

# Results for the year ended 31 December 2020

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29 April 2021



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# Transforming cancer care with a simple blood test

“ANGLE’s mission is to enable personalised cancer care by providing the complete picture of the patient’s cancer from a simple blood test.

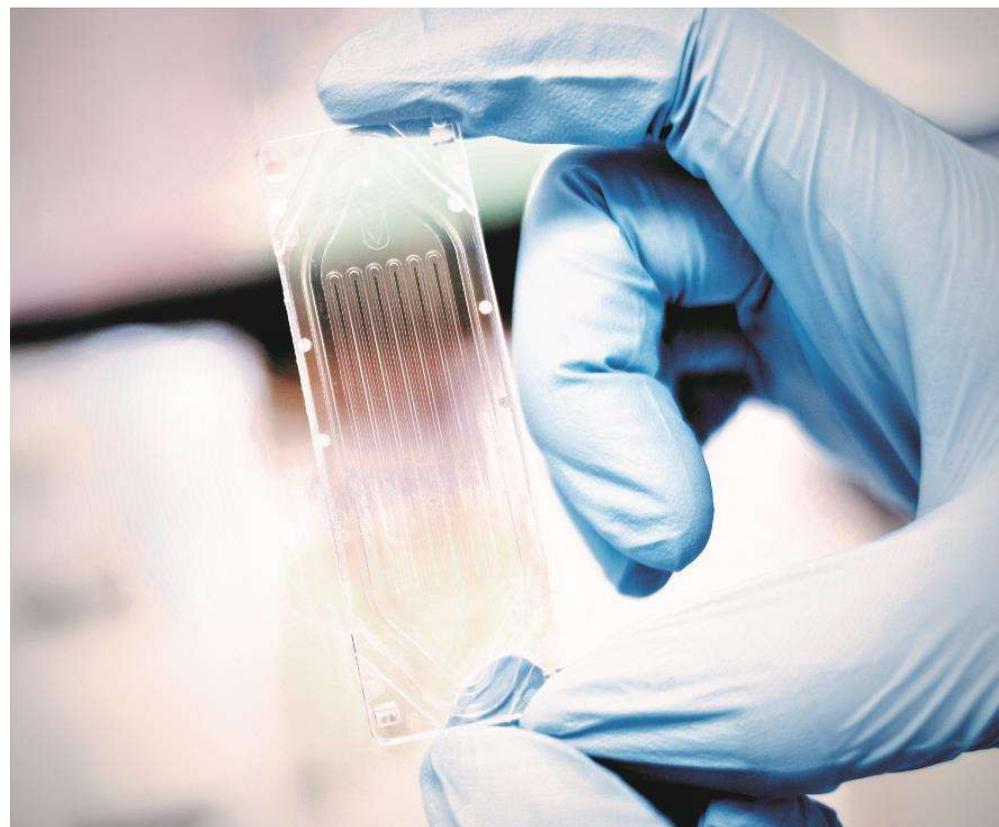
Our Parsortix® system has the potential to deliver profound improvements in clinical and health economic outcomes in the diagnosis and treatment of cancer.”

Andrew Newland, Chief Executive

National Cancer Institute United States

An estimated “40% of men and women will be diagnosed with cancer during their lifetime”

Parsortix® cassette



# 2020 Highlights

*Significant progress against key strategic objectives*



- Working practices adapted for COVID-19
- FDA De Novo Submission for Class II clearance in metastatic breast cancer submitted September 2020
  - over 15,000 samples and 400 reports / technical documents
  - successful FDA administrative review and acceptance for substantive review
- Ovarian cancer detection study progress despite COVID-19 impact on enrolment
- Development of PD-L1 assay for pharma services
- Successful fundraiser from US and UK investors
  - subsequent investment in clinical service laboratories
- Body of published evidence strengthened



## Further momentum post year end

- Additional Information Request received from FDA
  - encouraging that AIR received without undue delay
  - comprehensive response being prepared
- Clinical Services Laboratories launched
- First large-scale pharma services contract secured
- Ovarian cancer clinical verification study patient enrolment completed
- Presentation of Parsortix EMT and PD-L1 assays at AACR, a leading international cancer conference
- Further four peer-reviewed publications in leading industry journals



