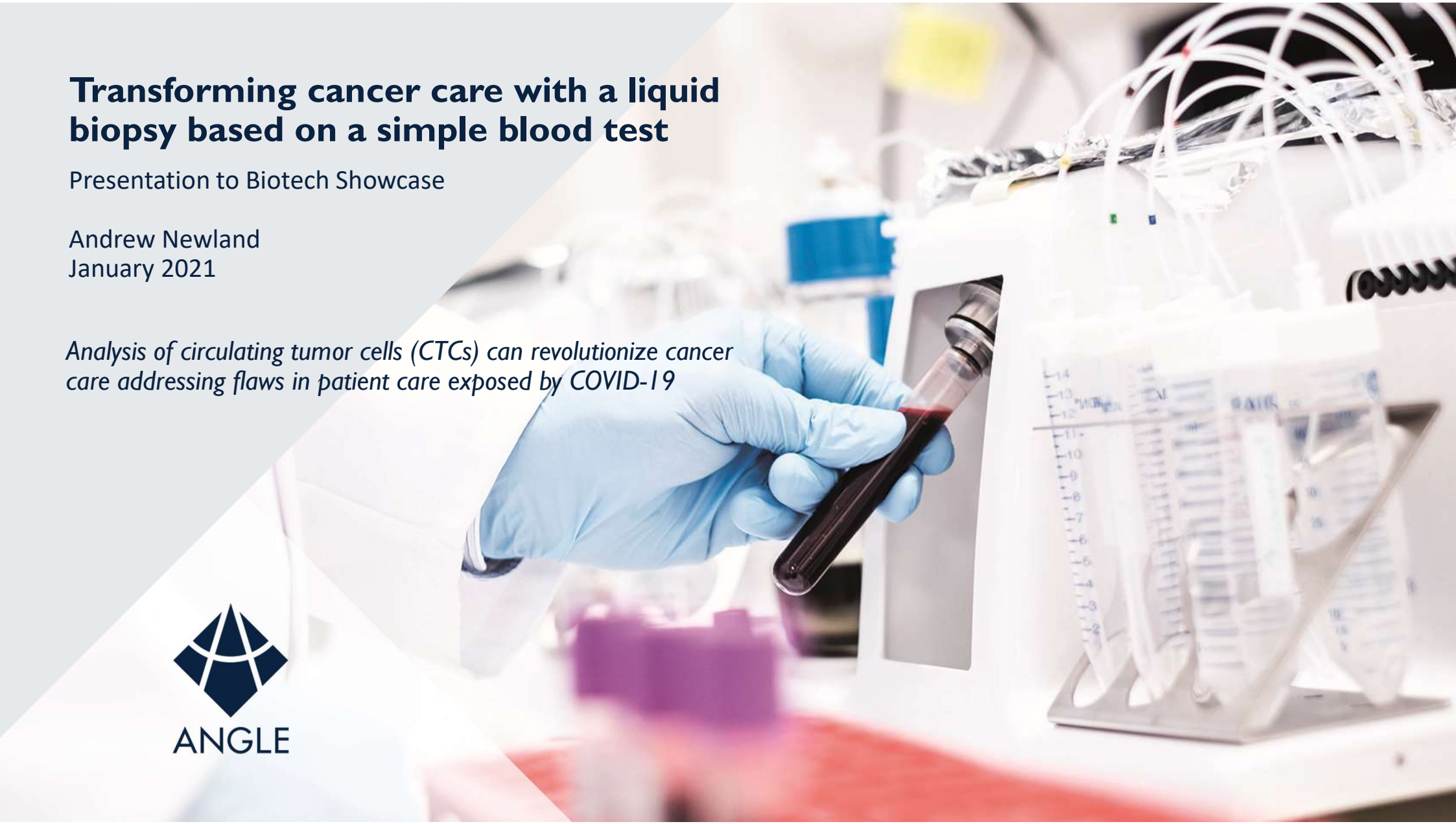
Transforming cancer care with a liquid biopsy based on a simple blood test

Presentation to Biotech Showcase

Andrew Newland
January 2021

Analysis of circulating tumor cells (CTCs) can revolutionize cancer care addressing flaws in patient care exposed by COVID-19



