



genedrive

Decentralising molecular diagnostics

Preliminary results 30 June 2017

17 October 2017

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COMPANY OVERVIEW GENEDRIVE PLC (LSE:GDR)

Rapidly developing, commercial-stage molecular diagnostics business



Manchester based ~ 80 people across 2 distinct divisions

Focused on a Diagnostics business model
Actively seeking disposal of services business

Genedrive®: a Point-of-Need, molecular diagnostic system

Focus on market opportunities where DNA can be used to diagnose and then treat patients

Raised c.£6.0m in July 2016

Early commercial stage and managing cash effectively

Received CE approval for HCV-ID test

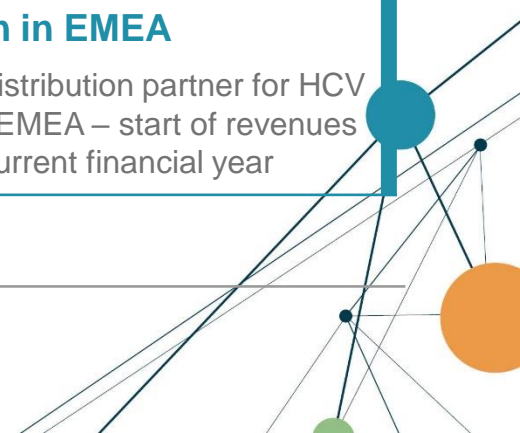
High sensitivity and specificity
Beginning commercialisation

Focus is on Global Health Problems

Such as TB, HCV

Signed deal for HCV distribution in EMEA

World class distribution partner for HCV with Sysmex EMEA – start of revenues expected in current financial year



COMPANY OVERVIEW GENEDRIVE ® TECHNOLOGY

Technology platform brings the power of molecular diagnostics outside of the hospital

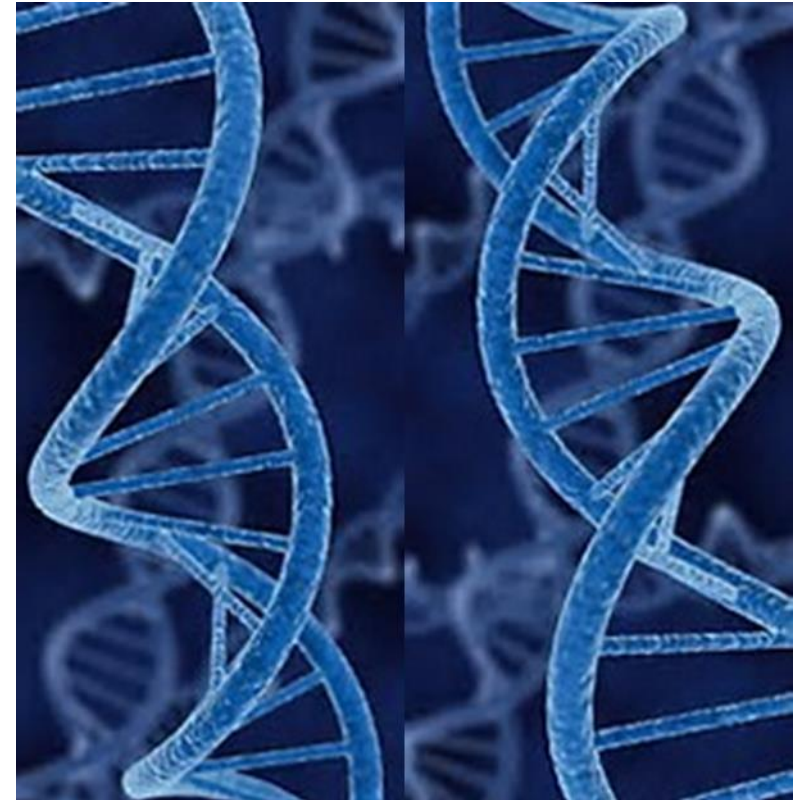


- **Rapid Results Outside of a Hospital Environment**
 - Prompt clinical decisions are possible - sample to result typically in 50-75 minutes vs days from a service laboratory
- **Easy to Use**
 - Single use disposable reagent cartridge (razor/ razor blade model)
 - Limited training required for operation
- **Real Word Robustness and Reliability**
 - Battery pack permits use in poor infrastructure settings
- **Versatile**
 - Core technology across a range of applications, including human health, animal health, and environmental testing
- **Affordable**
 - System and test price point accessible world-wide