# Financial Results for year ended 31 December 2020

	Year ended 31 December 2020	8 months ended 31 December 2019*
	£'000	£'000
<b>Statement of Comprehensive Income</b>		
Revenue and grant income	841	642
Cost of sales	(165)	(142)
Gross profit and grant income	676	500
Operating costs	(14,407)	(9,512)
Tax credit and net finance costs	2,125	1,456
Loss for the period	(11,606)	(7,556)
	<b>31 December 2020</b>	<b>31 December 2019</b>
<b>Statement of Financial Position</b>		
Trade and other receivables and R&D tax credit	3,570	4,025
Inventories	742	788
Cash and short-term deposits	28,618	18,766
Property, plant and equipment and right-of-use assets	2,409	3,022
Intangible assets	3,710	3,974
<b>Total assets</b>	<b>39,049</b>	<b>30,575</b>

## Comments

- Revenue reduced by COVID-19 impact on customers
- Gross margin 78%
- Planned expenditure on product development, clinical studies and launch of clinical services labs
- Cash position increased to £28.6m
- R&D tax credit recoverable £2.1m
- Fundraise of £18.5m (net) Nov 2020

\* Restated

# COVID-19 and cancer – urgent need for liquid biopsy

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- COVID-19 has caused an unprecedented crisis with impact on cancer diagnosis and care
- **Urgent priority to end delays and address backlogs** in cancer diagnosis and treatment
- Information provided by liquid biopsy could help clinicians diagnose, monitor, and treat cancer more efficiently
- Liquid biopsy is minimally invasive, can be undertaken safely in community clinics or in the home to provide patients with a rapid diagnosis and timely treatment with targeted therapies
- Liquid biopsy may also help to **safely monitor cancer patients** in remission to provide early warning of recurrence
- The adverse impact of COVID-19 on cancer care has shown that it is essential to have a diagnostic tool which is quick, easy and alleviates the burden of conducting hospital-based surgical tissue biopsies

# FDA substantive review in process for MBC

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**Seeking first ever FDA clearance** for a device to harvest cancer cells from patient blood for subsequent analysis

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- ahead of known competition with five years of clinical development already completed
- agreed with FDA to focus on metastatic breast cancer first
- plan to extend into other cancer types

## FDA clinical study - positive results

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- 200 metastatic breast cancer patients (MBC)
- **primary objective achieved** to capture and harvest cancer cells from the blood of a significant proportion of MBC
- **exploratory goals achieved** cytopathological evaluation, FISH for HER2, RT-qPCR and cDNA libraries for RNA-seq

**Four leading US cancer centres participated**

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- University of Texas MD Anderson Cancer Center
- University of Southern California Norris Cancer Center
- University of Rochester Wilmot Cancer Center
- Robert H Lurie Cancer Center Northwestern University

## Analytical studies positive results

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- precision and reproducibility
- limits of quantification and detection
- accuracy and linearity
- interferences and carryover

# Prospect of FDA clearance during H2 CY21

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- FDA De Novo Submission for Class II clearance in metastatic breast cancer submitted 25 September 2020
  - over 15,000 samples and 400 reports and technical documents
  - successful FDA administrative review and acceptance for substantive review
- Additional Information Request (AIR) received as expected
  - comprehensive response being prepared
  - targeted analytical studies in progress but no further patient samples required
  - response to AIR expected in May 2021
- COVID-19 priorities may impact timing of FDA review
- FDA regulatory decision anticipated during H2 CY21
- Only the third product-based liquid biopsy FDA clearance and the first ever CTC harvesting for subsequent analysis
- FDA clearance recognised as the gold standard globally

*ANGLE is following a De Novo FDA process for Parsortix as there is no predicate device. Consequently there is inherent uncertainty over the timing of the process and its ultimate success.*

# Clinical laboratories established ahead of schedule

Clinical services laboratories established in US and UK as **accelerators and demonstrators**



- Pharma services and initial clinical services
- Offer new tests:
  - epithelial, EMTing, mesenchymal CTCs and clusters
  - ER/PR/HER2 application
  - PD-L1 immunotherapy
  - ovarian cancer test (pelvic mass assay)
- **Accelerator for Parsortix LDT clinical applications**
- Enables early progress with payers and reimbursement codes ahead of FDA cleared product
- CLIA and ISO15189 accreditation planned by year end
- **Demonstrator for Parsortix clinical applications** supporting product sales and corporate partnerships

# First large-scale pharma services contract

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- Contract secured with **oncology focused pharma company** with multiple cancer trials ongoing and planned
- Parsortix ability to capture mesenchymal CTCs and **CTC clusters** seen as a key advantage
- Initial contract worth up to US \$1.2 million over 18 months
- Large global **Phase III study in prostate cancer** and two smaller Phase I studies
- Potential for the smaller studies to progress to larger studies and further contracts in due course
- Analysis being carried out in the newly established clinical laboratories in both the US and UK, in line with ANGLE's strategy of a **global services offering**
- **Discussions in progress with additional customers**, including several major pharma companies

# Ovarian cancer test study enrolment completed



“The next generation ANGLE PMT test has the ability to out-perform current clinical practice in accurately discriminating malignant from benign pelvic masses prior to biopsy or surgery. The improved accuracy of the test results in a high level of sensitivity as well as a substantial reduction in false positives.”

