Established Research Use Sales and progressed first clinical application in ovarian cancer

Andrew Newland & Ian Griffiths
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Liquid Biopsy: Cells for Precision Medicine

- First sales achieved
- Analytical and clinical studies developed for FDA clearance
- Ovarian cancer clinical studies started
- Growing body of published evidence from third party cancer centres
- Strengthened IP position with patents granted out to 2034

Post year end
- CRUK contract for clinical trials
- Breast and prostate cancer results
# Financial Results for the year ended 30 April 2016

## Statement of Comprehensive Income £’000

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>361</td>
<td>0</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>(107)</td>
<td>0</td>
</tr>
<tr>
<td>Gross profit</td>
<td>254</td>
<td>0</td>
</tr>
<tr>
<td>Operating costs</td>
<td>(5,703)</td>
<td>(3,878)</td>
</tr>
<tr>
<td>Other income</td>
<td>22</td>
<td>9</td>
</tr>
<tr>
<td>Loss before tax from continuing operations</td>
<td>(5,427)</td>
<td>(3,869)</td>
</tr>
</tbody>
</table>

## Statement of Financial Position 30Apr16 30Apr15

<table>
<thead>
<tr>
<th></th>
<th>30Apr16</th>
<th>30Apr15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade and other receivables and tax</td>
<td>798</td>
<td>1,008</td>
</tr>
<tr>
<td>Inventories</td>
<td>376</td>
<td>197</td>
</tr>
<tr>
<td>Cash</td>
<td>3,764</td>
<td>8,443</td>
</tr>
<tr>
<td>Property, plant and equipment</td>
<td>455</td>
<td>423</td>
</tr>
<tr>
<td>Intangible assets</td>
<td>1,346</td>
<td>1,149</td>
</tr>
<tr>
<td>Total assets</td>
<td>6,739</td>
<td>11,220</td>
</tr>
</tbody>
</table>

## Comments
- First sales achieved during the year
- Geomerics £0.7m received
- Cash position strengthened by post period end fundraising £9.6m net
Precision medicine: Right drug for the right patient at the right time

Cancer Research UK: “One in two people born after 1960 in the UK will be diagnosed with some form of cancer during their lifetime.”

- Each patient’s cancer is different
- Patient’s cancer changes over time
- Effective treatment requires personalised care
- Reducing healthcare costs

- Major pharma developing more selective drugs:
  - Colorectal cancer KRAS- Erbitux (Merck Serono)
  - Lung cancer EGFR+ Iressa (AstraZeneca)
  - Breast cancer HER2+ Herceptin (Genentech)
  - Immunotherapies
Parsortix™ and the advantages of CTCs for liquid biopsy

<table>
<thead>
<tr>
<th>Source</th>
<th>Primary tumor</th>
<th>Metastatic site</th>
<th>CTCs</th>
<th>cfDNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample type</td>
<td>Intact cells</td>
<td>Intact cells</td>
<td>Intact cells</td>
<td>Fragmented DNA</td>
</tr>
<tr>
<td>Procedure</td>
<td>Invasive</td>
<td>Invasive</td>
<td>Non-invasive</td>
<td>Non-invasive</td>
</tr>
<tr>
<td>Sample accessibility</td>
<td>Not always accessible</td>
<td>Less accessible</td>
<td>Accessible with Parsortix</td>
<td>Accessible</td>
</tr>
<tr>
<td>Patient recovery time</td>
<td>Varies</td>
<td>Longer</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Test costs</td>
<td>Varies</td>
<td>Higher</td>
<td>Lower</td>
<td>Lower</td>
</tr>
<tr>
<td>Test turnaround time</td>
<td>Varies</td>
<td>Longer</td>
<td>Shorter</td>
<td>Shorter</td>
</tr>
<tr>
<td>Repeatability</td>
<td>Varies - difficult</td>
<td>Very difficult</td>
<td>Easy</td>
<td>Easy</td>
</tr>
<tr>
<td>Molecular analysis</td>
<td>DNA</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>RNA</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Difficult</td>
</tr>
<tr>
<td>Protein</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Live cells</td>
<td>Cell culture</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Xenograft</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Standard of care</td>
<td>Proven</td>
<td>Proven</td>
<td>Not yet proven</td>
<td>Not yet proven</td>
</tr>
</tbody>
</table>

ANGLE’s Parsortix™ system provides a unique product based solution where others are offering only a laboratory-service based approach.

ANGLE is offering customers a Parsortix system for purchase comprising a desktop instrument and a one-time use consumable. Many competitor systems are so complicated that they have to offer a CLIA (certified laboratory) solution where the customer sends them the sample and they operate the system and provide a result. This approach is commercially less attractive as it requires large in-house investment, is less scaleable and deprives the clinical customer of much needed revenue in processing the samples.
ANGLE’s patented Parsortix system

- Stepped, microscale cell separators for fluid flow and cell separation
- Granted patents: US, Europe, China, Canada, Australia
- Patent expiry: 2023 to 2034
- Manufactured under ISO13485 quality control system
- European CE mark
Far-reaching market potential

**ANGLE targets**

**Research use**
- Screening trials

**Clinical use**
- Ovarian triage
- Prostate biopsy
- Metastatic breast

**Tissue sample provision**
- Platform feeding in to existing molecular analysis systems for applications in all cancers in all segments “Parsortix inside”
Growing research use sales

- Maiden sales achieved during the year

- Sales to multiple customers:
  - existing key opinion leaders transitioning to paying customers
  - leading cancer research centres
  - big pharma and immunotherapy companies
  - repeat customers and multiple instrument orders
  - first customer publishing results following their purchase of the system

