



Leading early cancer detection

Interim results for the half-year  
ended 30 November 2017

February 2018

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# A pioneer in early cancer detection



Early detection of cancer saves lives and money

Oncimmune's *Early***CDT**® technology detects cancer **up to four years earlier than other methods**

Based on a simple, robust, blood test – a liquid biopsy

## *Early***CDT<sup>®</sup>-Lung** commercial progress

- Framework agreement with Genostics Company Limited ("Genostics") for China with minimum royalty payments of £15.7m in first six years post market entry
- New agreements in multiple territories for kit with minimum payment guarantees of £9.9m in Europe and Asia (excluding China)
- First commercial batches of the kit shipped for introductory testing
- US distributor base being trained for the sale of *Early***CDT<sup>®</sup>-Lung** test
- Preliminary distribution partnership with a major US pulmonary sales force progressing well
- “Finger stick” test launched increasing speed and simplicity

## **R&D and Trials**

- Development of *EarlyCDT*<sup>®</sup> kit - expanding geographical reach
- Validated *EarlyCDT*<sup>®</sup>-**Liver** test; on track to begin commercial sales in H1 2018.
- NHS lung cancer screening trial fully recruited; Final study results expected in 2019.

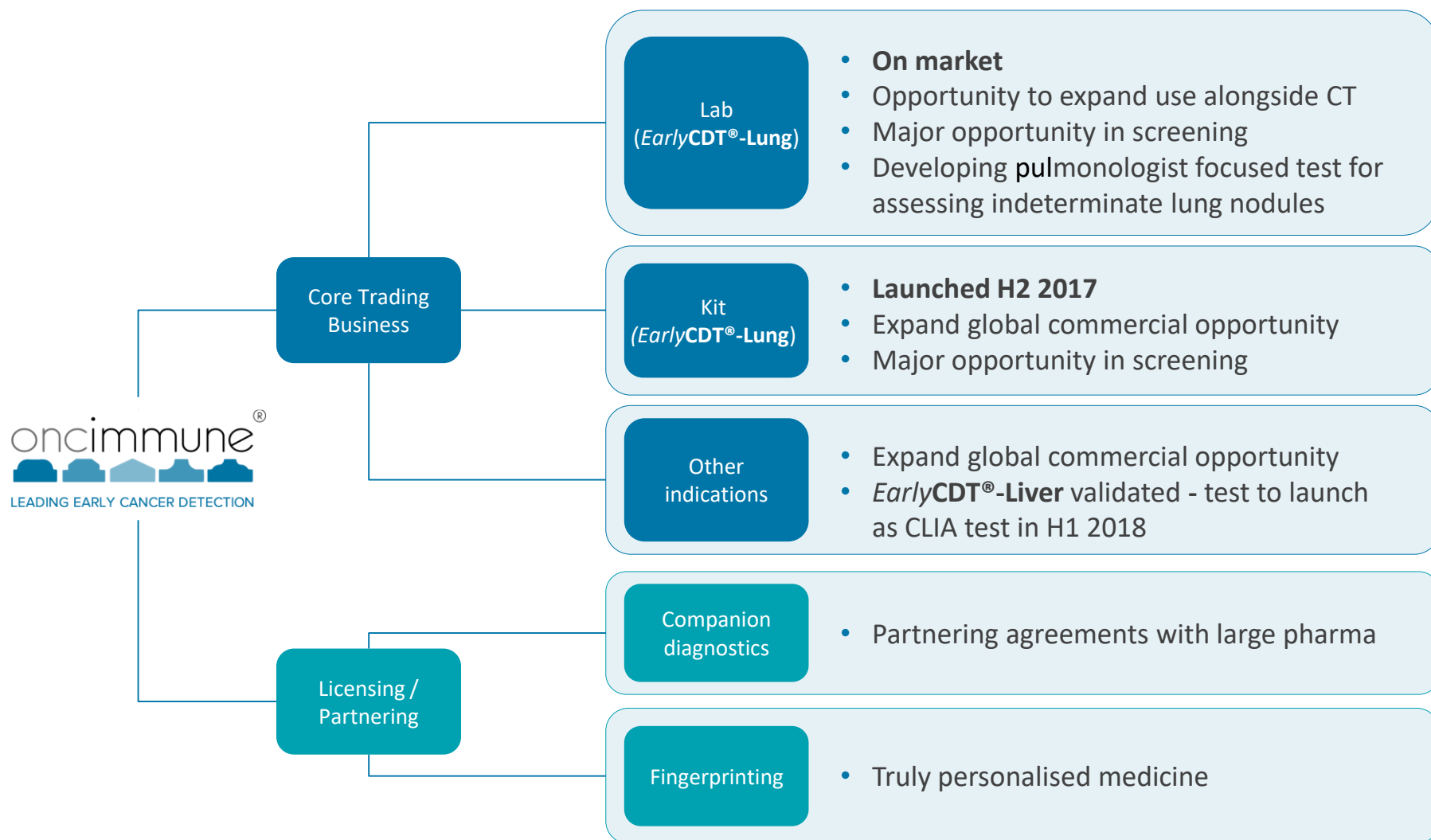
## **Personalised Medicine & Companion Diagnostics**

