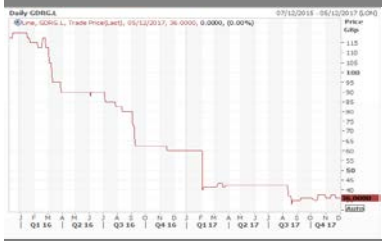
hardman&co

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	GDR
Price (p)	36.0
12m High (p)	65.0
12m Low (p)	30.0
Shares (m)	18.7
Mkt Cap (£m)	6.7
EV (£m)	6.3
Free Float*	60%
Market	AIM

**As defined by AIM Rule 26*

Description

Genedrive is a disruptive platform designed to bring the power of central laboratory molecular diagnostics to the point-of-care/need setting in a low-cost device offering fast and accurate results, initially for diagnosis of serious infectious diseases such as hepatitis.

Company information	
CEO	David Budd
CFO	Matthew Fowler
Chairman	Ian Gilham
	+44 161 989 0245
	www.genedriveplc.com

Key shareholders	
Directors	8.2%
Calculus	16.2%
Odey	12.8%
Hargreave Hale	7.0%
M&G	6.7%
River & Merc.	5.6%

Diary	
Jan-18	Trading update
Mch-18	Interims

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genedrive plc

Remodelled for growth

genedrive plc is a commercial-stage company focused on point-of-care/need molecular diagnostics and biomarkers. Its Genedrive® *in vitro* diagnostic testing platform is at the forefront of this technology, offering a rapid, low-cost, simple-to-use device with high sensitivity and specificity in infectious disease diagnosis. The rapid and accurate analysis of patient samples aids significantly the clinical decision process, with point-of-need testing particularly important in emerging markets. Hepatitis C diagnosis is a multi-million dollar market opportunity, which is well supported by the WHO and other philanthropic organisations.

- **Strategy:** Now that the Genedrive technology platform has received CE Mark, the new management team has completely re-focused the company onto the commercialisation pathway for diagnosis of infectious diseases, signing two important commercial agreements with Sysmex, a major global player.

- **Genedrive:** With global healthcare focused on early intervention, the need for fast, accurate point-of-care/need diagnosis, particularly in remote locations, is obvious. Genedrive has been validated through CE Mark and the Genedrive HCV ID Kit is being launched into a big commercial opportunity in emerging markets.

- **Valuation:** To highlight the disconnect in valuation, we have compared a number of quoted *in vitro* molecular diagnostic companies with an emphasis on those with hand-held/bench-top PoC/PoN analysers. About £30m has been invested, both in Diagnostics and Services, to get the company where it is today.

- **Risks:** The platform technology has been de-risked through the receipt of CE Mark for its first two assays – hepatitis C and tuberculosis. The main risk is commercial, given that it often takes time for new technologies to be adopted. However, partnering with a major global player significantly reduces this risk.

- **Investment summary:** Genedrive technology ticks all the boxes described for an 'ideal' *in vitro* diagnostic that satisfies the need for powerful molecular diagnostics outside the hospital setting. The hepatitis C market is a global opportunity end remains very large, even in the target developing countries. With a strong commercial partner, early evidence of sales traction will highlight the valuation anomaly.

Financial summary and valuation

Year end June (£000)	2015	2016	2017	2018E	2019E	2020E
Sales	4,517	5,063	5,785	5,130	5,630	7,950
Underlying EBIT	-3,858	-5,259	-4,812	-5,566	-3,808	-2,716
Reported EBIT	-4,040	-5,426	-7,292	-5,687	-3,966	-2,937
Underlying PBT	-3,242	-6,330	-5,007	-5,972	-4,223	-3,139
Statutory PBT	-3,424	-6,497	-7,487	-6,093	-4,381	-3,360
Underlying EPS (p)	-28.30	-54.58	-21.42	-26.65	-17.37	-10.62
Statutory EPS (p)	-30.11	-56.16	-34.85	-27.29	-18.17	-11.62
DPS (p)	0.00	0.00	0.00	0.00	0.00	0.00
Net (debt)/cash	903	-3,877	-70	-3,665	-6,190	-8,176
Shares issued	80	0	6,023	0	1,250	0
P/E (x)	-1.3	-0.7	-1.7	-1.4	-2.1	-3.4
EV/sales (x)	1.4	1.2	1.1	1.2	1.1	0.8

Source: Hardman & Co Life Sciences Research

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Executive summary

Background

The new management team has fully remodelled the strategy to take advantage of its leading position in Point-of-Care (PoC)/Point-of-Need (PoN) molecular diagnostics

genedrive plc (formerly Epistem) was founded in 2000 by Professor Potten and Dr Booth following several decades of research in to epithelial stem cell biology at the University of Manchester. It originally focused on facilitating advances in medicine through provision of personalised biotechnology services and innovative products. Now, genedrive plc is entering a new era by addressing diagnostic shortfalls, mostly in emerging markets, through development of fast and sensitive diagnostic assays for infectious diseases using its proprietary DNA testing platform, Genedrive®. The company floated on AIM in April 2007 and has its main facility in the UK; it employs around 80 people. Following a capital increase in July 2016, the new management team has fully remodelled its strategy to take advantage of its leading position in Point-of-Care (PoC)/Point-of-Need (PoN) molecular diagnostics and changed its name to genedrive plc.

Point-of-Care/Point-of-Need molecular diagnostic tests

Traditional antibody tests are effective but cannot distinguish between active or previous infections…

The current procedure for ascertaining if a patient has an infectious disease is to take a sample, usually blood or sputum, and test whether it contains antibodies against the pathogen *via* serological assays. Samples are generally analysed in central laboratories, with results hours to days later. Often, tests cannot distinguish among antibodies from active and previous infections, and overall, although these tests are relatively cheap to perform, such a process can be impractical or unavailable in remote locations where such diseases are common.

…PCR-based molecular diagnostics are more accurate and address this issue…

…but need to be performed in a large laboratory

An alternative is molecular diagnostic tests. For example, the polymerase chain reaction (PCR) can be used to detect pathogen DNA, rather than relying on patients' antibodies. PCR tests are accurate, can be performed relatively quickly, and there are few false positives. In addition, by monitoring the amount of pathogen DNA in the blood, these tests can determine the effectiveness of treatment over time. As such, they represent an ideal test; however, the challenge is to adapt them from those implemented in large, central laboratories to portable devices for use by non-experts in remote locations.

Genedrive is a fast, accurate, affordable PCR-based test that can be used at the point-of-care…

…and allow immediate treatment decisions

There is increasing need for a goal-orientated approach to address the so-called 'treatment-gap' for infectious diseases. As outlined by the Association of Public Health Laboratories (APHL) in the US, testing should not only focus on confirmatory tests, but should also facilitate immediate treatment decisions during a patient's first clinical encounter, in order to minimise return visits. The demand for both diagnosis and treatment in an ASSURED (Affordable, Sensitive, Specific, User-friendly, Rapid, Robust, Equipment-free, and Deliverable) manner is where the global market opportunity for portable molecular diagnostics lies.

Genedrive® technology

Genedrive is a cost-effective alternative that can be use in remote locations and takes just 50-90 minutes to get an accurate result

Genedrive is a rapid point-of-care molecular testing platform designed for accurate diagnosis of infectious diseases, patient stratification, and other molecular diagnostic applications. Suitable for operation in PoC/PoN settings by those with minimal training, the simple-to-use handheld device provides diagnosis of certain diseases from a body fluid sample in approximately 50-90 minutes. As such, it ticks most of the boxes described in the APHL definition of an 'ideal' test. Targeted at small and medium-sized clinical laboratories in emerging markets, Genedrive has been designed to overcome potential environmental and technical setbacks encountered in some locations.

