Preliminary Results for the year ended 31 December 2022

Transforming cancer care with the first FDA cleared medical device for the capture and harvest of circulating tumour cells

Andrew Newland and Ian Griffiths
21 April 2023
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**National Cancer Institute United States:**
An estimated 40% of men and women will be diagnosed with cancer during their lifetime

**Our Mission:**
Enable personalized cancer care with a simple blood test to guide treatment, improving patient outcomes and reducing healthcare expenditure

**Our Solution:**
The Parsortix system
- **first and only FDA cleared product** for harvesting CTCs for subsequent analysis
- ANGLE believes it provides the **best sample** of tumor material from a patient’s cancer using a liquid biopsy
- enables **effective, affordable, repeat** testing of intact cells
2022 Highlights

A breakthrough year for ANGLE and for liquid biopsy

Products

- **US FDA De Novo** (Class II) medical device application granted
- **First ever FDA cleared device** to harvest circulating tumour cells (intact living cancer cells) from patient blood for subsequent analysis
- **First mover advantage** for intact cancer cell analysis in the global liquid biopsy market
- With FDA grant, CE mark and UK MHRA in place, **global distributor network** being established

Services

- Global pharma services business **gathering momentum**
- **Repeat business secured** from early customers
- **Increased pipeline** of opportunities following FDA clearance
- **First bespoke assay** development project successfully completed
- **ISO 15189 accreditation** received for the United States clinical laboratory (UK to follow)

Clinical use

- **Excellent ovarian cancer headline results** - ROC-AUC 95.4% best-in-class – demonstrating validity of the assay in a difficult real-world setting. Now transferring to a third party molecular platform to maximise commercial potential
- **Prostate cancer** partnership with Solaris Health with study underway to develop a test to address major unmet need. Headline results of pilot study expected around year end with Solaris Health offering first route to clinical market
Outlook

Strong growth in 2023 and beyond

• **Q1 2023 revenues (unaudited) strongly ahead** with both products and services progressing well

• **New pharma services customers** such as Crescendo Biologics, repeat business from existing customers, and a growing pipeline of potential business opportunities

• **HER2 CTC assay development agreement** with BioView, opening up a major market opportunity in breast cancer with potential for additional large-scale commercial partners

• **Prostate cancer pilot study on track** for headline results anticipated around year end

• Assessment of third-party molecular platforms yielding **highly encouraging results**

• **Pipeline of assays in development adding ‘content’** for services and products

• **Management confident in delivering strong growth in 2023 and beyond**
## Financial Results for the year ended 31 December 2022

### Statement of Comprehensive Income

<table>
<thead>
<tr>
<th></th>
<th>2022 £'000</th>
<th>2021 £'000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>1,041</td>
<td>1,013</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>(428)</td>
<td>(302)</td>
</tr>
<tr>
<td>Gross profit</td>
<td>613</td>
<td>711</td>
</tr>
<tr>
<td>Operating costs - cash</td>
<td>(19,496)</td>
<td>(15,300)</td>
</tr>
<tr>
<td>Operating costs - non-cash (Share-based payments, Depreciation, Amortisation, unrealised FX)</td>
<td>(5,324)</td>
<td>(2,646)</td>
</tr>
<tr>
<td>Tax credit and net finance costs</td>
<td>2,521</td>
<td>2,223</td>
</tr>
<tr>
<td><strong>Total expenses</strong></td>
<td><strong>(21,686)</strong></td>
<td><strong>(15,012)</strong></td>
</tr>
</tbody>
</table>

### Statement of Financial Position

<table>
<thead>
<tr>
<th></th>
<th>2022 £'000</th>
<th>2021 £'000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade and other receivables and R&amp;D tax credit</td>
<td>4,673</td>
<td>5,779</td>
</tr>
<tr>
<td>Inventories</td>
<td>2,059</td>
<td>1,748</td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>31,896</td>
<td>31,839</td>
</tr>
<tr>
<td>Property, plant and equipment and right-of-use assets</td>
<td>8,476</td>
<td>4,376</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>2,764</td>
<td>3,573</td>
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<tr>
<td><strong>Total assets</strong></td>
<td><strong>49,868</strong></td>
<td><strong>47,315</strong></td>
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### Comments:

