



Parsortix Liquid Biopsy

**Shares Cenkos Growth & Innovation Forum**

Andrew Newland  
31 January 2017

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## Liquid biopsy improving healthcare and reducing costs: driving precision medicine



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

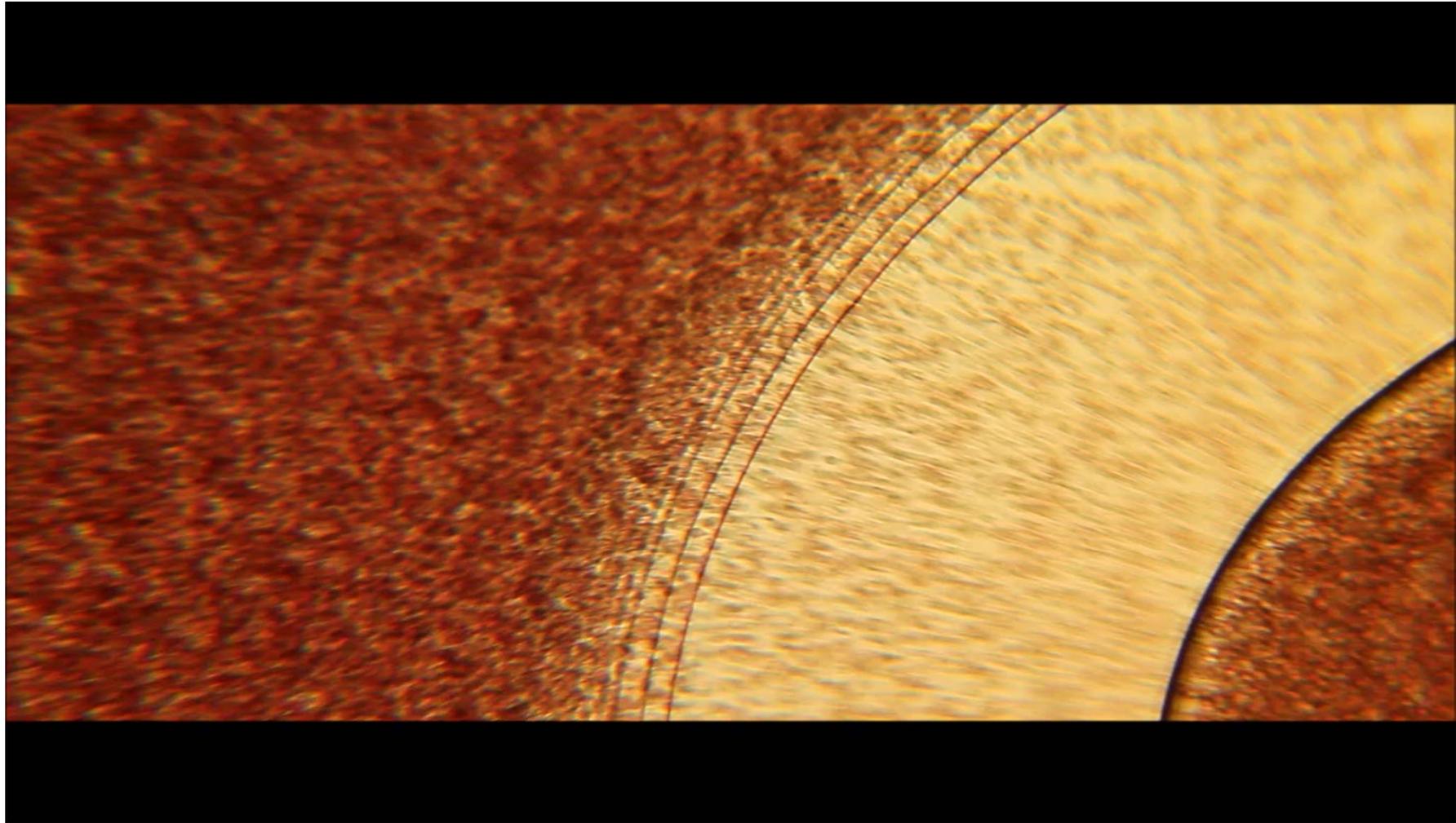
- ❖ Each patient's cancer is different
  - ❖ Patient's cancer changes over time
  - ❖ Effective treatment requires personalised care
  - ❖ Reducing healthcare costs
  - ❖ Big pharma developing more selective drugs
- ❖ Big pharma developing more selective drugs:
    - Colorectal cancer KRAS- Erbitux (Merck Serono)
    - Lung cancer EGFR+ Iressa (AstraZeneca)
    - Breast cancer HER2+ Herceptin (Genentech)
    - Immunotherapies



