

## Final Results Year Ended May 2018 and Strategy Update

31<sup>st</sup> October 2018



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### Beating cancer, one test at a time

#BeatingCancer





### **Company Overview**

Proven cancer-detection methodology combining autoantibody detection science with robust antibody capture technology

Commercial stage company changing how clinicians, researchers and patients understand, diagnose and treat cancer

Lead product (*EarlyCDT*<sup>®</sup>—Lung) with multiple distribution agreements in place; second product (*EarlyCDT*<sup>®</sup>—Liver) launched in May 2018; further products in development

Autoantibody profile is specific to cancer type and can be detected four years or more before standard diagnosis

Delivering value in multiple indications (cancers) by supporting clinical applications (decisions) across the cancer care pathway



### **Board and Management**

#### Meinhard Schmidt (Non-Executive Chairman): Formerly SVP of Roche Diagnostics

Dr Adam Hill (CEO): A qualified clinician and engineer with experience delivering growth strategy in life sciences, formerly Imperial academic and McLaren

Andrew Millet (CFO and Company Secretary): Chartered accountant and statutory auditor.

Tim Bunting (Non-Executive Director): Balderton Partner, formerly Global Head of Equity Capital Markets at Goldman Sachs

**Geoffrey Hamilton–Fairley (Non-Executive Vice Chairman):** An entrepreneur and investor with experience in taking start-ups through to successful exits.

Julian Hirst (Independent Non-Executive Director): Corporate Finance Director of Immunocore Ltd, formerly Vice Chairman of Panmure Gordon

Dr Annalisa Jenkins (Senior Independent Non-Executive Director): Leader in scientific research and development, formerly CEO of Dimension Therapeutics

Dr Carsten Schroeder (Independent Non-Executive Director): President of the Diagnostic Division at Grifols, S.A, formerly President of Novartis Diagnostics.

**Richard Sharp (Non-Executive Director):** Member of the Bank of England's Financial Policy Committee, formerly Chairman of Goldman Sachs' Principal Investment business.

Dr Cheung To (Non-Executive Director): Co-founder and Chairman of Gene Group Holdings Ltd, the parent company of Genostics Co Ltd

Andrew Unitt (Independent Non-Executive Director): Formerly Chief Financial Officer for the University of Nottingham and Boots Healthcare



### Foundations for success



### Pulmonary Distribution and Trading Update

- Our pilot distribution project with a major US pulmonology sales force was completed in February 2018, and the Company has been in negotiation regarding the terms of a full distribution contract since this time.
- These discussions have failed to reach a satisfactory conclusion and it has been agreed that discussions will cease. This arrangement now unlocks Oncimmune to focus more time on developing discussions with other US pulmonary salesforces.
- As a result of the Company's inability to reach agreement with the original distribution partner, revenue expectations for the current financial year are materially reduced by these events.
- Oncimmune will continue to sell to the physician practices already active from the pilot and to build the case for using *EarlyCDT<sup>®</sup>—Lung* to aid in assessing risk of indeterminant pulmonary nodules.

### Final results year ended 31 May 2018 (corporate and operational highlights)

#### Maintaining strong momentum in *Early*CDT<sup>®</sup>—Lung

- Exclusive licence agreement signed with **Genostics** Company
- New distribution agreements signed for *Early*CDT<sup>®</sup>—Lung
  - 15 agreements in total
  - Minimum sales commitments of **£29.5m** over their initial periods
- Continued progress in driving volumes of *Early*CDT<sup>®</sup>—Lung in the US
- EarlyCDT<sup>®</sup>—Liver test for hepatocellular cancer launched in May 2018 in US
- NHS ECLS trial continued to monitor 12,000+ patient cohort for occurrence of lung cancer. Final results expected in early 2019
- Data published in the Journal of Cancer Therapy (May 2018) in support of the role of *EarlyCDT®*—
  Lung in IPN management

### Final results year ended 31 May 2018 (corporate and operational highlights)

#### Board changes in line with strategy

- Dr Adam Hill, MB PhD, was appointed as new Chief Executive Officer having joined as Chief Medical Officer and Chief Strategy Officer in April 2018 and was appointed to the Board as an Executive Director
- Geoffrey Hamilton-Fairley takes on new role as Vice Chairman of the Board
- Appointment of Dr. Cheung To and Dr. Annalisa Jenkins to the Board as Non-Executive Directors



### Final results year ended 31 May 2018 (financial highlights)

£5m raised from new and existing investors in September 2017. A further £10m equity investment from Genostics in January 2018

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Revenue for the year was £240k (2017: £215k)

Operating expenses before share based charges and exceptional items were £5.56m (2017: £4.88m). R&D costs for the year were £281k (2017: £415k)

Net loss for the year was £6.34m (2017: £5.0m)

Cash balance at the period end was £12.95m (2017: £5.1m)