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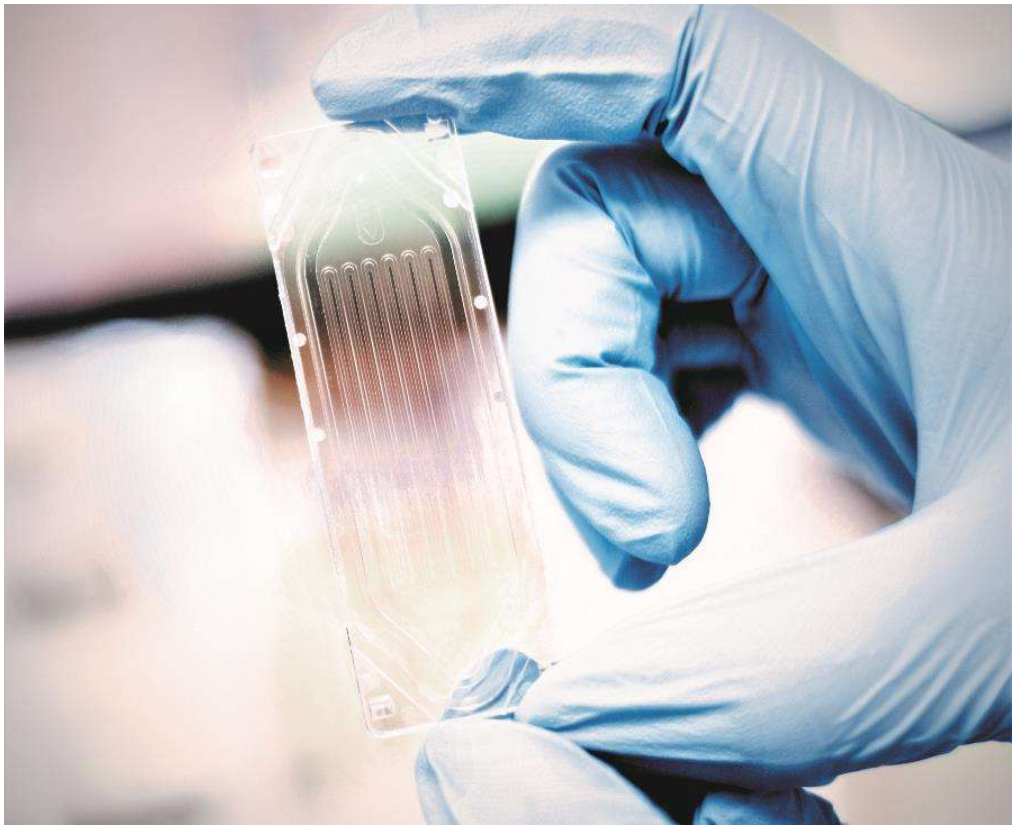
Liquid biopsy - improving patient outcomes and reducing healthcare costs

"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

Parsortix® cassette



National Cancer Institute United States

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

Leading CTC liquid biopsy solution

Strong progress over the last year

- Patent protected product-based platform drives leveraged R&D approach. **36 peer-reviewed publications** with 24 cancer types
- **FDA submission for the Parsortix platform made September 2020** for metastatic breast cancer. Over 15,000 samples processed and 400 reports and technical documents submitted
- **Prospect of FDA clearance earliest Q2 CY21***
- Evidence-based approach with **ovarian cancer** study demonstrating high performance (**AUC >95%**). 200 patient clinical verification study in process
- **Multiple corporate partnerships** being developed with leading global device and diagnostic companies

Why invest now?