Market & Operational Review

CORPORATE AND OPERATIONAL HIGHLIGHTS (INCLUDING POST-YEAR END)

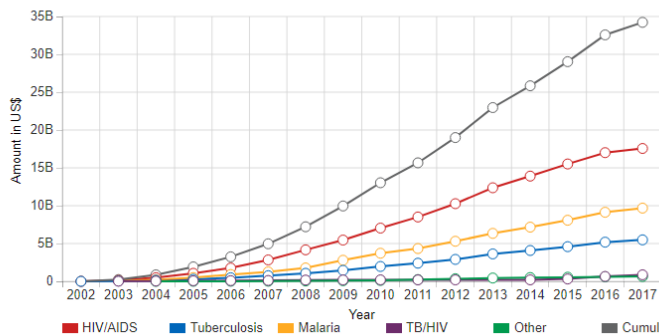
- CE marking obtained for Genedrive® HCV ID kit
- Distribution agreement with Sysmex Europe GmbH for Genedrive HCV ID kit in EMEA
- Continued positive progress with the US DoD biohazard identifier programme
 - Next stage worth approximately \$1.4m in development income and a further \$0.5m in product sales
- Disappointing uptake of MTB/RIF assay in India, in part owing to sample preparation problems specific to MTB and commercial issues
- £0.6m conditional grant offer from Innovate UK to fund centrifuge free plasma separation device



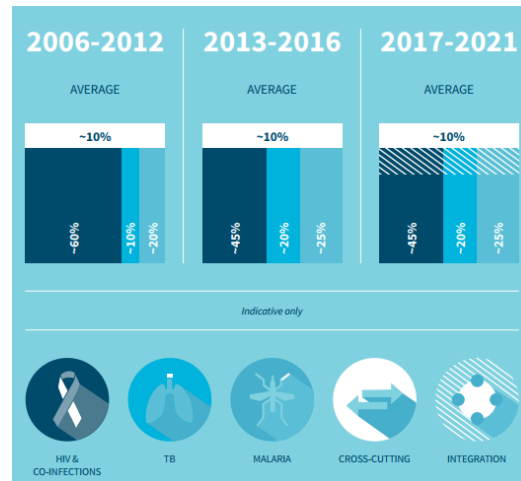
GLOBAL HEALTH PRIORITIES AND ~ \$4B/YR FUNDING



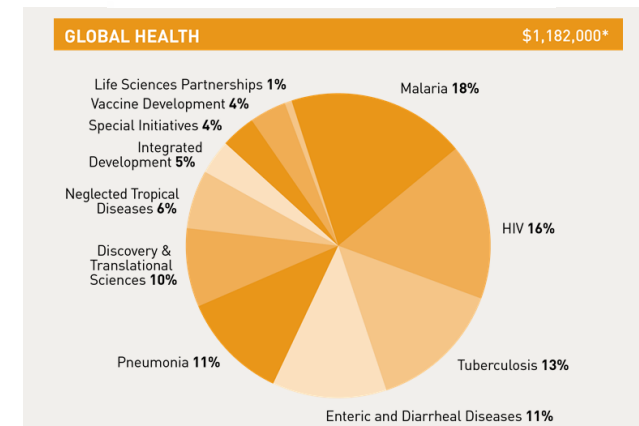
Disbursements 2002-2017



TB/HIV coinfection, and “Other” As of May 2017, the Global Fund had disbursed US\$33.8 billion. It targets HIV, mTB, Malaria



Unitaid’s Strategy for 2017-2021 is “contribute to scale up access to treatment for HIV/AIDS (and co-infections incl HCV), malaria and tuberculosis for the people in developing countries...”
Unitaid has invested over \$2B since 2016

