

# Interim results for the six months ended 30 June 2021

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30 September 2021



ANGLE



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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.

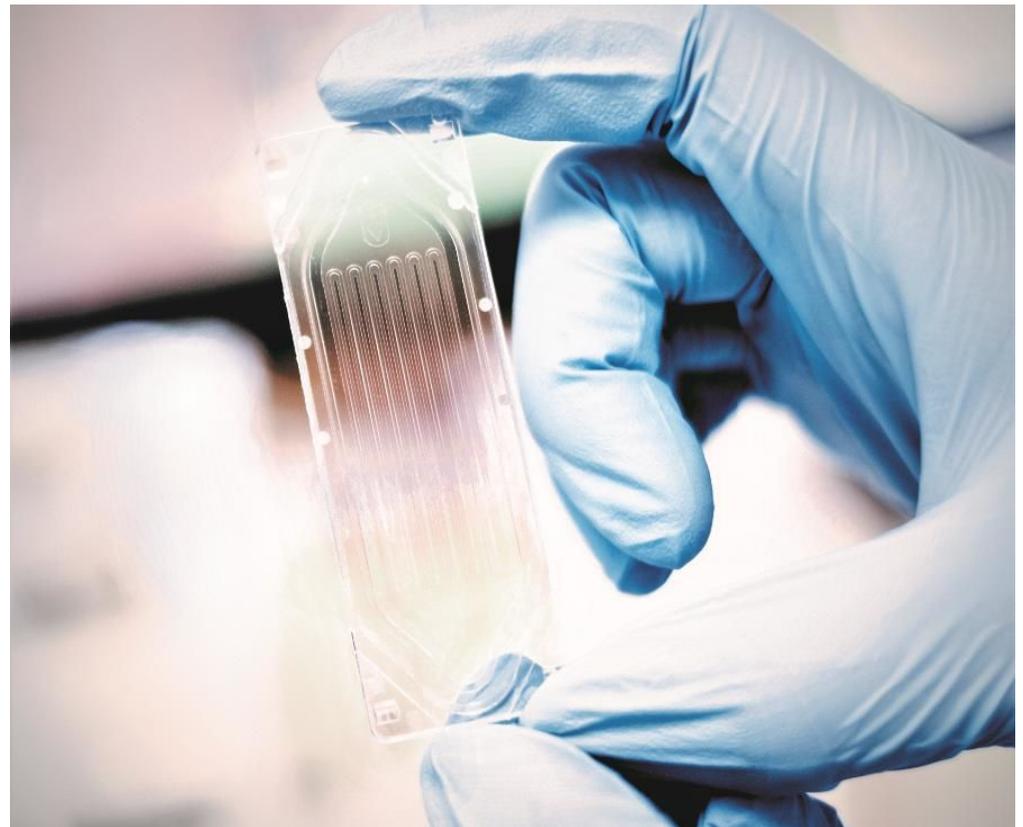
Product-based solution for simple, effective, affordable repeat testing of intact cells.”

Andrew Newland, Chief Executive

National Cancer Institute United States

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

Parsortix® cassette



# 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

|  | Six months ended<br>30 June 2021<br>£'000 | Six months ended<br>30 June 2020*<br>£'000 |
|--|---|--|
| <b>Statement of Comprehensive Income</b> |   |  |
| Revenue and grant income                 | 312                                       | 268  |
| Cost of sales                            | (77)                                      | (59)                                       |
| Gross profit and grant income            | 235                                       | 209  |
| Operating costs                          | (8,897)                                   | (4,645)                                    |
| Tax credit and net finance costs         | 979                                       | 1,037                                      |
| Loss for the period                      | (7,683)                                   | (3,399)                                    |