- Revenue flat but now growing strongly in Q1 2023
- Gross margin 59%
- Planned operating expenditure (cash) £19.5 million
- Streamlined operations, increased cash runway into H2 CY24
- Cash position maintained at £31.9 million
- R&D tax credit due £2.8 million
- Fundraise £18.9 million (net) July 2022
Commercial strategy

Key commercialisation drivers

- Regulatory clearance: FDA, CE mark and UK MHRA in place
- Assay development: to provide end-to-end solutions such as Pap staining, Portrait Flex, DDR and PD-L1
- Clinical studies: run in real-world conditions showing value of system, such as completed ovarian cancer study and ongoing prostate cancer study
- Partnerships: seeking deals with downstream analysis companies to leverage sales channels and fund commercialisation
- Reimbursement: a lengthy process with global complexity but progress being made in multiple territories

Business areas

- **Product business**
  - expanding existing research sales to clinical labs
  - setting up distributors to broaden sales capability
  - developing assay kits and molecular protocols to provide content

- **Services business**
  - clinical trials for pharma
  - potential for CDx
  - laboratory developed tests for clinical market

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**Commercial strategy**

*Major market opportunities for all business areas*

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**Growth**

**Near term (5 years)**

- **Services**: Pharma services
  - Potential annual revenue: c £50 million

**Mid-term (10 years)**

- **Services**: Laboratory Developed Tests
  - Potential annual revenue: c £100 million

**Long term (20 years)**

- **Products**: Instruments, consumables, kits
  - Potential annual revenue: c £500 million

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- For illustrative purposes only and based on current capabilities and capacity. Not intended to be at scale.
- Preliminary and subject to change, dependent on assumptions and uncertainties including, amongst other things, clinical trials, regulatory and commercial success and availability of supply.

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**Products - FDA clearance recognized as gold standard**

**First ever FDA clearance** for a device to harvest CTCs, intact living cancer cells, from MBC patient blood for subsequent analysis

- enabling platform for end users to develop clinical applications
- ahead of known competition with over six years of clinical development already completed
- initial clearance in metastatic breast cancer with plan to extend into other cancer types

**INTENDED USE**

The Parsortix® PCI system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K₂EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix PCI system for use in subsequent downstream assays.

The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.

*Any other product or services currently offered are for research use only and not for use in diagnostic procedures.
**Products - harnessing KOLs to raise Parsortix profile in clinical community**

**Michael F. Press, MD, PhD**  
**Parsortix Instruments Placed:** 2 Parsortix PC1 Systems  
**Area of study:** Evaluation of HER2 FISH in CTCs from breast cancer patients with matching HER2 FISH from tissue

**Massimo Cristofanilli, MD, FACP**  
**Parsortix Instruments Purchased:** 4 Parsortix PR1 Systems *  
* Owned by Liquid Biopsy Center Core Laboratory  
**Area of study:** Molecular characterization of CK+/CD45+ CTCs at the single-cell level by RNA sequencing

**Daniel F. Hayes, MD, FACP, FASCO**  
**Parsortix Instruments Planned:** 2 Parsortix PC1 Systems  
**Area of study:** Evaluation of Parsortix and Portrait+ assay and downstream evaluation using DepArray in comparison to CellSearch System

**James Reuben, PhD, MBA**  
**Parsortix Instruments Placed:** 2 Parsortix PR1 Systems 6 Parsortix PC1 Systems  
**Area of study:** Development of nanoString nCounter assay for metastatic breast cancer
Products - sales and distribution network being established for international penetration

- **Direct sales team** being expanded in United States and UK

- **Distribution partners** selected for other key territories based on:
  - local knowledge and language
  - exposure to oncology markets
  - compliance with quality systems
  - technical expertise and service capability

- **New content to drive adoption**:
  - Portrait+ kits
  - Portrait+ PD-L1 kits
  - Landscape+ molecular protocols
Services - clinical laboratories building capacity

- In 2021, ANGLE opened clinical laboratories in the US and UK
- ANGLE’s US Clinical Laboratory is A2LA accredited to ISO 15189 (certificate number 6569.01)
- The ISO 15189 accreditation demonstrates that ANGLE’s clinical laboratory maintains globally recognised standards
- Provides evidence for pharma services customers that the laboratories are stable, robust, compliant, and subject to periodic external inspections by recognised organisations
Services - differentiated pharma services offering

• **Customer base established and growing**
  – multiple customers secured, repeat business being received
  – new customers in 2023 and growing pipeline of others in discussion
  – anticipated to be the first significant revenue generator for ANGLE

