



ANGLE

Parsortix Liquid Biopsy

**Preliminary Results for the year ended
30 April 2018**

Andrew Newland and Ian Griffiths
25 July 2018

Legal disclaimer

LSE AIM: AGL

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- ❖ FDA clinical study set up and in progress
- ❖ **Large scale clinical studies in ovarian cancer out-perform standard of care**
- ❖ Acquisition of downstream analysis technology enables 'sample to answer'
- ❖ **Collaborative agreements with QIAGEN, Philips and Abbott**
- ❖ Installed base increased to 200 Parsortix™ systems and over 49,000 blood separations completed
- ❖ **Growing body of published evidence of performance** from 17 separate cancer centres

Financial Results for the year ended 30 April 2018 (unaudited)



Year ended 30 April	2018	2017
Statement of Comprehensive Income	£'000	£'000
Revenue and grant income	680	498
Cost of sales	(169)	(123)
Gross profit	511	375
Operating costs	(9,444)	(7,810)
Tax credit and other income	1,395	1,043
Loss for the year	(7,538)	(6,392)
Statement of Financial Position	30Apr18	30Apr17
Trade and other receivables and R&D tax credit	2,975	1,975
Inventories	599	665
Cash	7,645	5,536
Property, plant and equipment	1,475	824
Intangible assets	5,588	1,918
Total assets	18,282	10,918

Comments

- ◆ Revenue and grant income up 36%
- ◆ >70% gross margin
- ◆ Planned expenditure on clinical studies
- ◆ R&D Tax Credit £1.1m post year end
- ◆ Fund raise £12.7m post year end
- ◆ Funding strengthens the business in discussions with corporate partners, extends runway past FDA and prepares for revenue growth

FDA clearance



Seeking to be the first company ever to receive an FDA clearance for harvesting cancer cells from blood for analysis

- ❖ **Four leading US cancer centres recruiting patients**
- ❖ Over 80 subjects out of total of 400 already recruited as at 1 June 2018
- ❖ **FDA studies on track for completion in CY18**
- ❖ Prospect of FDA clearance in CY19
- ❖ **Abbott secured as commercialisation partner for HER-2 FISH analysis**

ANG-002 STUDY START-UP STATUS (1 June 2018)

Tasks	Site 01: MD Anderson	Site 02: USC	Site 03: URMC	Site 04: North- western
Institution/Investigator Check (FDA restrictions, debarment, etc.)	✓	✓	✓	✓
Received Clinical Protocol and Draft Contract/Budget sent to site	✓	✓	✓	✓
Site Inspection Completed (e.g. verify bench space for Parsortix instruments and CytoSpin, verify availability of fluorescent microscope and other equipment to be provided by lab, technicians, etc.)	✓	✓	✓	✓
Signed Confidentiality Agreements	✓	✓	✓	✓
Signed Master Clinical Study Agreement	NA	✓	✓	NA
Signed Clinical Study Agreement and/or Study Specific Exhibit	✓	✓	✓	✓
Signed Site/Central Laboratory Agreement	✓	✓	✓	NA
Redcap clinical database completed	NA	NA	✓	NA
Instrument Installation and User Training	✓	✓	✓	✓
IRB Approval of Protocol and Consent Form(s)	✓	✓	✓	✓
Regulatory Documentation Received (i.e. Signed CV's, Medical Licenses, Signed Financial Disclosures, GCP Certifications, Informed Consent SOP, Protocol Signature Page, Delegation of Authority Logs, etc.)	✓	✓	✓	✓
Study Binders and Initial supply of Sample Collection and Processing Kits Delivered to Site for SIV	✓	✓	✓	✓
Study Initiation Visit Scheduled/Completed	✓	✓	✓	✓
Site Officially Open/Activated to Enroll Patients/Subjects	16-Apr-18	31-May-18	03-Apr-18	23-May-18

Business growth post FDA clearance

- ❖ **FDA clearance would be a major validation**
 - generating increased interest from third parties to utilise Parsortix
 - widening the market
 - increasing third party investment in developing Parsortix applications

