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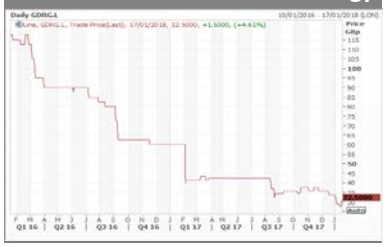
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	GDR
Price (p)	32.5
12m High (p)	60.0
12m Low (p)	25.0
Shares (m)	18.7
Mkt Cap (£m)	6.1
EV (£m)	7.0
Free Float*	47%
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%
M&G	13.1%
Odey	12.8%
Hargreave Hale	7.0%
River & Merc.	5.6%

Diary

20 March	Interims

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genedrive plc

Hepatitis C point-of-care diagnostic launched

genedrive plc is a commercial-stage company focused on point-of-care/need molecular diagnostics and biomarkers. Its Genedrive® molecular 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. Rapid analysis of patient samples greatly aids clinical and public health decision-making, with field testing particularly important in emerging markets. Hepatitis C diagnosis is a multi-million-dollar market opportunity; the company launched its Genedrive HCV ID Kit in 1H'18 at the IFCC World Lab conference in South Africa.

- **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.

- **Trading statement:** Group sales in 1H'18 were marginally ahead of forecasts, at £2.6m, down from £2.88m in 1H'17, representing a fall of 11%. The diagnostics division was slightly above forecasts, offsetting a weak performance in the services business. Cash at 31st December was also ca.£0.1m above forecasts.

- **Genedrive:** Distribution partner, Sysmex, has completed successfully the first field study in Africa of the Genedrive® Hepatitis C (HCV) ID Kit at an independent testing laboratory in Johannesburg. In 130 clinical samples from a number of countries, the kit demonstrated sensitivity and specificity of 100% compared with the Abbott M2000 HCV Real-time assay as a reference.

- **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, very large even in developing countries. With a strong commercial partner now in place, 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)	-28.3	-54.6	-21.4	-26.6	-17.3	-10.4
Statutory EPS (p)	-30.1	-56.2	-34.9	-27.3	-18.1	-11.4
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	903	-3,877	-70	-3,665	-6,190	-8,176
Capital increases	80	0	6,023	0	1,250	0
P/E (x)	-1.1	-0.6	-1.5	-1.2	-1.9	-3.1
EV/sales (x)	1.5	1.4	1.2	1.4	1.2	0.9

Source: Hardman & Co Life Sciences Research

1H'18 trading statement

genedrive plc has released a trading update to the market covering the first half sales (July to December 2017) for fiscal 2018. The full interim statement is expected to be will be released on the 20th March 2018.

Key headlines

- **Sales:** Group sales in 1H'18 were marginally ahead of forecasts, at £2.6m, down from £2.88m in 1H'17, representing a fall of 11%.
- **Genedrive:** The vast majority of diagnostics sales were derived from the US Department of Defense (DOD) project. Sales were well above expectations at £1.3m (£1.24m) representing underlying growth of about 6%.
- **Services:** There was a shortfall in the services business compared with forecasts, with sales down 22% at £1.3m (£1.65m). The reason for this was two-fold: first, the performance in 1H'17 was exceptionally strong; secondly, business activity has been affected by the division having a 'For Sale' sign over it for the past year.
- **Cash:** The period-end position was slightly stronger (+£0.1m) than forecast at £4.6m (£5.13m at 30th June 2017), benefiting from the receipt of a £1.2m R&D tax credit during the period.

GDR 1H'18 – actual vs expectations

Half-year (£m)	1H'17 actual	1H'18 actual	Growth %	1H'18 forecast	Delta Δ
Diagnostics	1.24	1.3	+6%	1.1	+0.2
Services	1.65	1.3	-22%	1.4	-0.1
Group sales	**2.88**	**2.6**	**-11%**	**2.5**	**+0.1**
Cash balance	5.7	4.6	nm	4.5	+0.1

Source: genedrive plc, Hardman & Co Life Sciences Research

Sales

Diagnostics business

The diagnostics business, which includes the biodefence development programme with the US DoD, made sales of £1.3m in the half year, which was about £0.2m above forecasts. This was due to the receipt of earlier-than-expected product order for the DoD collaboration, which had been expected to come in during 2H'18. However, given that this successful programme is coming to its close, this benefit is likely to reverse during 2H'18 such that our full-year forecast remains unchanged.

In line with company strategy, and as expected, there were no sales of the Genedrive infectious disease diagnostic platforms or kits during the first half, although we remain optimistic that a small contribution will be generated from the Genedrive HCV ID kit in the last quarter of this financial year.