Key features of the Genedrive platform

- **Rapid results:** From sample to result in 50-90 minutes allows prompt clinical decisions outside the hospital setting
- **Ease of use:** Limited operator training required to assay a single use disposable reagent cartridge
- **Robustness & reliability:** can be operated in the 'Real World' environment; supplied with a back-up battery pack for use in local settings with poor infrastructure
- **Versatile:** Core technology can be used across a range of applications – human health, animal health, environmental testing
- **Affordable:** The Genedrive system costs about $3,000-4,000 compared to $50-100k for a centralised lab-based system, with commensurate pricing for each individual test

Current approaches

The features described above compare favourably with current gold-standard approaches that need to be performed in a centralised laboratory/hospital setting. Gendrive provides a sensible solution to the problem of having a rapid PoC/PoN test that can be run locally/in remote areas lacking infrastructure.

Comparison of HCV assays

Assay type	Immunoassay	Lab-based PCR	Genedrive
Approach	Lab-based test to identify presence of HCV antibodies in blood serum	Lab-based PCR test for viral DNA in blood samples. High cost platform run in centralise lab	Field-based PCR test for viral DNA in plasma (blood sample)
Providers	Numerous Abbott/JNJ/BioRad/ DiaSorin	Numerous Abbott/Qiagen/ Roche/Cepheid	Genedrive
Diagnosis	✓	✓	✓
Viral detection	✓	✓	✓
Diagnose active infection	×	×	✓
Decentralised use	×	×	✓
Turnaround time	Days	Days	50-90 min
Price	$20	$20-30	$25-50
Limit of detection (LOD)	na	5-10 IU/ml	~2200 IU/ml
Sensitivity of LOD	na	100%	>99%

Source: genedrive plc; Hardman & Co Life Sciences Research

Current test

Following external independent validation, the Genedrive HCV ID Kit has received CE Mark. While this was not an absolute requirement, it is an important 'stamp of approval' that significantly helps when negotiating with potential distribution and commercial partners.

This test is run on plasma extracted from a blood sample by centrifugation. Further future adoption of the test closer to the point of care could be facilitated if the user was able to produce plasma without the need for a centrifuge. The company was recently awarded an Innovate UK grant to develop such a process.

Commercial opportunity

Diseases addressed by Genedrive are all on the WHO's global importance list

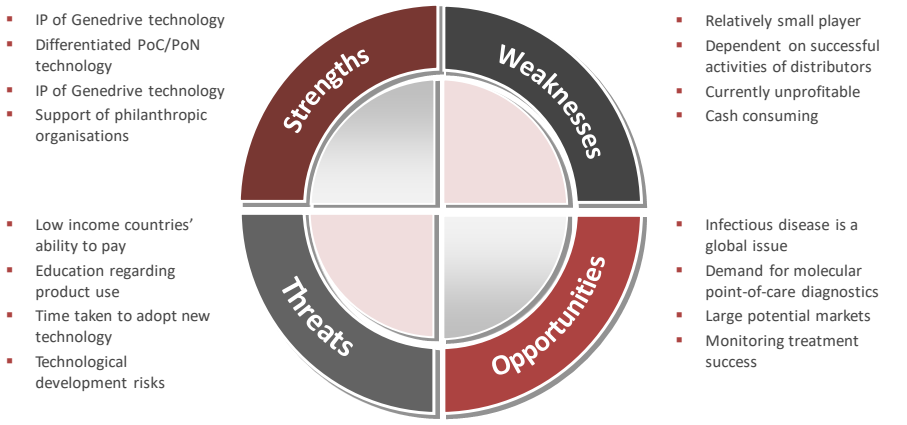
Applicable diseases that Genedrive could target appear on WHO's 'importance' list, indicating that the market opportunity is very large. Taking account of genedrive plc's current size and resources, management is focusing initially on making a success of the enormous hepatitis C opportunity and has signed a global partner, Sysmex Corp., to commercialise its HCV test in EMEA (initially Africa) and South-East Asia (excl. India).

genedrive plc has signed with an experienced global IVD player

Ultimately, commercial success will be dependent on Sysmex capitalising on Genedrive's USP listed above and the end-user price that it charges. However, an end-selling price of $25-50 per test suggests a market potential, just for 'emerging' countries in the range $3.4-6.8bn.

SWOT analysis

Strengths and weaknesses



Source: Hardman & Co Life Sciences Research

Sensitivity/risks

The prevalence of treatable infectious disease cases is a global problem. Genedrive offers a major advance in the rapid detection and subsequent treatment of such diseases. However, new technology can take time for adoption and genedrive plc may be reliant on philanthropic organisations to pay for its product and consumables in low income countries. Further, successful clinical trials and regulatory approval are not guaranteed.

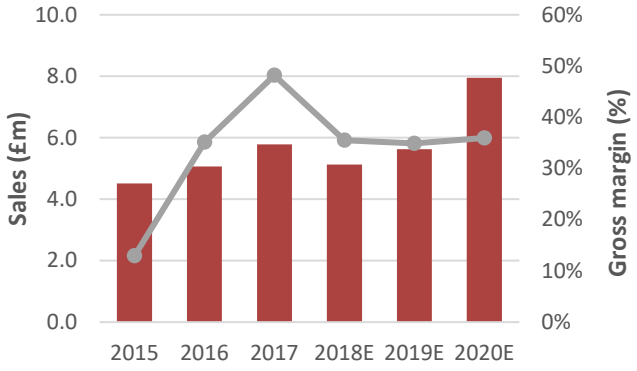
Investment conclusion

Peer group comparisons highlight the valuation disconnect

genedrive plc has, to date, been successful in developing its technology platform to the point of commercialisation. Given the market sizes and the support of major health organisations, Genedrive could transform the financial performance of the group, although further investment is required to expand its menu of assays. To highlight the disconnect in valuation, we have compared quoted *in vitro* molecular diagnostics companies, with an emphasis on hand-held/bench-top PoC/PoN analysis. Although no two companies are alike, it is an enlightening comparison:

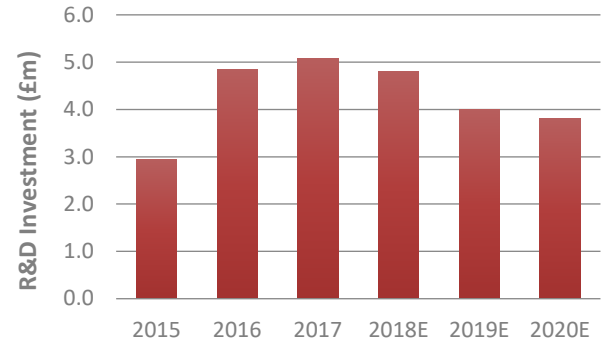
- Enormous differences in annual sales, ranging from <$1.0m to $27.0bn
- Wide range of enterprise values attributed by various markets with EV/sales from from 1.2x (genedrive plc) to 15.5x (MedMira Inc), with a weighted average of 4.1x heavily influenced by the two very large IVD players
- Noticeable disconnect in valuations ascribed to companies, including genedrive plc, by the UK market compared to the US market

Sales & gross margin



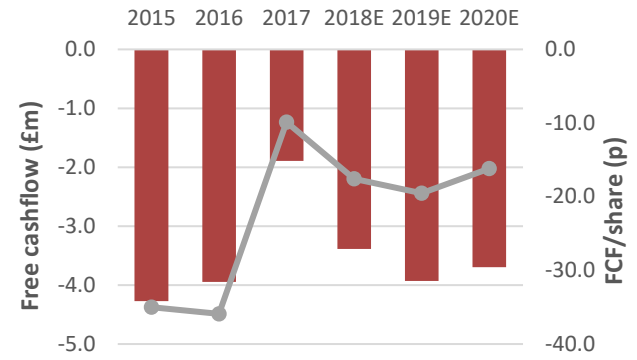
- Historic sales are for non-core operations and Genedrive related grant income
- Over the forecast period, Genedrive sales more than offset the reducing Department of Defense grant income
- Genedrive grant income is relatively high margin activity
- Margins on Genedrive units and disposable cartridges will increase with rising volumes

