



Parsortix Liquid Biopsy

**Interim Results for the six months ended
31 October 2018**

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31 January 2019

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

- ◆ **ANGLE's Parsortix™ system is a simple blood test for personalised cancer care, which harvests viable intact cancer cells (CTCs) for analysis**
 - unique **patented** microfluidic approach, strongly differentiated from competition
 - platform has been shown to work with **21 different cancer types**
 - also works for cancer lymph node analysis and for harvesting fetal cells
 - CTCs have greater clinical utility than ctDNA (fragments of dead cells) as viable intact cancer cells provide the **Complete Picture** including DNA, RNA, and protein analysis as well as the potential to culture the cells outside the patient
- ◆ **ANGLE's product-based solution provides a highly leveraged business model which is scaleable**
 - products are low cost but high value with instruments and consumables giving high **gross margins >70%**
 - **c. 200 instruments in active use with >60,000 blood separations**
 - Parsortix widely used by leading researchers, generating new applications for the platform through breakthrough research
 - third party published evidence of performance is growing rapidly with **16 peer-reviewed publications** and numerous posters published by **19 cancer centres**
 - outsourced manufacturing suppliers able to scale rapidly without Company capex
- ◆ **On track to be the first company with FDA clearance for harvesting cancer cells from blood for analysis**
 - enrolment of 400 subjects for FDA clinical study is **92% complete**
 - clinical and analytical studies to support FDA clearance due to complete in Q1 CY19
 - prospect of FDA clearance in metastatic breast cancer in CY 2019
 - major validation as only the third FDA clearance in liquid biopsy
- ◆ **Large scale clinical studies in ovarian cancer significantly out-performed existing standard of care**
 - **400 patient** studies serve as the exemplar for other applications
 - Parsortix HyCEAD Zplex combination showed **95.1% accuracy (AUC-ROC) in detecting ovarian cancer** in women having surgery for an abnormal pelvic mass
 - abnormal pelvic mass conditions affect 5-10% of all women
 - estimated market size is \$1 billion p.a.
 - ovarian assay has been further optimised and a new clinical verification study is due to start in early 2019
- ◆ **Commercial partnership strategy to leverage sales and distribution channels**
 - combines ANGLE's cancer cell harvesting capability with existing large players' downstream analysis platforms
 - partnership with **Abbott** for HER-2 testing in breast cancer
 - partnership with **QIAGEN** for AR-V7 testing in prostate cancer
 - European research project with **Philips** combining liquid biopsy with imaging
 - progressing other partnerships in cancer and non-invasive prenatal diagnosis
- ◆ **ANGLE's HyCEAD Zplex downstream analysis system offers sample-to-answer growth potential**
 - optimised to provide high sensitivity for multi-gene panel analysis
 - first use ovarian but also offers access to new markets

Continued strong progress during half year

- ❖ FDA analytical and clinical studies nearing completion
- ❖ HyCEAD Zplex platform further developed delivering outstanding sensitivity for multi gene panel downstream analysis
- ❖ Ovarian cancer test combining Parsortix and HyCEAD Zplex systems successfully developed with clinical verification study pending ethics approval
- ❖ Leveraged partnership strategy delivers key benefits
 - ANGLE and QIAGEN co-marketing of combined product offering
 - CTC clusters research breakthrough
 - lymph node analysis
 - pilot study in fetal



❖ Analytical studies progressing well

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

❖ FDA clinical study in progress

- 200 metastatic breast cancer patients and 200 age appropriate healthy volunteers
- enrolment already at 369 subjects 92% complete
- MD Anderson leading primary endpoint analysis to confirm CTCs harvested for analysis
- Secondary endpoints qPCR, FISH (Abbott), RNA-Seq

❖ Four 4 leading US cancer centres enrolling

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

❖ Studies expected to complete Q1 CY19

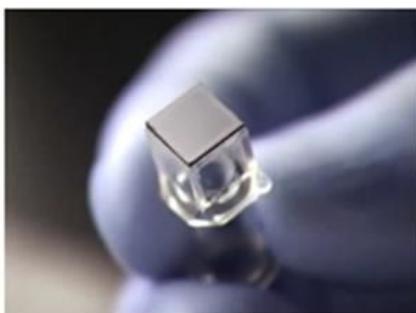
❖ Analysis of results and detailed drafting of submission to allow FDA filing

❖ Prospect of FDA clearance in CY 2019

HyCEAD Zplex[®] high performance multiplex downstream analysis solution



Ziplex System incorporating flow-thru expression panels



Flow-thru TipChip

❖ **Downstream analysis platform HyCEAD Zplex**

- acquired November 2017 providing multiplex cancer gene expression
- Analysis of >100 genes in a single reaction
- similar to targeted NGS at price of PCR

❖ **Completed extensive improvements to the platform**

- sensitivity sufficient to detect a single cancer cell harvested by Parsortix
- process controls incorporated to track assay and instrument performance
- patient blood stability demonstrated for up to 96 hours

❖ **Potential to open up a completely new set of markets** as it can be deployed with many other sample types not just CTCs

