in the USA
- Poised for significant growth
- Platform technology with multiple revenue streams – diversified risk / high reward investment proposition

## Corporate and operational

- 14 fully operational distributors in the US for *EarlyCDT<sup>®</sup>-Lung* test
- Final validation of the kit version of *EarlyCDT* tests
  - Will enable the company to expand its distributor discussions into new geographical territories
- Signed research agreements with Egybiotech and Aarhus University Hospital, Denmark
  - A further step in the final clinical validation of *EarlyCDT<sup>®</sup>-Liver* and *EarlyCDT<sup>®</sup>-Ovarian*
- Journal of Thoracic Oncology published new data demonstrating the effectiveness of using *EarlyCDT-Lung* tests to distinguish between malignant and benign lung nodules
- Final validation of addition of material new markers to *EarlyCDT-Lung* test to further enhance test performance
- Significant progress on our second-generation fingerprint test and companion diagnostics
- Board and senior appointments - appointment of Andrew Millet as CFO, Carsten Schroeder and Julian Hirst as Non-Executive Directors, Maarten Brusse as Chief Commercial Officer, Asia Pacific and DeeDee Rivas as VP, Americas Sales

## Post-period end

- **EarlyCDT-Lung<sup>®</sup>**, ECLS study with the NHS Scotland is now fully recruited with over 12,000 high-risk smokers
  - World's largest randomised trial for the early detection of lung cancer using biomarkers ever conducted
  - Positive interim data presented in December 2016 at the 17<sup>th</sup> World Conference on Lung Cancer in Vienna
  - Shift to early detection of lung cancer (stage 1 & 2) from 20% in the population today to 75% with commensurate mortality and cost saving benefit.

## Financial

- Revenues of £0.1m (FH1 2016: £0.27m) generated from sales of the *EarlyCDT*<sup>®</sup>-Lung test
- Cash balance at the period end was better than expected at £7.6m (FH1 2016: £1.1m)
- Loss for the period was £2.3m (FH1 2016: £0.8m) reflecting recruitment of staff, product development and commercialisation activities
- Foreign exchange gain of £0.15m (FH1 2016: £0m) as a result of the strengthening of the US dollar against the pound during the period

## Market opportunities for a broad product pipeline

- In the US **EarlyCDT<sup>®</sup>-Lung** test via central lab (CLIA) market
  - 14 US distributors fully operational
  - Implemented a new process, led by new Vice President, Americas Sales, DeeDee Rivas, to ensure partners deliver high quality and long-term sales
  - In final validation of the addition of new markers to enhance **EarlyCDT<sup>®</sup>-Lung** test's sensitivity whilst maintaining specificity. Expected to be added to the test based in our CLIA lab in Kansas during 2017
- Outside the US targeting further growth in Asian markets
  - Pursuing discussions, led by Maarten Brusse, Chief Commercial Officer, Asia Pacific with a number of parties to drive sales and target out-licensing opportunities
- **EarlyCDT-Lung** tests to distinguish between malignant and benign lung nodules
  - Need for pulmonologists to have a new test to help them identify the nodules that need more immediate investigation
  - Commenced discussions with a number of specialist sales forces visiting pulmonologists both in the US and in other territory

## Market opportunities for a broad product pipeline

- Product pipeline broadening cancer coverage
  - *EarlyCDT*<sup>®</sup>-**Liver** expected to be ready for commercialisation before the end of 2017
  - *EarlyCDT*<sup>®</sup>-**Ovarian** to follow
- Next generation tests provide long term opportunities
  - Personalised immune profiling ('fingerprinting')
  - Companion diagnostics – patient targeting & monitoring responses to therapy



# Lead Product - *EarlyCDT*<sup>®</sup>-Lung



## *EarlyCDT*<sup>®</sup>-Lung - Kit format potentially transformative

- Potential step change through development of *EarlyCDT*<sup>®</sup>-Lung ‘kit’
- Higher margins
- Many times greater volumes
- Lower cost to the customer
- No barriers to adoption – hospital lab friendly (platform neutral, 96-well plate ELISA)
- Marketing through KOLs, conferences, and education programme - No need for large GP sales force
- Key driver to open up new markets beyond USA - Ex-US sales primarily through licensed distributors

2021 <i>EarlyCDT</i> <sup>®</sup> -Lung sales estimates (including Kit) <sup>1</sup>	
USA	\$275 million
EU	\$195 million
UK	\$60 million
China	\$60 million
<b>Total</b>	<b>\$590 million</b>