## **Strategy Update**

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## We have demonstrated:

the clinical utility and commercial viability of the Oncimmune Platform through our lead product - EarlyCDT<sup>®</sup>—Lung - and its potential for further wide-ranging indications and applications



the ability to **partner for scale** in the fragmented healthcare market, leveraging existing investment as affirmed by our Genostics partnership



our capacity for operating across multiple continents with opportunity for further growth in the **US** but also in **China and the wider Asia-Pacific region**, where needs are significant and distribution is cost effective



### Core scientific principle

#### Early cancer detection based on autoantibodies

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



### Antibody capture technology

#### Patent-Protected Immunogenic Protein Library

175 distinct tumour antigens/435 variants

**Proven cancer** 

detection methodology

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





### Positioned to deliver

**Development & Innovation** 



People & Culture

#### Structured to continuously innovate and gain early entry to market

**Multi-Industry Partnerships** 



### The Oncimmune platform underpins multiple revenue streams

Measurement

Decision

Actuation





- Proprietary immunogenic protein library
- Capture protein scale-up capability
- Commercialised
  *Early*CDT<sup>®</sup> for lung and liver cancer

- Reproducible platform
  performance
- Data science capability
- Decision support through tools, e.g. the Swenson-Mayo risk calculator



- High-throughput discovery
- Structural biology knowhow
- Deep science partnerships



Measurement, decision-making and actuation capabilities are required along the entire patient care pathway





### Paths to value



#### Combined Diagnostics

Work with other groups to develop test including our markers

Risk Stratification

Partner to deliver discrete or non-specific cancer risk stratification as a service



Complementary



Measurement Decision

Actuation



### **EarlyCDT®** Platform





# *EarlyCDT®*: ECLS – in collaboration with NHS Scotland, it is the largest randomised control trial using biomarkers ever conducted in lung cancer



Over 14% of the world's population smoke\*; Scotland alone has over 800,000\*\* smokers. A positive final read-out from ECLS leading to the NHS using the test for population screening would be transformational for the company. This would strongly influence adoption in other geographies



### **EarlyCDT®** clinical test portfolio & pipeline





### Content



- Incorporate immunogenic protein library and panels into a third-party ecosystem
- The ecosystem might be, for example, a testing equipment or EMR software installed base

#### Example

- Partner with a **diagnostic software solution provider** with a large installed base of hospitals
- Integrate *EarlyCDT®—Lung* into clinical decision support tools

#### Motivation

- No additional development of *EarlyCDT<sup>®</sup>—Lung* required
- Creates a new distribution channel
- *Content* is a natural adjacency to the core testing business



#### **Next Steps**

Continue to build a portfolio of potential partnerships



Prioritise most promising opportunities



Develop organisational capability in partnership management



Initiate revenue generation with at least one partner in 2019



### **Combined Diagnostics**

#### Profile

- Combine *EarlyCDT*<sup>®</sup>—Lung (or another indication) with the diagnostic tools of another provider
- Principle is that combined diagnostics could deliver greater insight than the individual constituent tools

#### Example

- Develop a breast cancer-specific panel and combine it with the tools of a mammography imaging supplier
- Improve the performance of both case selection and diagnosis

#### Motivation

- The right partnership could deliver an industry-leading diagnostic framework for a particular cancer
- Enhancement of partner's diagnostic capability could enhance its market share with Oncimmune sharing in the upside



#### **Next Steps**

Develop preliminary partner conversations, prioritising the most promising opportunities

Initiate data sharing and modelling with at least one channel partner in 2019

Develop data science competence



Be study-design ready by end of 2019



### **Risk Stratification**

#### Profile

- Assist an insurer (or reinsurer) to either reduce claims cost and/or change pricing structures by stratifying insured risk
- Incorporate *EarlyCDT*<sup>®</sup> into the insurance onboarding process (possibly for high-risk individuals only in the first instance)

#### Example

Apply *Early*CDT<sup>®</sup>(—Lung) to enhance the risk models of a major ٠ health/life insurer with an additional input parameter at the point of onboarding or as an annual adjustment to the risk profile

#### **Motivation**

- Commercial benefit to repricing risk and managing down claims is ٠ significant given costs of cancer treatment
- Additional R&D would be required, however, to tailor panel performance to • the population at risk



#### **Next Steps**

Initiate preliminary partner conversations and prioritise most promising opportunities

Gather population data and run analysis and stratification with at least one partner



Prepare groundwork for FDA approval



### **Complementary Diagnostics**

#### Profile

- Develop panels against specific immunocology biomarkers (such as PDL1 and CTLA4) rather than a specific indication
- Improve therapy selection and identify cost-effective interventions

#### Example

- Work with a **Big Pharma** partner operating in immunotherapy
- Develop a panel to enhance performance of (e.g.) PDL1 (currently predicts only a 25% response to immunotherapy)