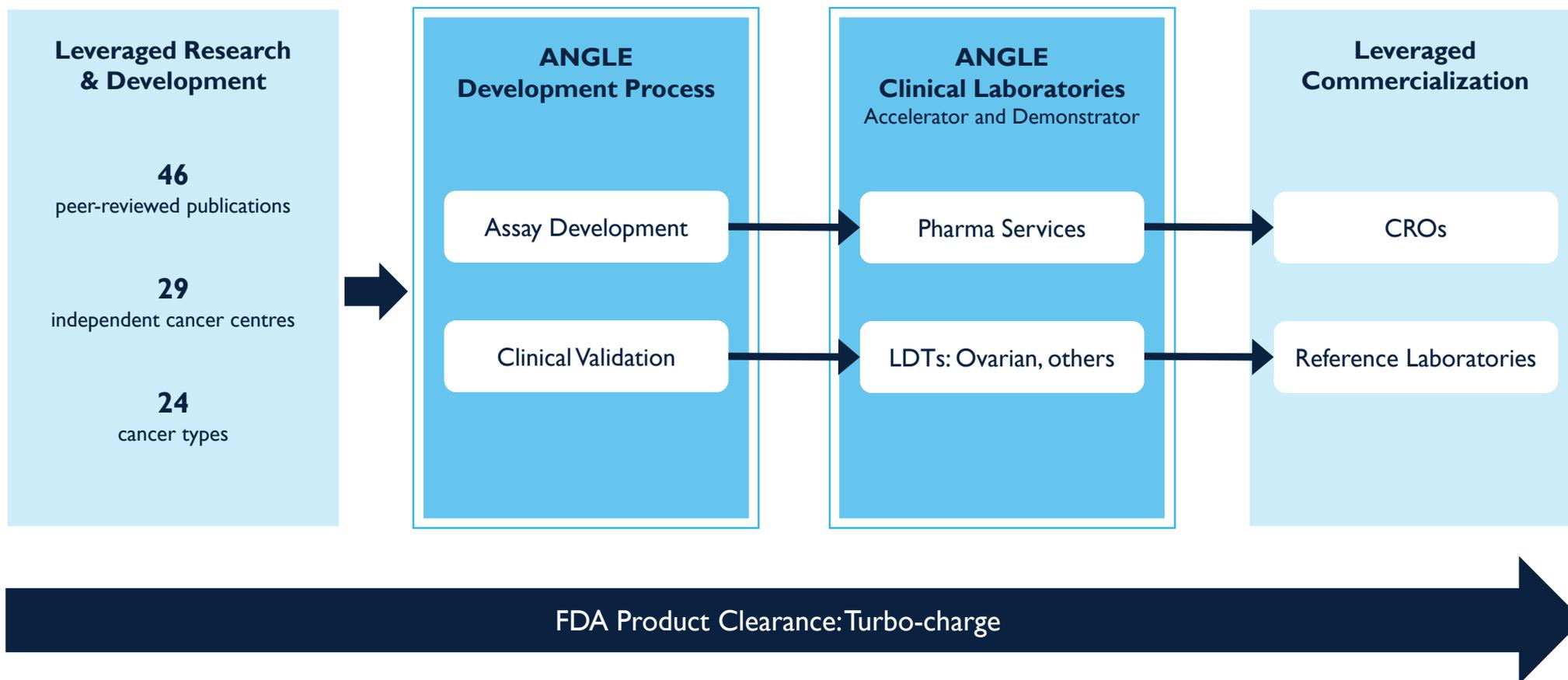
## Comments

- 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

|   | 30 June 2021  | 31 December 2020 |
|---|---------------|------------------|
| <b>Statement of Financial Position</b>                |               |                  |
| Trade and other receivables and R&D tax credit        | 4,583         | 3,570            |
| Inventories   | 1,076         | 742              |
| Cash and short-term deposits                          | 21,031        | 28,618           |
| Property, plant and equipment and right-of-use assets | 4,409         | 2,409            |
| Intangible assets                                     | 3,653         | 3,710            |
| <b>Total assets</b>                                   | <b>34,752</b> | <b>39,049</b>    |