- "**Liquid biopsies have multiple applications and mark a mega-trend for at least the next decade**"
  - "record investor interest and investments"
  - "COVID-19 has created unprecedented opportunities"
  - "less invasive tests (i.e. blood over tissue) will accelerate adoption of liquid biopsies in cancer testing"

  BTIG October 2020
- **ANGLE accelerating commercialisation**
  - clinical laboratories being established
  - pharma services business getting early traction
  - PD-L1 immunotherapy assay being developed
  - corporate partnerships being progressed
  - both an equipment supplier *and* a diagnostic test provider
- Potential **first mover advantage with FDA clearance**
- **Key clinical advantages over ctDNA liquid biopsies**

** 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.*

Parsortix liquid biopsy addresses flaws in standard of care

- **Existing approach: solid tissue biopsy**
  - clinicians cut out tumor and analyse the cancer cells
  - difficulty in accessing some tumors such as pancreatic, lung, brain, liver and bone cancers
  - repeat tissue biopsy problematic, expensive and can cause adverse reactions
- **NCCN Guidelines recommend tissue biopsies for metastatic breast cancer (MBC)**
  - tissue biopsies from the primary are out-of-date
  - up-to-date information is needed to select treatment for personalized care
  - only samples a single metastatic site at one time point
- **Half of all MBC patients do not have successful biopsies**
  - too ill for the surgery
  - tumor inaccessible
  - insufficient tissue
- **New approach: Parsortix liquid biopsy**
  - harvest intact cancer cells from blood
  - non-invasive, repeatable, real time, cost effective
  - can be COVID-secure with blood draw at patient's home

Total addressable market > US $100 billion p.a.

USC Norris Comprehensive Cancer Center

"Successful validation of our approach in future clinical studies could revolutionize clinical management of metastatic breast cancer."

Julie E. Lang, MD, FACS, Director, USC Breast Cancer Program, Associate Professor of Surgery, Norris Comprehensive Cancer Center, University of Southern California

	2018	2012
New cancer incidence (per annum)	18.1 million	14.1 million
Living with and after cancer	43.8 million	32.5 million
Deaths from cancer (per annum)	9.6 million	8.2 million

[1] Source: GLOBOCAN: Global burden of cancer

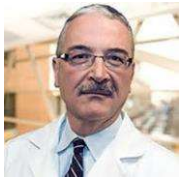
Current focus		Medium term		Longer term
Detection of cancer in high risk groups Ovarian pelvic mass Active surveillance Watchful waiting	Therapy selection Breast HER-2 Abbott Prostate AR-V7 Qiagen Immunotherapy PD-L1	Assessing treatment Assessing minimal residual disease	Remission monitoring Repeat testing to ensure CTCs not present	Early screening for cancer Need to assess aggressiveness and avoid false positives

Liquid biopsy emerging multi US$ billion market: estimates

Cowen[2]	Up to ~$130 billion per annum	Up to $5 billion	Up to $2.5 billion	Subset Remission	Up to $75 billion	Up to $50 billion
Frost & Sullivan[3]	$100 billion per annum					
Guardant Health[4]	$51 billion per annum	Subset Screening	$6 billion	Subset Therapy	$15 billion	$30 billion
Grail (Illumina)[5]	$75 billion per annum	Subset screening	$14 billion		$ 15 billion	$46 billion

[2] Source: Cowen September 18, 2020: US only; [3] Source: Frost & Sullivan November 2018 report: US only; [4] Source: Guardant Health Company Overview Presentation September 15, 2020: US only [5] Source: Grail Press Release September 21, 2020: US only

CTCs provide the complete picture for repeat biopsies



Robert H. Lurie Comprehensive Cancer Center of Northwestern University

CTC cultures

"Widely adopted, this approach has the potential to transform the way we treat cancer patients."

Professor Massimo Cristofanilli

MD Associate Director, Translational Research, Robert H Lurie Comprehensive Cancer Center, Northwestern University, Chicago

Analysis of CTCs is the closest proxy to tissue biopsy

Tissue	ctDNA	CTCs	CTC clusters	CTC cultures
Clinicians cut out part of the tumor and analyse cancer cells Invasive Not repeatable May be difficult to access	Fragments of dead cells Partial DNA picture No RNA or protein information	Harvest intact living cancer cells (CTCs) Complete picture of the cancer Non-invasive Repeatable Real-time Cost-effective	80x greater metastatic potential in a mouse model	Growth of cancer outside patient Potential to test drugs outside patient
DNA, RNA, Protein	DNA only	DNA, RNA, Protein		
Current practice	Generic lab process	**Patent-protected Parsortix® product solution**		

Genomic Health LIFE. CHANGING.

