

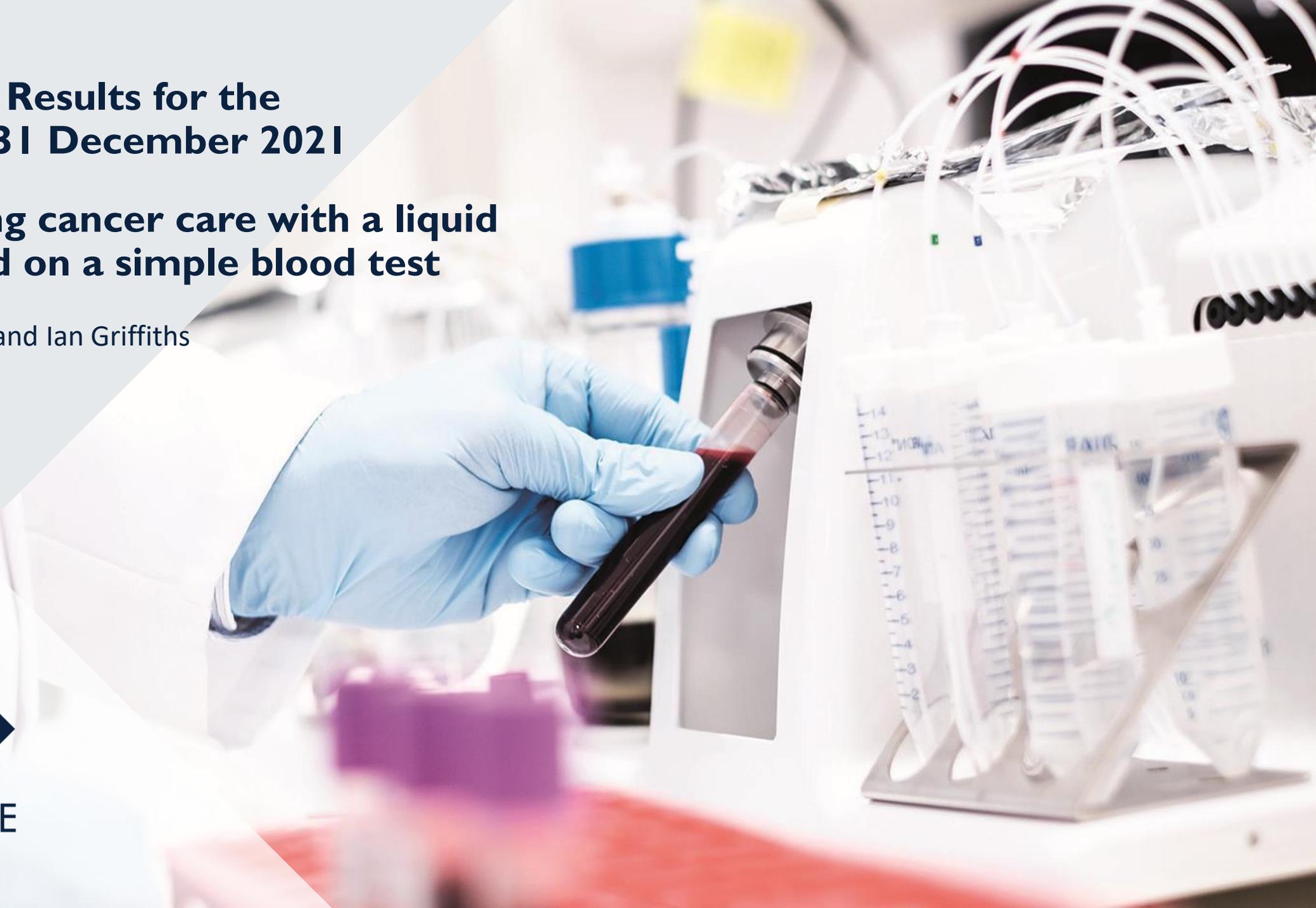
Preliminary Results for the year ended 31 December 2021

Transforming cancer care with a liquid biopsy based on a simple blood test

Andrew Newland and Ian Griffiths
28 April 2022



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 **best sample** of the patient’s cancer from a simple blood test.

