genedrive

Interim Results
31 December 2016

April 17

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Company Overview

Commercialising Point of Need Molecular Diagnostics

genedrive plc
48 Grafton Street,
Manchester
M13 9XX

www.genedriveplc.com

Company operates with 2 distinct areas of focus

Newly focused Diagnostics business with the Genedrive® system and legacy business in Contract Research and Pharmacogenomics

Raised £6.0m in July 2016 to fund Genedrive® opportunity

Investment being made only into Diagnostics
Cash of £5.7m as of Dec 2016 and £0.8m R&D tax credit received post period end

Strategic Review of Legacy Business

Seeking divestment to fund Diagnostics focus
Process ongoing

Company re-branded as genedrive plc

To reflect the direction and investment of the company post-fundraise

Large attractive markets exist (c. $1bn for infectious disease pipeline)

Today generally delivered from expensive, hospital based settings
Growing validation of Genedrive® system outside of infectious diseases

Operational Highlights

- **Genedrive® HCV ID test submitted for CE marking**
  Excellent clinical trials yielding >99% sensitivity and 100% specificity in study cohort

- **Further successful progress with US Department of Defense Programme**
  Units and assays delivered to support field trials

- **MTB/ RIF assay uptake disappointing**
  End user engagement challenging and some sample prep issues in the period

- **Successful Genedrive® validation for aquaculture**
  Detection of white-spot disease in shrimps in collaboration with the Centre for Environment, Fisheries and Aquaculture Science (CEFAS)

- **Improved first half revenues from our non-Genedrive® Services operations**
  Services revenue up 30.7% on the same period in 2015

- **Further steps taken to become a focused molecular diagnostics company**
  Company name changed to genedrive plc, Strategic Review initiated, £6.0m raised on share issue.

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Validating Genedrive®

Hepatitis C (HCV)	Tuberculosis (TB)	US DoD Biohazard ID	Pharma-cogenomics	Aquaculture
Blood-based, viral testing	Sputum testing Developing world capability	$7.8m programme Multiplexing 'Ruggedness'	Buccal swab Human genotyping	Non-healthcare applications

Genedrive® Development

Low Cost

- System and test costs are lower than alternatives
- Appropriate for target markets

Rapid, Point of need or Clinic based results

- Prompt treatment decisions - sample to result typically in 60-90 minutes

Easy of Use

- Single use disposable reagent cartridge (razor/ razor blade business model)
- No other extensive laboratory equipment required

