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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“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
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.

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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

<table>
<thead>
<tr>
<th>2018</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>New cancer incidence (per annum)</td>
<td>18.1 million</td>
</tr>
<tr>
<td>Living with and after cancer</td>
<td>43.8 million</td>
</tr>
<tr>
<td>Deaths from cancer (per annum)</td>
<td>9.6 million</td>
</tr>
</tbody>
</table>

Liquid biopsy emerging multi US$ billion market: estimates

<table>
<thead>
<tr>
<th>Source</th>
<th>2018 market</th>
<th>2012 market</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cowen</td>
<td>Up to ~$130 billion per annum</td>
<td>Up to $5 billion</td>
</tr>
<tr>
<td>Frost &amp; Sullivan</td>
<td>$100 billion per annum</td>
<td>Up to $2.5 billion</td>
</tr>
<tr>
<td>Guardant Health</td>
<td>$51 billion per annum</td>
<td>Subset Remission</td>
</tr>
<tr>
<td>Grail (Illumina)</td>
<td>$75 billion per annum</td>
<td>Up to $75 billion</td>
</tr>
<tr>
<td>Grail Press Release</td>
<td>Set screening $14 billion</td>
<td>Up to $50 billion</td>
</tr>
<tr>
<td>Cowen September 18, 2020</td>
<td>US only</td>
<td>Grail Press Release September 21, 2020: US only</td>
</tr>
</tbody>
</table>

1. Source: GLOBOCAN: Global burden of cancer
2. Source: Cowen September 18, 2020: US only;
4. Source: Guardant Health Company Overview Presentation September 15, 2020: US only

"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
CTCs provide the complete picture for repeat biopsies

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

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

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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

**Parsortix samples processed**
Current – 110,000

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Samples Processed</td>
<td>4,000</td>
<td>12,000</td>
<td>25,000</td>
<td>42,000</td>
<td>67,000</td>
<td>96,000</td>
</tr>
</tbody>
</table>

**Peer-reviewed publications**
Current – 36

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publications</td>
<td>0</td>
<td>2</td>
<td>4</td>
<td>8</td>
<td>14</td>
<td>26</td>
</tr>
</tbody>
</table>

**Research use pricing**

<table>
<thead>
<tr>
<th>Price</th>
<th>Instrument</th>
<th>Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>$50,000</td>
<td>$15,600&lt;sup&gt;2&lt;/sup&gt;</td>
<td>$15</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>PD-L1 Drug Trials</th>
<th>Price per sample (US$)</th>
<th>Number of patients per trial</th>
<th>Number of trials</th>
<th>Number of patients in trials</th>
<th>Number of repeat samples per patient</th>
<th>Addressable number of samples</th>
<th>Addressable market per annum</th>
<th>Target market entry</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Phase 1</td>
<td>$1,200</td>
<td>84</td>
<td>273</td>
<td>22,932</td>
<td>2</td>
<td>45,864</td>
<td>$55 million</td>
<td>CY21</td>
</tr>
<tr>
<td>2 Phase 2</td>
<td>$1,200</td>
<td>102</td>
<td>867</td>
<td>88,434</td>
<td>3</td>
<td>265,302</td>
<td>$318 million</td>
<td>CY22</td>
</tr>
<tr>
<td>3 Phase 3</td>
<td>$1,200</td>
<td>719</td>
<td>233</td>
<td>167,527</td>
<td>4</td>
<td>670,108</td>
<td>$804 million</td>
<td>CY23</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,373</td>
<td>278,893</td>
<td>981,274</td>
<td>$1,178 million</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 enrolling, 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)

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

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)

- 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

### Application

<table>
<thead>
<tr>
<th>Application</th>
<th>Reimbursement potential (US$)</th>
<th>Number of patients p.a. (US)</th>
<th>Number of tests per patient p.a.</th>
<th>Addressable number of tests per annum</th>
<th>Addressable market per annum</th>
<th>Target market entry</th>
</tr>
</thead>
<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 monitoring</td>
<td>$1,000</td>
<td>550,000</td>
<td>2</td>
<td>1,100,000</td>
<td>$1,100 million</td>
<td>CY22</td>
</tr>
<tr>
<td>3 Remission monitoring</td>
<td>$1,000</td>
<td>230,000</td>
<td>2</td>
<td>460,000</td>
<td>$460 million</td>
<td>CY23</td>
</tr>
<tr>
<td></td>
<td></td>
<td>980,000</td>
<td></td>
<td>1,760,000</td>
<td>$1,760 million</td>
<td></td>
</tr>
</tbody>
</table>

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

Corporate partnerships being developed

*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.
Please contact us directly for more information on investor@angleplc.com

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