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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.

Product-based solution for simple, effective, affordable repeat testing of intact cells.”

Andrew Newland, Chief Executive

National Cancer Institute United States
An estimated “40% of men and women will be diagnosed with cancer during their lifetime”.

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Highlights

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

- FDA submission made post-period end: passed administrative review by FDA and now under substantive review
- Ovarian cancer clinical verification study enrolling
- Body of published evidence strengthened

This week raised £19.6 million funding (gross) through conditional share placing

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

Corporate partnerships being developed

Abbott  PHILIPS  QIAGEN
Financial Results for six months ended 30 June 2020

### Six months ended 30 June

<table>
<thead>
<tr>
<th>Statement of Comprehensive Income</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>£235</td>
<td>£384</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>(59)</td>
<td>(96)</td>
</tr>
<tr>
<td>Gross profit</td>
<td>176</td>
<td>288</td>
</tr>
<tr>
<td>Operating costs</td>
<td>(6,009)</td>
<td>(6,445)</td>
</tr>
<tr>
<td>Tax credit and other income</td>
<td>1,070</td>
<td>1,310</td>
</tr>
<tr>
<td>Loss for the period</td>
<td>(4,763)</td>
<td>(4,847)</td>
</tr>
</tbody>
</table>

### Comments
- Revenue down 40%; COVID-19 impact on customers
- Gross margin 75%
- Planned expenditure on product development and clinical studies
- Cash position at £13.8m
- R&D tax credit recoverable £2.6m; £1.6m received post period end
- Conditional fundraise this week strengthens cash with £18.5m (net)

### Statement of Financial Position

<table>
<thead>
<tr>
<th></th>
<th>30Jun20</th>
<th>31Dec19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade and other receivables and R&amp;D tax credit</td>
<td>3,315</td>
<td>4,025</td>
</tr>
<tr>
<td>Inventories</td>
<td>905</td>
<td>788</td>
</tr>
<tr>
<td>Cash</td>
<td>13,786</td>
<td>18,766</td>
</tr>
<tr>
<td>Property, plant and equipment and right-of-use assets</td>
<td>3,053</td>
<td>3,022</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>8,448</td>
<td>7,701</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td><strong>29,507</strong></td>
<td><strong>34,302</strong></td>
</tr>
</tbody>
</table>
FDA substantive review in process for MBC

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

- 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

**Four leading US cancer centres participated**

- 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

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Prospect of FDA clearance earliest Q2 CY21

- 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

- Q-Submission process followed to de-risk process

- Successful FDA administrative review and now in substantive review

- 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

- FDA clearance would be a major validation
  - clinical use for breast cancer
  - pharma services
  - corporate partnerships
  - research use

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.
Commercial pathways open up post FDA clearance

- Existing research use only (RUO) sales to leading translational researchers is expected to accelerate with FDA clearance and **expand with sample-to answer solutions**
- Expansion into RUO sales for **pharma services** in drug trials with FDA clearance a requirement for CDx
- **Product-led strategy** for clinical sales of Parsortix instruments and consumables direct to hospitals and corporate partners
- **Clinical laboratory** as an accelerator and demonstrator

**Research**
- Leveraged R&D drives new applications

**Pharma**
- Large scale research use sales
- Drug trials
- Companion Diagnostics

**LDTs**
- Laboratory developed tests in a service laboratory
- Ovarian
- Metastatic breast

**Clinical products**
- Product sales worldwide to hospitals and corporate partners
- Metastatic breast
- Abbott - PathVysion

---

*The Parsortix system is a product-based solution using the optimum sample (intact living cancer cells), compatible with multiple downstream analysis techniques. This allows ANGLE to be both an equipment supplier and a diagnostic test provider.*
Ovarian cancer pelvic mass triage test
clinical study in progress

"The next generation ANGLE PMT test has the ability to outperform 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

- 5-10% of women suffer from abnormal pelvic mass. 295,000 women diagnosed globally with ovarian cancer in 2018
- Two 200 patient studies already completed with best in class results AUC >95% accuracy achieved. Potential for high sensitivity and high specificity
- Clinical verification 200 patient study in progress with the University of Rochester Wilmot Cancer Center
- 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
- Following COVID-19 delays, targeting completion of patient enrolment by Q2 CY21
- Establish the test as an LDT in an accredited clinical laboratory
Growing body of evidence
Leveraged R&D strategy identifying new applications