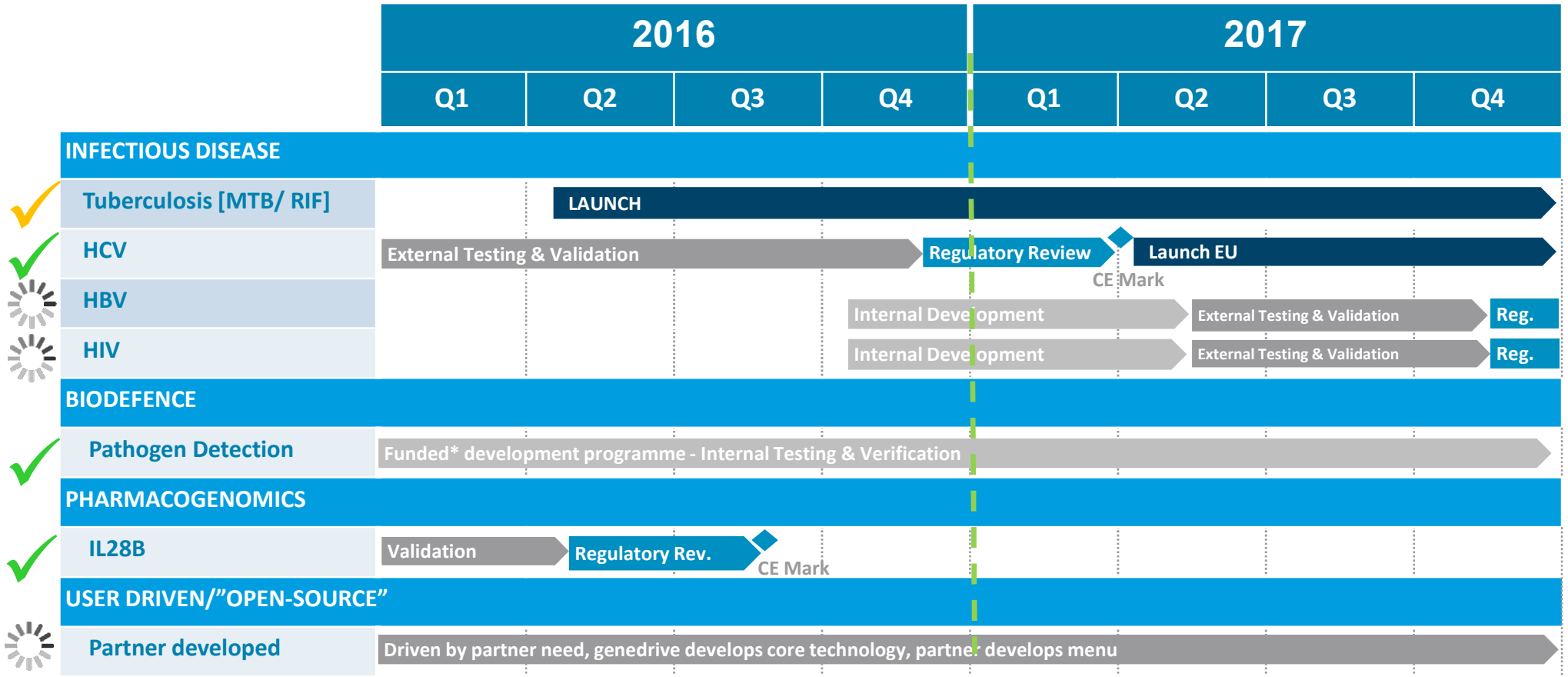
Real World Robustness

- Battery pack permits use in poor infrastructure countries
- Operates in hot and humid conditions present in target markets

Versatile

- Diverse sample types can be tested including sputum, blood plasma, and buccal cheek swabs

Genedrive® Pipeline



Commercial Opportunities and Strategy

Genedrive® is an effective, low cost, molecular solution across a broad range of applications

Genedrive® - Internally Develop and Drive Proprietary Menu

- HCV > $500m diagnostics market
- MTB/RIF > $120m in top 4 markets
- Independent sample collection strategy with broad application to other blood borne viruses (HIV, HEP B)

Genedrive® - Externally Develop and Drive Open or Proprietary Menu

- Leverage Open Innovation Partnerships
- Effective capital deployment
- BD opportunities for co-development or OEM

Tuberculosis (MTB/ RIF)

Market potential

TB is the largest single infectious cause of death among young people and adults

TB diagnosis in many countries is still reliant on older tools, but new diagnostics are changing the landscape

- 77m sputum smear microscopy tests performed annually in 22 high burden countries at 42,000 dedicated microscopy centres

Molecular testing is the fastest growing TB diagnostic test segment and is expected to erode market share in smear microscopy

- 13m Cepheid GeneXpert® MTB/RIF tests sold since launch in 2010

Highest priority is a rapid, low-cost, sputum-based, molecular test with DST capability for microscopy centres

Current situation

End user sales engagement in India for the Genedrive® MTB/RIF assay continues to be challenging

Performance related issues in field use related to sample preparation complexities - unique to TB assay

Issues have been isolated to specific component and being rectified

No unit or assay sales from Indian distributor or increase to initial £0.2m stocking order

We continue to work to address the issues and assess our position in the Indian MTB market

Outlook

- The overall potential for MTB/RIF will be reviewed alongside that of HCV and next menu items considering Group resources
- Continue to review the potential of the MTB/RIF product in India
- Ongoing commercial issues coupled with recent test-specific sample preparation problems make short term revenue growth unlikely