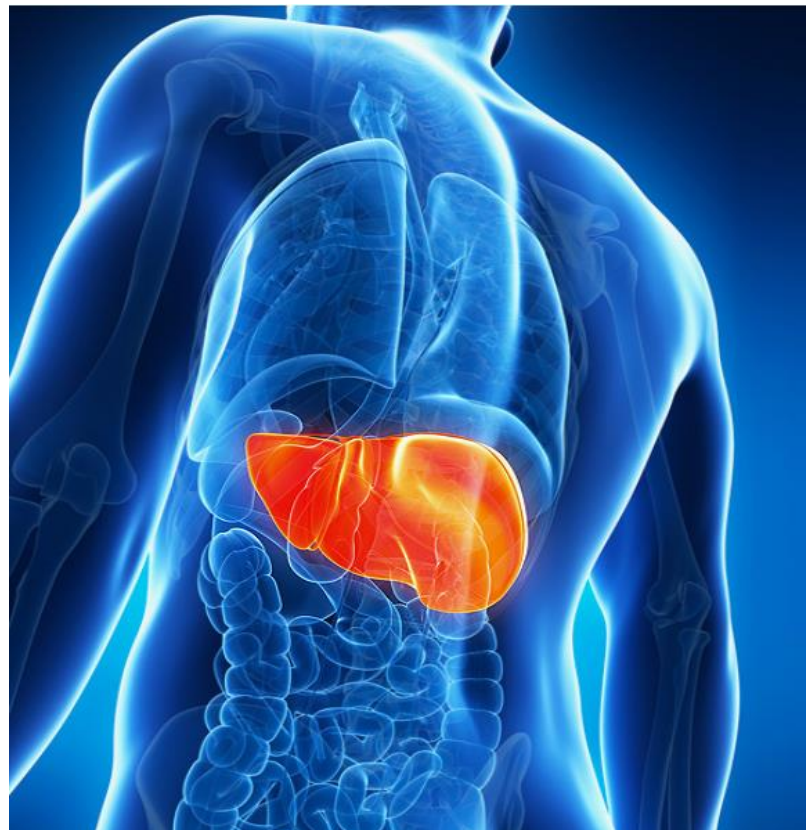


The BMGF focusses on Malaria, HIV, mTB, and tropical diseases

genedrive’s test development priorities are aligned to HCV, TB and other global healthcare priorities

GENEDRIVE® OPPORTUNITY IN HCV DIAGNOSTICS

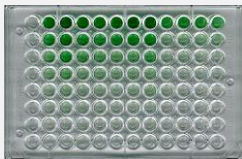


- Strong need for affordable and accurate decentralised molecular tests to ensure treatments can reach patients
- HCV is a blood-borne virus which primarily affects the liver - no vaccine
- Direct Acting Antiviral Therapy (DAAs) make HCV a curable disease; investment now flowing for diagnostics and treatment
- Only 20% of people infected with HCV are diagnosed, and only 7.4% of those are treated¹
- Approx. 11 million hospital tests performed globally, however supported screening programmes could increase this X10