- ❖ 400 patient clinical studies demonstrate potential to **significantly out-perform current clinical care** in discriminating malignant from benign with HyCEAD Zplex study demonstrating **ROC-AUC 95.1%**
- ❖ **Extensive optimisation of the ovarian assay following detailed user requirement survey.** Entire “sample-to-answer” process has been analytically validated and is now ready to evaluate in the clinical setting
- ❖ Optimisation now offers the **ability to detect and analyse a single cancer cell** in a Parsortix harvest from 10ml of patient blood
- ❖ A **clinical verification study has been designed and submitted** to the University of Rochester Wilmott Cancer Center for ethics IRB approval
- ❖ Ovarian **clinical verification study is expected to commence in Q1 CY2019** with completion expected 12 months later
- ❖ **ANGLE intends to engage with large scale clinical laboratories and/or women’s health companies** to secure a partner for clinical deployment utilising their sales and distribution channels to scale deployment

Leveraged partnership strategy

◆ **Abbott: breast cancer HER-2**

- process for using Abbott HER-2 FISH test with Parsortix harvested CTCs developed and deployed in FDA clinical study
- discussions with Abbott being progressed regarding sales and distribution of the test

◆ **QIAGEN: prostate cancer AR-V7**

- joint poster published at international cancer conference
- joint marketing flyer prepared
- further work on combining ANGLE cancer cell harvesting with QIAGEN downstream analysis

◆ **Philips: combination of liquid biopsy with imaging**

- European research funded collaboration over 4 years

◆ **Other: multiple other partnerships under consideration**

- fetal and HyCEAD Zplex as well as other Parsortix cancer collaborations

- ❖ **Growing user base** (in-house, KOLs, customers and evaluations)
 - over 60,000 blood separations performed with c. 200 Parsortix instruments in active use
 - 16 peer-reviewed publications and numerous posters from 19 cancer centres
- ❖ **Basel CTC cluster study identifies therapies to reduce metastasis**
 - breakthrough research over three years by leading customer reducing metastasis in mouse model by 80x
 - prospect for routine repeat use of Parsortix as a companion diagnostic
 - Basel planning breast cancer clinical study in 2019
- ❖ **Glioblastoma**
 - ability to harvest CTCs and CTC clusters from blood opens potential for non-invasive biopsy
- ❖ **Lymph node analysis in melanoma**
 - improved process for detecting cancer cells in lymph node with added benefit of facilitating molecular analysis
- ❖ **Fetal cells in pregnant women blood**
 - pilot study demonstrates ability to harvest fetal cells from the blood of pregnant women
 - potential to provide much wider information on fetal health than current NIPT which is based on cell-free fetal DNA
 - seeking partner for commercialisation

Financial Highlights for the six months ended 31 October 2018



Six months ended 31 October	2018	2017
Statement of Comprehensive Income	£'000	£'000
Revenue and grant income	370	188
Cost of sales	(69)	(54)
Gross profit and grant income	301	134
Operating costs	(5,340)	(4,245)
Other income	10	1
Loss before tax from continuing operations	(5,029)	(4,110)
Statement of Financial Position		
	31Oct18	30Apr18
Trade and other receivables and R&D tax credit	2,591	2,975
Inventories	880	599
Cash	14,874	7,645
Property, plant and equipment	1,403	1,475
Intangible assets	5,797	5,588
Total assets	25,545	18,282

Comments

- ◆ Revenue and grant income up 97%
 c. 200 Parsortix instruments in active use
 >60,000 blood separations have already been performed on the Parsortix system
- ◆ >70% gross margin
- ◆ Planned expenditure on clinical studies
- ◆ Cash position strengthened with £12m fundraise (net)
- ◆ Strengthening a leading position in \$ multi-billion emerging market

Team strengthened with new appointments

Board appointment: Non-executive director



Dr Jan Groen

CEO MDxHealth, a genomic diagnostics company in prostate and bladder cancers. Previously President Agendia, co-founder of ViroClinics and DxOrange. Management positions at Focus Diagnostics, a subsidiary of Quest Diagnostics, and Akzo-Nobel. PhD Medical Microbiology, BSc in Clinical Laboratory Studies

Scientific Adviser appointments



Dr Joseph Khoury, Professor of Pathology and Laboratory Medicine at The University of Texas MD Anderson Cancer Center in Houston. Director of the MD Anderson Institutional Immunohistochemistry Laboratory. Member of the College of American Pathologists.



Mr Greg L Shaw, Consultant Urological Surgeon at University College Hospital in London. Chief investigator for NIHR portfolio studies investigating 1) the effects on refinements to robotic surgery and 2) the use of drugs to prevent progression in men on active surveillance for prostate cancer respectively. Expert in robotic surgery with a high case volume

Key next steps



- ❖ Clinical and analytical studies to support first ever FDA clearance to harvest cancer cells from patient blood for subsequent analysis expected to complete in Q1 CY19
- ❖ Prospect of FDA clearance in CY 2019
- ❖ Ovarian cancer clinical verification study due to start in Q1 CY19 utilising sample-to-answer system (Parsortix-HyCEAD-Ziplex) with completion expected 12 months later
- ❖ Progression of existing partnerships and establishment of new partnerships with medtech (downstream analysis), pharma (companion diagnostics), CRO (drug trials), clinical laboratories (LDT)

QIAGEN

Abbott

PHILIPS



MANCHESTER
INSTITUTE

MDAnderson
~~Cancer Center~~

Barts
Cancer Institute



WILMOT
CANCER INSTITUTE



Universitätsklinikum
Hamburg-Eppendorf

USC Norris Comprehensive
Cancer Center
Keck Medicine of USC



MEDICAL
UNIVERSITY
OF VIENNA

ROBERT H. LURIE
COMPREHENSIVE CANCER CENTER
OF NORTHWESTERN UNIVERSITY

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