## Animation showing Parsortix patented steps



## Video showing blood flowing in Parsortix cassette



## ANGLE differentiation

- ◆ The Complete Picture  
*Intact CTCs not just ctDNA. Compatible with all downstream analysis techniques*
- ◆ Evidence-based driven by KOLs and clinical studies
- ◆ Patented product solution  
*Overcomes problems with service labs*
- ◆ Scalable business with third party manufacture



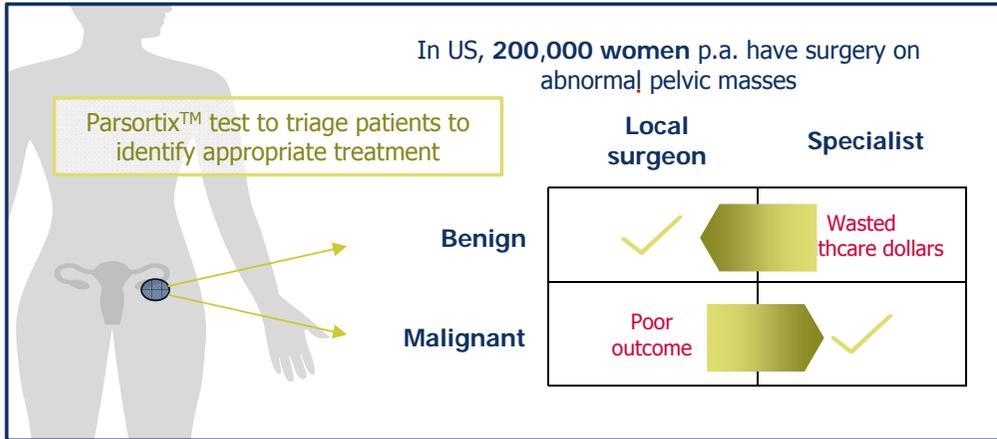
## Growing research use sales

- ❖ First sales achieved FY16
- ❖ Sales pipeline increasing
- ❖ Cancer Research UK contract
  - 1,100 patient samples in 16 clinical trials
- ❖ Medical University of Vienna drug trial
  - 400 patient samples
- ❖ Progressing towards adoption of Parsortix in numerous pharma drug trials
- ❖ Installed base of >135 instruments and ~24,000 samples processed
- ❖ Targeting sales to leading cancer centres
  - broaden range of users of the system with additional posters, publications and clinical evidence
  - new clinical applications and companion diagnostics
- ❖ 50% of top 10 breast cancer researchers worldwide have now adopted Parsortix
  - top 10 as measured by number of CTC publications
- ❖ 40% of US NCCN Centres purchased or considering Parsortix
  - National Comprehensive Cancer Network comprises 27 Centres
- ❖ Cancer centres independently researching 14 different cancer types using Parsortix
  - funded and developed by third parties themselves

# Ovarian cancer clinical application in development



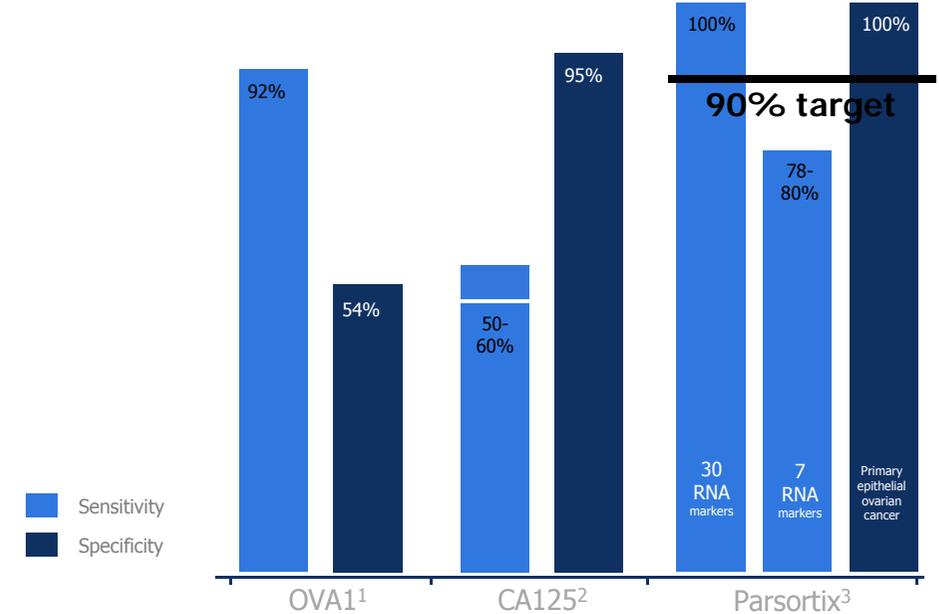
Ovarian sales potential >£300m p.a.