## P&L

	Unaudited 6 months to 30 Nov 2016 £'000	Unaudited 6 months to 30 Nov 2015 £'000	Audited 12 months to 31 May 2016 £'000
<b>Revenue</b>	<b>114</b>	<b>272</b>	<b>430</b>
COS	(109)	(24)	(147)
Admin	(1,992)	(1,992)	(4,269)
R&D	(435)	(388)	(789)
HDL	-	1,564	1,564
Finance costs	(38)	(419)	(4,858)
Tax and Forex	154	255	590
<b>Loss before share- based payments</b>	<b>(2,306)</b>	<b>(31)</b>	<b>(7,479)</b>
Share-based payments	(16)	(872)	(939)
<b>Loss</b>	<b>(2,322)</b>	<b>(841)</b>	<b>(8,418)</b>

## Balance Sheet

	Unaudited 6 months to 30 Nov 2016 £'000	Unaudited 6 months to 30 Nov 2015 £'000	Audited 12 months to 31 May 2016 £'000
Fixed assets	375	325	384
Current assets	8,230	1,743	10,824
Liabilities	1,180	5,857	1,477
<b>Capital and reserves</b>	<b>7,425</b>	<b>(3,789)</b>	<b>9,731</b>
Cash	7,623	1,066	10,197

# Expected Key Newsflow in next 12 months



## Commercial

- Further distributors in US - ongoing
- Distributors / Partners in Asia

## Expected New Product Launches

- Additional markers to the current *EarlyCDT<sup>®</sup>-Lung* test with better performance Q1 2017
- *EarlyCDT<sup>®</sup>-Liver* H2 2017 and thereafter *EarlyCDT<sup>®</sup>-Ovarian*
- *EarlyCDT<sup>®</sup>-Lung* kit Q2 2017

## Clinical results from prospective clinical trials of *EarlyCDT<sup>®</sup>-Lung*

- UK – NHS results presented in Vienna IASLC Conference, December 2016
- USA – National Jewish Hospital, 1,600 patient study (IASLC Conference, December 2016)

## Publications published or expected by end of year

- Pierre Massion (Vanderbilt) – the value of *EarlyCDT<sup>®</sup>-Lung* in assessing risk in CT identified nodules – JTO published
- Validation studies on *EarlyCDT<sup>®</sup>-Liver* *EarlyCDT<sup>®</sup>-Ovarian*
- Validation of improved performance of *EarlyCDT<sup>®</sup>-Lung*
- Autoantibody profiling – ‘Fingerprinting’

## Oncimmune – Leading early cancer detection

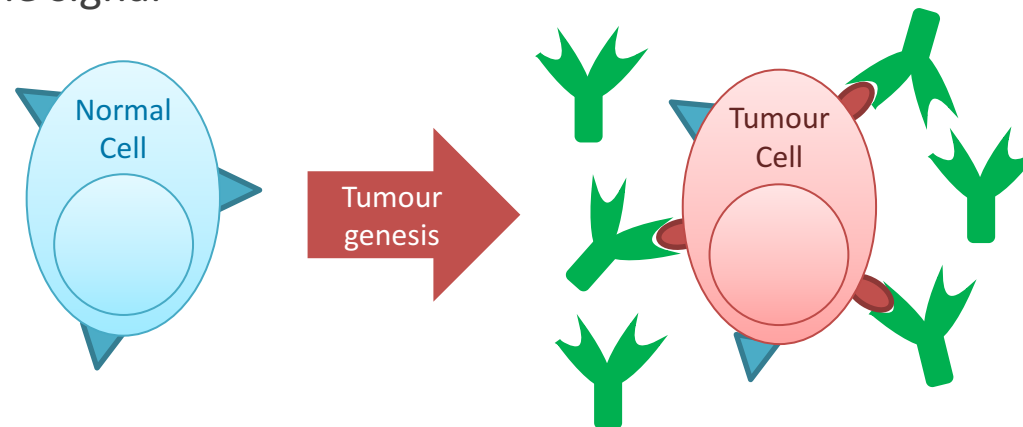
- Pioneering proprietary approach to cancer detection
- Extensively validated, highly regarded science
- Poised for significant growth
  - Multiple opportunities with distributors and potential partners
  - Product development projects maturing
    - *EarlyCDT-Lung* kit, the fingerprinting test, liver and ovarian cancer tests and companion diagnostics
  - Kit development potentially transformative
  - Clear roadmap for commercialisation