Dr Richard Moore, Director of the Gynecologic Oncology Division, University of Rochester Medical Center Wilmot Cancer Institute

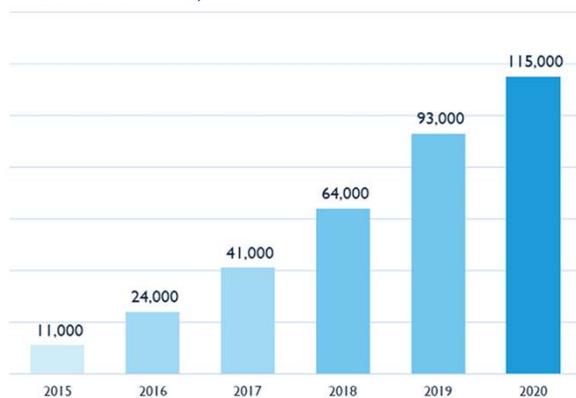
- **Clinical verification 200 patient study in progress** with the University of Rochester Wilmot Cancer Center
- Two 200 patient studies already completed with **best in class results AUC >95%** accuracy achieved. **Potential for high sensitivity and high specificity**
- **Patient enrolment completed post year end.** Surgical procedures in progress and sample analysis in preparation
- Clinical status of patients blinded until analysis complete with study designed to support an LDT regulatory process
- **Establish the test as an LDT in the accredited clinical laboratories around the year end**
- 5-10% of women suffer from abnormal pelvic mass
  - over 750,000 women diagnosed with pelvic mass annually in the US alone
  - over 200,000 women undergo pelvic mass surgery each year
  - up to 12% will subsequently be diagnosed with ovarian cancer

# Leveraged strategy delivers growing body of evidence

- Installed base of over 200 Parsortix systems in active use

## Parsortix samples processed

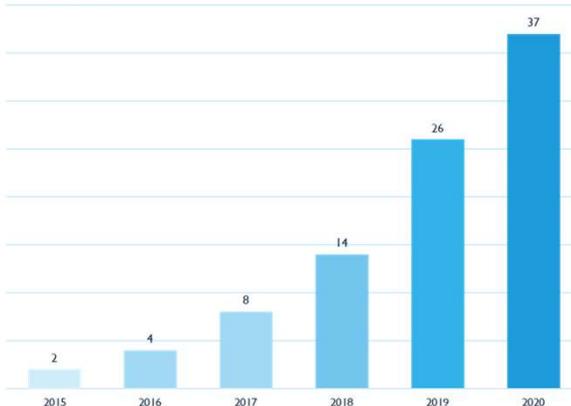
Current – 115,000



Cumulative samples processed at 31 December

## Peer-reviewed publications

Current – 41



Cumulative publications to 31 December

## Eleven peer-reviewed publications in 2020

- Nine independent cancer centres
  - Edith Cowan University, Perth, Australia
  - University Medical Center Hamburg-Eppendorf, Germany
  - Istituto Nazionale Tumori di Milano, Milano, Italy
  - University of Athens, Greece
  - University of Southern California, USA
  - Liquid Biopsy Analysis Unit Santiago, Spain
  - Laboratory of Translational Oncology, Crete, Greece
  - University of Basel, Switzerland
  - University of Texas MD Anderson Cancer Center, USA
- Seven different cancer types
  - melanoma
  - breast cancer
  - renal cell carcinoma
  - brain metastasis
  - head and neck cancer
  - prostate cancer
  - lung cancer
- Since year end, further four publications

# Commercialisation aim to enable entire industry

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## Product-based commercialisation delivers numerous opportunities