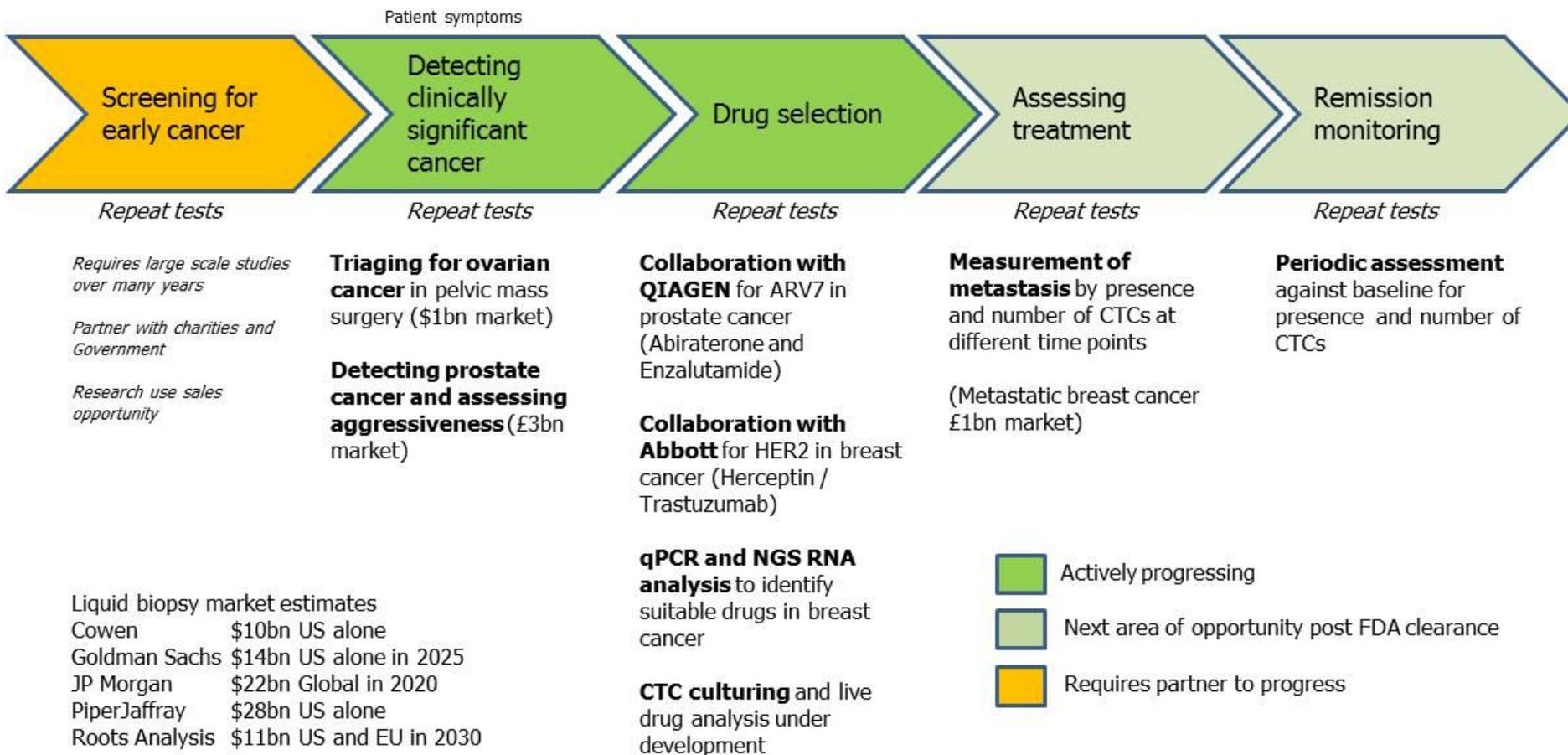
- ❖ **Revenues from clinical applications will be possible** with the potential for rapid growth
 - partnership strategy will increase distribution capability whilst keeping sales costs down