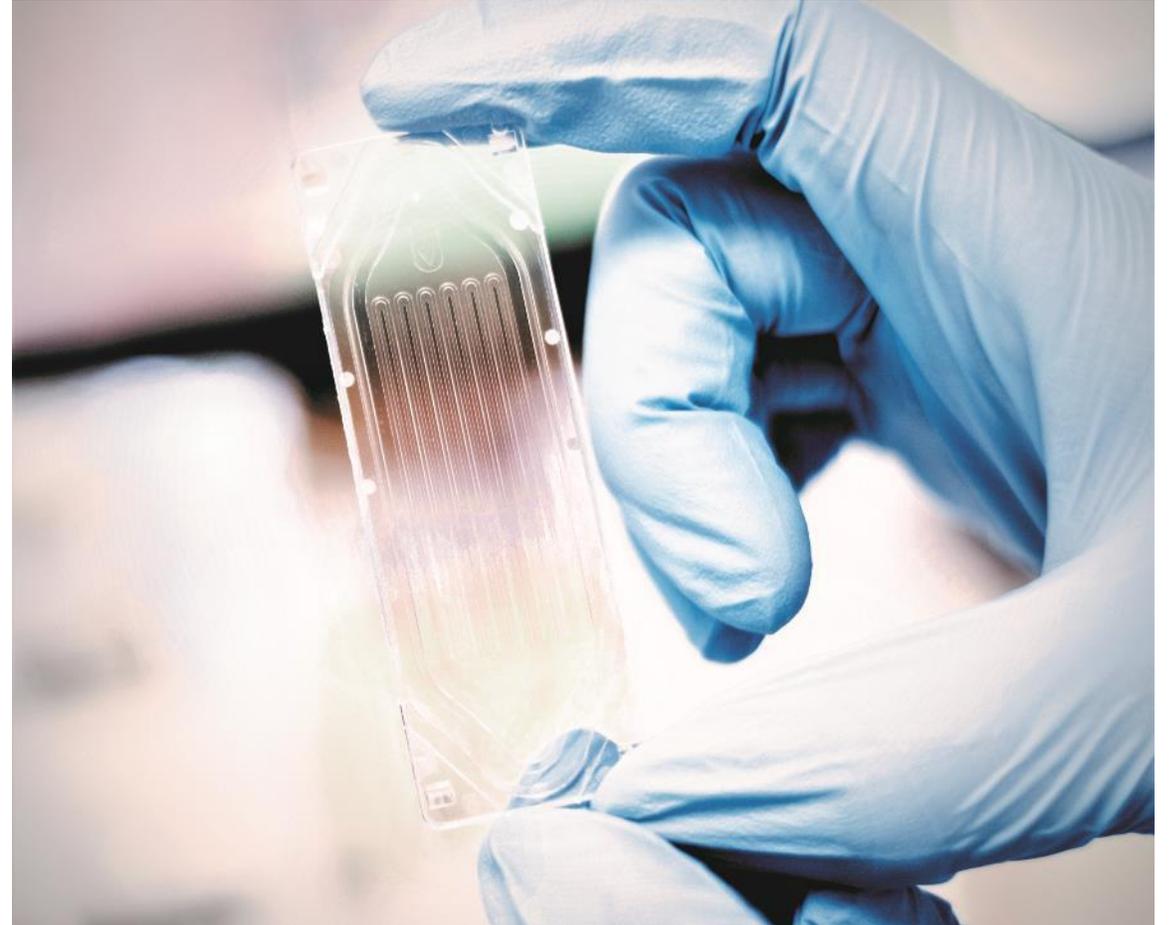
Product-based solution for simple, effective, affordable repeat testing of intact cells.”