- Medtech companies to expand revenue opportunities for installed base
  - expand from one-off tissue biopsy to repeat liquid biopsy tests
- Pharma companies to enable precision medicines
  - expand use of immunotherapy and other drugs
- Contract research organisations (CROs) to expand their pharma services revenue
- Clinical laboratories to expand the range of clinical tests they can offer
  - providing an additional analyte for investigation (CTCs) for RNA and protein expression
  - run from the same blood sample (CTCs as well as ctDNA)
- Cancer screening companies to classify clinically relevant cancer
  - address critical question as to whether the cancer is clinically significant and requires action

# Near term commercialisation plan

- Expanding pharma services business
- Prospect of FDA clearance H2 CY21\*
- Ovarian cancer headline results expected Q4 CY21
- Seeking to launch ovarian cancer test by end CY21 subject to lab accreditation and study results
- Working with others to leverage commercialisation including medtech, pharma, CROs and clinical laboratories
- Increasing body of peer-reviewed customer studies showcasing breadth of utility

## Leading cancer centres with original research and peer-reviewed publications using ANGLE's Parsortix system (selection)

Barts  
Cancer Institute



Fraunhofer  
ITEM

HOUSTON  
Methodist  
LEADING MEDICINE

MDAnderson  
Cancer Network™

MEDIZINISCHE  
UNIVERSITÄT  
WIEN

ROBERT H. LURIE  
COMPREHENSIVE CANCER CENTER  
OF NORTHWESTERN UNIVERSITY

HELLENIC REPUBLIC  
National and Kapodistrian  
University of Athens

University  
of Basel

UKD Universitätsklinikum  
Düsseldorf



USC  
NORRIS  
COMPREHENSIVE  
CANCER CENTER

## Corporate partnerships being developed

**Abbott PHILIPS QIAGEN**

\* ANGLE is following a De Novo FDA process for Parsortix as there is no predicate device. Consequently there is inherent uncertainty over the timing of the process and its ultimate success.

# Questions and answers

# Investment Overview

## ANGLE's Parsortix® system is a simple blood test for personalised cancer care, which harvests viable intact cancer cells (CTCs) for analysis

- unique **patented** microfluidic approach, strongly differentiated from competition
- platform has been shown to work with **24 different cancer types**
- also works for cancer lymph node analysis and for harvesting fetal cells
- CTCs have greater clinical utility than ctDNA (fragments of dead cells) as viable intact cancer cells provide the **complete picture** including DNA, RNA, and protein analysis as well as the potential to culture the cells outside the patient
- multiple areas of new product development

## ANGLE's product-based solution provides a highly leveraged business model which is scalable

- products are low cost but high value with instruments and consumables giving high **gross margins >70%**
- **over 200 instruments in active use with >115,000 samples processed**
- Parsortix widely used by leading researchers, generating new applications for the platform through breakthrough research
- third-party published evidence of performance is growing rapidly with **41 peer-reviewed publications** and numerous posters published by **26 cancer centres**
- outsourced manufacturing suppliers able to scale rapidly without Company capex

## On track to be the first company with FDA clearance for harvesting cancer cells from blood for analysis

- **200 patient FDA clinical study primary objective achieved**
- exploratory goals achieved cytopathological evaluation, FISH for HER-2, RT-qPCR and cDNA libraries for RNA-seq
- **additional information request received** and response being prepared
- prospect of FDA clearance in metastatic breast cancer H2 CY21

## Large scale clinical studies in ovarian cancer significantly out-performed existing standard of care

- **2x 200 patient** studies serve as the exemplar for other applications
- Parsortix HyCEAD Zplex combination showed **95.1% accuracy (AUC-ROC) in detecting ovarian cancer** in women having surgery for an abnormal pelvic mass
- pre-study results confirm success of sample-to-answer optimisation
- clinical verification 200 patient study in progress
- study patient enrolment completed, surgical procedures in progress and sample analysis in preparation
- Study expected to report in Q4 CY21
- abnormal pelvic mass conditions affect 5-10% of all women

## Clinical services laboratories accelerating commercial adoption

- Laboratories in US and UK launched ahead of schedule
- Post year end, first large scale pharma services contract secured
- Sample to answer solutions for EMT and PD-L1 being optimised
- Discussions with additional customers in progress
- CLIA and ISO 15189 accreditation planned for year end
- Ovarian cancer pelvic mass triage test expected to be first Laboratory Developed Test launched by ANGLE

## ANGLE's HyCEAD downstream analysis system offers sample-to-answer growth potential

- optimised to provide high sensitivity for multi-gene panel analysis
- first use ovarian but also offers access to new markets



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