- ❖ **Major competitive advantage supporting research use sales**
 - sales to pharma and CROs for drug trials
 - sales to reference laboratories developing laboratory developed tests (LDTs)
 - development of companion diagnostics (CDx)

- ❖ **Establishment of additional major partnerships will be facilitated**
 - potential for milestone, royalty and development revenues in addition to sales

- ❖ The Parsortix product-based solution married to the partnership approach will provide **significant leverage potential for large scale growth**

Driving commercialisation in a \$ multi-billion market



- ❖ **400 patient clinical studies completed**
- ❖ **Potential to significantly out-perform current clinical care** in discriminating malignant from benign
 - up to 95% sensitivity and nearly double specificity of CA125. ROC-AUC 95.1% considered excellent
- ❖ **Ziplex worked very well with 60 genes in this study**
- ❖ Optimisation in progress to improve performance still further
- ❖ **Further studies (12-18 months) to support launch as a clinical assay**
- ❖ Opportunities for accelerated commercialisation via commercial partnerships
- ❖ **750,000 women p.a. with abnormal pelvic mass in US market alone**

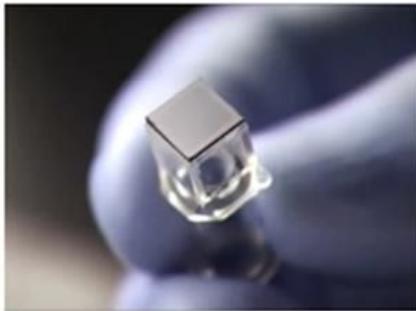


Dr Richard Moore, Director of the Gynecologic Oncology Division, University of Rochester Medical Center Wilmot Cancer Institute “The next generation ANGLE PMT test has the ability to out-perform current clinical practice in accurately discriminating malignant from benign pelvic masses prior to biopsy or surgery. The improved accuracy of the test results in a high level of sensitivity as well as a substantial reduction in false positives.”

Ziplex[®] high performance multiplex downstream analysis solution



Ziplex System incorporating flow-thru expression panels



Flow-thru TipChip

◆ Ziplex system

- benchtop laboratory platform designed for routine and focused multiplex analysis of DNA, RNA and protein biomarkers
- sample to answer solution for distributed testing under development

◆ HyCEAD chemistry

- enables simultaneous measurement of 100's of genes while eliminating multiplex PCR constraints
- rapid content creation for new applications: >500 target genes to date

◆ Consumables

- Flow-thru TipChip[®] containing gene or protein expression panels for common pathways or disease processes
- HyCEAD reagents and assay controls

- ◆ Software: embedded software for method creation, data gathering and data analysis

◆ Patented product solution

❖ Analytical studies progressing well

- precision and reproducibility
- accuracy and linearity
- limits of quantification and detection
- interferences and carryover

❖ ANG-002 clinical study in progress

- 200 metastatic breast cancer patients and 200 age appropriate healthy volunteers
- enrolment over 80 subjects achieved as at 1 June 2018 over a two month period with two centres

❖ MD Anderson leading primary endpoint analysis to confirm CTCs harvested for analysis

❖ Secondary endpoints qPCR, FISH (Abbott), RNA-Seq

❖ 4 leading US cancer centers enrolling

- University of Texas MD Anderson Cancer Center
- University of Rochester Wilmot Cancer Center
- University of Southern California Norris Comprehensive Cancer Center
- Robert H Lurie Comprehensive Cancer Center Northwestern University

❖ Studies expected to complete CY18

- ❖ CTCs harvested and RNA-Seq analysis successful for 100% of patients (21 patient study)
- ❖ **CTCs from Parsortix liquid biopsy had similar patterns of expression for 192 genes to the traditional biopsy of cancer cells from metastatic sites in all cases**
- ❖ Wide range of metastatic sites
 - skin, pleural effusion (fluid around the lung), pericardial effusion (fluid around the heart), breast, cerebrospinal fluid (fluid found in brain and spine) and bone tissue
- ❖ **CTCs provide information on 66 different pathways that may be targeted by new or existing cancer drugs**



USC Norris Comprehensive Cancer Center

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

“Successful validation of our approach in future clinical studies could revolutionize clinical management of metastatic breast cancer and advance the promise of personalized cancer therapies, ultimately positively changing the outcome for patients with metastatic disease.”