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



2021 Highlights

Significant progress against key strategic objectives



- FDA review of De Novo Submission for Class II clearance in metastatic breast cancer response awaited
 - comprehensive response to AIR submitted as planned
 - regular and constructive dialogue with FDA
- Clinical laboratories in the UK and United States opened ahead of plan and services business building
 - first three pharma services customers secured
 - post year end, two new customers and two new contracts with existing customers for further clinical trials
 - discussions with multiple potential customers in progress
 - United States laboratory registered with CLIA post year end
- Ovarian cancer detection study nearing completion
 - patient enrolment completed
 - delayed reagents received post year end and being validated
 - sample analysis to resume and headline results anticipated mid-year
- Prostate cancer study design completed and discussions progressed with a major group of United States urology clinics
- Capital raise of £20 million well supported by new and existing shareholders in UK and United States

Financial Results for the year ended 31 December 2021

	2021 £'000	2020 £'000
Statement of Comprehensive Income		
Revenue and grant income	1,054	841
Cost of sales	(302)	(165)
Gross profit and grant income	752	676
Operating costs	(17,987)	(14,407)
Tax credit and net finance costs	2,223	2,125
Loss for the period	(15,012)	(11,606)

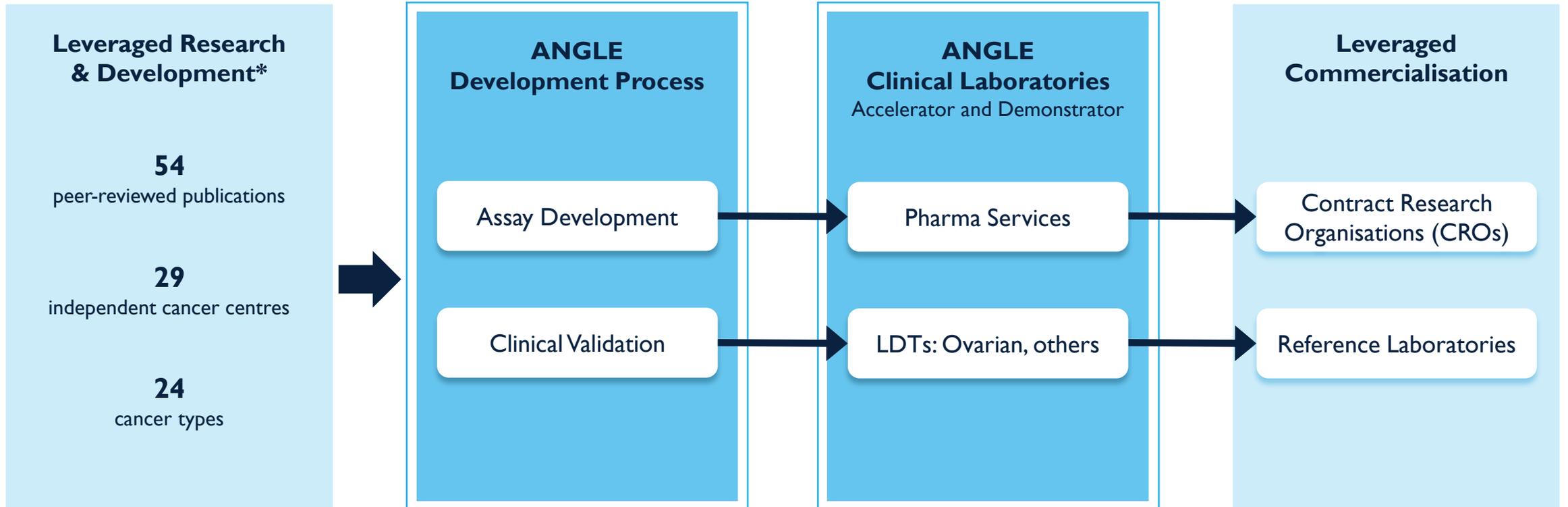
Comments

- Revenue increased by 33% excluding grant income
- Gross margin 70%
- Planned operating expenditure £18.0 million

	2021 £'000	2020 £'000
Statement of Financial Position		
Trade and other receivables and R&D tax credit	5,779	3,570
Inventories	1,748	742
Cash and short-term deposits	31,839	28,618
Property, plant and equipment and right-of-use assets	4,376	2,409
Intangible assets	3,573	3,710
Total assets	47,315	39,049

- Cash position increased to £31.8 million
- R&D tax credit due £4.5m
- Fundraise £18.9 million (net) July 2021