R&D investment



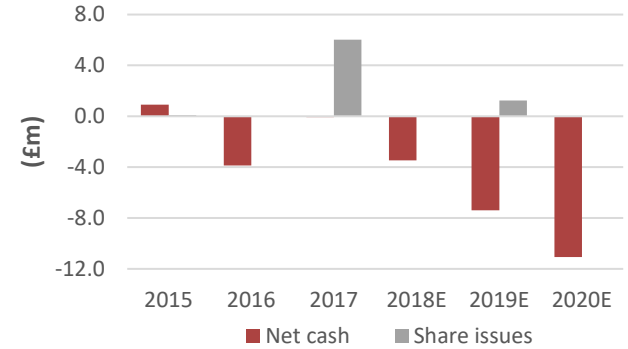
- R&D investment is written-off in the year in which it is incurred
- To date, an estimated ca.£20m has been spent on R&D by the company since incorporation (although not exclusively spent on diagnostics)
- Further investment over the next three years to add more tests onto the Genedrive platform
- Future investment will be largely dependent on the commercial success of the HCV test

Free cashflow



- The non-core services segment is profitable and cash generative; a disposal would provide a cash injection
- The Services business is valued at around £2m – a discount reflecting the >1year duration a disposal has been sought
- During the investment phase for Genedrive launch, genedrive plc is burning £3-4m cash per annum
- Forecasts are dependent on Genedrive gaining early sales traction and generating recurring disposable revenues

Net cash/capotal increases



- To date, genedrive plc has raised only ca.£26m of capital and has received a modest level of non-equity grant funding (note the funding has not been used solely to develop the Genedrive device)
- The GHIF Convertible Bond ($8m) is out-of-the money and should be considered as long-term debt
- There remains a possibility that non-core services will be disposed, generating cash for working capital purposes and boost the balance sheet

Source: Company data; Hardman & Co Life Sciences Research

Genedrive®

Genedrive® unit

Source: genedrive plc

Genedrive is a rapid point of care molecular testing platform designed for diagnosis of infectious diseases, human genotyping, and other molecular diagnostic applications using real-time PCR technology. Suitable for use in 'Point-of-Care' (PoC) or 'Point of Need' (PoN) settings, the simple-to-use handheld device provides detection and diagnosis in approximately 50-90 minutes. Currently targeted at small and medium sized laboratories in emerging markets, Genedrive has been designed to overcome potential environmental (temperature, humidity) and technical (power failure) setbacks faced when trying to achieve accurate and efficient diagnosis in these markets.

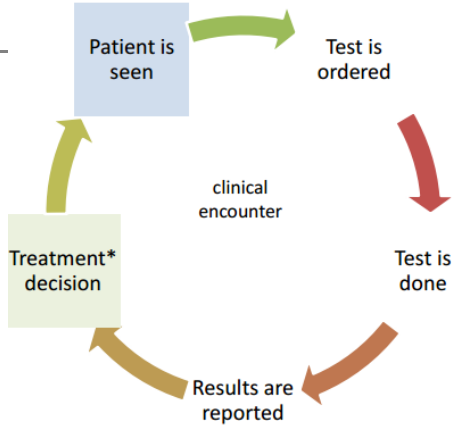
Genedrive is thought to tick most of the boxes of an ideal PoC/PoN diagnostic product – ASSURED criteria – as described by the Association of Public Health Laboratories. An issue highlighted by this organisation is that, while most people agree on the need for PoC/PoN testing, there is little agreement on what constitutes an accurate definition of such a test.

The APHL has set out guidelines regarding its view of the ideal PoC/PoN test for initiating both diagnosis and treatment in a single clinical encounter, while the patient waits, such that it can be used as part of the 'test and treat' loop.

Genedrive has the attributes of an 'ideal' PoC/PoN test

Attributes for an 'ideal' PoC/PoN diagnostic test

Attributes	Genedrive
Affordable	✓
Sensitive	✓
Specific	✓
User-Friendly	✓
Rapid & **R**obust	✓
Equipment-free	X
Deliverable	✓



Source: APHL Pai 2013

Genedrive technology

Genedrive® disposable

Source: genedrive plc

Conditions of heat, humidity, frequent power outages and low testing volumes have previously provided setbacks in diagnostic testing. genedrive plc has sought to overcome these through the creation of an affordable device with an operating temperature of 0-60 degrees Celsius and a supplementary battery pack to ensure that power outages do not affect the running of the device.

The Genedrive assay

At the heart of Genedrive technology is the plug-in cartridge and the use of Radio-frequency identification (RFID) to programme assay metrics into the Genedrive unit. This technology allows re-configuration of the unit for specific assays. Assays are compatible with multiple specimen types e.g. blood, buccal swabs and sputum.

Used in a point of care setting, the test is designed to both speed up diagnosis and treatment and improve prognosis.

What can the assays be used for?

- **Infectious diseases:** Rapid and accurate diagnosis for infectious diseases, facilitating patient treatment decisions
- **Pharmacogenomics:** Development of drug therapies based on individuals' genotypes and drug responses
- **Future Applications**: Bio-surveillance, pathogen detection and forensics, veterinary science and agriculture/aquaculture

Currently available assays

genedrive plc has developed assays against a number of common diseases and conditions for which rapid, accurate, PoC/PoN results would be very useful to allow the immediate initiation of treatment:

- **Hepatitis C:** Human genotyping for IL28B from buccal swabs for testing the presence of hepatitis C (HCV) infection and treatment responses. However the key HCV test is the CE Marked HCV ID kit, the first cost-effective, rapid PoN test to detect HCV. CE Mark will help overcome regulatory hurdles in some countries.
- **MTB/RIF** – Identification of *Mycobacterium tuberculosis* and resistance to rifampicin from a sputum sample

Assay Workflow

Source: Hardman & Co Life Sciences Research

Assay workflow

The Genedrive diagnostic process consists of four simple steps: (i) collection of the relevant sample e.g. blood, a buccal swab or sputum; (ii) sample is used in conjunction with the plug-in assay cartridge, which is (iii) inserted into the Genedrive platform that uses its RFID capacity to programme the assay metrics into the Genedrive unit; (iv) through a single button operation, the Genedrive unit delivers diagnostic results in 45-90 minutes depending on the test.

Product development

The company has adopted a step-by-step approach. First, it developed and validated the test unit in conjunction with its tuberculosis assay cartridge, then started the process of expanding its range of test cartridges for diagnosis of other diseases. It has recently received validation of its hepatitis C test, which has been given a CE Mark. While this is not necessarily required for commercialisation, it does provide a stamp of approval and is important for attracting potential partners. Timing and rate of expansion into other tests will be dependent on the early commercial success of hepatitis C which will generate the necessary development capital.

Infectious disease

With EU FP7 grant funding and collaboration with INSERM…

…genedrive plchas completed the development of an HCV diagnostic

Hepatitis C virus (HCV)

With funding support from a European Union FP7 grant and collaboration with INSERM, the French National Institute of Health and Medical Research, genedrive plc completed the development of its HCV-ID® diagnostic for detecting HCV in blood plasma, covering all HCV genotypes.

- Hepatitis C is a virus that causes chronic liver disease
- 150–200 million people globally have chronic HCV infection
- Globally, it is estimated that 59% of HCV infected individuals have no access to HCV diagnostics (see Global Market Opportunity)

Mycobacterium tuberculosis and rifampicin resistance (MTB/RIF)

The MTB/RIF assay, aimed at small and medium-sized laboratories, identifies TB infection and rifampicin-resistant MTB – i.e. identifying individuals that will not respond to treatment with rifampicin, the most commonly used antibiotic. Used in a decentralised setting, the test is designed to speed up diagnosis and treatment. genedrive plc reached a key milestone in mid-'16 with regulatory clearance to import the product into India. It is now working to improve engagement with end-users.

Biodefence and Other

genedrive plc has also undertaken several other development programmes including biodefence to:

- develop Genedrive tests for undisclosed biohazards, funded by the US Department of Defense (DoD)
- develop Genedrive tests for diagnosis of white spot disease in shrimps, in collaboration with the UK's Centre for Environment, Fisheries and Aquaculture Science (CFAS)

Technology validation

Throughout the development and validation process, the company has received a number of validations in support of the genedrive diagnostic programme.