Collaboration with Abbott for HER-2 FISH application

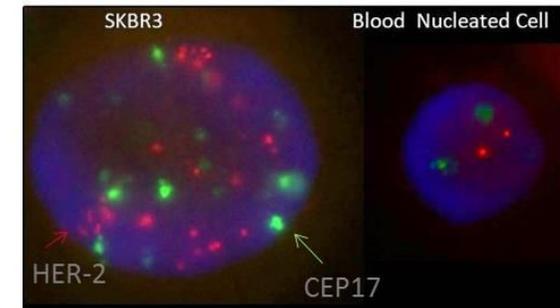
◆ Abbott is the global leader for FISH testing in solid tissue biopsies

◆ Physicians use the FISH HER-2 result to determine whether a patient should receive Herceptin (Trastuzumab)

- about 1 in 5 breast cancer patients have a positive HER-2 result
- FISH 2016 market estimate \$0.5 billion p.a. CAGR 6.8% (source: Grand View Research)

◆ A patient's HER-2 status can change and there is a need to assess HER-2 status at later points when a tissue biopsy is not feasible

◆ ANGLE's ANG-002 FDA clinical study is assessing the use of Abbott's PathVysion FISH probes on CTCs harvested from blood



SKBR3 cells enriched by the Parsortix system and hybridized using PathVysion HER-2 DNA Probe Kit
ANGLE's internal data



Kathryn B Becker, PhD, Franchise Director Oncology and Companion Diagnostics, Abbott

"Abbott is pleased to collaborate with ANGLE in this important evaluation of PathVysion in liquid biopsy specimens. The PathVysion HER-2 DNA FISH Probe kit is reliable and accurate in tissue biopsy samples and the Parsortix system may unlock the potential for PathVysion use in a simple blood test."

- ❖ Barts Cancer Institute pilot studies
 - harvested CTCs in 100% of patients (52 patient study)
 - number of mesenchymal CTCs showed good correlation to Gleason score (80 patient study)
- ❖ **Simple blood test ahead of a standard tissue biopsy test to reduce unnecessary tissue biopsies**
 - **detect presence of prostate cancer**
 - **assess aggressiveness of disease**
 - patient risk stratification – differentiate between active surveillance (indolent) or intervention (aggressive)
- ❖ Blood cell discovery: cells identified as megakaryocytes linked to patient survival (40 patient study)
 - **option for worldwide exclusive licence over megakaryocyte IP**