• **Significant revenue and profitability potential**
  – each contract can be over US$1 million
  – margins over 75%
  – each customer can offer numerous repeat contracts
  – only a small number of large-scale pharma customer relationships
    opens up a very large market

• **Assay development capability**
  – offers pharma bespoke services not possible otherwise
  – targeting the protein of action of the drug
  – cannot be achieved with ctDNA
  – longitudinal monitoring not possible with tissue biopsy

• **CRO out-source growth potential**

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Howard I. Scher, MD
Medical Oncologist
Head of the Biomarker Development Program; D. Wayne Calloway Chair in Urologic Oncology Prostate Cancer

Dr Scher identifies the presence or absence of CTCs as being the best biomarker to assess the effectiveness of a treatment. This enables the early determination of whether a drug is efficacious for a particular patient and might speed up clinical trials and greatly reduce pharma costs

Content - assay development for products and services

**Product business area**
- **Product kits, reagents and protocols**
- **Distributors**
- **Clinical laboratory customers**

**Services business area**
- **Verification and Validation of assays**
- **Transfer to ANGLE clinical laboratories**
- **Pharma and biotech customers**

**Imaging Assays**
- **Immunofluorescent staining of CTCs including:**
  - Portrait Flex for mesenchymal and epithelial CTCs in combination with custom biomarker
  - Portrait PD-L1
  - Portrait DNA Damage repair (DDR)
  - Portrait HER2
  - Custom assays

**Molecular Assays**
- **Molecular analysis of CTCs including:**
  - Landscape DNA dPCR
  - Landscape RNA dPCR
  - Landscape DNA next-generation sequencing
  - Landscape RNA next-generation sequencing
  - Custom assays and panels

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Content - assay development pipeline for 2023

Q1 2023
- Portrait Flex

Q2 2023
- Portrait™ PDL1
- Portrait™ DDR
- Portrait™ HER2

Q3 2023
- Landscape+™ KRAS (DNA dPCR)
- Landscape+™ EGFR (DNA dPCR)

Q4 2023
- Landscape+™ PIK3CA (DNA dPCR
- Landscape+™ RNA dPCR panels inc for ovarian and prostate samples

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Spotlight on Portrait™ Flex assay

• ANGLE has developed Portrait™ Flex, an immunofluorescence assay for the identification of epithelial, mesenchymal and EMTing CTCs

• Additionally, this assay offers the possibility of adding any bespoke protein biomarker, based on customer needs

• The clinical utility of CTC biomarkers is a rapidly growing field facilitating the identification of druggable targets as well as providing prognostic information, predicting treatment response, resistance, and patient relapse.

• Assay has high analytical sensitivity and specificity (>90%) for the detection of epithelial and mesenchymal CTCs (known to be involved in metastasis and drug resistance)

• Launched as a service in Q2, 2023

<table>
<thead>
<tr>
<th></th>
<th>Analytical Sensitivity</th>
<th>Analytical Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epithelial</td>
<td>99.1%</td>
<td>95.8%</td>
</tr>
<tr>
<td>Mesenchymal</td>
<td>93.5%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Harvest Linearity - Spiked Cells

\[ y = 0.4517x + 1.1974 \]

\[ R^2 = 0.85 \]
Spotlight on DDR assays

- Tumour progression is strongly correlated with defects in the DDR pathway which result in uncontrolled cell proliferation

- **ANGLE has developed two DNA Damage Repair (DDR) immunofluorescence assays for biomarkers gamma-H2AX (γH2AX) and phospho-KAP1 (pKAP1)**

- An increase in γH2AX positive CTCs can be seen after a single dose and can be utilised to rapidly assess the pharmacodynamic effects and treatment response to support drug development

- ANGLE’s DDR assays will be launched as a service in Q3 CY23

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**US$ 3.5bn**
estimated global market value of DDR therapeutics in 2020

**US$ 24.8bn**
estimated global market value of DDR therapeutics by 2030 with a **CAGR of 21.3%**

**123,000**
participants currently enrolled in active DDR clinical studies

**105**
DDR drugs in development
 DDR Assay performance

- High analytical sensitivity and specificity (>90%)

<table>
<thead>
<tr>
<th></th>
<th>Analytical Sensitivity</th>
<th>Analytical Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>γH2AX</td>
<td>87%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>pKAP1</td>
<td>82%</td>
<td>100%</td>
</tr>
</tbody>
</table>

- Clear dose response observed

Dose response of γH2AX positivity in MCF7 cells following treatment with increasing doses of Etoposide

Dose response of pKAP1 positivity in H226 cells following treatment with increasing doses of Etoposide.

