Interim results for the six months ended 30 June 2021

Andrew Newland and Ian Griffiths
30 September 2021
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Liquid biopsy - improving patient outcomes and reducing healthcare costs

“ANGLE’s mission is to enable personalized cancer care by providing the best sample 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

Parsortix® cassette

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

Significant progress against key strategic objectives

• FDA review of De Novo Submission for Class II clearance in metastatic breast cancer progressing as expected
  – comprehensive response to AIR submitted as planned

• Clinical laboratories in the UK and United States opened ahead of plan
  – first pharma services contracts secured
  – further assay development contract signed post period end
  – discussions with multiple potential customers initiated

• Ovarian cancer detection study nearing completion
  – patient enrolment completed
  – sample analysis in preparation

• Body of published evidence strengthened

• Post period end, capital raise of £20 million well supported by new and existing shareholders in UK and United States

• Proceeds to fund:
  – clinical studies in prostate cancer. Design discussions with major US urological group initiated
  – build out of commercial management team in United States
  – assay development capability
  – commercialisation in breast and ovarian cancers and support of pharma services growth
## Financial Results for six months ended 30 June 2021

<table>
<thead>
<tr>
<th></th>
<th>Six months ended 30 June 2021</th>
<th>Six months ended 30 June 2020*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>£’000</td>
<td>£’000</td>
</tr>
<tr>
<td><strong>Statement of Comprehensive Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenue and grant income</td>
<td>312</td>
<td>268</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>(77)</td>
<td>(59)</td>
</tr>
<tr>
<td>Gross profit and grant income</td>
<td>235</td>
<td>209</td>
</tr>
<tr>
<td>Operating costs</td>
<td>(8,897)</td>
<td>(4,645)</td>
</tr>
<tr>
<td>Tax credit and net finance costs</td>
<td>979</td>
<td>1,037</td>
</tr>
<tr>
<td>Loss for the period</td>
<td>(7,683)</td>
<td>(3,399)</td>
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<table>
<thead>
<tr>
<th></th>
<th>30 June 2021</th>
<th>31 December 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statement of Financial Position</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade and other receivables and R&amp;D tax credit</td>
<td>4,583</td>
<td>3,570</td>
</tr>
<tr>
<td>Inventories</td>
<td>1,076</td>
<td>742</td>
</tr>
<tr>
<td>Cash and short-term deposits</td>
<td>21,031</td>
<td>28,618</td>
</tr>
<tr>
<td>Property, plant and equipment and right-of-use assets</td>
<td>4,409</td>
<td>2,409</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>3,653</td>
<td>3,710</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>34,752</td>
<td>39,049</td>
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</tbody>
</table>

### Comments
- Revenue increased by 26%
- Gross margin at 74%
- Planned expenditure of £8.9 million
- Cash position increased to £21.0 million
- Fundraise of £18.9 million (net) July 2021

* Restated
Commercialization process

- Leveraged Research & Development
  - 46 peer-reviewed publications
  - 29 independent cancer centres
  - 24 cancer types

- ANGLE Development Process
  - Assay Development
  - Clinical Validation

- ANGLE Clinical Laboratories
  - Accelerator and Demonstrator
  - Pharma Services
  - LDTs: Ovarian, others

- Leveraged Commercialization
  - CROs
  - Reference Laboratories

FDA Product Clearance: Turbo-charge
FDA clearance: regulatory response anticipated in H2 2021

• FDA De Novo Submission for Class II clearance in metastatic breast cancer submitted 25 September 2020
  – 400 subject clinical study with four leading United States cancer centres
  – over 15,000 samples and 400 reports and technical documents
  – successful FDA administrative review and acceptance for substantive review

• Additional Information Request received as expected
  – comprehensive response submitted, announced 4 June 2021
  – targeted analytical studies but no further patient samples required
  – over 1,000 additional samples and 20 reports and technical documents