EXACT SCIENCES

GUARDANT

GRAIL

FOUNDATION MEDICINE

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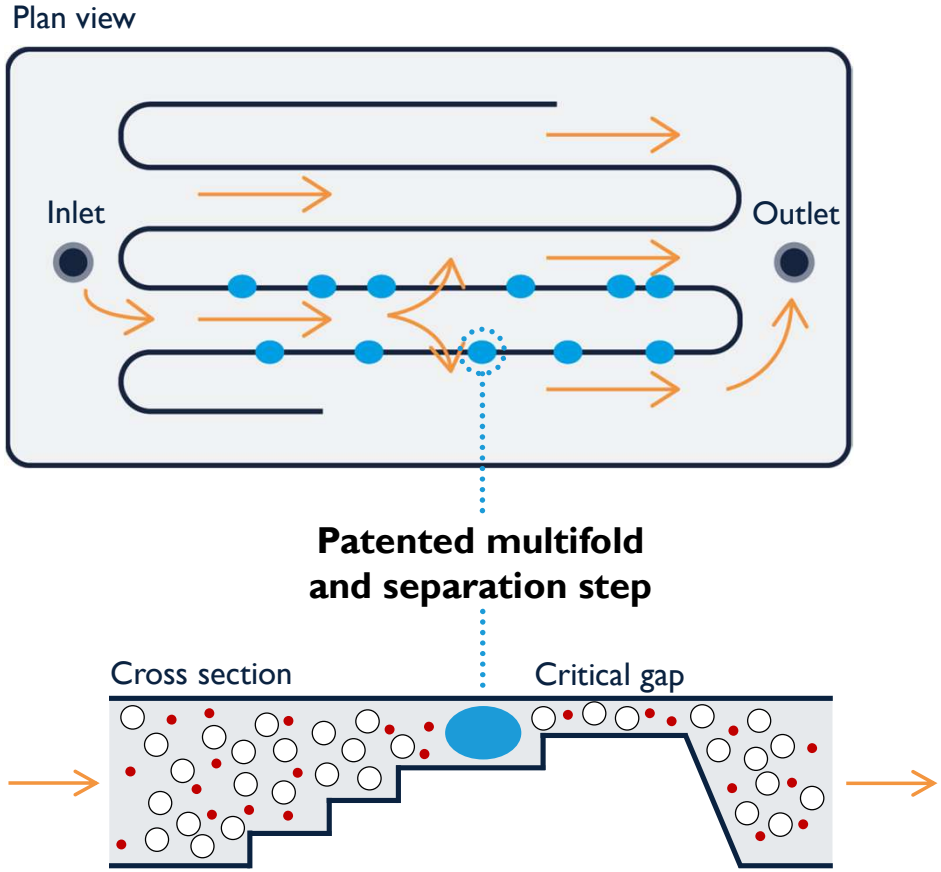
Over 90%

of cancer deaths are caused by metastasis

Parsortix capturing and harvesting living cancer cells



Platform technology

The Parsortix system harvests **cancer cells from blood** based on their larger size and lack of deformability.

Other cells can be captured:

- **megakaryocytes** (frequency may relate to cancer)
- **fetal cells** from maternal blood