Validations

Funding/regulatory body	Summary
European Union	CE-IVD approval for Genedrive® device; CE Mark for MTB and HCV assays
Government of India	Formal import license for TB assays
US Department of Defense	Funding of $7.8m over five years
European Commission	€1.5m as part of EUFP7 grant for development work on HCV PoC assays
The Centre for Environment, Fisheries & Aquaculture Science (CEFAS)	Confirmation of £0.4m funding in collaboration with CEFAS for the development of the Genedrive® platform in an aquaculture application
Global Health Investment Fund (GHIF)	$8m (£4.7m) funding agreement with the Global Health Investment Fund (GHIF)
Innovate UK	Share of £0.6m grant for the development of a disposable centrifuge-free plasma separation consumable device

Source: genedrive plc; Hardman & Co Life Sciences Research

Market opportunity

HCV market

>185m people worldwide have been infected with hepatitis C

The hepatitis C virus (HCV) causes chronic liver disease. More than 185m people worldwide have been infected with HCV and most will develop chronic infection, putting them at risk of liver cancer, liver failure and death. Indeed, 500,000 people die each year from HCV-related liver disease. Infection typically results from use of contaminated needles or blood transfusions, but can also, rarely, be sexually transmitted[1]. Intravenous drug users are at high risk of acquiring HCV; this frequently occurs shortly after initial use.

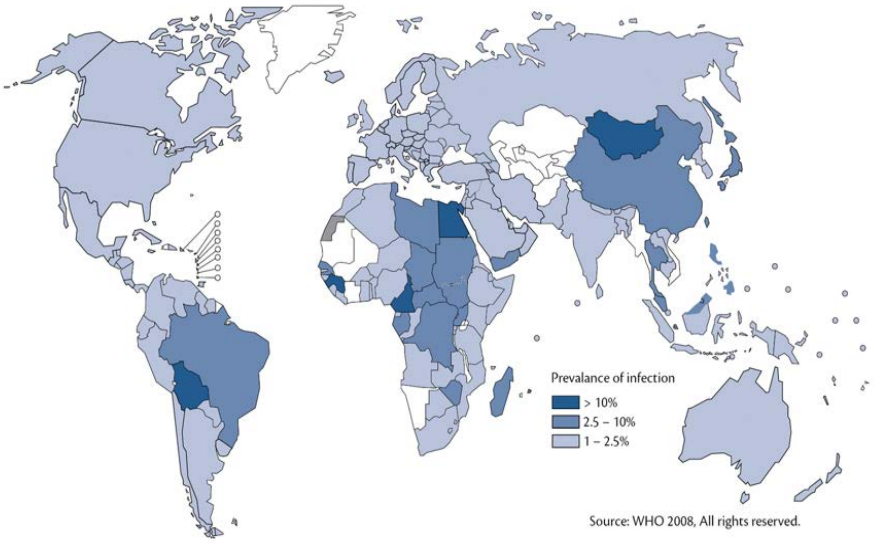
- Global burden: approximately 3-4 million new cases annually
- UK burden: approximately 214,000 people infected with HCV

Ca.3% of the global population carry hepatitis C virus

Given that 3% of the global population carry HCV, a key component of any programme designed to scale-up treatment will be improved case finding and diagnosis. In the US, an estimated 45-85% of people with HCV are unaware of their infection[2]. In Europe, surveys have suggested that under 1-in-5 infected individuals know that they are infected. Linked to this are the new direct-acting anti-virals (DAA) that are being made available as generics in developing markets. DAA are much more effective drugs with high success rates, and are now available at affordable rates.

- The earlier that the disease is diagnosed, the better the patient outcome
- Around 59% of HCV infected individuals have no access to HCV diagnostics[3]
- US studies show that PoC HCV tests were preferred to standard testing due to speed and reduced patient discomfort

HCV global prevalence



Source: WHO

[1] Shepard et al., Lancet Infectious Diseases (2005), 5, 558-567
[2] Smith et al., MMWR Recommendation Report (2012), 61, 1-32
[3] WHO HCV Factsheet

HCV testing and Genedrive

New assay developed with support from an EU grant…

A commercialised Genedrive HCV assay provides a big opportunity. With support from European Union FP7 grant funding and collaboration with INSERM, the French National Institute of Health and Medical Research, a new HCV diagnostic assay has been developed for the Genedrive platform. The aim was to overcome limited access to hospital-based HCV testing through a PoN assay for detection of HCV.

…and assessed externally at Institut Pasteur

Genedrive HCV has been validated independently at Institut Pasteur and Queen's Medical Centre, Newcastle, on reference material and patient samples. These clinical validation data and the Genedrive platform and the HCV ID Kit were presented at the International Liver Conference held in Amsterdam in April 2017. The results supported the regulatory submission in March 2017 for CE marking, which was formally received in September 2017.

Commercialisation

Following regulatory authorisation of the Genedrive HCV ID Kit, genedrive plc has signed distribution deals with Sysmex Corporation, a major player in clinical laboratory systemization and solutions, covering EMEA and Asia Pacific (excluding India). Initial sales are expected to be made during fiscal 2018.

Sysmex Corporation

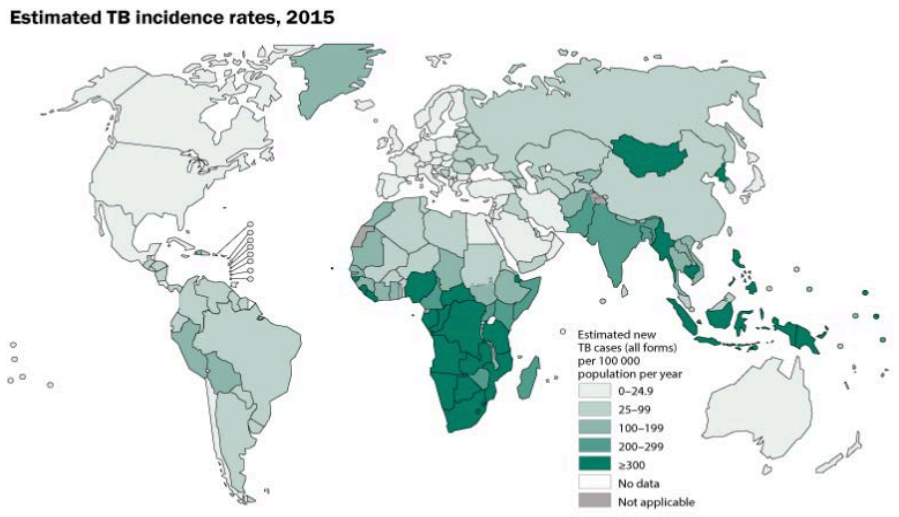
genedrive plc has signed to separate agreements with subsidiaries of Sysmex Corporation, a Tokyo-listed multinational capitalised at about $13bn with annual sales of $2.2bn. It is ranked #8 globally in *in vitro* diagnostics (IVD), with a very strong presence in haematology where is is ranked world #1.

Sysmex intends to have a phased launch programme. The focus of initial launches will be in countries that have screening programmes, an established funding policy and where drugs for the treatment of hepatitis C are available.

Tuberculosis market

Globally

TB global incidence



Source: World Health Organisation

TB ranks alongside HIV as a leading cause of death worldwide, and 10.4m (5.9m men, 3.5m women, 1.0m children) new cases were estimated in 2015. Of these, only 6.1m were reported to the WHO, leaving around 37% cases undiagnosed or unreported. TB ranks alongside HIV as a leading cause of death worldwide, and 10.4m (5.9m men, 3.5m women, 1.0m children) new cases were estimated in 2015. Of these, only 6.1m were reported to the WHO, leaving around 37% cases undiagnosed or unreported.