- Presentation of data on autoantibody technology with Scancell Holding plc's SCIB1 immunotherapy
- Autoantibody “fingerprint” technology progressing; data presented at IASLC in November 2017

## **Board Changes**

- Appointment of Dr. Annalisa Jenkins to the Company's Board as Non-Executive Director

# Platform to drive multiple revenue streams





Core Trading Business

# Business/revenue model



## United States

- **EarlyCDT®-Lung** (detection and nodule risk assessment)
  - Physician ordered test
  - ELISA test in Oncimmune's CLIA lab
- Indirect/distributor sale to primary care
  - Reimbursed at \$123 per test for Medicare (30% of mkt). Process underway to sell "in network" with insurers paying \$300-\$550 (70% of mkt)
  - Distributer claims and pays Oncimmune c.50% of reimbursement/selling price
  - 14 distributors signed up, ongoing discussion with number of pulmonology distributors
  - Hard costs for the test are less than \$10; fixed overhead means significant margin improvement with volume

## Rest of the world

- **EarlyCDT®-Lung Kit**
  - Sale of Reagent and software kits in 10 test batches
  - Significant volume expectations - lower retail price and easy to use (sample does not have to be sent to a US lab)
- Asia/Middle East – indirect/distributor with key focus for kit sales
  - China framework and license agreement in place
  - Lower price – c.£350 to £450 price for 10 tests to hospital. Current cost of goods £60 for 10 tests
  - 6 distributors signed up (Israel, Iran, South Korea, Taiwan, Hong Kong and Singapore) – min aggregate sales >£7.9m with more in discussion
  - Manufacture tender underway from suppliers in Europe and Asia. Target cost per test is <£2
- UK – Sell direct to private medical companies
  - Private pay/GP referral
  - NHS – final trial results 2019 - expected to result in inclusion in NHS guidelines potentially 500,000 plus sales
- Europe – Distribution deals being finalised
  - 4 distributors signed up (Denmark, Norway, Sweden and Poland) – min aggregate sales >£2.0m with more in discussion

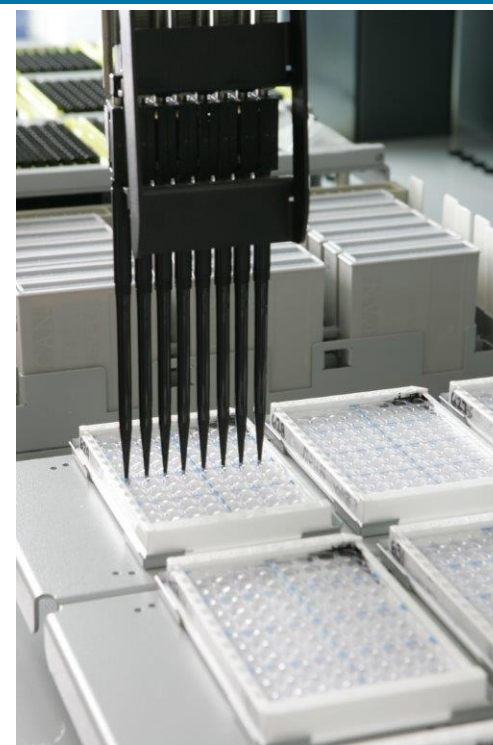


# Lead product - *EarlyCDT*®-Lung



## First product from Oncimmune platform

- 120,000 patient samples run before commercial launch
- Over 150,000 commercial tests have been sold
- Well established Central Laboratory Test in US (CLIA)
  - Distribution and product development
  - Distribution agreements across the US - covering all the major US markets
- Complementary to other technologies
  - Risk stratification of CT identified nodules