Hepatitis C (HCV) – Disease and Market

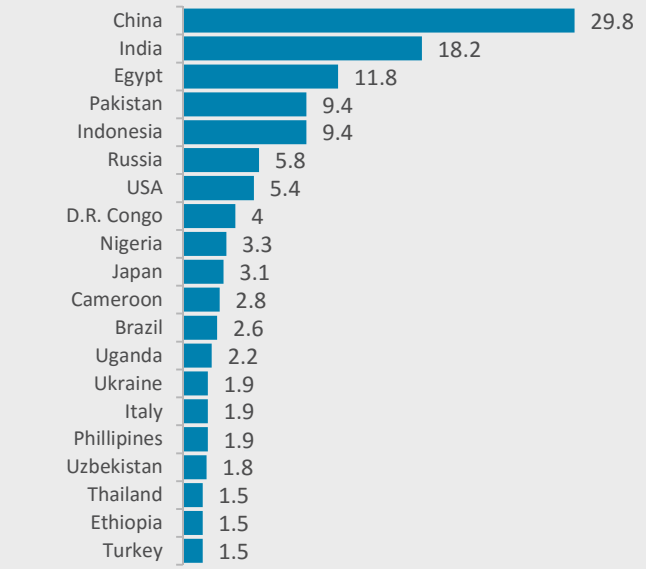
HCV is a growing global healthcare crisis with c.170m people infected globally

- HCV is a blood-borne virus which primarily affects the liver - no vaccine currently available
- Chronic HCV infection is curable if diagnosed: opportunity to reduce costs of chronic infection and treatment (e.g. liver transplant)
- Global HCV diagnostic market is estimated to be ~$500m and is now a strategic target of the World Health Organisation

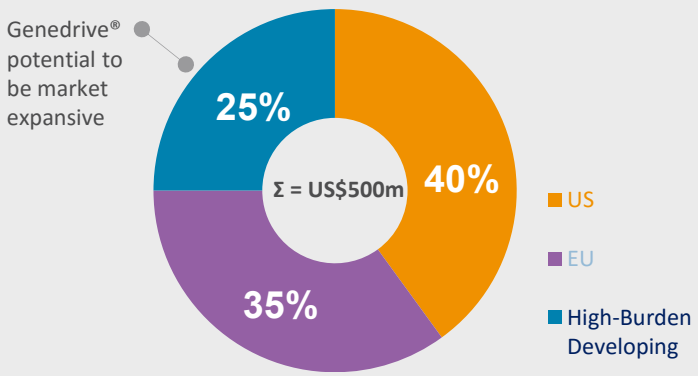
In May 2016, The World Health Assembly adopted the first "*Global Health Sector Strategy on Viral Hepatitis, 2016-2021*". The strategy has a vision of eliminating viral hepatitis as a public health problem and this is encapsulated in the global targets of reducing new viral hepatitis infections by 90% and reducing deaths due to viral hepatitis by 65% by 2030**.

**http://www.who.int/mediacentre/factsheets/fs164/en/

Prevalence of HCV in Top 20 countries (millions)



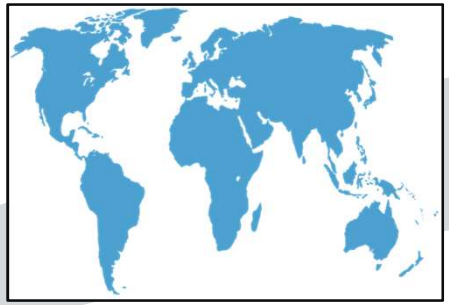
Current HCV Testing Market



HCV Diagnostics (HCV ID Kit)

1. Seismic Shift in Drug Landscape

Direct acting antivirals made available to selected low income countries at pricing 95% less than European pricing



2. New Target Market

Availability of curative therapies creates new opportunities for testing and treatment

3. First to Market Product

CE marking submission during H1 of 2016/17 means Genedrive® has unique opportunity to be first to market with a decentralised testing solution

