# Interim Results for the six months ended 31 October 2019

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30 January 2020

ANGLE

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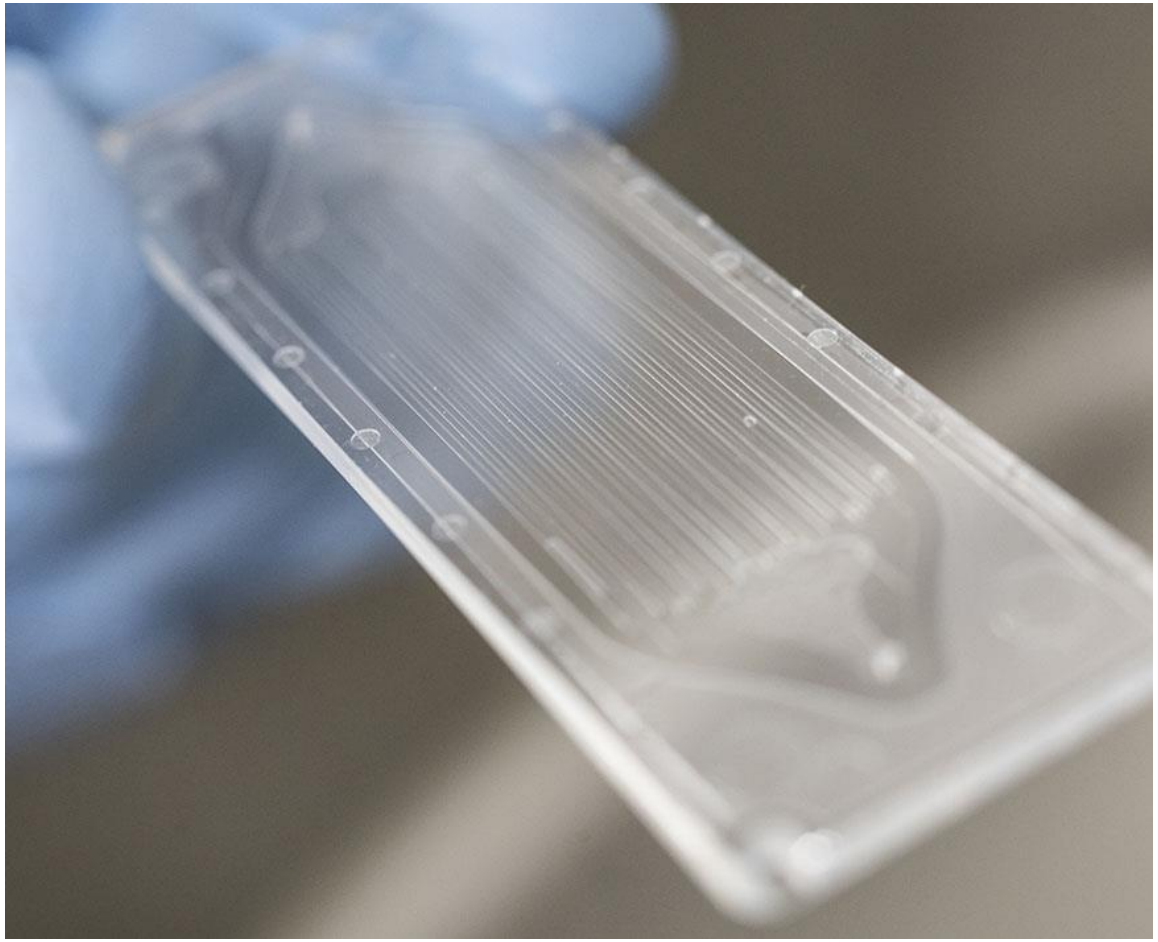
# Liquid biopsy - improving patient outcomes and reducing healthcare costs

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

Simple, effective, affordable repeat testing."

Andrew Newland, Chief Executive



Cancer Research UK

"One in two people born after 1960 in the UK will be diagnosed with some form of cancer during their lifetime."

# Highlights

*Sustained focus on four pronged strategy is delivering*
*clinical studies, regulatory approval, published evidence, and partnerships*

- Clinical and analytical studies completed in support of FDA clearance for metastatic breast cancer
- Ovarian cancer clinical verification study initiated
- Body of published evidence strengthened
- Partnerships with large healthcare companies progressed
- Cash position strengthened

## Leading cancer centres

Barts Cancer Institute
CANCER RESEARCH UK | MANCHESTER INSTITUTE
Fraunhofer ITEM
HOUSTON Methodist LEADING MEDICINE
MD Anderson 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
Universitätsklinikum Hamburg-Eppendorf
MELIORA UNIVERSITY of ROCHESTER
USC NORRIS COMPREHENSIVE CANCER CENTER