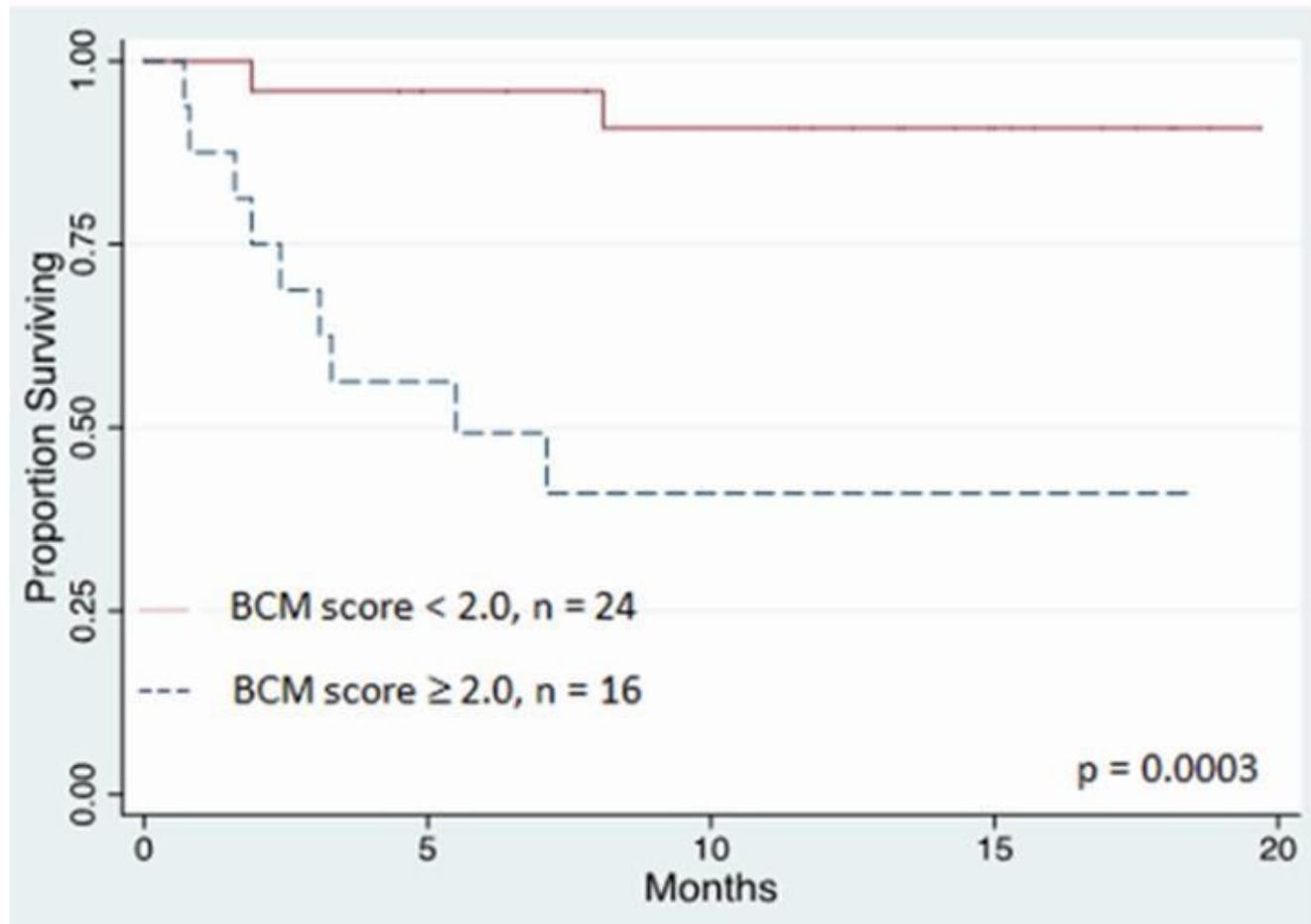


Barts
Cancer Institute

Dr Yong-Jie Lu, Reader in Medical Oncology at Barts Cancer Institute

“Parsortix has shown the potential to detect more severe cancer cases where the patient is likely to die sooner thereby providing information which may enable clinicians to provide different treatment for their patients, potentially extending lives of those battling with cancer.”

Prostate cancer aggressiveness – the key question



- ◆ Kaplan-Meier curve: 40 patient study
- ◆ **Patients classified as high risk using the Parsortix system 10x more likely to die than those classified as low risk**

Source: "The novel association of circulating tumor cells and circulating megakaryocytes with prostate cancer prognosis" Barts Cancer Institute published by Clinical Cancer Research, June 2017

Co-marketing agreement with leading molecular testing company, QIAGEN



❖ QIAGEN leading molecular testing company

- 500,000 customers and \$1.3bn revenues
- NGS (next generation sequencing), PCR (polymerase chain reaction), single cell analysis products and bioinformatics capabilities

❖ Selected Parsortix after year long evaluation process identifying key benefits of Parsortix

- 1) Epitope-independent: captures all relevant cells
- 2) Cells harvested intact and alive
- 3) Highly sensitive: works with almost all patients

❖ First application AR-V7 in prostate cancer



QIAGEN

Michael Kazinski, QIAGEN's Senior Director Molecular Preanalytic Technologies

"ANGLE's Parsortix system is a unique, epitope-independent CTC solution offering easy, automated processing of whole blood to harvest all types of CTCs, including the clinically relevant mesenchymal CTCs, for analysis. It complements very well with our AdnaTest CTC portfolio, now allowing for both phenotypic and molecular characterization of CTCs. The combination will allow scientists and clinical researchers to significantly advance their research."