HCV – Current Diagnostic Options for HCV

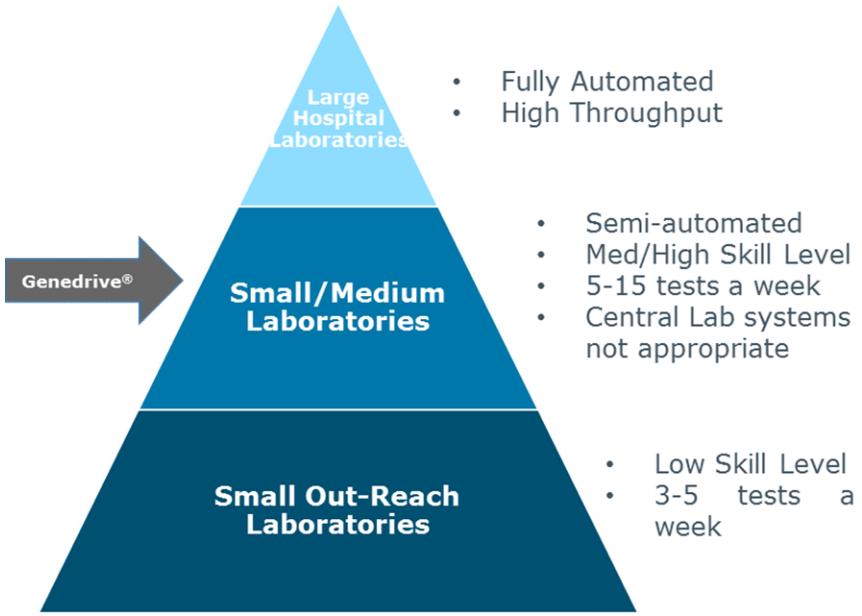
As a point of need solution, Genedrive® is uniquely positioned to support FIND*'s HCV strategy

Blood sample

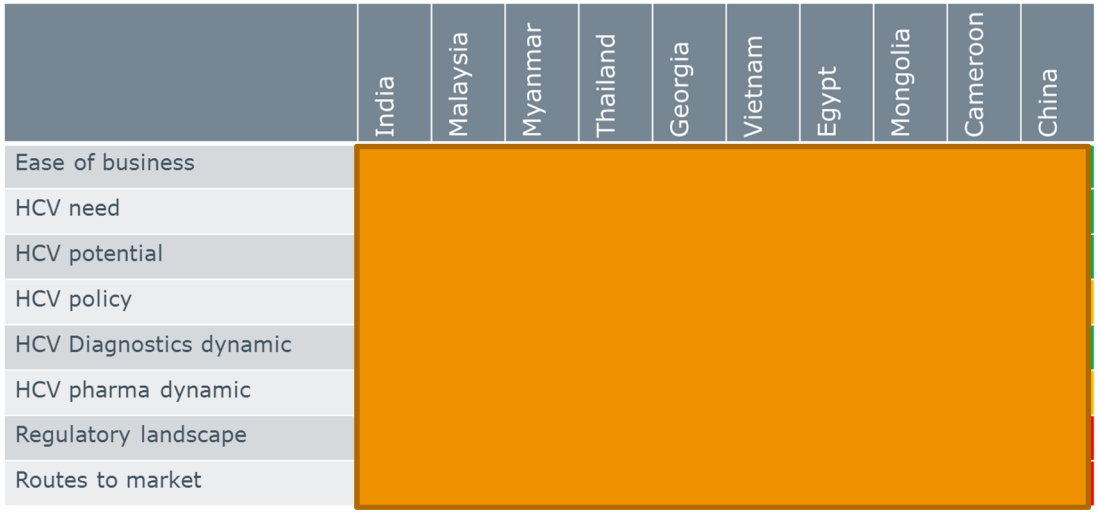
	Immunoassay	PCR-based	Genedrive®
			
Approach	Lab-based test to identify the presence of HCV antibodies in patient's blood serum. EIAs/ CIAs/ RDTs.	Lab-based PCR based tests for viral DNA run on blood samples. High-cost platforms in centralised, high-resource labs	Field-based PCR based test in development 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 [1]
Sensitivity at LOD	n/a	100%	> 99%

**FIND = Foundation for Innovative New Diagnostics*
**Time from sample to patient/ physician receiving result*
1 Clinically valid and within the FIND parameters

HCV – Launch Country Dynamics



Target Laboratories



HCV Launch

- Prioritised target list of countries based on HCV dynamics
- Positive engagement with NGO(s) for in country evaluation(s)
- Company in active discussions with both regional and country specific commercial partners. Targeting to have agreement(s) in place to align with CE availability for HCV