# China deal announced 2 January 2018



## Exclusive framework agreement and licence of *EarlyCDT*<sup>®</sup> technology to Genostics for China and a £10m investment

- Provides access to market in which lung cancer is the number one killer, with over 700,000 cases diagnosed annually, and 350 million adult smokers in 2015
- Licence agreement of *EarlyCDT*<sup>®</sup> Technology for China, with initial focus on *EarlyCDT*<sup>®</sup>-Lung
  - Distribution, manufacturing and future development of all products related to Oncimmune's *EarlyCDT*<sup>®</sup> platform for PRC
- Minimum royalty payments total £15.7 million in first six years post market entry
  - Royalty of 8% to 12.5% on minimum of the gross revenue
  - Sales of *EarlyCDT*<sup>®</sup>-Lung within 36 months, subject to CFDA approval, although expected sooner
- £10m equity investment in Oncimmune at 49% premium
  - Investment at £1.56 at 49% premium to the share price of 105p (market close on 29 December 2017)
- Potential transfer of manufacturing to China to be explored
  - For China and RoW
  - Research and development to progress the Oncimmune *EarlyCDT*<sup>®</sup> platform technology into new areas of prevalent cancers

# Performance of *EarlyCDT*<sup>®</sup>-Lung For Pulmonary Nodule Population



**Specificity**



**PPV**

## “High Level” result

- A High Level result shifts the risk of intermediate risk nodules (10-65% risk) to intervention risk



**Specificity**



**PPV**

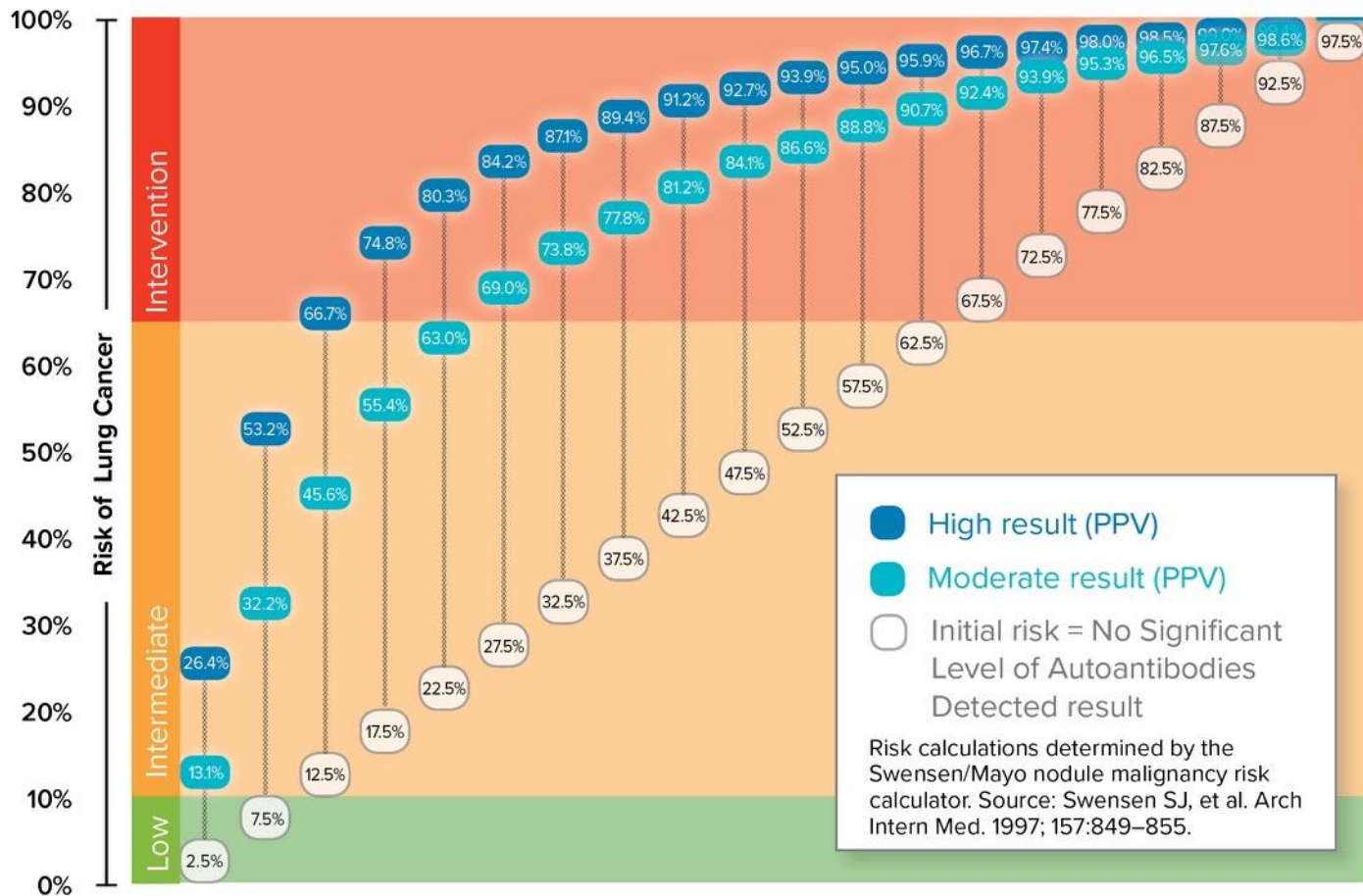
## “High Level” and “Moderate Level” result