Circulating Tumor Cells (CTCs) deciphered with label-free enrichment and molecular characterization

Parsortix™ Cell Separation System from ANGLE

- Antibody-independent (i.e., label-free) enrichment of CTCs – including capture of mesenchymal cells and clusters of cells
- Easy access to CTCs for downstream molecular and functional analysis
- Delivers viable cells
- Simple, flexible system

QIAGEN® AdnaTest

- A broad range of cancer-specific assays/panels for cancer gene pathway profiling
- Highly sensitive RT-PCR technology (using a combination of mRNA tumor markers) provides highest degrees of analytical specificity and sensitivity
- Open-ended design enables broad, custom use of the CTC-derived cDNA



Figure 1. Parsortix Cell Separation System.

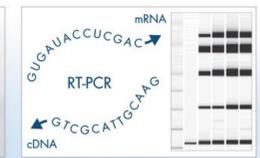


Figure 2. AdnaTest procedure. mRNA purified from the cell lysate is transcribed into cDNA, followed by multiplex PCR or qPCR analysis for several genes in parallel.

Sample to Insight

Research use - growing body of evidence – becoming the CTC system of choice



❖ **Growing user base** (in-house, KOLs, customers and evaluations)

- over 200 Parsortix instruments in active use (30Apr17: 145)
- over 49,000 blood separations performed (30Apr17: 30,000)

❖ **Product based solution drives leveraged R&D model**

- access KOL/customer experience, expertise and facilities (patients, downstream analysis such as NGS, etc.)
- R&D funded and developed by customers

❖ **KOLs and customers researching 21 different cancer types**

- proven performance with multiple leading translational researchers
- publish evidence of utility and present at conferences - viral marketing
- informs NPD and generates pipeline of new clinical applications
- breakthrough research offers potential to expand IP

❖ **Horizon 2020 EU grant €6.3m with Philips (£0.4m to ANGLE)**

- ❖ Potential to be first FDA cleared system for harvesting CTCs
 - **first mover advantage** (third in liquid biopsy) and new “Gold Standard”

	Instrument	Cassette
Price ¹	£40,000	£100
Cost ¹	£12,000 ²	£14
Margin	70%	86%

1 Indicative. High margins allow flexibility in pricing for competitive advantage

2 Includes maintenance, technical support, sales and distribution

Published evidence (cumulative)		
	30Apr18	30Apr17
Publications	10	4
Posters ¹	21	13

1 Publicly available only. Additional posters withheld for patent / peer-reviewed publications

Research use sales £250m p.a. potential
Cancer research centres
Cancer drug trials:
- 750 addressable Phase II @ £100k / trial
- 120 addressable Phase III @ £750k / trial

Strengthening a leading position in emerging \$ multi-billion liquid biopsy market



- ❖ Providing the **Complete Picture** - viable, intact CTCs for DNA, RNA, and protein analysis (not just ctDNA)
- ❖ Clinical study in progress to support **first ever FDA clearance** in metastatic breast cancer expected to complete in H2 CY18
- ❖ Ovarian cancer application successfully completed 400 patient studies with AUC 95.1% **out-performing standard of care** and in optimisation
- ❖ Zplex system provides further differentiation for CTC sample to answer in liquid biopsy
- ❖ Collaboration agreements with QIAGEN, Abbott and Philips

QIAGEN

Abbott

PHILIPS



MANCHESTER
INSTITUTE

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~~Cancer~~ Center

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