#### Motivation

- Value to be realised by Big Pharma in building the evidence for 1<sup>st</sup> or 2<sup>nd</sup> line-therapy for their assets cannot be underestimated
- Stratification of response is critical to the future positioning and economics of a therapeutic asset



#### **Next Steps**

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Define target partner type and build 'longlist'



Pick partners and design studies



Agree Heads of Terms



Initiate one study before the end of 2019



### Antigen Targeting

#### Profile

- Tumour autoantibodies (TAAs) present druggable targets for therapeutic intervention, e.g. therapy phasing in early cancer
- Oncimmune's TAA-optimised panels are particularly suitable given high levels of specificity and minimal cross-talk

#### Example

 Use Oncimmune's immunogenic protein library to support **Big Pharma** in the development of a polyclonal Antibody-Drug Candidate (ADC) for use in a specific indication, or immune profile

#### Motivation

 Whilst speculative and early stage, repeat validation of the immunogenic protein library developed by Oncimmune suggests that the science is robust and has considerable utility and value in this use case



#### **Next Steps**



Refine proposition to maximise chances of success



Define target partner type and build 'longlist'



Develop drug targeting capability



Enter into study design discussions with research collaborators



### Use of Resources



## **Outlook and Summary**



### Outlook

We will continue to provide the focus and leadership that Oncimmune needs to execute current and future commitments

We will be working with future partners to ensure that we are maximising the latent value of our immunogenic protein platform technology

We will continue to lay the groundwork so that our seminal results – such as with our imminent ECLS read out – have the right platform for distribution to maximise the reach and impact of our science



### Summary

Autoantibody platform with world-leading proprietary immunogenic protein library at its core

Strong foundations built on a world-leading immunogenic protein library, over 220 patents covering 50 territories, two commercial tests and £29.5m of sales commitments

Outstanding delivery capability underpinned by a combination of leading development and innovation, unmatched people and culture and growing base of multi-industry partnerships

A high-potential platform driving rapid revenue growth through multiple streams spanning measurement decision-making, and actuation

Multiple paths to value creation starting with the core testing business – lead assets in lung and liver - and extending out across combined diagnostics, risk stratification, complementary diagnostics and antigen targeting

## Appendices

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### Summary Profit and Loss

£'000	Audited 12 months to 31 May 2018	Audited 12 months to 31 May 2017
Revenue	240	215
Cost of sales	(917)	(532)
R&D expenses	(800)	(1,025)
Administrative expenses	(4,759)	(3,857)
Finance gains/expenses	32	(43)
Tax and forex gains/expenses	(23)	515
Loss before share-based payment charges	(6,227)	(4,727)
Share-based payment charges	(138)	(74)
Loss after share-based payment charges	(6,365)	(4,801)



### **Summary Balance Sheet**

£'000	Audited at 31 May 2018	Audited at 31 May 2017
Fixed assets	872	748
Current assets	13,539	5,659
Liabilities	(849)	(1,403)
Capital and reserves	13,562	5,004
Cash	12,953	5,075



### Oncimmune<sup>®</sup>

### Key Patents – Early Detection

Family	Claim	Key Territories	Expiry Dates
1	<b>Panel Assay</b> A method of testing for the presence or absence of AAbs in a bodily fluid by contacting said sample with a panel of two or more tumour marker antigens and detecting the presence or absence of the two or more AABs bound to said tumour marker antigens	Granted in US and Europe	2019
5	<b>Titration Method</b> A method for assay optimisation where test samples suspected of containing AAb are tested against a number of different amounts of antigen. The amount of specific antigen/AAb binding is then plotted against each amount of antigen dilution	Granted in all major countries	2026
7	<b>Calibrator for Immunoassays</b> The use of reagents sourced from bodily fluids of cancer patients (e.g. ascites and pleural effusions) for use as a calibrator in autoantibody assays (as a quality control standard)	Granted in Europe, China, Australia, Japan Pending in US, Canada, India	2028
9	Antibody Panels for Hepatocellular Cancer A method of detecting liver cancer by detecting an autoantibody immunologically specific for a tumour marker protein selected from the group consisting of MMP9, AIF1, EpCAM and CDKN1B	Fast tracked in China Pending worldwide	2037



### Oncimmune<sup>®</sup>

### Key Patents – Therapeutics

Family	Claim	Key Territories	Expiry Dates
1	<b>Panel Assay</b> A method for the determination of the tumour marker profile of an individual at increased risk of cancer in a population of asymptomatic individuals	Granted in US and Europe	2019
5	<b>Titration Method</b> An in vitro method of determining an autoantibody profile in a test sample either prior to the onset of disease, or throughout the course of disease, wherein the method is repeated to build up a profile of antibody production	Granted in all major countries	2026
	A method of identifying an anti-cancer treatment comprising detecting one or more autoantibodies specific for tumour marker proteins		
9	Antibody Panels for Hepatocellular Cancer A method of predicting response to an anti-liver cancer treatment	Fast tracked in China Pending worldwide	2037

### The End

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