- A Moderate Level result will add >25% risk
- A Moderate Level result will shift some nodules from Intermediate risk to Intervention risk

# EarlyCDT®-Lung fits in with ACCP guidelines by helping to assess the probability of malignancy of a nodule



## Difficult-to-assess nodules (i.e., 8-20mm)



# EarlyCDT<sup>®</sup>-Lung - Risk Assessment of Intermediate pulmonary nodules

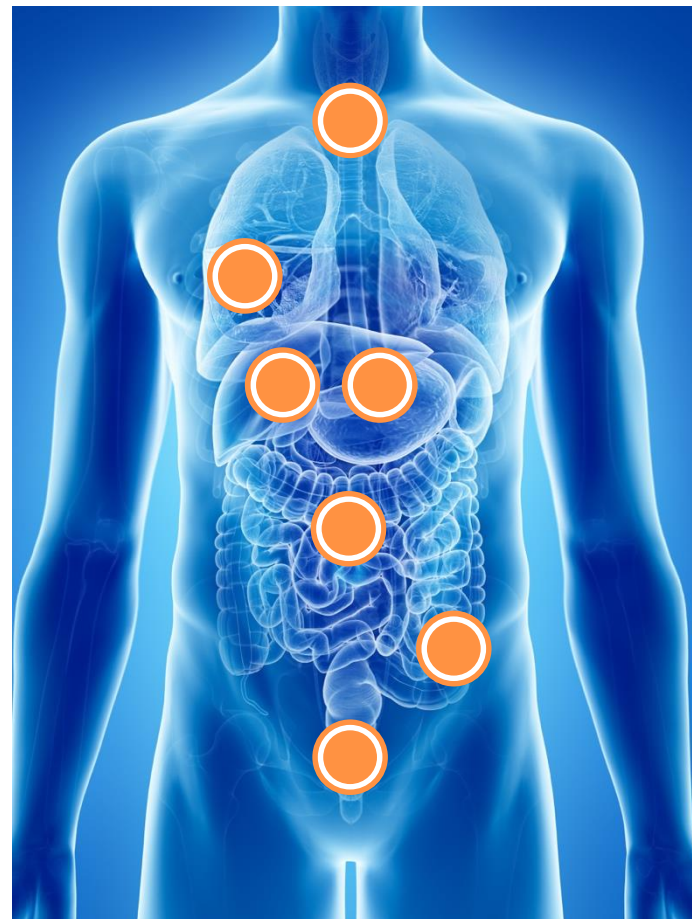


- Preliminary distribution partnership with a major US pulmonary sales force
- >1.5m patients with pulmonary nodules per annum in US & growing rapidly with expected increased adoption of CT screening for high risk patients
- Sales of EarlyCDT<sup>®</sup>-Lung to pulmonologists has potential to reach \$400m (Health Advances Boston)