Test Result	Cancer	No Cancer
	Sensitivity	Specificity
Positive	True Positive	False Positive
Negative	False Negative	True Negative

Medical University of Vienna

65



65 patient study  
 1. Vermillion Inc  
 2. Patient.co.uk / Fritsche HA, et al. (1998). CA-125 in ovarian cancer: advances and controversy. Clinical Chemistry. 44(7):1379-1380  
 3. Medical University of Vienna Initial Pilot Data (a) sensitivity with 30 RNA markers (b) sensitivity with 7 RNA markers (c) specificity in primary epithelial ovarian cancer (no false positives)

Disclaimer: For Research Use Only: Not for Use in *In-vitro* diagnostics



**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.”

## Ovarian cancer clinical studies

- ❖ 200 patient European study (ANG-001)
  - Medical University of Vienna, Charité and Vivantes
- ❖ 200 patient United States study (ANG-003)
  - University of Rochester Wilmot Cancer Center
- ❖ Both studies positive interim evaluations of first 50 patients
- ❖ Potential to out-perform current clinical care in discriminating malignant from benign
- ❖ **and** provide valuable gene expression information on malignant cases
- ❖ European study >95% patient enrolled, due to complete enrolment in February 2017
- ❖ US Study 70% patient enrolled, due to complete enrolment in April 2017
- ❖ Headline data both studies expected Q2, CY17
  - Studies blinded and run by independent centres
- ❖ LDT tests to be established once studies completed
  - based on hospital laboratories' own quality control systems
- ❖ Validation studies to enable unrestricted diagnostic device sales



**Dr Richard Moore, Director of the Gynecologic Oncology Division, University of Rochester Medical Center Wilmot Cancer Institute** “The early data points are very promising and indicate that use of a multiplex RNA assay on harvested circulating tumour cells will help to accurately discriminate malignant from benign pelvic masses before surgery and at the same time provide valuable tumour specific genomic information that can help manage patients and their disease in a way not currently possible.”

## FDA authorisation progress

- ❖ Potential to be first FDA cleared system for harvesting cancer cells from blood
- ❖ Success will position Parsortix as the gold standard worldwide
- ❖ Seeking FDA clearance in metastatic breast cancer
  - breadth of clearance to provide flexibility
  - base clearance to which specific clinical uses can be added
  - ovarian cancer and other cancer types to follow
- ❖ ANG-002 analytical studies in progress
  - functionality tests
  - testing of clinical instrument
  - planning for remote site analytical studies
  - reproducibility, limit of detection, interferents
- ❖ ANG-002 clinical study plan developed in consultation with three world-class US breast cancer centres
  - designed to meet FDA remaining requirements
  - 200 metastatic breast cancer patients and 200 matching healthy volunteers
- ❖ Clinical study plan submitted to Scientific Review Committees at the three centres for formal review
- ❖ Following positive reviews, ethics and contractual arrangements, clinical study will be initiated
- ❖ Target is completion of ANG-002 studies in CY17 allowing updated submission to FDA

## Other key areas of development

- ❖ Breast cancer blood test alternative to invasive metastatic biopsy (RNA)
  - successful pilot study by University of Southern California
  - FDA study being extended to cover this form of analysis
  - clinical data expected in CY17
- ❖ Prostate cancer blood test alternative to prostate biopsy (mesenchymal CTCs)
  - successful pilot study by Barts Cancer Institute
  - working on plans to progress this to a full clinical study
- ❖ Growing body of published evidence
  - fourth peer-reviewed paper published by University Medical Centre Hamburg-Eppendorf
  - since year end, multiple other leading cancer centres have presented research using Parsortix at leading cancer conferences including EACR 2016, AACC 2016, NCRI 2016, SABC 2016
  - on track to becoming the most widely published CTC harvesting system
- ❖ Intellectual property strengthened with further patent grants in Japan and the United States



Parsortix™ patented system seeking a leading position in emerging \$ multi-billion liquid biopsy market

- ◆ Providing the **Complete Picture** (intact CTCs not just ctDNA)
- ◆ Ovarian cancer clinical studies headline data due Q2, CY17
- ◆ FDA study to support metastatic breast cancer clearance due to complete in CY17
- ◆ Widespread adoption of Parsortix by leading cancer centres in Europe and the United States driving evidence base





ANGLE Europe Ltd  
3 Frederick Sanger Road  
The Surrey Research Park  
Guildford GU2 7YD  
United Kingdom

Website: [www.ANGLEplc.com](http://www.ANGLEplc.com)

ANGLE North America Inc  
3711 Market Street  
University Science Center 8<sup>th</sup> floor  
Philadelphia PA 19104  
USA