## Corporate partnerships

Abbott
PHILIPS
QIAGEN

# Financial Results for six months ended 31 October 2019

| Six months ended 31 October | 2019 | 2018 |
|---|---|---|
| **Statement of Comprehensive Income** | **£'000** | **£'000** |
| Revenue | 401 | 273 |
| Cost of sales | (101) | (69) |
| Gross profit | 300 | 204 |
| Operating costs | (6,727) | (5,340) |
| Tax credit and other income | 1,084 | 888 |
| Loss for the period | (5,343) | (4,248) |

| Statement of Financial Position | 31Oct19 | 30Apr19 |
|---|---|---|
| Trade and other receivables and R&D tax credit | 3,618 | 2,842 |
| Inventories | 847 | 988 |
| Cash | 20,408 | 11,010 |
| Property, plant and equipment | 3,101 | 1,347 |
| Intangible assets | 6,765 | 6,833 |
| **Total assets** | **34,739** | **23,020** |

## Comments

- Revenue up 47%
- Gross margin 75%
- Planned expenditure on clinical studies
- Cash increased to £20.4m
- R&D tax credit receivable £3.0m
- Runway to Summer 2021

# FDA clearance: clinical and analytical studies positive results in metastatic breast cancer

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

- ahead of known competition with over three years of sustained work already completed
- agreed with FDA to focus on metastatic breast cancer first
- plan to extend into other cancer types

## Four leading US cancer centres participating

- 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

## FDA clinical study positive results

- 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

## Analytical studies positive results

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

# Full De Novo FDA Submission in preparation

- **FDA Q-Submission made 29 October 2019**
- Written response to Q-Submission and meeting with FDA in January 2020
  – limited additional analytical studies with contrived samples
  – already in progress at ANGLE laboratories, no impact on timescales, de minimis additional costs
- FDA De Novo Submission for Class II clearance in metastatic breast cancer now in preparation
  – targeting Q1 CY20 submission
- **Prospect of FDA clearance in Q3 CY20**
- Only the third liquid biopsy FDA clearance and the first ever CTC harvesting for subsequent analysis
- **FDA clearance would be a major validation**
  – clinical use for breast cancer -- corporate partnerships
  – pharma services -- research use
- Metastatic breast cancer US $2.4 billion p.a. market potential

*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. Q-Submission process used to mitigate risk.*

# Ovarian cancer pelvic mass triage test
# US $1 billion p.a. market potential

UR MEDICINE | WILMOT CANCER INSTITUTE

"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

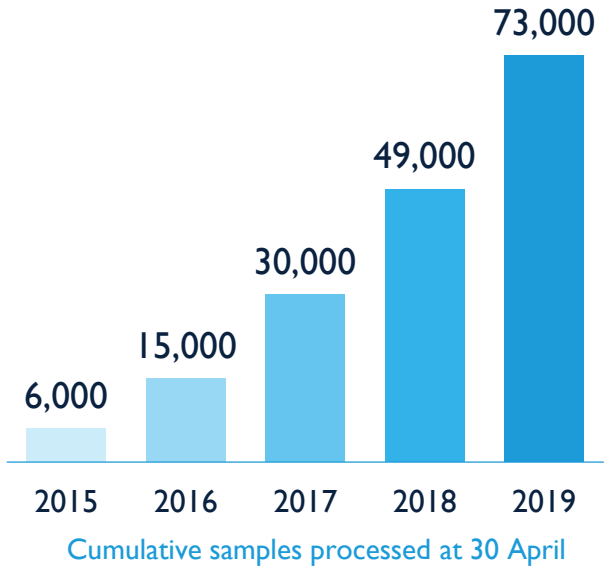
- Two 200 patient studies already completed with **best in class results AUC >95%** accuracy achieved
- Sample-to-answer Parsortix® HyCEAD® Ziplex™ optimised
- Pre-study results demonstrate potential for high sensitivity and high specificity and confirm **success of sample-to-answer optimisation**
- **Clinical verification 200 patient study in progress** with the University of Rochester Wilmot Cancer Center
- **Completion of study patient enrolment expected in Q1 CY20**
- Samples processed using Parsortix and then stored for batch processing with HyCEAD Ziplex at ANGLE laboratories
- Clinical status of patients blinded until analysis complete with study designed to support an LDT regulatory process
- **Study results expected to be reported mid year CY20**
- 5-10% of women suffer from abnormal pelvic mass
- 750,000 women p.a. with abnormal pelvic mass in US market alone

# Body of published evidence continues to grow

Installed base of c.200 Parsortix® systems in active use

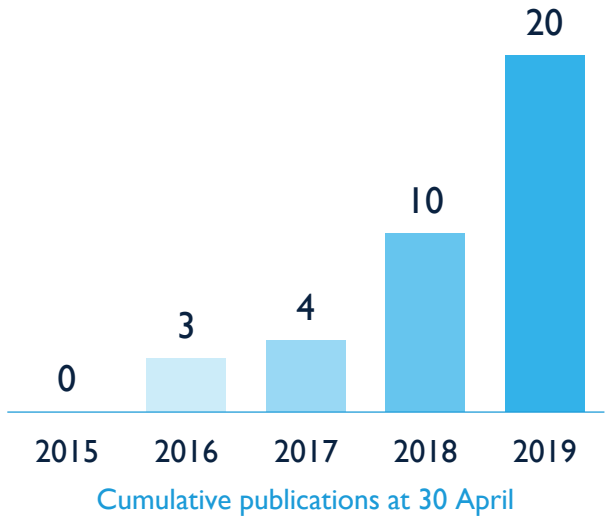
**>16,000 samples and six new publications in the half year**