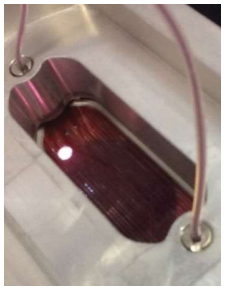
Captured CTCs

White blood cells

Red blood cells

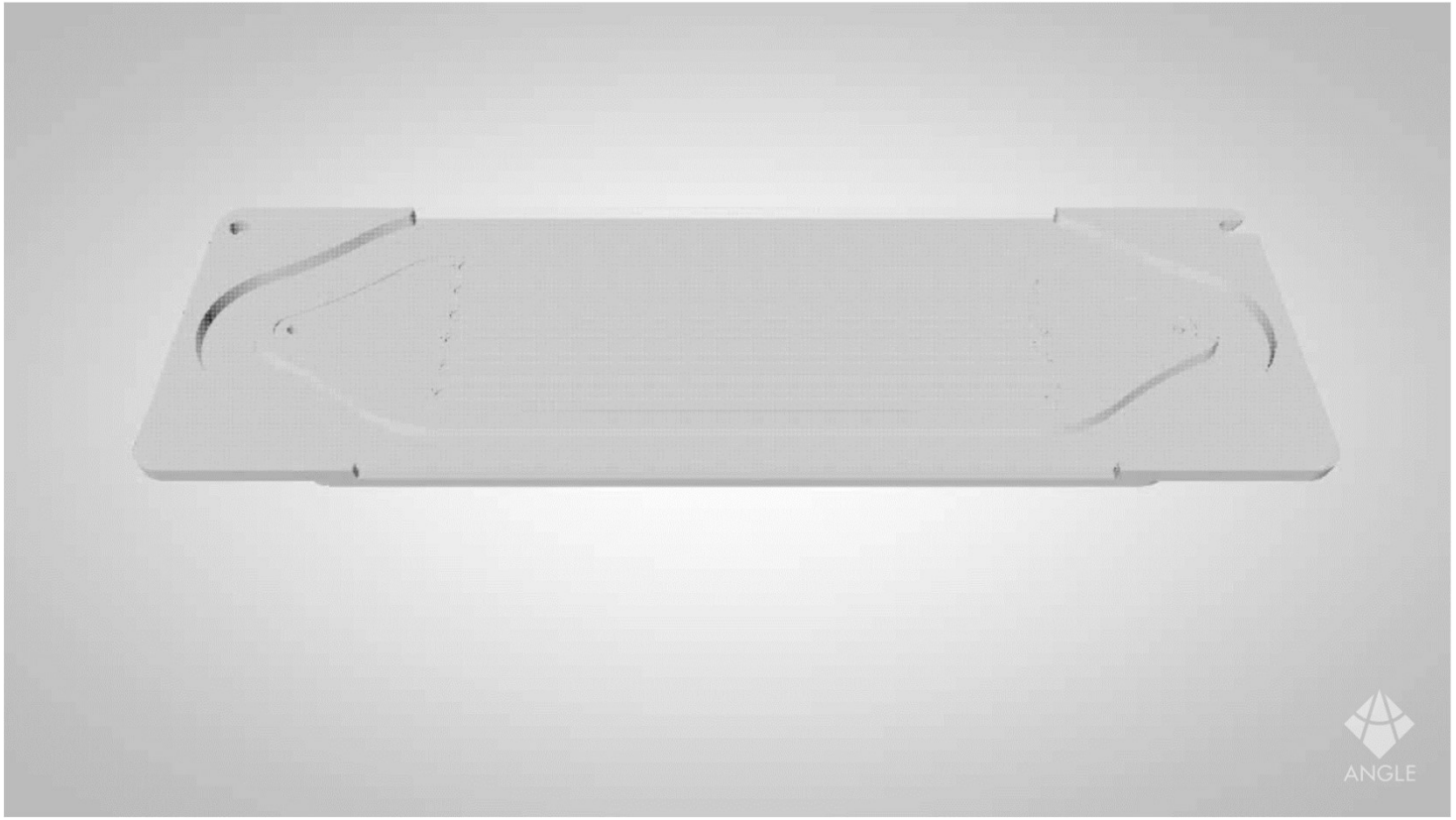
Blood flow

Parsortix® system patent protected worldwide

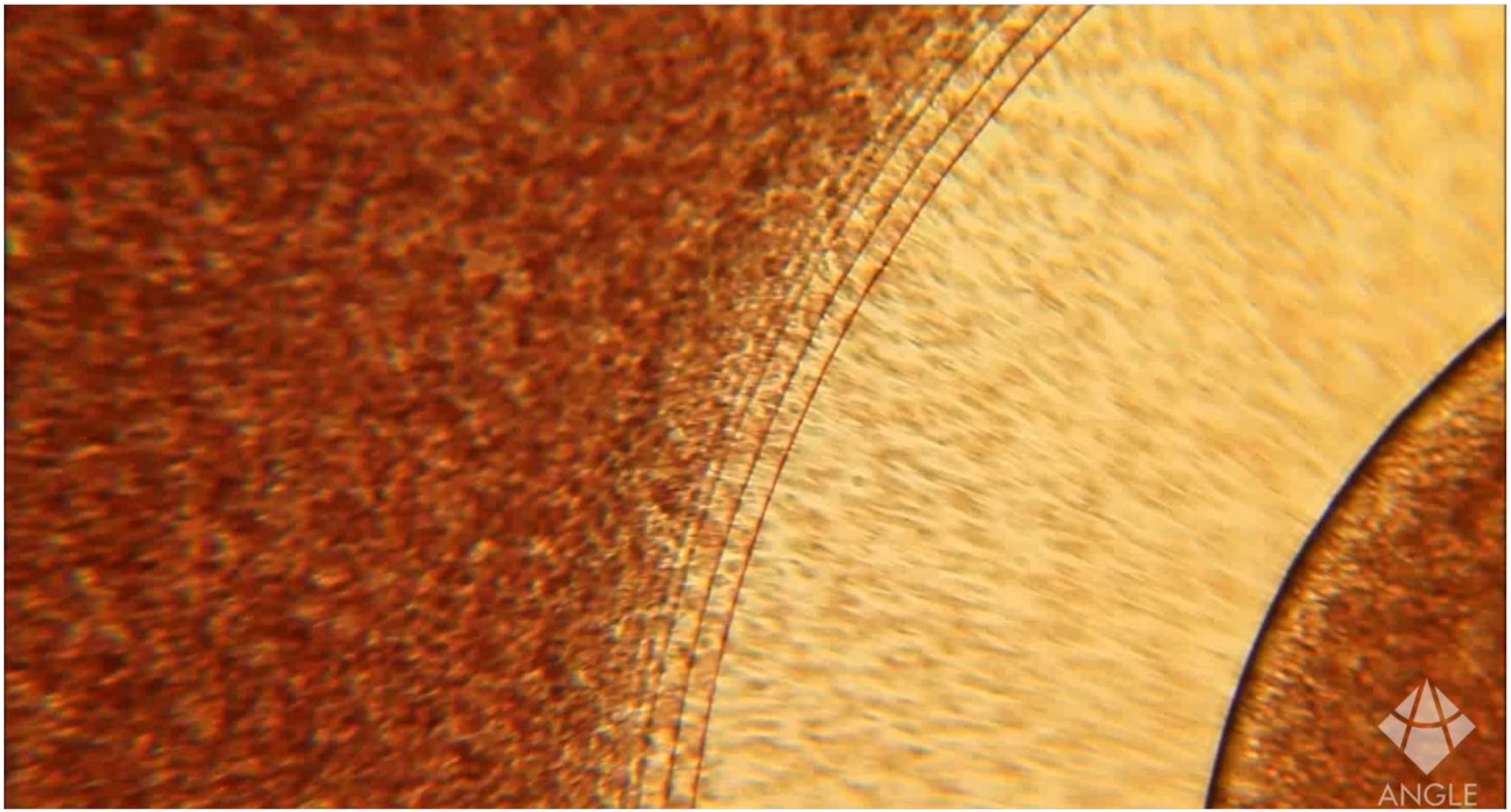


- Stepped, microscale cell separators for fluid flow and cell separation
- Manufactured under ISO 13485:2016 quality control
- **Scalable business with third party manufacture**
- 26 granted patents: United States, Europe, China, Australia, Canada, Japan, Mexico with patent coverage to 2034
- Proprietary technology with copyright on software and designs, technical know-how, manufacturing and operating procedures, methods and processes