\* Restated

# Commercialization process



# FDA clearance: regulatory response anticipated in H2 2021

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- 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



| PD-L1 Drug Trials | Price per sample (US\$) | Mean # of patients per trial | Number of trials | Number of patients in trials | Number of samples per patient | Addressable number of samples | Addressable market p.a. (US\$) |
|-------------------|-------------------------|------------------------------|------------------|------------------------------|-------------------------------|-------------------------------|--------------------------------|
| 1 Phase 1         | \$1,200                 | 82                           | 533              | 43,812                       | 2                             | 87,624                        | \$105 million                  |
| 2 Phase 2         | \$1,200                 | 95                           | 1,557            | 147,231                      | 3                             | 441,693                       | \$530 million                  |
| 3 Phase 3         | \$1,200                 | 589                          | 339              | 199,738                      | 4                             | 798,952                       | \$959 million                  |
|                   |                         |                              | <u>2,429</u>     | <u>390,781</u>               |                               | <u>1,328,269</u>              | <u>\$1,594 million</u>         |

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

- 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*

# First pharma services contracts secured

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- 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

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

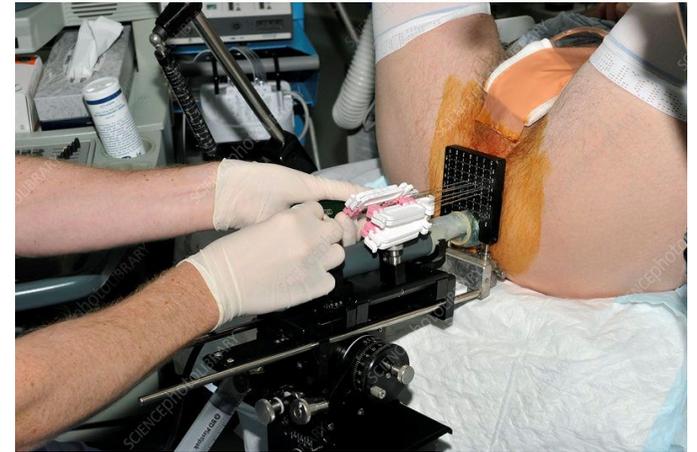


| Application                  | Reimbursement potential (US\$) | Number of patients p.a. | Number of tests per patient p.a. | Addressable number of tests p.a. | Addressable market p.a. (US\$) | Target market entry |
|------------------------------|--------------------------------|-------------------------|----------------------------------|----------------------------------|--------------------------------|---------------------|
| 1 Pelvic mass surgery triage | \$1,000                        | 200,000                 | 1                                | 200,000                          | \$200 million                  | Q4 CY21             |
| 2 Watchful waiting           | \$1,000                        | 300,000                 | 2                                | 600,000                          | \$600 million                  | CY22                |
| 3 Remission monitoring       | \$1,000                        | 235,000                 | 2                                | 470,000                          | \$470 million                  | CY23                |
|                              |                                | <u>735,000</u>          |                                  | <u>1,270,000</u>                 | <u>\$1,270 million</u>         |                     |

- 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-I has same intended use - Aspira 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**

# 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                |
|                               |                                | <u>4,448,000</u>        |                                  | <u>6,722,000</u>                 | <u>\$6,749 million</u>              |                     |

- 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

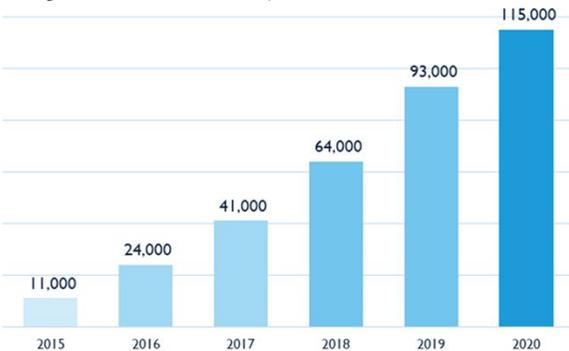
## Leveraged R&D strategy identifying new applications



- 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



Cumulative samples processed at 31 December



# 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
  - 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

## 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

Universitätsklinikum  
Hamburg-Eppendorf

UNIVERSITY of  
ROCHESTER

USC  
NORRIS  
COMPREHENSIVE  
CANCER CENTER

## Corporate partnerships being developed

**Abbott PHILIPS QIAGEN**

\* 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

## 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 >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

## 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

## 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

## 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

## 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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