- Despite advances in treatment, TB killed around 1.8m people in 2015
- Global TB diagnostics market expected to reach $2.26bn by 2020 (WHO)
- $1bn is currently spent each year on TB diagnostics

The current inaccurate smear test costs over US$87m per annum…

The predominant diagnostic method used across the four countries in 2012/13 was sputum smear microscopy; ca.55m tests were performed, with a market size of US$87m[4]. However, this test has lower sensitivity and specificity, and requires considerable input from personnel.

…the WHO believes an accurate test could be sold for USD5 giving a potential public market of USD155m…

The WHO recently published a market assessment study about replacing smear diagnosis with an accurate molecular diagnostic assay. In 22 high burden countries, it estimated that 62m smear tests were carried out on 31m patients. Replacing all of these with an accurate test, which would only be performed once per patient, would reduce this to 31m tests. At a price of US$5 per test, this gives a commercial market of US$154m annually. Therefore, even though the test would be more expensive, it would reduce expenditure even without taking into account cost savings related to personnel. The WHO also stated that this underestimated the true market because it only represented public sector healthcare; in many high burden countries, there is a sizeable or even dominant private sector.

…with an even larger private market in some countries

Opportunities to expand the MTB testing market

As confirmed by the WHO, the market opportunity for TB tests may expand due to:

- Testing in peripheral settings
- Detecting both pulmonary and extra pulmonary TB
- Finding undiagnosed cases
- Repeat testing for treatment monitoring
- Expansion to 18 high-burden countries, adding 35% of global TB cases diagnosed

MTB Testing and Genedrive

Having received regulatory clearance to import the Genedrive MTB assay to India in 2015, the product was launched in 2016 by genedrive plc's commercialisation partner Xcelris Labs, with its USP being a test that both diagnose TB infections and predicts responsiveness to rifampicin treatment.

Although PCR-based molecular tests are accepted, they are only available through central laboratories in large hospitals, therefore Xcelris aimed to target the 5,000 private clinical testing laboratories. However, commercialisation of the test proved a challenge. First, there was a specific sample preparation problem which was identified subsequently to originate from a supplier component specific to the MTB/RIF test.

[4] https://www.mcgill.ca/tb/files/tb/tb_diagnostics_market_in_select_high-burden_countries_current_market_and_future_opportunities_for_novel_diagnostics.pdf

Secondly, although corrective action was taken, genedrive plc experienced difficulties in assessing the impact of this through its commercial partner. Consequently, the commercial deal with Xcelris was terminated in November 2017 and management will reassess its options regarding commercialisation of its MTB test. Given the obvious applicability of TB testing and the new routes to market now afforded via the Sysmex distribution arrangements, the company is reformulating its product for global applicability and could reintroduce a version 2 of the mTB product.

Other opportunities for Genedrive®

Genedrive can be used for a number of infectious diseases beyond HCV and TB

Although genedrive plc will be focusing its resources initially on making a success of its HCV assay, as mentioned earlier, the Genedrive platform has potential in a number of other infectious diseases. Diseases likely to be targeted are all high on the WHO's importance list. While the approach will be to get clinical evidence to allow for regulatory approval on an individual disease basis, another consideration is that many patients have more than one disease, and the combined diagnosis often dictates the treatment modality. Full market potential may only be achieved once a single PoC/PoN diagnostic is available for parallel diagnosis of several infectious diseases.

Genedrive also has a number of potential uses outside infectious diseases

The versatility of the Genedrive platform also permits a number of market segments to be targeted, from emerging markets to pharmaceutical, government, and other organisations with its infectious disease, pharmacogenomics, and biohazard assays. The company has existing relationships in these sectors, such as with the US Department of Defense (DoD) and the UK's Centre for Environment, Fisheries and Aquaculture Science (CFAS). It has also been approached by a major pharmaceutical group interested in developing a companion diagnostic for its Alzheimer's drug.

Financials & Investment case

Genedrive sales model

Genedrive device units

- Units are placed/sold into the market each year, which will need to be replaced or upgraded after about five years
- Initially, an average of 0.7 tests are performed per day; equivalent to about 250 tests per device per annum
- The initial cost of a Genedrive unit is $4,000, with the company receiving an estimated 60% from its distributors
- Manufacturing and validation cost of the Genedrive unit is initially $500

Diagnostic assays

- Timing of launch of the tests is as follows: HCV (fiscal 2018), TB (fiscal 2019) and potentially a new assay (fiscal 2020), although the short-term thrust will be on HCV
- HCV tests will be priced initially at ca.$35 per test at the end-user level; TB tests would be priced much lower – estimated $15-25
- The transfer price to genedrive plc is in the undisclosed distribution agreement with Sysmex – our model estimated this to be ca.50% of the end-user price
- At low volumes, the manufacturing cost is thought to be relatively high – initially ca$15 for HCV per test – but will fall with increased volumes
- Cost of producing the TB assay is thought to be approximately half that of the other tests

These assumptions are driving our sales model and financial forecasts that appear on the following pages.

Profit & Loss

- **Sales:** Fluctuation in the sales forecast is due to tailing off of the Department of Defense contract over the next two years, offset by the build-up of Genedrive sales. The non-core services business has stable sales of ca.£3m per annum
- **Gross margin:** During the build-up phase for the HCV test, coupled with lower DoD income, gross margins are expected to be stable at around 35-36%
- **SG&A:** Expected to be stable around current levels, as much of the marketing costs for tests will be borne by distribution partners
- **R&D:** Investment in new tests, initially HIV, will be dictated by the success of the HCV assay. There remains some flexibility about both the quantum and timing of investment into additional tests
- **Services business:** Sales of ca.£3m p.a. with small cash and profit contribution

Profit & Loss account

Year end June (£000)	2015	2016	2017	2018E	2019E	2020E
Genedrive	814	1,906	2,619	2,000	2,562	4,905
Services	3,703	3,157	3,166	3,130	3,068	3,045
Sales	**4,517**	**5,063**	**5,785**	**5,130**	**5,630**	**7,950**
COGS	-3,933	-3,285	-2,998	-3,530	-3,180	-4,200
Gross profit	**584**	**1,778**	**2,787**	**1,600**	**2,450**	**3,750**
Gross margin	12.9%	35.1%	48.2%	31.2%	43.5%	47.2%
R&D	-2,942	-4,836	-5,086	-4,800	-4,000	-3,800
SG&A	-1,500	-2,201	-2,513	-2,516	-2,592	-2,666
EBITDA	**-4,243**	**-6,433**	**-3,740**	**-4,650**	**-2,892**	**-1,800**
Depreciation	-241	-240	-216	-216	-216	-216
Amortisation	-144	-934	-856	-700	-700	-700
Other income	0	0	0	150	334	0
Underlying EBIT	**-3,858**	**-5,259**	**-4,812**	**-5,566**	**-3,808**	**-2,716**
Share based costs	-182	-167	-101	-121	-158	-221
Statutory EBIT	-4,040	-5,426	-7,292	-5,687	-3,966	0
Net financials	616	-1,071	-195	-406	-415	-423
Pre-tax profit	**-3,242**	**-6,330**	**-5,007**	**-5,972**	**-4,223**	**-3,139**
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-3,424	-6,497	-7,487	-6,093	-4,381	-3,360
Tax payable/credit	399	582	1,051	992	827	785
Tax rate	12%	9%	14%	16%	19%	23%
Minorities	0	0	0	0	0	0
Underlying net income	**-2,843**	**-5,748**	**-3,956**	**-4,980**	**-3,397**	**-2,354**
Statutory net income	-3,025	-5,915	-6,436	-5,101	-3,554	-2,574
Ordinary 1.5p shares						
Period-end (m)	10,564	10,565	18,689	18,689	22,162	22,162
Weighted average (m)	10,048	10,532	18,466	18,689	19,558	22,162
Fully diluted (m)	11,869	12,490	20,527	24,222	21,618	24,222
Underlying Basic EPS (p)	**-28.3**	**-54.6**	**-21.4**	**-26.6**	**-17.4**	**-10.6**
Statutory Basic EPS (p)	-30.1	-56.2	-34.9	-27.3	-18.2	-11.6
U/l Fully-diluted EPS (p)	**-24.0**	**-46.0**	**-19.3**	**-20.6**	**-15.7**	**-9.7**
Stat. Fully-diluted EPS (p)	-25.5	-47.4	-31.4	-21.1	-16.4	-10.6
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Net cash:** The net cash/(debt) position at 30th June 2017 was -£70k, comprising cash of £5.1m offset by long-term debt (convertible bond) of £5.2m. Cashflow suggest that the company will have net debt of -£3.7m by the end of June 2018
- **Tax credits:** Some of its R&D investment attracted tax credits from HMRC. Going forward, the R&D tax credit is expected to be approaching £1m per annum
- **Working capital:** Given that the company will be selling to a large distributor and the non-core business is relatively stable, Genedrive is not expected to have significant working capital requirements during its growth phase
- **Convertible bond:** The collaborative funding agreement for a total of $8.0m initiated in July 2014, and revised in July 2016, with the Global Health Investment Fund (GHIF) is treated as long-term debt