• COVID-19 priorities may impact timing of FDA review

• FDA regulatory response anticipated in H2 2021*

• Only the third product-based liquid biopsy FDA clearance and first ever for CTC harvesting for subsequent analysis

• FDA clearance recognised as the gold standard globally and would be a major validation

* ANGLE is following a De Novo FDA process for the Parsortix system as there is no predicate device. Consequently there is inherent uncertainty over the timing of the process and its ultimate success.
Clinical laboratories established in UK and United States

• **Pharma services business growing**
  – first pharma services contracts signed including first assay development contract signed post period end
  – initial capacity intended for 50,000 samples p.a. at $1,000 baseline price and up to $2,000 per sample
  – only a small number of large-scale pharma customer relationships opens up a very large market
  – discussions ongoing with multiple potential customers

• **Accelerator for clinical applications**
  – clinical laboratory accreditation targeting year end 2021
  – ovarian cancer LDT first clinical application planned
  – early progress with payers and reimbursement codes

• **Demonstrator for Parsortix applications**
  – supporting product sales and corporate partnerships
  – pharma services transferred to CROs
  – clinical applications established by independent clinical laboratories
Pharma services – immunotherapy
PD-L1 biomarker assay c. US $1.6 billion p.a. global market

• 2020 spend on PD-L1 immunotherapy drugs US $27 billion growing at >22% p.a. yet only 13%-50% of patients respond to treatment which costs c. US $170,000 per patient and has significant side effects

• CTCs uniquely placed as the only liquid biopsy able to assess PD-L1 protein expression status

• “Understanding proteins is critically important when developing drugs, selecting treatments, and predicting treatment response. Integration of proteomic information is the next step in precision oncology.” National Cancer Institute, August 2020

<table>
<thead>
<tr>
<th>PD-L1 Drug Trials</th>
<th>Price per sample (US$)</th>
<th>Mean # of patients per trial</th>
<th>Number of trials</th>
<th>Number of patients in trials</th>
<th>Number of samples per patient</th>
<th>Addressable number of samples</th>
<th>Addressable market p.a. (US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Phase 1</td>
<td>$1,200</td>
<td>82</td>
<td>533</td>
<td>43,812</td>
<td>2</td>
<td>87,624</td>
<td>$105 million</td>
</tr>
<tr>
<td>2 Phase 2</td>
<td>$1,200</td>
<td>95</td>
<td>1,557</td>
<td>147,231</td>
<td>3</td>
<td>441,693</td>
<td>$530 million</td>
</tr>
<tr>
<td>3 Phase 3</td>
<td>$1,200</td>
<td>589</td>
<td>339</td>
<td>199,738</td>
<td>4</td>
<td>798,952</td>
<td>$959 million</td>
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</table>

2,429 390,781 1,328,269 $1,594 million

Note: the same assay can be used for all three Phases. However sales will generally progress through the trial phases. Hence early sales will typically be Phase 1 trials.

Note: revenues shared with the contract research organization providing the test.

Note: successful drug trials may lead to ongoing clinical revenues as a companion diagnostic.

Data from Clinical Trials.gov. Search completed at 08.52 on 28 May 2021. Search terms PD-L1/PD-1 interventional trials which are enrolling or in progress
First pharma services contracts secured

• ANGLE’s pharma services business launched in Q1 2021, addressing a new market for use of the Parsortix system in cancer drug trials. Sales processes being developed to demonstrate capability, quality systems, sample handling and reporting

• Contracts already secured with three oncology-focused pharma companies

• Samples now being processed and analysis being carried in ANGLE’s laboratories and results being provided to customers, as a global services offering

• Contracts include a global Phase III study in prostate cancer and the development of bespoke immunofluorescence assays to detect specific target proteins

• Assay development a major step for ANGLE, building a menu of pre-developed tests that can be offered to pharma customers and used for longitudinal analysis of patient samples in clinical trials

• Potential for existing customers to progress to larger studies and further contracts in due course