**Parsortix samples processed**




Cumulative samples processed at 30 April

**Peer-reviewed publications**



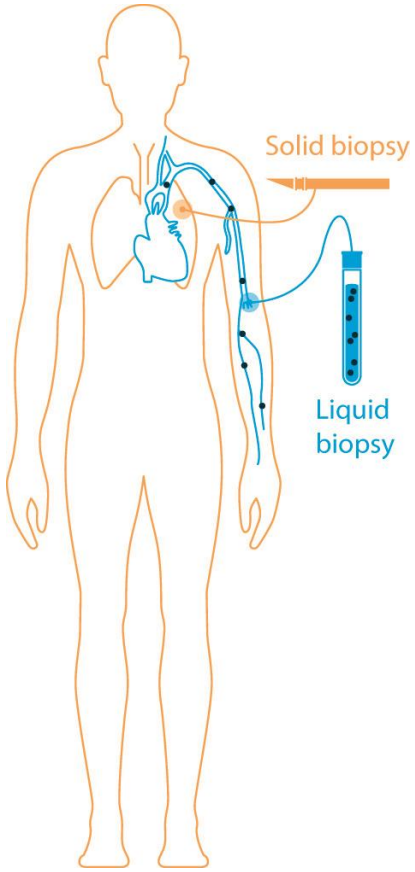

Cumulative publications at 30 April

- University Medical Centre Hamburg-Eppendorf (UKE) **immunotherapy** lung cancer
- Disseminated Cancer Cell Network (DCCNet), Duesseldorf, **single cell** analysis breast cancer
- Medical University of Vienna **neuroendocrine** analysis small cell lung cancer
- Queen Mary University of London's Barts Cancer Institute **unnecessary biopsies** in prostate cancer
- University of Birmingham **head and neck** cancer
- University Medical Centre Hamburg-Eppendorf (UKE) **prediction and monitoring** of therapy melanoma

# Partnerships with large healthcare companies

Work has continued to progress corporate partnerships with the potential to:

- **Expand revenue opportunities** for installed base of medtech companies from tissue biopsy to blood-based repeat tests
  – Abbott breast cancer FISH HER2
  – Qiagen prostate cancer
  – Philips imaging
- **Reduce the cost** of pharma drug trials and enable companion diagnostics for pharma companies
- Provide additional revenue opportunities for clinical laboratories and CROs **providing an additional analyte** for investigation (CTCs as well as ctDNA)




Solid tissue biopsy is invasive

Liquid biopsy from a simple peripheral blood draw

The cancer cells are circulating tumour cells (CTCs) shed by the primary tumour in the process of metastasis. The CTCs travel in the blood and if they take root in another organ are the cause of a secondary cancer at a new location

# Building on a leading position in the liquid biopsy market

- **Highly differentiated solution** for the emerging $ multi billion liquid biopsy market
- **Prospect of first ever FDA clearance** for harvesting cancer cells for analysis in Q3 CY20
- **Ovarian cancer** clinical verification study expected to complete enrolment Q1 CY20 and report mid year CY20
- **Growth planned** through sample-to-answer, pharma services and service laboratory
- **Partnerships with medtech** (downstream analysis), pharma (companion diagnostics), CRO (drug trials), clinical laboratories (LDT)

## Leading cancer centres

Barts Cancer Institute

CANCER RESEARCH UK | MANCHESTER INSTITUTE

Fraunhofer ITEM

HOUSTON Methodist LEADING MEDICINE

MD Anderson 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

Universitätsklinikum Hamburg-Eppendorf

University of Rochester

USC Norris Comprehensive Cancer Center

## Corporate partnerships

Abbott PHILIPS QIAGEN

# Investment Highlights

**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 **23 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

**ANGLE's product-based solution provides a highly leveraged business model which is scaleable**

- products are low cost but high value with instruments and consumables giving high **gross margins >70%**
- **c. 200 instruments in active use with >90,000 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 **26 peer-reviewed publications** and numerous posters published by **23 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
- **positive results for FDA analytical studies achieved**
- prospect of FDA clearance in metastatic breast cancer in Q3 CY20

**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 Ziplex 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
- completion of study patient enrolment Q1 CY20 with reporting mid year CY20
- abnormal pelvic mass conditions affect 5-10% of all women

**Commercial partnership strategy to leverage sales and distribution channels**

- combines ANGLE's cancer cell harvesting capability with existing large players' downstream analysis platforms
- partnership with **Abbott** for HER-2 testing in breast cancer
- partnership with **QIAGEN** for AR-V7 testing in prostate cancer
- European research project with **Philips** combining liquid biopsy with imaging
- progressing other partnerships in cancer and non-invasive prenatal diagnosis

**ANGLE's HyCEAD Ziplex 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