Balance sheet

@30th June (£000)	2015	2016	2017	2018E	2019E	2020E
Shareholders' funds	9,545	3,753	3,441	-1,660	-3,964	-6,539
Cumulated goodwill	0	0	0	0	0	0
Total equity	9,545	3,753	3,441	-1,660	-3,964	-6,539
Share capital	158	158	280	280	332	332
Reserves	9,387	3,595	3,161	-1,940	-4,297	-6,871
Provisions/liabilities	0	1,250	1,250	1,250	0	0
Deferred tax	-30	0	0	0	0	0
Long-term loans	4,025	4,991	5,199	5,473	5,761	6,064
Short-term debt	0	0	0	0	0	0
less: Cash	4,928	1,114	5,129	1,808	-430	-2,112
less: Deposits	0	0	0	0	0	0
less: Non-core invests.	0	0	0	0	0	0
Invested capital	**8,612**	**8,880**	**4,761**	**3,255**	**2,226**	**1,637**
Fixed assets	805	713	568	452	351	267
Intangible assets	7,191	6,273	3,038	2,338	1,638	938
Inventories	163	202	444	564	719	1,015
Trade debtors	*1,725*	*2,290*	*1,376*	*1,220*	*1,339*	*1,891*
Other debtors	*466*	*507*	*278*	*256*	*261*	*266*
Tax liability/credit	*685*	*757*	*1,213*	*992*	*827*	*785*
Trade creditors	*-696*	*-914*	*-816*	*-961*	*-866*	*-1,143*
Other creditors	*-1,727*	*-948*	*-1,340*	*-1,606*	*-2,042*	*-2,382*
Debtors less creditors	453	1,692	711	-99	-482	-583
Invested capital	**8,612**	**8,880**	**4,761**	**3,255**	**2,226**	**1,637**
Net cash/(debt)	**903**	**-3,877**	**-70**	**-3,665**	**-6,190**	**-8,176**

Source: Hardman & Co Life Sciences Research

Cashflow

- **Cashburn:** The underlying cashburn is forecast to trend downwards after fiscal 2018 to between -£2.5m, followed by -£2.0m
- **Working capital:** Only modest changes in working capital are anticipated given the non-core services business is stable and the supply agreement is with a large, well-capitalised distribution partner
- **R&D tax credit:** Payment of the amount shown in the balance sheet at the end of June 2017 has already been received; management intends to get annual claims submitted to HMRC in a timely manner
- **Cap-ex:** The company does not have any immediate requirement for significant expenditure for capital investment

Cashflow

Year end June (£000)	2015	2016	2017	2018E	2019E	2020E
Underlying EBIT	-3,858	-5,259	-4,812	-5,566	-3,808	-2,716
Depreciation	241	240	216	216	216	216
Amortisation	144	934	856	700	700	700
Inventories	*-163*	*-39*	*-242*	*-120*	*-155*	*-296*
Receivables	*-1,066*	*-606*	*1,266*	*156*	*-119*	*-552*
Payables	*107*	*689*	*284*	*145*	*-95*	*278*
Change in working capital	-1,122	44	1,308	181	-369	-571
Exceptionals/provisions	-36	0	0	0	0	0
Disposals	0	0	0	0	0	0
Other	-202	-151	-162	-274	0	0
Company op cashflow	**-4,833**	**-4,192**	**-2,594**	**-4,742**	**-3,261**	**-2,371**
Net interest	-196	-280	14	35	-141	-309
Tax paid/received	1,513	691	757	1,213	992	827
Operational cashflow	**-3,516**	**-3,781**	**-1,823**	-3,495	-2,411	-1,853
Capital expenditure	-758	-164	-70	-100	-115	-132
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	**-4,274**	**-3,945**	**-1,893**	**-3,595**	**-2,526**	**-1,985**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	0	-1,250	0
Disposals	0	0	0	0	0	0
Other investments	0	0	0	0	0	0
Cashflow after invests.	**-4,274**	**-3,945**	**-1,893**	**-3,595**	**-3,776**	**-1,985**
Share repurchases	-22	-44	0	0	0	0
Capital increase	80	0	6,023	0	1,250	0
Currency effect	292	-791	-323	0	0	0
Borrowings acquired	589	0	0	0	0	0
Change in net debt	**-3,335**	**-4,780**	**3,807**	**-3,595**	**-2,526**	**-1,985**
Hardman FCF/share (p)	-35	-36	-10	-19	-12	-8
Opening net cash	4,238	903	-3,877	-70	-3,665	-6,190
Closing net cash	**903**	**-3,877**	**-70**	**-3,665**	**-6,190**	**-8,176**

Source: Hardman & Co Life Sciences Research

Valuation

Discounted cashflow

One method that could be used to value genedrive plc is discounted cashflow. However, given that the forecast period of three years is a) relatively short, and b) loss making and cash outflow, the NPV is wholly driven by the terminal value. The latter is derived largely from a simple growth rate which is pure guesswork and prone to large error. Therefore, this is not an appropriate methodology for a company at this stage of development and commercialisation.

Comparative valuation

What is clear is that the company has a point-of-need molecular technology at the point of commercialisation, together with some profitable non-core trading assets. To get to this point with Genedrive an estimated £30m has been invested in R&D (ca.£20m; although not exclusively on diagnostics) and working capital (ca.£10m). Another company starting afresh today would require at least £50m (£100m including FDA approvals) to reach the same stage. Therefore, the current EV of ca.£7m attributed by the market is clearly wrong.

Consequently, we have also constructed a table of comparable *in vitro* molecular diagnostics companies, preferably with an emphasis on hand-held/bench-top PoC/PoN analysis of samples, that are quoted on various stock exchanges around the world. There is a plethora of information available[5] but the difficulty in making direct comparisons is that such a list includes:

- Subsidiaries of major diagnostics companies
- Private companies
- Distributors, rather than IP holders/originators, of diagnostic products

Consequently, we have selected the companies that are operating in the same field and are direct competitors to genedrive plc, and companies that have similar offerings but are operating in a different field.

Comparative valuation

Company	Abbott	Danaher	genedrive	MedMira	Omega	OPKO	Orasure	Trinity Bio.
Ticker	ABT	DHR	GDR	MIR.V	ODX	OPK	OSUR	TRIB
	USD	USD	GBPp	CAD	GBPp	USD	USD	USD
Share price	54.9	93.2	36.0	0.03	20.5	5.5	17.3	5.5
Shares in issue (m)	1,740.6	695.6	18.7	658.5	127.0	559.4	60.7	24.0
Market cap (lcm)	95,629	64,831	6.7	19.8	26.1	3,076.8	1051.7	132.2
Mkt cap (£m)	70,836	48,023	6.7	11.4	26.1	2,279.1	779.0	97.9
Cash	11,199	649	5.1	0.1	3.7	100.4	160.1	62.5
Debt	-23,521	-10,909	-5.2	-7.2	-0.4	-44.7	0.0	-95.3
EV (lcm)	107,951	75,091	6.8	12.4	22.8	3,021.1	891.5	165.0
EV (£m)	79,963	55,623	6.8	7.1	22.8	2,237.8	660.4	122.2
2017E sales	27,000	17,000	5.5	0.8	14.5	1,000.0	150.0	100.0
EV/sales	4.0x	4.4x	1.2x	15.5x	1.6x	3.0x	5.9x	1.7x

Prices/Currencies taken at close of business on 12th December 2017; lcm = local currency millions
Source: Company reports; Hardman and Co Life Sciences Research

[5] http://www.researchandmarkets.com/research/cq8l42/the_top_200 The Top 200 Point-Of-Care Diagnostics Companies Worldwide, 2016.