• Discussions in progress with additional customers, including several major pharma companies
Ovarian cancer pelvic mass triage test
clinical study in progress

“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

- 5-10% of women suffer from abnormal pelvic mass
- Over 200,000 women p.a. in US alone have surgery for pelvic mass with advance diagnosis of ovarian cancer a critical unmet medical need
- Two 200 patient studies already completed
- Best in class results AUC >95% accuracy achieved through the combination of ANGLE’s proprietary Parsortix and HyCEAD systems – potential for high sensitivity and high specificity
- Clinical verification study in progress with the University of Rochester Wilmot Cancer Center – patient enrolment complete – clinical status of patients blinded until analysis complete with study designed to support LDT regulatory process – headline results expected Q4 2021
- Planning to offer LDT test from ANGLE clinical laboratories

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Ovarian cancer clinical tests c. US $1.3 billion p.a. market (United States only)

- 500,000 p.a. diagnosed with abnormal pelvic mass, c. 200,000 surgery with c. 22,000 ovarian cancer

- Critical unmet medical need to ensure suspected ovarian cancer patients referred to specialist
  - OVA-1 has same intended use - Aspria Women’s Health - market cap c. US $380 million at 28 September 2021
  - 92.4% sensitivity, 53.5% specificity; reimbursement code $897; test volume 2020 ~13,600 tests
  - prevalence only 11% so PPV <20% with 4 false positives for each true positive

- Watchful waiting - monitoring women diagnosed with pelvic mass who have not yet had surgery
- Remission monitoring for 235,000 cancer survivors with 85% risk of recurrence

<table>
<thead>
<tr>
<th>Application</th>
<th>Reimbursement potential (US$)</th>
<th>Number of patients p.a.</th>
<th>Number of tests per patient p.a.</th>
<th>Addressable number of tests p.a.</th>
<th>Addressable market p.a. (US$)</th>
<th>Target market entry</th>
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<tbody>
<tr>
<td>1 Pelvic mass surgery triage</td>
<td>$1,000</td>
<td>200,000</td>
<td>1</td>
<td>200,000</td>
<td>$200 million</td>
<td>Q4 CY21</td>
</tr>
<tr>
<td>2 Watchful waiting</td>
<td>$1,000</td>
<td>300,000</td>
<td>2</td>
<td>600,000</td>
<td>$600 million</td>
<td>CY22</td>
</tr>
<tr>
<td>3 Remission monitoring</td>
<td>$1,000</td>
<td>235,000</td>
<td>2</td>
<td>470,000</td>
<td>$470 million</td>
<td>CY23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>735,000</td>
<td>$1,270 million</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,270,000</td>
<td></td>
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Prostate cancer next major investment focus

• **1 in 8 men will be diagnosed with prostate cancer**
  – in the United States alone, estimated 250,000 new cases (2021) and 3.2 million (2018) living with prostate cancer

• **1 million prostate biopsies undertaken each year in United States**
  – despite advances in imaging, a tissue biopsy is required to establish diagnosis
  – 75% of biopsies are negative so unnecessary but miss 30%-40% of cancer cases
  – 25% of tissue biopsies diagnose prostate cancer (15% indolent / 10% aggressive)

• **Procedure has high incidence of complications**
  – 98% some side effects, 32% moderate and 1.4% major complications
  – post-biopsy sepsis occurs in 2-5% of cases with up to 25% of these admitted to ICU

*Liquid biopsy offers a unique opportunity to triage men with elevated PSA avoiding the need for invasive core tissue biopsy for the 90% of patients with benign or indolent disease*

*Barts Cancer Institute published a study in Clinical Cancer Research of 81 prostate cancer patients (43 CRPC and 38 localized) where using the Parsortix system they found CTCs in 100% of CRPC patients and 79% of localized patients (90% of all patients)*
Prostate cancer clinical tests c. US $6.7 billion p.a. market (United States only)