Commercialisation process



* as at 31 December 2021

FDA clearance: regulatory response awaited

- FDA De Novo Submission for Class II clearance in metastatic breast cancer submitted 25 September 2020
 - 600 subjects in clinical studies 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
- Regular constructive dialogue with FDA continues
- FDA regulatory response **awaited***
- 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
 - 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
 - five customers on-boarded, repeat business with two early customers
 - discussions with multiple other potential customers in progress
- **Accelerator for clinical applications**
 - clinical laboratory accreditation in progress
 - US laboratory registered with CLIA post year end
 - ovarian cancer LDT first clinical application planned
- **Demonstrator for Parsortix applications**
 - supporting product sales and corporate partnerships
 - pharma services transferred to CROs
 - clinical applications established by independent clinical laboratories

Pharma services – early growth market for ANGLE

PD-LI immunotherapy alone c. US \$1.6 billion p.a. global market



PD-LI 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 I	\$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 I 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-LI/PD-I interventional trials which are enrolling or in progress

- 2021 spend on PD-LI immunotherapy drugs US \$31 billion growing at >17% 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-LI 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*

Ovarian cancer test in development

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
 - required reagents being validated and sample analysis to be resumed
 - headline results anticipated mid-year
- Planning to offer LDT test from ANGLE clinical laboratories

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

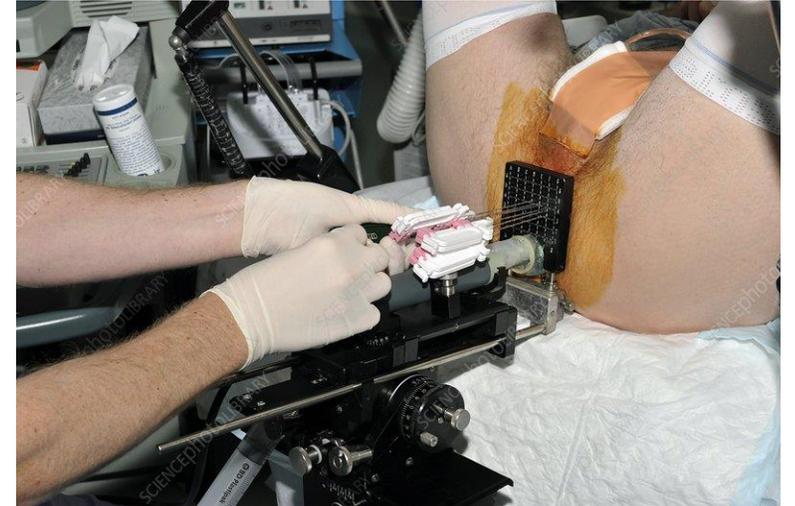


Application	Reimbursement potential (US\$)	Number of patients p.a.	Number of tests per patient p.a.	Addressable number of tests p.a.	Addressable market p.a. (US\$)
1 Pelvic mass surgery triage	\$1,000	200,000	1	200,000	\$200 million
2 Watchful waiting	\$1,000	300,000	2	600,000	\$600 million
3 Remission monitoring	\$1,000	235,000	2	470,000	\$470 million
		<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
 - 92.4% sensitivity, **53.5% specificity**; reimbursement code **\$897**; test volume 2021 ~17,400 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 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 market opportunity c. US \$6.7 billion p.a. (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\$)
1 High risk screening	\$1,000	1,203,000	1	1,203,000	\$1,203 million
2 Active surveillance	\$1,000	738,000	2	1,476,000	\$1,476 million
3 Therapeutic decision making	\$1,500	512,000	4	2,048,000	\$3,072 million
4 Remission monitoring	\$500	1,995,000	1	1,995,000	\$998 million
		<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

Parsortix widely adopted by independent cancer research centres



- Translational research market **US\$50 million p.a.**
- FDA clearance expected to help Parsortix become the CTC **system of choice**
- Installed base of **over 230** Parsortix systems in active use

Parsortix samples processed



Cumulative samples processed at 31 December

As at 31 December 2021



Commercialisation aim 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 such as Grail (Illumina), Thrive (Exact Sciences), Freenome 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

Near term milestones

- Expanding pharma services business: five customers in place and growing
- FDA clearance: regulatory response awaited*
- Ovarian cancer headline results anticipated mid-year
- Lab accreditation in progress to enable laboratory developed tests to be offered
- 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)



Corporate partnerships being developed



* 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



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