¹ <http://www.who.int/mediacentre/factsheets/fs164/en/>

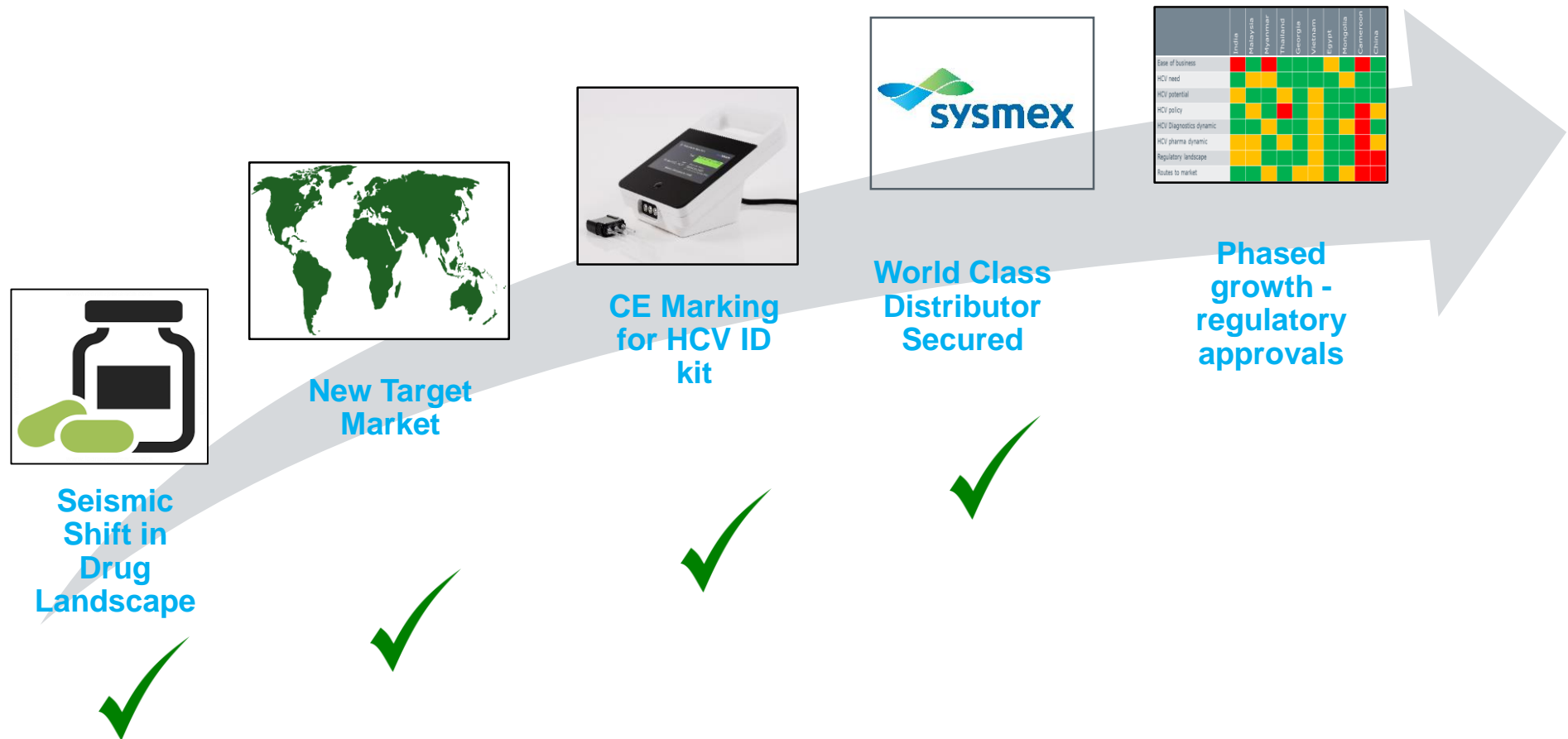
GENEDRIVE® OPPORTUNITY IN HCV DIAGNOSTICS

As a point of need solution, genedrive® is uniquely positioned to support HCV strategy

	Blood sample	Immunoassay	PCR-based	Genedrive®
				
Approach		Lab-based test to identify the presence of HCV antibodies in patient's blood serum. EIAs/ CIAs/ RDTs.	Lab-based PCR based tests for viral DNA run on blood samples. High-cost platforms in centralised, high-resource labs	Field-based PCR based test in development for viral DNA to be run on blood samples at patient location
Providers		Numerous providers: Abbott/ J&J/ BioRad/ DiaSorin	Numerous providers: Abbott/ Qiagen/ Roche/ Siemens/ Cepheid	Genedrive
Diagnosis		✓	✓	✓
Viral Detection		✓	✓	✓
Diagnose Active Infection		✗	✓	✓
Decentralised use		✗	✗	✓
Service Turnaround Time*		Slow (weeks/ days)	Slow (weeks/ days)	Fast (90 mins)
Price		\$20	\$20-30	\$20-35
Limit of Detection (LOD)		n/a	5-10 IU/ml	~2200 IU/ml
Sensitivity at LOD		n/a	100%	> 99%

*Time from sample to patient/ physician receiving result

HCV OPPORTUNITY-TO-COMMERCIALISATION



First to market with a decentralised product
Revenues to start in the current financial year

DISTRIBUTOR AGREEMENT FOR HCV



- Sysmex Europe exclusively contracted for EMEA region, initially focused on Africa
- Sysmex Africa consists of 29 distributors covering 46 Sub-Saharan African countries
- Genedrive HCV ID kit will compliment the product offering and public health focus
- Product launch Oct 22-25, IFCC Durban
- Further geographies will follow with the potential for further diseases



About Sysmex

- Listed on Tokyo exchange, market cap \$13Bn , \$2.2Bn annual turnover, 8,000 employees in 190 countries
- 8th largest IVD diagnostics company in the world, #1 in haematology
- World leader in the development, manufacture, sales and export/import of diagnostic systems