## In Development - opportunities in other cancer indications

- **HCC (Liver)** – expected launch H1 2018
  - Validated *EarlyCDT<sup>®</sup>-Liver* test on schedule
  - Clear clinical need for this test
  - Highly cost effective screening tool, complements AFP
- **Ovarian** – expected launch H2 2018
  - Clear clinical need for this test
  - Highly cost effective screening tool, complements CA125
- Other solid tumours
  - **Breast**
    - Addresses key challenges of mammographic screening
  - **Prostate**
    - Will be able to identify aggressive rather than benign cancers
  - **Colon, Stomach, Esophagus**
    - Currently no patient acceptable cost effective screening tools available

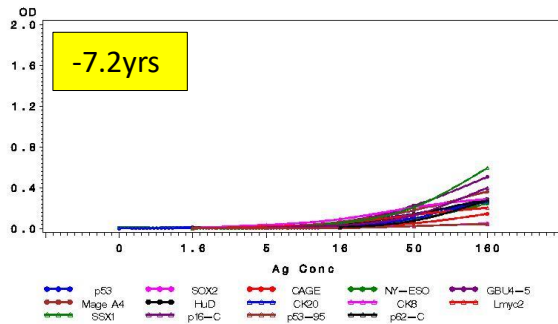




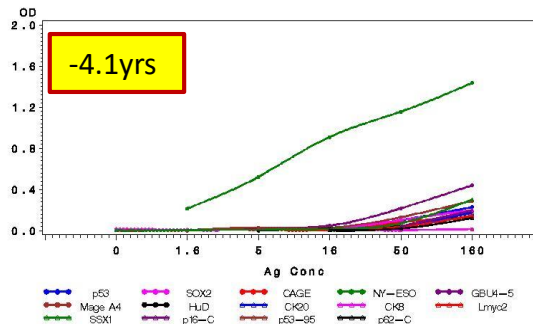
Licensing / Partnering  
Opportunities

# Fingerprinting showing early evidence of cancer

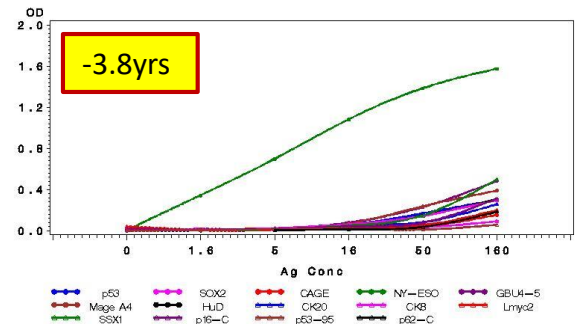
Subject OIM67 sample 1, OD vs Ag conc



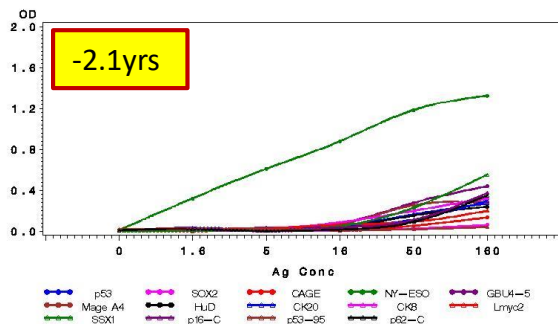
Subject OIM67 sample 2, OD vs Ag conc



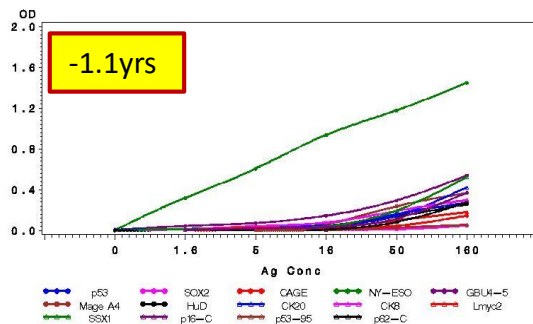
Subject OIM67 sample 3, OD vs Ag conc