Patient CTCs showing diffuse and foci IF staining
Spotlight on Portrait PD-L1 assay

- Because CTCs are live, intact cancer cells, **PD-L1 protein expression can be measured on CTCs** (something not achievable using ctDNA).

- Eight independent peer-reviewed publications in 373 patients report on the assessment of PD-L1 on CTCs isolated using the Parsortix system. These studies report on CTC PD-L1 status across four cancer types – lung, breast, ovarian and head and neck cancer.

- In addition to patient selection, studies suggest that an increase in **PD-L1+ CTCs** could have the **potential to predict resistance** to PD-L1/PD-1 inhibitor treatment.

- ANGLE has developed a Portrait PD-L1 immunofluorescence assay for determination of PD-L1 expression levels.

- The performance of the assay is in the process of being verified in ANGLE's clinical laboratories.

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**US$1.7bn**
PD-L1 pharma services market value

**US$31.4bn**
growing at 5-year CAGR of 27%
Spend on PD-1 and PD-L1 immunotherapy drugs in 2021

~430,000 patients
Currently enrolled on an active PD-L1/PD-1 clinical study

**US$175,000**
Average ICI treatment cost per patient per year
PD-L1 assay performance

- High analytical sensitivity and specificity
  - PD-L1: 81% Sensitivity, 98% Specificity
  - Epithelial markers: 98% Sensitivity, 99% Specificity
  - Mesenchymal markers: 97% Sensitivity, 92% Specificity

- Easy visualisation of PD-L1 positive CTCs
  (representative staining of a patient CTC cluster)

- Strong linearity observed in spiked samples

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R² = 0.9064

# of Cells Harvested

Actual # of Cells Spiked

Harvest Linearity Based on Actual Spike Level
HER2 assay – collaboration with BioView

- Breast cancer is highly heterogeneous and HER2 status can change over time
- New antibody-drug conjugates (ADCs) to treat patients with low HER2 status, which cannot be assessed by FISH alone, are disrupting the HER2 market
- These factors have created a **significant need for a quantitative CTC based HER2 assay** that can monitor HER2 status over time. This cannot be achieved with tissue-based assays
- Combining ANGLE’s Parsortix system and Portrait Flex assay with BioView’s automated microscopy system has the potential for a **unique CTC HER2 assay kit with major commercial potential**
- Development phase due to commence shortly and take ~12 months to complete. PathVysion FISH tests to be provided by Abbott
- First phase to generate **revenues of £1.2 million** for ANGLE
- ANGLE and BioView in discussion with third parties to explore routes to market and potential for additional project funding

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**80.2%**
Predicted increase in global cases of breast cancer from 2020 to 2040

**55%**
of all breast cancer cases are HER2-low and could therefore be treated with ADCs like Enhertu

**$12.5bn**
Global sales forecast for HER2 drugs in 2023

**US$ 313.4m**
Global value of HER2 diagnostics market in 2021. This is forecast to reach US$ 627.7m by 2031
HER2 assay – proof of concept

**Analytical**
Evaluation of HER2 amplification by HER2 FISH assay in circulating cancer cells from contrived samples previously stained with ANGLE’s Portrait Flex assay proved to be highly analytically specific: ~100% of HER2-overexpressing cancer cells showed HER2 amplification and ~80% of HER2-negative cancer cells did not show HER2 amplification (calculated as the percentage of HER2- amplified cancer cells over the total number of cancer cells found in the slide), as previously reported in literature.

The percentage recovery of cancer cells found on slides from contrived samples after combined IF and FISH staining is comparable to that of slides stained with HER2 FISH assay only (data not shown).