Non Clinical Applications

Low-cost, speed and simplicity make Genedrive® an attractive solution in other point of need uses

Pathogen Detection - Biodefence

- Agreement with the US Department of Defense to develop Genedrive® as a handheld bio-agent pathogen identifier assay
- US DoD began assessing Genedrive® for biodefence use in 2011
- Positive review was followed up by US$7.8m in milestone funding due over 5 years (US$2.4m in 2016)
- Independent validation of Genedrive® technology over competing systems
- $2.9m extension confirmed in March 2016

Non Clinical Applications

Low-cost, speed and simplicity make Genedrive® an attractive solution in other point of need uses

Pathogen Detection - Aquaculture

- Collaboration with Centre for Environment, Fisheries & Aquaculture Sciences (CEFAS)
- Point of need aquaculture test for diagnosis of pathogens
- Main pathogen identified: White Spot Syndrome Virus
- Successful in country testing by CEFAS in Thailand in November 16
- Seeking further Development Partners for development and commercialisation

Services Operations

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

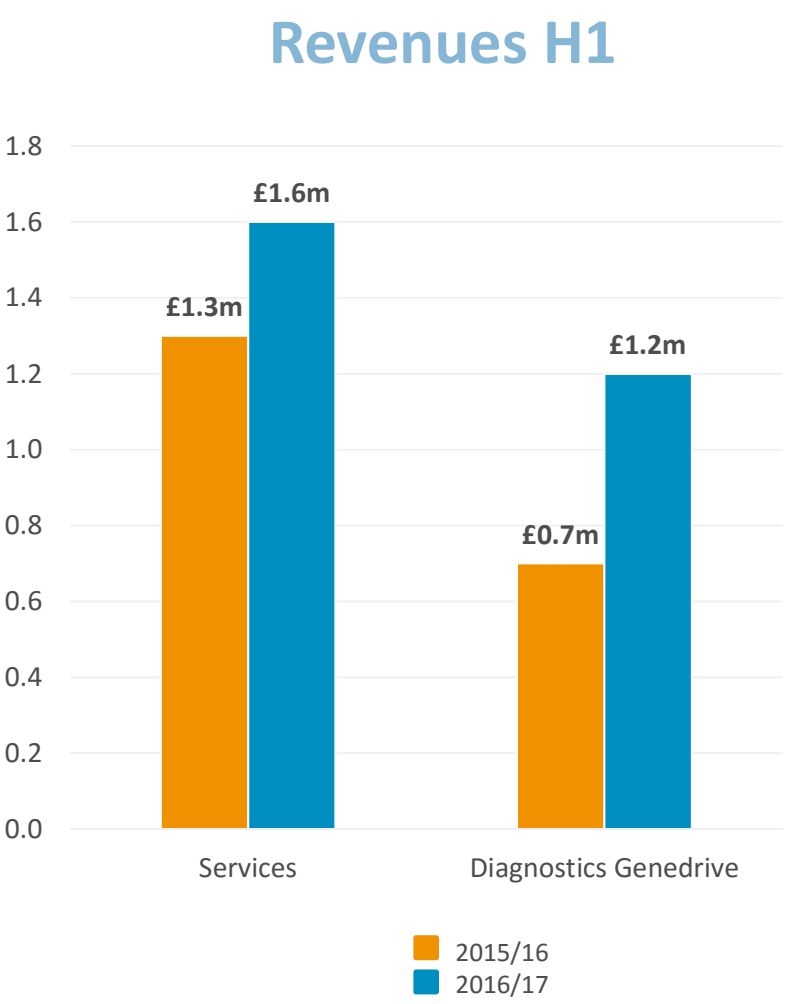
Pharmacogenomics

- Genomic markers of drug and disease effect
- 2016 Interim revenues £0.7m (2015: £0.3m)
- Trading result £0.1m (2015: £0.3m loss)
- GSK preferred supplier

Pre-clinical (CRO) Research

- Experts in epithelial stem cells and specialists in pre-clinical efficacy testing
- 2016 Interim revenues £0.9m (2015: £1.0m)
- Trading result £0.1m (2015: £0.1m)