Application | Reimbursement potential (US$) | Number of patients p.a. | Number of tests per patient p.a. | Addressable number of tests p.a. | Addressable market per annum (US$) | Target market entry
--- | --- | --- | --- | --- | --- | ---
1 High risk screening | $1,000 | 1,203,000 | 1 | 1,203,000 | $1,203 million | Q4 CY22
2 Active surveillance | $1,000 | 738,000 | 2 | 1,476,000 | $1,476 million | CY23
3 Therapeutic decision making | $1,500 | 512,000 | 4 | 2,048,000 | $3,072 million | CY24
4 Remission monitoring | $500 | 1,995,000 | 1 | 1,995,000 | $998 million | CY24

|  | 4,448,000 | 6,722,000 | $6,749 million |

- 11 million men have a PSA test in the US each year – c. 1.2 million will have an abnormal result
- Average cost of prostate biopsy ~ US$2,000
- NCCN guidelines recommend biomarker testing for all stages of prostate cancer to inform targeted treatment including BRCA1, BRCA2, ATM, CHEK2, PALB2, microsatellite instability (MSI) and mismatch repair (MMR)
- Active surveillance - monitoring men diagnosed with indolent cancer to assess any change in status
- Remission monitoring for 2 million cancer survivors with 24%-48% risk of recurrence
Growing body of evidence
Leveraged R&D strategy identifying new applications

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

Parsortix samples processed
30 June 2021 – >127,000

Variety of downstream analysis techniques:
- RT-qPCR
- dd-PCR
- RNAseq
- Immunofluorescence
- WGS
- WES & WTA
- Mass Spectrometry

# of publications by cancer type: top 5
- Breast 21
- Lung 11
- Prostate 9
- Melanoma 6
- Head and neck 3

46 Peer-reviewed journal publications

39 published in high impact journals

Complete picture
DNA, RNA & proteins

29 independent centres in 12 countries

10 studies enabling breakthrough research

At least 1,700 patient samples processed

24 cancer types representing 89% of solid tumours

9 studies demonstrating superiority to market leader

2nd most published CTC system in last 5 years

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Commercialisation aim to enable entire industry

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
  – potential to mitigate risk of over-diagnosis and unnecessary treatment
Near term milestones

• Expanding pharma services business

• FDA clearance: regulatory response anticipated in H2 2021*

• Ovarian cancer headline results expected Q4 2021

• Seeking lab accreditation by year end 2021 to enable launch of ovarian cancer test

• Partnerships to leverage commercialisation including medtech, pharma, CROs and clinical laboratories

• Increasing body of peer-reviewed customer studies showcasing breadth of utility

• Major new opportunity in prostate cancer

* ANGLE is following a De Novo FDA process for the Parsortix system 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 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 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
• potential to address risks of early stage screening by identifying clinically significant disease

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 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 and sample analysis in preparation
• study expected to report headline results in Q4 2021
• 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%
• over 200 instruments in active use with >122,000 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 46 peer-reviewed publications and numerous posters published by 29 cancer centres
• outsourced manufacturing suppliers able to scale rapidly without Company capex

Clinical services laboratories accelerating commercial adoption
• laboratories in UK and United States launched ahead of schedule in Q1 2021
• first large scale pharma services contract secured
• first assay development contract won
• Sample-to-answer solutions for EMT and PD-L1 being optimised
• discussions with multiple additional pharma 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

On track to be the first company with FDA product clearance for harvesting cancer cells from blood for analysis
• 400 subject 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 submitted
• prospect of FDA clearance in metastatic breast cancer, regulatory response anticipated in H2 2021

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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ANGLE Europe Ltd
10 Nugent Road
Surrey Research Park
Guildford GU2 7AF
United Kingdom

ANGLE North America Inc
5100 Campus Drive
Suite 120
Plymouth Meeting
PA 19462
USA

ANGLE Biosciences Inc
50 Ronson Drive, Suite 105
Toronto
Ontario M9W 1B3
Canada

www.angleplc.com