**Clinical**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients ≥ 1 CTC</td>
<td></td>
<td>81% (13/16)</td>
</tr>
<tr>
<td>CTC range</td>
<td></td>
<td>0-200</td>
</tr>
<tr>
<td>CTC mean</td>
<td></td>
<td>24</td>
</tr>
<tr>
<td>Patient Phenotype</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epithelial &amp; mesenchymal</td>
<td>12.5% (2/16)</td>
<td></td>
</tr>
<tr>
<td>Mesenchymal only</td>
<td></td>
<td>56.3% (9/16)</td>
</tr>
<tr>
<td>EMT and mesenchymal</td>
<td>12.5% (2/16)</td>
<td></td>
</tr>
<tr>
<td>Patients ≥1 CTC cluster</td>
<td>77% (10/13)</td>
<td></td>
</tr>
<tr>
<td>N clusters per patient</td>
<td></td>
<td>1 to 29</td>
</tr>
<tr>
<td>N CTCs per cluster</td>
<td></td>
<td>2 to 110</td>
</tr>
<tr>
<td>Patients with ≥ 1 HER2+ CTC (in patients with ≥ 1 CTC)</td>
<td>38.5% (5/13)</td>
<td></td>
</tr>
</tbody>
</table>
**Spotlight on Landscape⁺ molecular assays**

- **Landscape⁺ DNA digital PCR assay** - detection of mutations (e.g. EGFR, KRAS and PIK3CA) in DNA from CTCs and ctDNA

- **Landscape⁺ RNA digital PCR assay** - gene expression analysis for CTC detection and evaluation (development of panels for prostate and ovarian cancer)

- **Landscape⁺ DNA NGS assay** - sequencing of both DNA from CTCs and ctDNA

- **Landscape⁺ RNA NGS assay** - sequencing of RNA from CTCs

The assays under development utilise commercially available third-party cancer gene panels and commonly used instrumentation (e.g., Illumina sequencing platforms etc), therefore **leveraging an existing installed base**
Clinical studies supporting commercialisation

**ANG-006 (EMBER): Pelvic mass – completed with transfer to molecular platform in progress**
- **Objective:** Verification of Performance
- **Targeted Enrolment:** 200 patients

**ANG-010 (INFORM): Metastatic cancers**
- **Objective:** Assay development / Parsortix performance
- **Targeted Enrolment:** 1,000 patients

**ANG-012 (DOMINO): Prostate pilot study**
- **Objective:** Cancer presence and severity
- **Targeted enrolment:** 100 patients

**ANG-011 (PRECISE): Lung cancer pilot study**
- **Objective:** PD-L1 Assay performance
- **Targeted Enrolment:** TBD

PD-L1 Assay Development/Transfer

Larger verification study if pilot study is successful
Real-world clinical study
Ovarian cancer – positive headline results

“The next generation ANGLE pelvic mass triage 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

• Excellent results in ovarian cancer with ROC-AUC 95.4% based on molecular analysis of Parsortix harvest

• Sensitivity 90%, Specificity 93% for the prediction of malignancy, maintaining best in class performance

• 50% or greater reduction in false positives and false negatives

• Strong clinical validation in this difficult to diagnose setting
  – demonstrating ability to undertake complex molecular analysis of the Parsortix harvest
  – confirming its suitability for use in both hospital laboratories and central laboratories requiring sample shipping

• Transferring to third-party molecular platform to maximise commercialisation. Evaluating platforms using samples already in hand.
Real-world clinical study
Prostate cancer in collaboration with Solaris Health

Agreement signed with MidLantic Urology
• MidLantic Urology, affiliate of Solaris Health Partners
• >500 providers across 179 locations in 9 States with 729,000 patients p.a.
• Solaris Health to provide first route to market

Study design
• 100 patients scheduled to undergo prostate tissue biopsy
• Study being conducted at 3 study sites in Pennsylvania over 9-month period
• Test to predict presence of clinically significant prostate cancer
• Headline results anticipated around year end 2023

“Preliminary data suggests that we may be able to create an assay for the detection of clinically significant prostate cancer that has high specificity and sensitivity. Moreover, the assay can be customized to operate in a wide spectrum of prostate cancer disease states, including pre-prostate biopsy, after a negative biopsy, active surveillance, after local failure, and in early and late metastatic disease states.”

Dr Jose Moreno, Principal Investigator, MidLantic Urology
Near term milestones

- Convert pipeline into **new pharma services contracts** including major global pharma

- Roll out of new assays in 2023 (**Portrait Flex, PD-L1, and DDR**) for pharma services

- Launch **Portrait+ product kit** alongside instruments and cassettes by year end 2023

- **Completion of prostate cancer pilot study** before year end 2023

- **Transfer of ovarian cancer test** to third party molecular platform by year end 2023

- Complete technology evaluations and **select third-party molecular solutions** by year end 2023