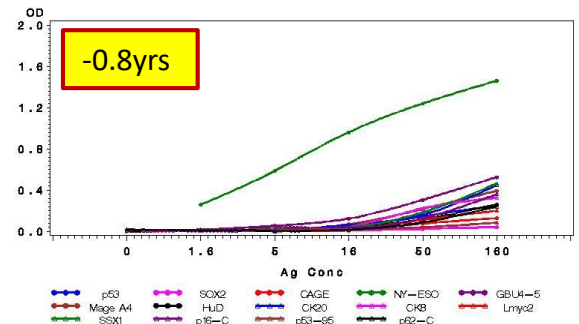
Subject OIM67 sample 4, OD vs Ag conc



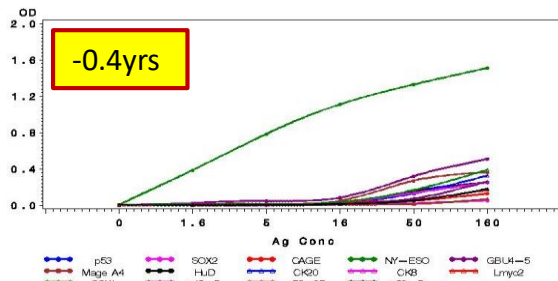
Subject OIM67 sample 5, OD vs Ag conc



Subject OIM67 sample 6, OD vs Ag conc



Subject OIM67 sample 7, OD vs Ag conc

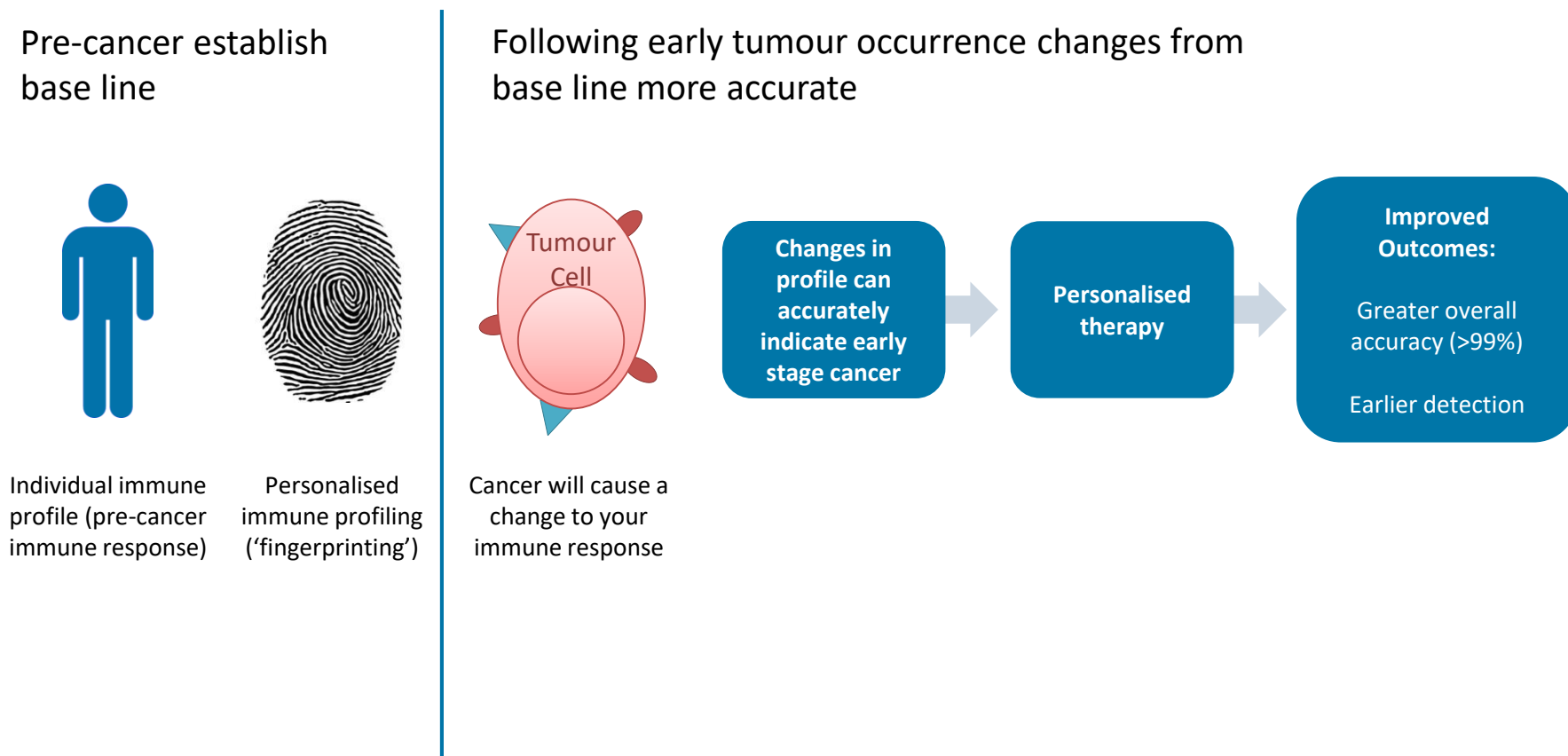


Indicates *EarlyCDT*  
Negative

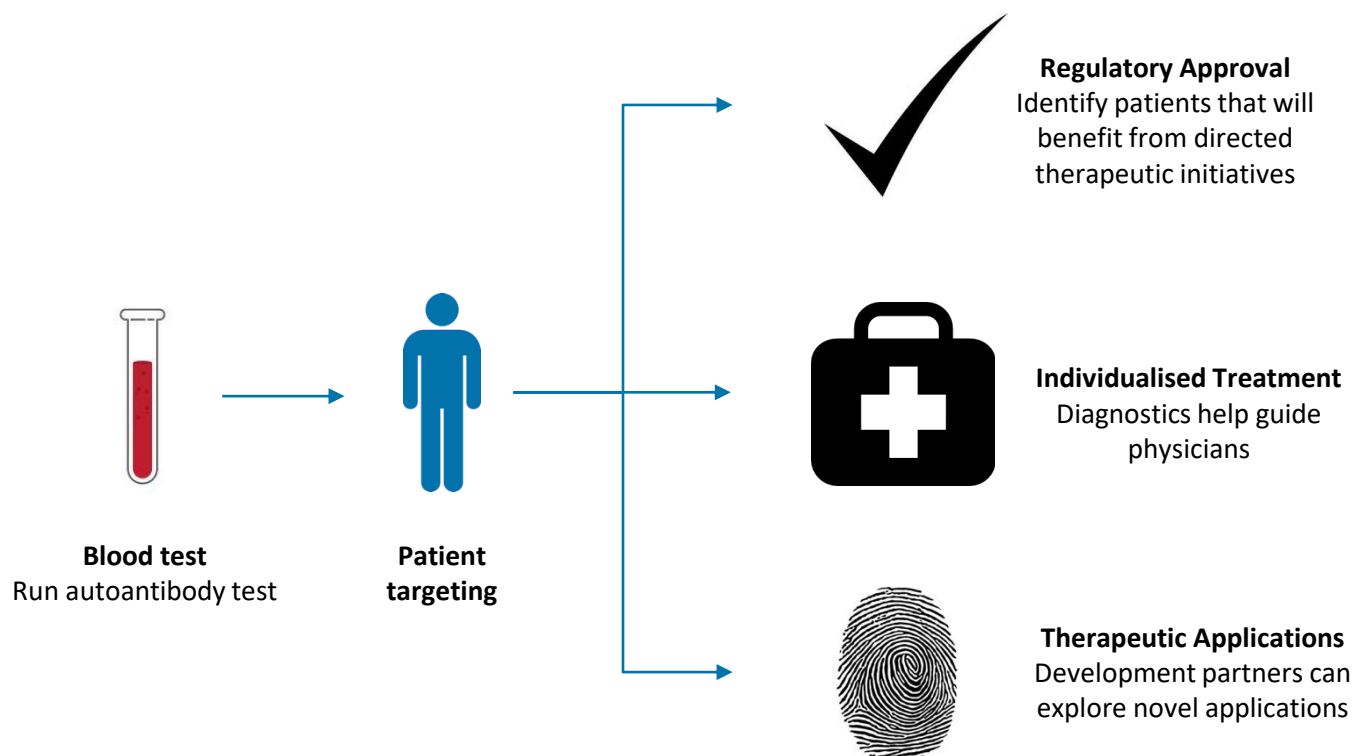
Indicates *EarlyCDT*  
Positive



## Next generation tests provide long term opportunities



## Companion diagnostics – patient targeting & monitoring responses to therapy





Financials

# Financial Highlights (including post-period end)



- Revenues for the period of £0.1m (H1 2016: £0. 1m)
- Loss for the period before one-off and non-cash items of £3.04m (H1 2016: £2.3m)
- £5.0m raised from new and existing investors.
- Cash balance at the period end was £6.3m (H1 2016: £7.6m).
- Post period end receipt of first tranche equity subscription of £7m from Genostics making the cash balance £11.8m at the time of these results

## P&L

	Unaudited 6 months to 30 Nov 2017 £'000	Unaudited 6 months to 30 Nov 2016 £'000	Audited 12 months to 31 May 2017 £'000
<b>Revenue</b>	<b>77</b>	<b>114</b>	<b>215</b>