## Appendices

## Early cancer detection based on autoantibodies

- Produced early in tumour genesis – years ahead of clinical symptoms
- Absent or low concentrations in healthy & benign cohorts
- One abnormal (cancer) antigen will lead to many 1,000's of autoantibodies = early measurable signal



	Normal host protein
	Abnormal 'tumour associated' antigen
	Autoantibodies specific for TAA

## Proprietary approach: autoantibodies = early cancer detection

- Detect cancers up to four years earlier than other methods <sup>1</sup>
- First cancer blood-test based on a panel of autoantibodies
- Simple blood test – high detection rates for early stage cancers
- Complementary to other technologies (CT scan, Therapeutics)

### Extensively validated, highly regarded science

- 90%+ accuracy with high specificity at 93%
- Substantial history of academic collaboration & peer-reviewed publication

### Strong IP position

- 9 patent families, 276 patents, 23 pending
- 16 territories (minimum coverage - USA and Europe)

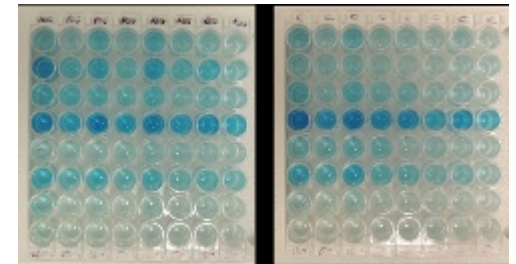


# Lead Product - *EarlyCDT*<sup>®</sup>-Lung



## First product from Oncimmune platform

- 120,000 patient samples run before commercial launch
- Largest ever randomised NHS trial (12,000 volunteers) – ECLS study
  - Early detection of lung cancer using biomarkers
  - Strong results – 50% greater early detection
  - Improving survival and reducing healthcare costs
- Commercialised laboratory test
- Over 150,000 tests sold in the USA and UK



## *EarlyCDT*<sup>®</sup>-Lung – the only early lung cancer detection blood test

- Lab test used in screening high-risk patients i.e. smokers
- *EarlyCDT*<sup>®</sup>-Lung can detect cancer 4 years before CT scans
- Significantly greater accuracy – only 7% false positive (50% for CT scans) for a “one-off” scan
- Detects Stage 1 & 2 cancers - better prognosis (75 % vs 20%) & reduced costs<sup>1</sup>
- ECLS landmark NHS 12,210 participant study<sup>1</sup> – *June 2016 study now full recruited*

Sep 2015	Control	Test		
		CDT-ve	CDT+ve	All Test
Non-LC	n/a	5,486	583	6,071
LC	n/a	3	16	19
<b>Total</b>	<b>6,121</b>	<b>5,489</b>	<b>599</b>	<b>6,090</b>

Sensitivity = 81.3% (13/16)  
 Specificity = 90.7% (5,486/6,090)  
 Negative Predictive Value = 99.9% (5,486/5,489)

# Growth - Broad Development Pipeline



## Portfolio highlights

<p><i>EarlyCDT</i><sup>®</sup> – Current</p>	<p>Lung Test</p>	<ul style="list-style-type: none"> <li>• Additional opportunities include                             <ul style="list-style-type: none"> <li>• US and WW post-nodule</li> <li>• Screening sales in the EU and the US</li> </ul> </li> </ul>
<p><i>EarlyCDT</i><sup>®</sup> – Proof of concept completed</p>	<p>HCC (Liver)</p> <p>Ovarian</p> <p>Breast</p> <p>Prostate</p> <p>Colon, stomach, Esophagus</p>	<ul style="list-style-type: none"> <li>• Clear clinical need for this test</li> <li>• Highly cost effective screening tool, complements AFP</li> <li>• Clear clinical need for this test</li> <li>• Highly cost effective screening tool, complements CA125</li> <li>• Addresses key challenges of mammographic screening</li> <li>• Will be able to identify aggressive rather than benign cancers</li> <li>• Currently no cost effective screening tools available</li> </ul>
<p>Future opportunities</p>	<p>Personalised Medicine – ‘Fingerprinting’</p> <p>Companion Diagnostics</p>	<ul style="list-style-type: none"> <li>• Process of personalised autoantibody detection – “fingerprint”                             <ul style="list-style-type: none"> <li>• Greater overall accuracy (&gt;99%)</li> <li>• Earlier detection</li> </ul> </li> <li>• Opportunity to use Oncimmune’s blood tests for directed therapeutic initiatives</li> <li>• Development partners can explore therapeutic applications to the fingerprinting technology</li> </ul>