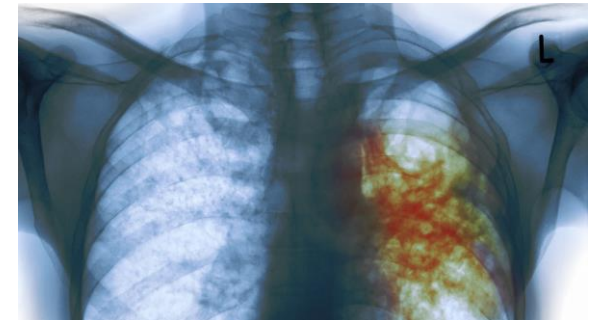
PHASED GROWTH- POST REGULATORY APPROVALS



AFRICA	APAC	ROW
<ul style="list-style-type: none">• Rwanda• Cameroon• Ghana• Burkina Faso	<ul style="list-style-type: none">• Nepal• Sri Lanka• Cambodia• Bangladesh	<ul style="list-style-type: none">• India• S America• C America• China
<ul style="list-style-type: none">• S Africa• Nigeria• Uganda• Kenya	<ul style="list-style-type: none">• Pakistan• Thailand• Philippines	
<ul style="list-style-type: none">• Egypt• Morocco	<ul style="list-style-type: none">• Vietnam• Malaysia• Singapore• Indonesia	

GENEDRIVE® MTB/RIF ASSAY IN INDIA

- Disappointing uptake of MTB/RIF assay in India, in part owing to sample preparation problems specific to MTB and commercial issues
- Alternative solution successfully tested in laboratories however there are difficulties validating this in the field through our commercial partner
- Considering how best to address the Indian MTB/RIF market and the broader potential of Genedrive®
- No additional short term revenues are expected at present
- Defined TB market is large and there is significant potential for Genedrive®



OTHER GENEDRIVE® APPLICATIONS

Agreement with the US Department of Defense to develop Genedrive® as a handheld bio-warfare testing system

Identification of biological agents and pathogens in a military setting. US\$7.8m in milestone funding paid over 5 years
Multiple units ordered and shipped



Collaboration with Centre for Environment, Fisheries & Aquaculture Sciences (CEFAS)

Point of need aquaculture test for diagnosis of pathogens
Estimated at ~\$US 1B annual loss



VALIDATING GENEDRIVE®

Hepatitis C (HCV)

Blood-based,
viral testing



Tuberculosis (TB)

Sputum testing
Developing
world capability



US DoD Biohazard ID

\$7.8m programme
Multiplexing
'Ruggedness'



Pharmacogenomics

Buccal swab
Human genotyping



Aquaculture

Non-healthcare
applications



Genedrive® Development



SERVICES OPERATIONS

Strategic review of our historical and revenue generating business ongoing to focus on commercialisation of diagnostic business

Pharmacogenomics

- Genomic markers of drug and disease effect
- Revenue £1.1m (2016: £1.1m)
- £nil EBITDA
- GSK preferred supplier



Pre-clinical (CRO) Research

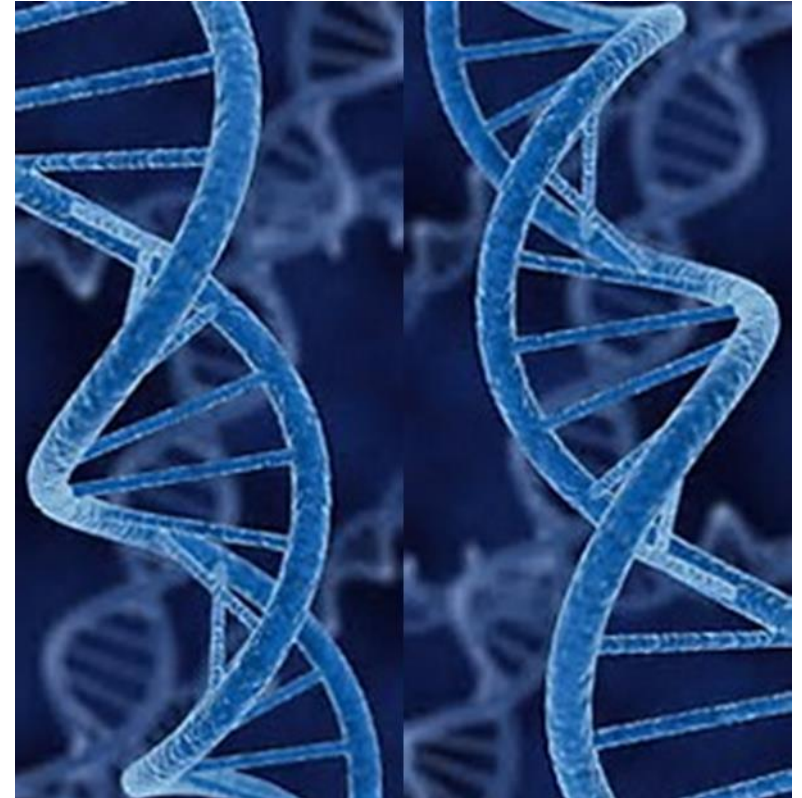
- Experts in epithelial stem cells and specialists in pre-clinical efficacy testing
- Revenue £2.1m (2016: £2.0m)
- £0.3m EBITDA