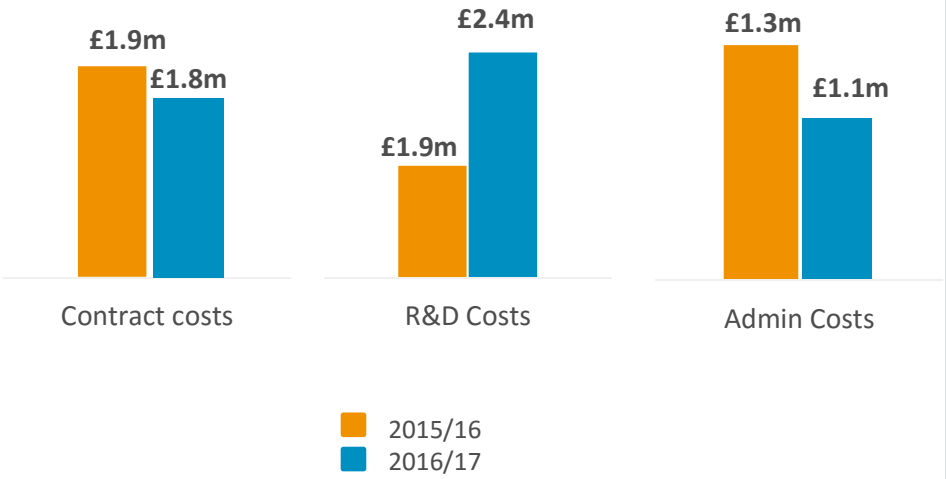
Financial Review



- H1 revenues of £2.9m up 45.0% on 2015. Increase driven by Genedrive® development income
- Diagnostics Genedrive® revenues of £1.2m up 77.2% from prior year of £0.7m
- Diagnostics revenue aided by the US DoD programme which was £0.9m compared to £0.6m in 2015
- Services revenue up 29.3% on the same period in 2015
- Customer concentration risk in Services significantly removed and revenues supported from a broad customer base

Financial Review

Cost Analysis H1



- Contract costs edged down owing to a different mix of revenue
- R&D costs up 27.5% reflecting our continued investment in the Genedrive platform, particularly in the area of HCV
- Admin costs lower after one-off staff costs in 2015 and reduced IFRS2 charge
- Financing costs of £0.6m, includes £0.5m of exchange losses on the movement in the dollar denominated GHIF bond
- Tax credit calculated at half year – total tax credit of £0.4m as £0.1m included above the line
- Loss on ordinary activities £3.0m (2015: £3.6m), with loss per share 14.8p (2015: 31.7p)
- Net assets at £7.1m (June 16: £3.8m) and GHIF bond maturity in July 2021

Financial Review

Cashflow H1

	2015 £'000	2016 £'000
EBITDA	(2,511)	(1,897)
Working capital	6	609
Interest expense	(132)	(150)
Tax	-	-
Other	2	(33)
Cashflow before financing	(2,635)	(1,471)
Share issue	-	6,021
Net cash flow	(2,635)	4,550
B/f	4,928	1,114
Cash at Bank	**2,293**	**5,664**

- EBITDA losses reduced owing to contribution from the increased revenue in both Diagnostics and Services
- Debtor improvements in 2016 driven from changes to the billing cycle and process with DoD, changes resulted in £0.5m cash inflow in the period
- Prior year payables high owing to one-off employee related severance cost
- Interest expense consistent with prior period, however option taken to defer future interest payments
- No tax cashflows in the period, but £766k received post period end
- Share placing in July 2016 raised £6.0m after fees
- Cash at bank closed at £5.7m and owing to post period tax receipts, above £5.0m at April 2017

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Summary

Rapidly developing commercial-stage molecular diagnostics business

1. Company is refinanced and executing on its development plan
2. HCV remains on track and attention from NGOs is positive
3. Company will seek additional distribution partners for HCV in selected countries, including India
4. Company has route to overcoming issues in TB but cost vs opportunity still needs assessment
5. Accelerate market opportunities through an active programme of Open Innovation (Partnerships)
6. Plan to emerge as pure-play molecular diagnostics business via a successful outcome to the strategic review