- Enormous difference in the annual sales of this group of companies, ranging from $0.8m to $27.0bn
- Wide range of enterprise values attributed by various markets with EV/sales from 1.2x (genedrive plc) to 15.5x (MedMira Inc), with a weighted average 4.1x heavily influenced by the two very large IVD players
- Noticeable disconnect among valuations ascribed to companies, including genedrive plc, by the UK markets compared to US corporates

The problem with peer comparisons is that they only reflect a point in time valuation. Whereas some companies in the table have established sales and profits from their activities, genedrive plc is only just at the point of launch and, therefore, on the cusp of realising the commercial potential of its investment activities. Under such circumstances, the valuation point used, in this case 2017 sales, does not necessarily provide a proper comparison. For example, the EV/sales for genedrive plc starts to fall based on fiscal 2020 forecasts when Genedrive assays start to drive the business.

gendrive plc – EV/sales

Year end June	2017	2018E	2019E	2020E
Sales (£m)	5.79	5.13	5.63	7.95
EV/sales	1.2x	1.3x	1.2x	0.9x

Source: Hardman & Co Research Life Sciences Research

M&A activity

Once the commercial success of new technology has been established, there is no shortage of interest from the major *in vitro* diagnostics players in acquiring it. However, the most recent activity has centred on the large players filling gaps in their portfolios through the addition of other established IVD companies, rather than investing in early breakthrough technology. This suggests that genedrive plc will need to show sales transaction through its commercial partners before it become a potential take-over target.

- **Abbott Labs** closed its protracted acquisition of **Alere** in October 2017 at a reduced price of ca.$6.9bn (including debt, less cash), ascribing an EV/sales multiple of 3.9x
- **Danaher** closed the acquisition of **Cepheid** in November 2016 at $53 per share valuing the company at just over $4bn and ascribing an EV/sales take-out multiple of 6.4x

Company matters

Registration

Incorporated in the UK with company registration number: 06108621

Registered Office
48 Grafton Street
Manchester
MX13 9XX

+44 161 606 7258
www.genedriveplc.com

Board of Directors

Board of Directors				
Position	**Name**	**Nominations**	**Remuneration**	**Audit**
Chairman	Ian Gilham	M	M	M
Chief Executive Officer	David Budd			
Chief Financial Officer	Matthew Fowler			
Managing Director	Dr Catherine Booth			
Non-executive director	Roger Lloyd	M	M	M
Non-executive director	Robert Nolan	M	M	M

M = member; C = chair
Source: Company reports

Ian Gilham – Non-executive Chairman

Alongside his responsibilities as non-executive chairman of genedrive plc, having been appointed on the May 11th 2015, Dr Gilham is also non- executive chairman if three life sciences companies, Horizon Discovery, Multiplicom NV and Biosurfit SA. He was formally Chief Executive Officer of Axis-Shield plc and is Director and founder of Stowhealth Ltd, an advisory service for private equity and corporate finance organisations investing in clinical diagnostics and medical devices. Dr. Gilham behaved as interim Chief Executive Officer for genedrive plc from the 4th of August 2015 till the appointment of David Budd announced on the January 13th 2016.

David Budd – Chief Executive Officer

David joined genedrive plc on 1st March 2016. He has over 20 years of international commercial and operational experience in the diagnostics and medical devices field, launching multiple diagnostics products into international markets. He joins from Leica Biosystems (a Danaher company), a fast growing organization where he served as General Manager of Leica Biosystems Amsterdam. David previously served as Commercial Director at Leica Biosystems Newcastle, with global responsibility for marketing, market research and product launches for diagnostic tests. Prior to joining Leica Biosystems, David's previous roles included Point-of-Care, molecular, and central laboratory marketing and commercialization responsibilities as a Director of Marketing at Siemens Healthcare Diagnostics, Business Unit Leader at Bayer Diagnostics UK, and Sales Manager at Visible Genetics Inc.

Matthew Fowler –Chief Financial Officer

Matthew Fowler was appointed Chief Financial Officer and a Director of the Company on 13 December 2016. Matthew has extensive experience in senior positions in the manufacturing, power, and support services industries. Prior to this new position, Matthew was Group Financial Controller of Scapa Group plc, where he was responsible for shaping and managing finance, strategy development, and other core processes. Before Scapa, Matthew was Finance Manager for three years at British Nuclear Group. Matthew trained and qualified in the audit department of Deloitte & Touche.

Dr Catherine Booth – Managing Director, Contract Research Services

Catherine is a co-founder of genedrive plc and prior to starting genedrive plc she worked for ten years with Professor Chris Potten at the Paterson Institute. Whilst at the Paterson Institute, she developed many pre-clinical assays. This knowledge is at the core of the genedrive plc contract Research Service. Catherine received her Ph.D. from Emmanuel College, University of Cambridge.

Dr Roger Lloyd – Non-Executive Director

Roger joined the Board as a non-executive director on 1 July 2007. Trained as a biochemist, Roger has 37 years' experience in the healthcare and biotechnology sector, particularly in the areas of strategic planning and business development. International business management with ICI Plc and AstraZeneca Plc included living and working in the United States and Germany, and having territorial responsibilities for Europe, Japan, Korea, Mexico and the Middle East. As Executive Director of Global Licensing at AstraZeneca he personally completed 24 transactions. He operates as a Board Adviser in the Biotech sector.

Dr Robert Nolan – Non-Executive Director

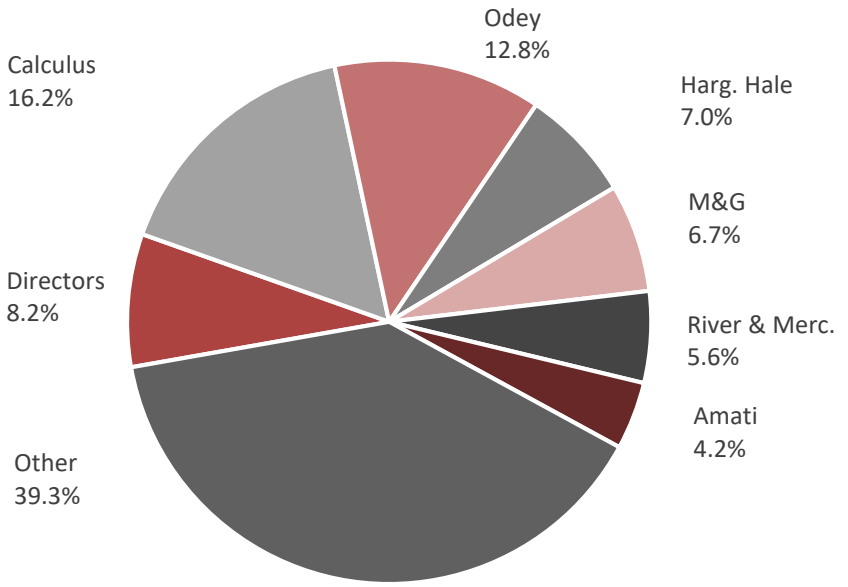
Robert has been a non-executive director of the Company since 2004. Having gained US post-doctoral experience at Dartmouth Medical School and MIT, he joined SANDOZ Forschungsinstitut in Vienna in 1972 to work on mechanism of antibiotic action and was also co-opted on to Sandoz global strategic planning group. He joined ICI pharmaceuticals (which became AstraZeneca) in 1979 to head up a natural products discovery programme and subsequently joined their product licensing group. He brings with him a wealth of expertise in partnering and licensing negotiations with both small biotechnology and large pharmaceutical companies. Prior to his retirement he was Director, Global Licensing, at AstraZeneca. He is also a non-executive director of Phico Therapeutics Ltd.