Financial Review

FINANCIAL HIGHLIGHTS (INCLUDING POST-YEAR END)

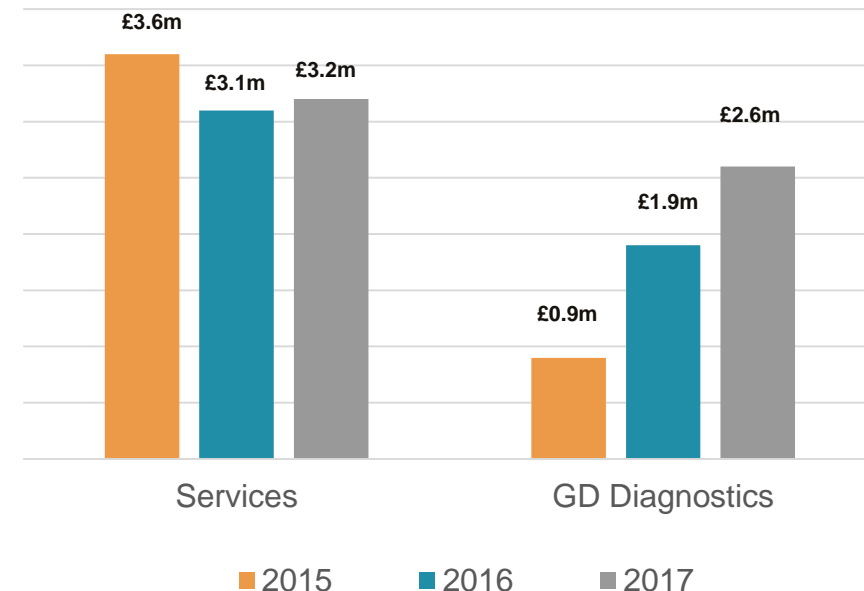
- Turnover of £5.8m, up 13.7% (2016: £5.1m)
 - Strong growth in Genedrive[®] development income to £2.6m (2016: £2.0m)
 - Moderate increase in Service income to £3.2m (2016: £3.1m)
- Trading loss improvement to £4.9m (2016: £5.4m) despite increased Research & Development and Administrative costs
- Cash at 30 June 2017 of £5.1m (2016: £1.1m) post £6.0m equity fund raising in July 2016
- Loss for the year £6.4m, up 8.5% from £5.9m in the prior year reflecting an impairment charge and tax credit