Animation showing operation of Parsortix cassette



Patient blood flowing in Parsortix cassette



Growing body of evidence
Leveraged R&D strategy identifying new applications

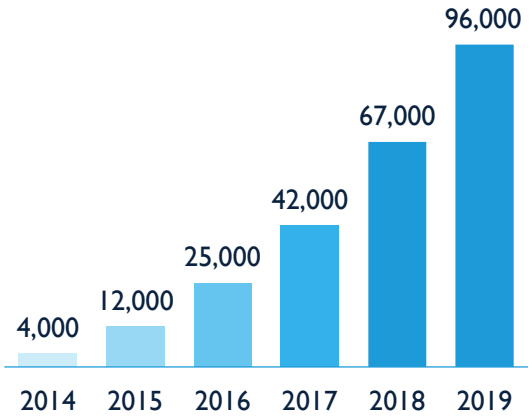
- Translational research market US $50 million p.a.
- FDA clearance expected to help Parsortix become the CTC system of choice
- Installed base of c.200 Parsortix systems in active use

Research use pricing	Instrument	Cassette
Price[1]	$50,000	$100
Cost	$15,600[2]	$15
Margin	69%	85%

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

Parsortix samples processed

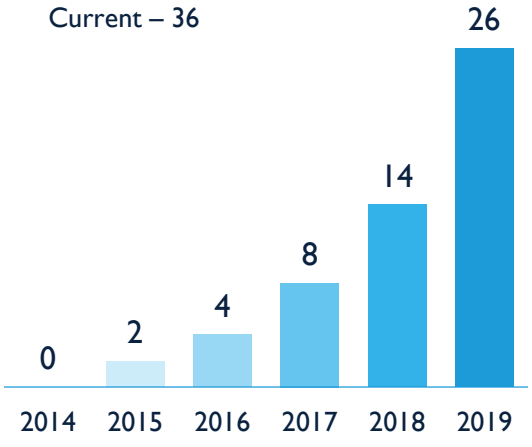
Current – 110,000



Cumulative samples processed at 31 December

Peer-reviewed publications

Current – 36



Cumulative publications to 31 December

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

Seven separate studies demonstrate Parsortix outperforms CellSearch

*Based on Impact Factor quartiles Q1 & Q2

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

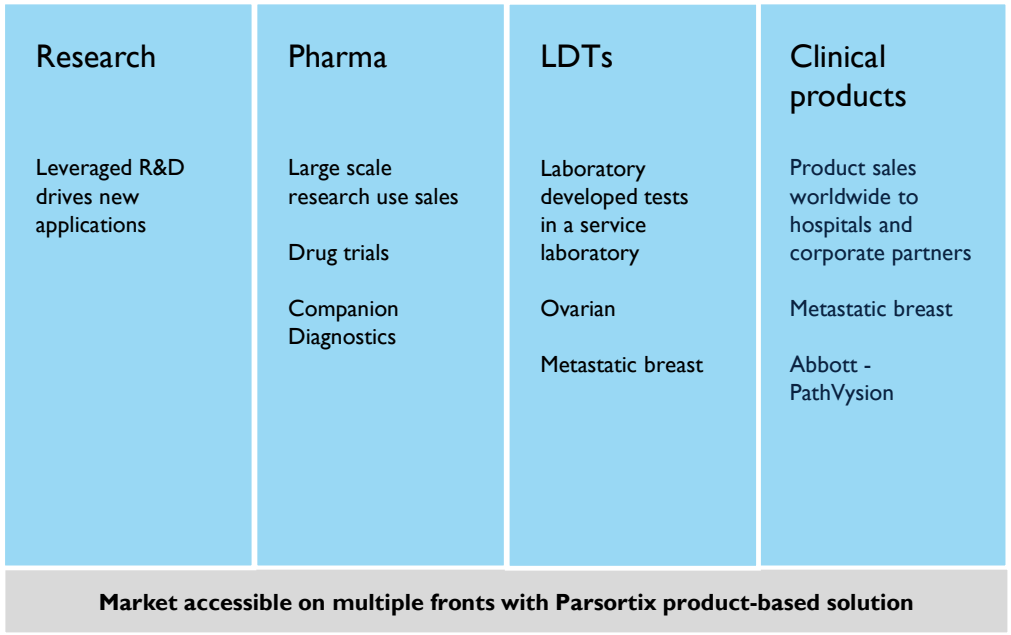
Prospect of FDA clearance earliest Q2 CY21