- Cancer Research UK contract
  - routine clinical use
  - 10 clinical trials and 4 more planned

- Targeting sales to leading cancer centres
  - broaden range of users of the system additional posters, publications and clinical evidence
  - new clinical applications and companion diagnostics

- Installed base of 90 instruments and >17,000 samples processed

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Cassette</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price(^1)</td>
<td>£40,000</td>
</tr>
<tr>
<td>Cost(^2)</td>
<td>£12,000</td>
</tr>
<tr>
<td>Margin</td>
<td>70%</td>
</tr>
</tbody>
</table>

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

- Seeking to be first FDA cleared system for harvesting cancer cells from blood
- FDA clearance of the system first for metastatic breast cancer with ovarian cancer and other cancer types to follow
  - breadth of authorisation to provide flexibility in clinical deployment, allowing a range of downstream analytical procedures
  - base authorisation to which (i) additional cancer types and (ii) specific clinical uses can be added facilitating roll out across a wide range of applications
- Detailed analytical and clinical studies developed (ANG-002)
  - numerous technical, planning and ethics issues successfully addressed
  - 196 metastatic breast cancer patients and 196 matching HNV
- Three world class US cancer centres selected
  - patient accrual and clinical evidence to secure the FDA clearance
  - major customers in the future
  - Key Opinion Leaders in securing uptake of the Parsortix system once FDA secured
- Target for submission to FDA in CY17
Ovarian cancer detection: triaging for pelvic mass surgery

Medical University of Vienna

- Highly successful patient study (n=65)
  - 100% specificity in primary epithelial ovarian cancer (no false positives)
  - 78/80% sensitivity with 7 RNA markers
  - 100% sensitivity with 30 RNA markers

- Parsortix results “sensational”
  - best CTC alternative only 24.5% sensitivity

Clinical application in triaging patients with abnormal pelvic mass
- to identify those at high risk of ovarian cancer
- in US, 200,000 women p.a. have surgery on abnormal pelvic masses c. 10% have cancer
- Medicare reimbursement of $516/test

Ovarian sales potential >£300m p.a.

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Parsortix effectiveness compared to other tests

**Sensitivity**
The test correctly identifies those with the disease (true positive). A low sensitivity means the test may miss many people who have cancer (false negative).

**Specificity**
The test correctly identifies those without the disease (true negative). A low specificity means patients are told they may have the disease when they do not (false positive).

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1 Target for clinical studies
2 Vermillion Inc
Clinical application

**Ovarian cancer clinical studies**

- **200 patient European study in progress (ANG-001)**
  - Medical University of Vienna, Charité - Universitätsmedizin Berlin, Vivantes Klinikum Auguste Viktoria, and Vivantes Hospital Neukölln
  - Target completion end CY16

- **200 patient United States study in progress (ANG-003)**
  - University of Rochester Medical Center
  - Target completion H1 CY17

- **LDT test in Europe once study completed**
  - Based on hospital laboratories’ own quality control systems

- **Next step validation studies to enable unrestricted diagnostic device sales**

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**Dr Eva Obermayr, Principal Investigator at the Medical University of Vienna**

“The use of qPCR with the Parsortix system is both highly sensitive and specific and offers the potential for a liquid biopsy (simple blood test) to diagnose ovarian cancer. This would greatly improve the standard of the care that can be offered to women with this condition.”
Clinical application under consideration

Non-invasive metastatic breast cancer biopsy

- Non-invasive, repeatable, lower cost, more effective
- Larger study to replicate the RNA-Seq comparison between biopsy of metastatic site and Parsortix liquid biopsy
- Multiple commercial opportunities
  - repeat biopsy allowing targeted treatment
  - tool for identifying drug targets in metastatic breast cancer
  - tool to assess the effectiveness of drugs under development in clinical trials
- Most common cancer in women - 1.7 million cases recorded in 2012 and 6.3 million women living with breast cancer. 20% to 30% will become metastatic

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

“As a breast cancer surgeon, I am very enthusiastic about the potential of liquid biopsy ... Our pilot data shows that potentially the same information can be obtained from a simple blood test using Parsortix as from an invasive tissue biopsy and indeed may be advantageous over invasive tissue biopsies in regards to the diverse sites of metastatic disease ...”
Non-invasive prostate biopsy

- Barts Cancer Institute new results
  - detected 100% of the metastatic prostate cancer patients (n=52)
  - detected 75% early stage including “active surveillance”

- Simple blood test before solid biopsy test
  - detect prostate cancer
  - assess the aggressiveness of the disease
  - patient risk stratification – differentiate between active surveillance (indolent) or intervention (aggressive)

- Avoid surgical intervention
  - >1 million solid prostate biopsies p.a. in US
  - 75-80% no cancer and >50% with cancer “watchful waiting” / “active surveillance”
  - only 10% with cancer that needs treatment
  - painful, may miss cancer, can cause infection

- number of mesenchymal CTCs good correlation to Gleason score
- metastatic or localised: higher level of accuracy than Gleason score
How ANGLE intends to secure its market position

- Build research use sales
  - pipeline growing becoming system of choice

- Secure Level 1 data
  - ANG-001 and ANG-003 clinical studies
  - ANG-002 FDA studies

- Secure FDA clearance
  - extensive work in progress
  - first mover opportunity

- Prove ovarian cancer clinical application
  - triaging women with pelvic mass

- Evaluate opportunities in breast and prostate cancer
Summary

Liquid biopsy

Parsortix™ patented system changing the paradigm in an emerging $ multi-billion market

- High performance in ovarian, prostate, and breast cancers
- Growing research use sales with a clear competitive advantage
- CE Mark for indicated clinical use. FDA clearance in process
- Ovarian cancer first clinical application in development
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