FINANCIAL OVERVIEW

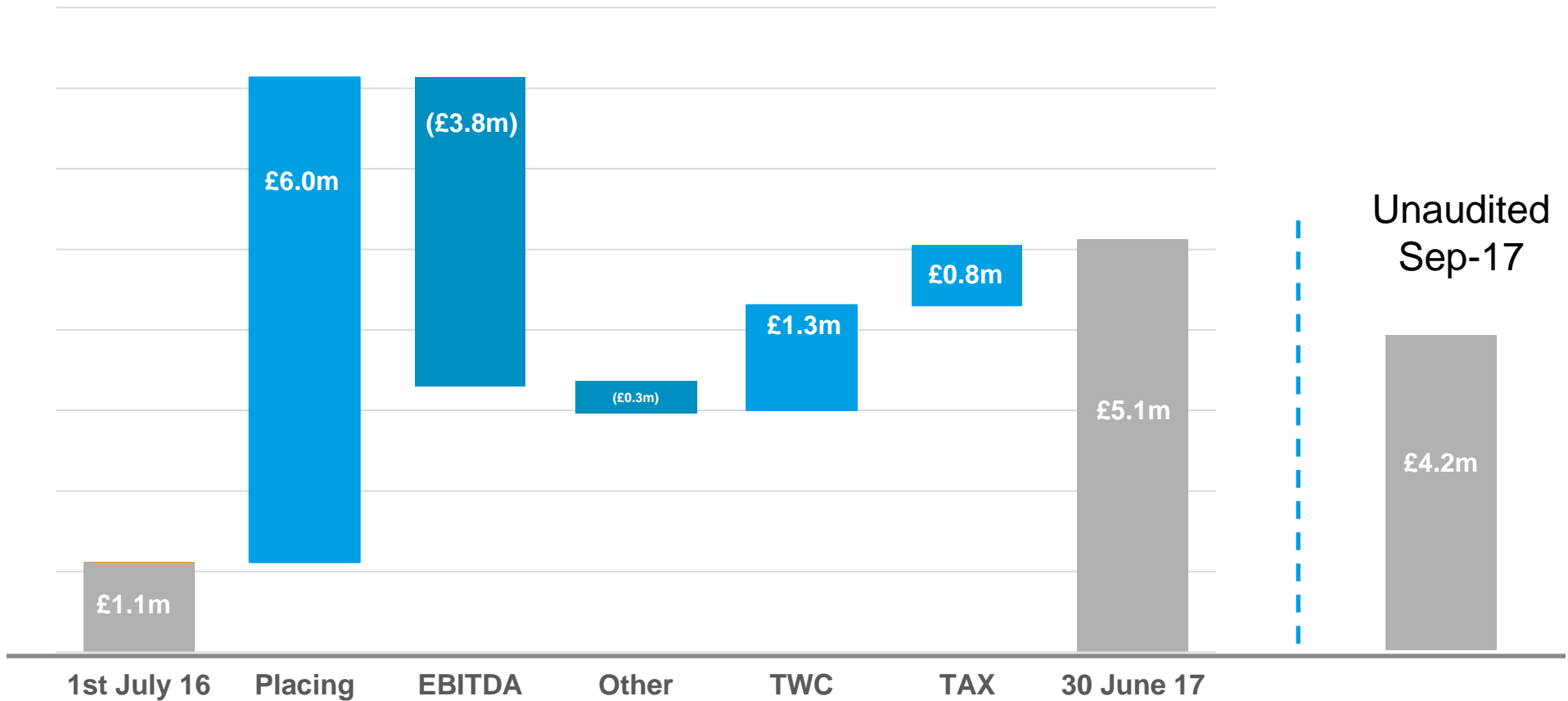
REVENUE

- Diagnostics Genedrive® revenues of £2.6m up 30.0 % from prior year of £2.0m
- Diagnostics Genedrive® 3 year CAGR of 70%, aided by the US DoD programme
- US DoD contract extended into 2017/18, expectation of up to \$1.9m
- Services revenue up slightly to £3.1m and £0.3m EBITDA (2016: £0.1m)
- Trading loss down £4.9m (2016: £5.4m) despite increased overhead costs
- £2.4m non-cash impairment



FINANCIAL OVERVIEW

CASHFLOW



FINANCIAL OVERVIEW

CASHFLOW

	2016 £'000	2017 £'000
EBITDA	(4,252)	(3,842)
Working capital	44	1,308
Interest expense	(297)	14
Tax	691	757
Other	(192)	(130)
fx	192	(115)
Cashflow before financing	(3,814)	(2,008)
Share issue	-	6,023
Cash (outflow)/ inflow	(3,814)	4,015
B/f	4,928	1,114
Cash at Bank	1,114	5,129

- EBITDA losses reduced owing to contribution from the increased revenue in both Diagnostics and Services
- Significant improvement in working capital especially around debtors, driven from focus on over-dues
- DoD billing process also helped debtor improvements, changes resulted in £0.5m cash inflow
- Interest expense consistent with prior period, however option taken to defer future interest payments
- Share placing in July 2016 raised £6.0m after fees
- Cash at bank closed at £5.1m
- Net assets of £3.4m after £2.4m non-cash impairment of intangibles charge

RAPIDLY DEVELOPING COMMERCIAL-STAGE MOLECULAR DIAGNOSTICS BUSINESS

- 1 Innovative, cost effective technology with unique USPs
- 2 First to market opportunity for newly approved HCV test
- 3 World class distributor secured
- 4 Large and well funded markets to sell into
- 5 Growth in genedrive revenues FY2017, supporting strategy in near term



genedrive

Thank-you

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