Share capital

Since incorporation, genedrive plc has issued shares to the value of £20.15m gross, mostly for working capital purposes. Some shares have been issued directly to the vendors as consideration/earn-outs related to acquisitions. The most relevant share issues are shown in the table below. Together with the cash raised at IPO, genedrive plc has had six share Placings. There are currently 18.69m shares in issue.

£20m of capital raised to fund the working capital of the business to date

Shareholders



Source: Company reports; RNS announcements

Directors own 8.2% of the enlarged share capital

The Directors own 8.2% of the equity and are further incentivised by the share option scheme, which currently has 1.82m (10% dilution) outstanding at an average price of 227p. genedrive plc has good institutional support, with 47% of the issued share capital in the hands of five institutions.

genedrive plc has received £1.3m of non-equity grant funding…

…with a further £0.5m recently awarded

Also, the company has received €1.5m/£1.3m of non-equity funding in the form of research grants. This was part of an €6.0m consortium project with Institut Pasteur, amongst others, to develop accurate and sensitive PoC hepatitis C assays. A further £0.48m Innovate grant has been awarded to develop a disposable centrifuge-free plasma separation consumable device over the next two years.

Relevant genedrive plc share issues

Comment	Date	Shares ('000)	Price (p)	Raised (£m)	Shares o/s ('000)	Valuation (£m)
	2007				4,045.6	
IPO at 124p	Apr-07	2,512.5	124	2.60	6,538.1	8.11
Placing at 163p per share	Nov-07	653.8	163	1.07	7,191.9	11.72
Placing at 400p per share	Nov-09	720.0	400	2.90	7,934.0	31.74
Placing at 350p per share	Nov-11	793.4	350	2.78	8,727.4	30.55
Placing at 545p per share	Dec-12	793.4	545	4.32	9,659.7	52.65
Visible Genomics earn-out	Jun-15	491.2			10,564.4	
Placing at 80p per share	July-16	8,125.0	70	6.50	18,689.4	15.0
Total				**20.15**	**18,689.4**	

Source: Company announcements; Hardman & Co Life Sciences Research

Use of funds

The capital increase in July 2016 was needed by the new leadership team to enact the remodelled strategy and to take advantage of its leading position in point-of-care molecular diagnostics. Of the gross £6.5m funds raised, net funds of £6.0m were allocated broadly as follows:

- £2.4m (40%) for development, testing and validation work to expand the assay menu from the original TB test into the other infectious diseases
- £1.2m (20%) to obtain regulatory approvals and via CE Mark for the hepatitis C test
- £0.9m (15%) to support commercial activities and provide partner support for the assays and also for business development
- £1.5m (25%) for group infrastructure including capital expenditure, manufacturing and quality assurance

Collaborative funding agreement

More recently, funding has been derived from a convertible bond which was part of a collaborative funding agreement in July 2014 with the Global Health Investment Fund (GHIF). Under the terms of the agreement, genedrive plc issued a five-year convertible bond totalling $8.0m (£4.7m at USD1.70 at time of signing), maturing on 21st July 2019. In return, genedrive plc agreed to make its technology platform available for sale in emerging markets under a pricing framework that reflected the needs of those in low- to middle-income countries. As part of the recent Placing, the Terms of the GHIF bond were revised, with the maturity date being extended by two years to 21st July 2021 and with the bond being split into two tranches. The GHIF Amendment Agreement was conditional on the closure and receipt of Placing funds no later than 31st July 2016, which has been achieved.

Revised bond terms

- **Coupon:** The Bond carries a coupon of 5% paid semi-annually in arrears (unchanged)
- **Tranche 1:** GHIF has the option to convert $2.0m of the Bond into 788,288 Ordinary Shares at a conversion price of 150p at any time up to 15 May 2019
- **Tranche 2:** GHIF has the option to convert the remaining $6.0m 726,060 Ordinary Shares at a conversion price of 489p at any time up to 15 May 2019
- genedrive plc has the option to convert Tranche 1 into Ordinary Shares if the closing price for 20 consecutive days is greater than or equal to 250p

Risks

General

Investments in small early stage companies carry a significant risk and investors must be aware of this fact. In our opinion, the following risks are particularly relevant. Each of them could have an impact on time to reach market, cash flow breakeven and profitability.

Development risk

Given the development of its Genedrive platform and assays, genedrive plc has undertaken a significant number of activities relating to the launch of new products, therapies and services. However, as recognised by the company, there can be no guarantee that these developments will meet the technical and intellectual property hurdles required for a commercial launch to be undertaken.

Competition

The PoC/PoN diagnostics market is commercially attractive (see Global Market Opportunity, page 13), especially in emerging markets given the WHO's continued focus on facilitating more efficient diagnostics and advances in diagnostic technology by a number of companies. Competition in the market is increasing, which should be a strong consideration for genedrive plc especially given that other established and well capitalised diagnostics companies are also working to utilise the commercialisation opportunities available to genedrive plc. Fierce competition exists not only in emerging markets, but also in the developed world which is important, should genedrive plc seek to commercialise its HCV assay beyond emerging markets.

Key markets

genedrive plc are initially focussing the launch of Genedrive on emerging markets in which there may be risks affiliated with these countries' ability to pay and where support of non-governmental organisations such as the WHO can be needed for commercial success. Consequently, genedrive plc may consider expanding to developed markets, especially given the potential of their HCV assay, in which case existing competition in the developed market should be considered (see above 'competition').

Regulatory

Despite having achieved regulatory approval for the launch of its Genedrive MTB assay in India, approval for the Genedrive platform/assays will be needed in other markets. The time to achieve this could potentially slow down commercialisation. Furthermore, the continuation of clinical trials requires liaison with regulatory bodies, thereby potentially increasing costs should the company need to invest in personal to provide this skillset. genedrive plc has employed a business development advisor in India, and may adopt a similar strategy in other markets.

Financing risk

genedrive plc raised £6.0m net proceeds from a Placing in July 2016. This refinancing means that the company does have cash presently, however, this is offset by the $8m GHIF Convertible Bond, which must be considered as long-term debt repayable in 2019. Furthermore, the Group, directly or indirectly, is somewhat reliant on funding from philanthropic organisations, which can be unpredictable.

Glossary

APHL	Association of Public Health Laboratories
Biomarkers/biological markers	A naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease, etc. can be identified.
Buccal	Relating to the mouth or cheek
Epithelial tissue	Thin layer of tissue that provides a barrier between the body and the environment.
FP7 Grant	European Commission's 7th Framework Programme
Genotype	The genetic composition of an individual organism.
HBV	Hepatitis B viral infection
HCV	Hepatitis C viral infection
HIV	Human immunodeficiency virus
IL28B assay	The test related to testing for the IL28B gene involved in the immune response to certain viruses, including HCV
IVD	*In vitro* Diagnostics
MDR TB	Multi-drug resistant TB
MTB/RIF	The Genedrive assay for identification of MTB and MTB's resistance to rifampicin
Patient stratification	individual and group tailoring of therapies and diets depending on patients' genetic make-up and molecular profiling
PoC	Point-of-Care
PoN	Point-of-Need
RFID technology	Radio-frequency identification – the wireless use of electromagnetic fields to transfer data
Rifampicin	An antibiotic drug that is commonly used to treat tuberculosis
Sputum	A mixture of saliva and mucus coughed up from the respiratory tract, typically as a result of infection or other disease and often examined microscopically to aid medical diagnosis
Stem cells	Cells derived from early embryos that have the capability of generating every type of tissue in the body
TB	Tuberculosis – an infectious disease caused by infection with the *Mycobacterium tuberculosis* (MTB) bacterium
WHO	World Health Organisation

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www.quantumdx.com

www.wave80.com

www.who.int/en

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