- Translational research market US $50 million p.a.
- FDA clearance expected to help Parsortix become the CTC system of choice
- Installed base of c.200 Parsortix systems in active use

81% of research published in high impact journals*
including Cell (3) and Nature (1)

Enabling breakthrough research into:
1) CTC Clusters
2) Cancer Cell Culturing
3) Metastatic cancer including brain
4) Biomarkers for immunotherapy

Second most published CTC system (2017-2020) after CellSearch
7 separate studies demonstrate Parsortix outperforms CellSearch

*Based on Impact Factor quartiles Q1 & Q2

### Parsortix samples processed
- Current – 110,000

### Peer-reviewed publications
- Current – 36

#### Research use pricing

<table>
<thead>
<tr>
<th></th>
<th>Instrument</th>
<th>Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price¹</td>
<td>$50,000</td>
<td>$100</td>
</tr>
<tr>
<td>Cost</td>
<td>$15,600²</td>
<td>$15</td>
</tr>
<tr>
<td>Margin</td>
<td>69%</td>
<td>85%</td>
</tr>
</tbody>
</table>

1. Indicative. High margins allow flexibility in pricing for competitive advantage
2. Includes installation, maintenance, technical support, sales and distribution

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Nine peer-reviewed publications 2020 year-to-date

- Edith Cowan University in Perth, Australia treatment response in melanoma
- University Medical Center Hamburg-Eppendorf, Germany in breast cancer including single cell analysis
- Istituto Nazionale Tumori di Milano, Milano, Italy in renal cell carcinoma
- University Medical Center Hamburg-Eppendorf, Germany brain metastasis in non-small cell lung cancer (NSCLC)
- University of Athens, Greece demonstrating molecular analysis in head and neck squamous cell carcinoma (HNSCC)
- University of Southern California, USA developing a workflow for RNA gene expression in prostate cancer
- Liquid Biopsy Analysis Unit at the Health Research Institute of Santiago, Spain MET alterations on CTCs

Following the period end

- University of Southern California, USA comparing Parsortix liquid biopsy to tissue biopsy of a metastatic site in metastatic breast cancer
- Laboratory of Translational Oncology, School of Medicine, University of Crete, Greece breakthrough research using Parsortix to assess response to immunotherapy drugs
Partnership potential to enable entire industry

Wide variety of partnerships possible due to product-based approach with:

- **Medtech companies to expand revenue opportunities** for installed base
  - expand from one-off tissue biopsy to repeat liquid biopsy tests
  - Abbott breast cancer FISH HER2

- **Pharma companies to enable precision medicines**
  - biomarker trials have better outcomes than trials lacking biomarkers
  - reduce the cost and time of pharma drug trials
  - enable companion diagnostics

- **Clinical laboratories and CROs to provide additional revenue opportunities**
  - providing an additional analyte for investigation (CTCs)
  - run from the same blood sample (CTCs as well as ctDNA)

- **Screening companies (Grail, Guardant, Foundation etc) to classify clinically relevant cancer**
  - ctDNA detection of cancer associated mutations does not translate to requirement for intervention
  - risk of over-diagnosis and over-treatment
  - CTCs may address critical question as to whether the cancer is clinically significant and requires action
New funding will accelerate commercialisation

Accredited clinical laboratories being established in US and UK as accelerator and demonstrator

- 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
- **Demonstrator for Parsortix clinical applications**
  supporting product sales and corporate partnerships
Building on a leading position in the liquid biopsy market

• Highly differentiated solution for the emerging multi US$ billion liquid biopsy market

• Prospect of FDA clearance earliest Q2 CY21*

• Ovarian cancer clinical verification study expected to complete enrolment Q2 CY21

• Growth planned through sample-to-answer, pharma services and service laboratory

• Expanding partnerships with medtech (downstream analysis), pharma (companion diagnostics), CRO (drug trials), clinical laboratories (LDT)

• Substantial 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)

Corporate partnerships being developed

*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.

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**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

**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 Q2 CY21
- abnormal pelvic mass conditions affect 5-10% of all women

**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 >110,000 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 36 peer-reviewed publications and numerous posters published by 24 cancer centres
- outsourced manufacturing suppliers able to scale rapidly without Company capex

**Commercial partnership strategy to leverage sales and distribution channels**
- combines ANGLE’s cancer cell harvesting capability with existing large players’ downstream analysis platforms and solutions
- 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

**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 earliest Q2 CY21

**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