COS	(444)	(109)	(532)
Admin	(1,944)	(1,992)	(3857)
R&D	(446)	(435)	(1025)
Other income	14	-	26
Finance costs	(17)	(38)	(69)
Tax and Forex	(211)	154	515
<b>Loss before share- based payments</b>	<b>(2,971)</b>	<b>(2,306)</b>	<b>(4,727)</b>
Share-based payments	(65)	(16)	(74)
<b>Loss</b>	<b>(3,036)</b>	<b>(2,322)</b>	<b>(4,801)</b>

## Balance Sheet

	Unaudited 6 months to 30 Nov 2017 £'000	Unaudited 6 months to 30 Nov 2016 £'000	Audited 12 months to 31 May 2016 £'000
Fixed assets	698	375	748
Current assets	6786	8230	5659
Liabilities	658	1,180	1,403
<b>Capital and reserves</b>	<b>6,826</b>	<b>7425</b>	<b>5004</b>
Cash	6,302	7,623	5,075

**The Company's cash position is now strong**

**The cash burn continues to be managed carefully**

**The Company recently raised £5m by way of placing to focus on the below key areas**

Balance sheet strength to complete major distribution deals in the following areas:

- USA for *EarlyCDT®-Lung*
- China for *EarlyCDT®-Lung*
- “Fingerprint”

Following completion of the major distribution deals the cash position is to be used for:

- R&D
  - Additional NHS studies (to aid accelerated adoption)
  - Additional markers for lung test in US - “pulmonology test”
  - Additional trials to enhance reimbursement in US
  - Validation of other cancer tests
- Direct marketing to general practice in the US



## Summary & Outlook



# Next steps of strategy - poised for growth



## Core Business

- **EarlyCDT®-Lung** test via central lab (CLIA) market
  - Gaining US traction (pulmonology focus followed by screening)
  - Final NHS trial results report 2019 – UK driver (and RoW)
  - Finger stick expected to grow market substantially
- Potential step change through development of **EarlyCDT®-Lung** ‘kit’
  - Open new markets, in particular Asia, through Genostics agreement for China region
  - Transform margins
- Product pipeline broadening cancer coverage
  - Launch in US of **EarlyCDT®-Liver** as CLIA test in H1 2018 and as kit in RoW H2 2018
  - **EarlyCDT®-Ovarian, EarlyCDT®-Breast**

## Licensing / partnering

- Next generation tests provide licensing/partnering opportunities
  - Personalised immune profiling (‘fingerprinting’)
  - Companion diagnostics – patient targeting & monitoring responses to therapy