- 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



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.***

Clinical laboratories

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

Pharma services immunotherapy PD-L1 testing >US $1 billion p.a. global market

	PD-L1 Drug Trials	Price per sample (US$)	Number of patients per trial	Number of trials	Number of patients in trials	Number of repeat samples per patient	Addressable number of samples	Addressable market per annum	Target market entry
1	Phase 1	$1,200	84	273	22,932	2	45,864	$55 million	CY21
2	Phase 2	$1,200	102	867	88,434	3	265,302	$318 million	CY22
3	Phase 3	$1,200	719	233	167,527	4	670,108	$804 million	CY23
				1,373	278,893		981,274	$1,178 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 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 14.28pm on 09/10/2020. Search terms - Cancer and PD-L1 interventional trials which are enroling, in progress or active

- **First pharma services contracts under negotiation**
- Only a small number of large scale pharma customer relationships opens up a very large market
- **FDA clearance would provide further credibility and facilitate clearance as a CDx**

CY19 spend on PD-L1 immunotherapy drugs US $22 billion growing at >40% p.a. only 20-50% of patients respond to treatment which costs c. US $170,000 per patient and has side effects

Breast cancer clinical tests c. US $4 billion p.a. market (United States only)

	Application	Reimbursement potential (US$)	Number of patients p.a. (US)	Number of tests per patient p.a.	Addressable number of tests per annum	Addressable market per annum	Target market entry
1a	MBC CTC harvesting (initial assay where biopsy not possible), analysis undertaken by clinical lab	$500	42,000	1	42,000	$21 million	CY21
1b	MBC presence, monitoring and therapy selection (complete assay offered)	$1,500	84,000	4	336,000	$504 million	CY22
2	Primary BC presence and monitoring	$1,000	280,000	4	1,120,000	$1,120 million	CY23
3	Remission monitoring in first 5 years after diagnosis	$500	985,000	2	1,970,000	$985 million	CY23
3	Remission monitoring beyond 5 years	$500	2,615,000	1	2,615,000	$1,308 million	CY23
					6,041,000	$3,917 million	

Note: revenues shared with the clinical laboratory providing the test.

- **NCCN Guidelines recommend tissue biopsies for metastatic breast cancer**
  – half of all MBC patients do not have successful biopsies
- **Market expansion opportunities**
  – remission monitoring – 3.6 million US breast cancer survivors with 30% risk of recurrence
  – high risk screening – variant genes such as BRCA 1/2

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
- 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
- **Targeting completion of patient enrolment by Q2 CY21**
- Establish the test as an LDT in an accredited clinical laboratory

Ovarian cancer clinical tests c. US $1.8 billion p.a. market (United States only)

Application	Reimbursement potential (US$)	Number of patients p.a. (US)	Number of tests per patient p.a.	Addressable number of tests per annum	Addressable market per annum	Target market entry
1 Pelvic mass surgery triage	$1,000	200,000	1	200,000	$200 million	Q4 CY21
2 Watchful waiting monitoring	$1,000	550,000	2	1,100,000	$1,100 million	CY22
3 Remission monitoring	$1,000	230,000	2	460,000	$460 million	CY23
		980,000		1,760,000	$1,760 million	

Note: revenues shared with the clinical laboratory providing the test.

- 750,000 p.a. diagnosed with abnormal pelvic mass, c. 200,000 surgery with c. 22,000 ovarian cancer
- **High unmet medical need** to ensure suspected ovarian cancer patients referred to specialist
  - OVA-1 has same intended use - Aspira Women's Health - market cap c. US $340 million at October 9, 2020
  - 92.4% sensitivity, **53.5% specificity**; reimbursement code $897; test volume 2019 – 13,000 tests
  - prevalence only 11% so **PPV <20%** with 4 false positives for each true positive
- "Watchful waiting" monitoring women diagnosed with pelvic mass not yet having surgery
- Remission monitoring for 230,000 cancer survivors with 85% risk of recurrence

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

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)

Barts Cancer Institute
CANCER RESEARCH UK | MANCHESTER INSTITUTE
Fraunhofer ITEM
HOUSTON Methodist LEADING MEDICINE
MD Anderson 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

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