Services business

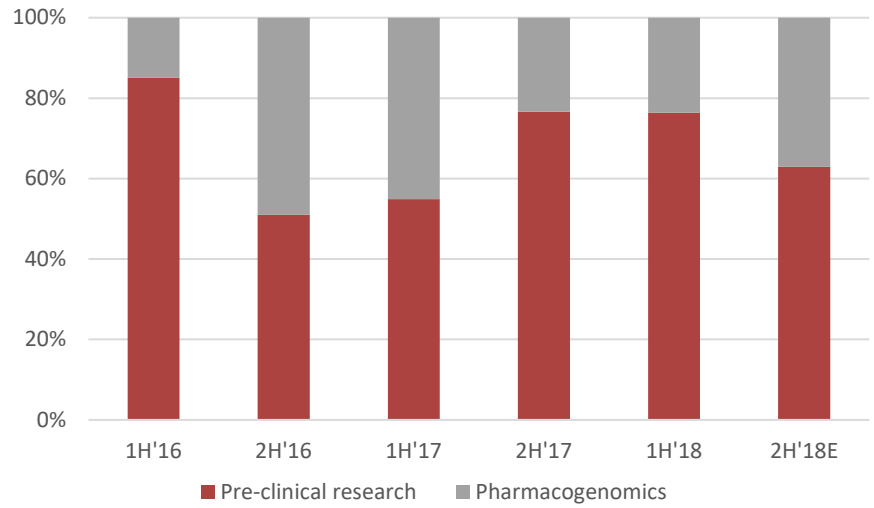
Sales performance – services business

Business unit	1H'16	2H'16	1H'17	2H'17	1H'18	2H'18E
Pre-clinical research	1.0	1.0	0.9	1.2	1.0	1.2
Pharmacogenomics	0.2	1.0	0.7	0.4	0.3	0.7
Services sales	**1.2**	**2.0**	**1.6**	**1.5**	**1.3**	**1.8**

Source: genedrive plc, Hardman & Co Life Sciences Research

In the six months to December 2017, sales from the services business were around £1.3m, representing a fall of ca.22%, which was £0.1m below our forecast. Although the pre-clinical research services component continued to produce a stable sales performance (estimated at ca.£1.0m for 1H'18), the pharmacogenomics segment was weak, falling ca.60% to £0.3m. However, this was broadly in line with the performance in the second half of fiscal 2017. The magnitude of this decline is due partly to unusually strong sales in 1H'17, but also likely represents a drop-off in orders now that management has announced divestment of the business.

Service business unit sales composition



Source: genedrive plc, Hardman & Co Life Sciences Research

The services business is modestly profitable and generates a small amount of cash. However, management's strategy is focused on becoming a pure-play diagnostics products company and to concentrate efforts on making a success of Genedrive. Therefore, its stated intention is to dispose of the services division, which has an estimated value of ca.£2m. The trading statement indicated that discussions are ongoing regarding its divestment.

Full-year forecasts

The next six months are set to be an exciting period for genedrive plc as the company transitions to commercialisation of its diagnostics products. It remains on track to report full-year sales in line with our forecasts (£5.1m), which include a boost to the diagnostics business from the first sales of the Genedrive HCV ID platform and kits to its distributer, Sysmex, towards the end of the second half.

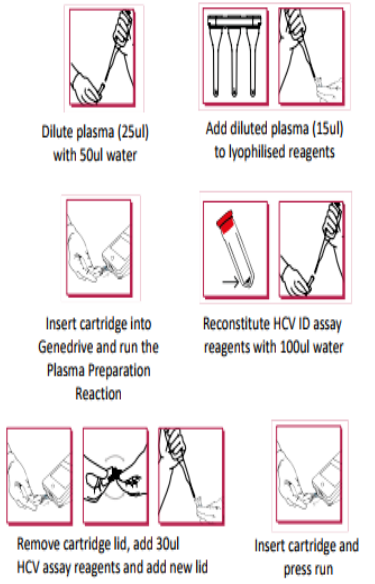
Genedrive HCV ID

Route-to-market

Diagnostic assays

Accurate and timely diagnosis is essential for early intervention that both disrupts the transmission chain and results in better outcomes for the patient. However, due to it prevalence in under-resourced populations and the lack of symptoms in acute infection, hepatitis C virus (HCV) infection is widely under-diagnosed. Moreover, conventional serological and molecular diagnostic approaches are slow and inconvenient in the field, with the more accurate molecular diagnosis requiring the expertise of centralised laboratories that possess PCR and/or DNA sequencing facilities. Availability of newer, high-throughput genome sequencing technologies has spurred development of methods that deliver detailed information on the variants of hepatitis C virus causing infections – while this can underpin clinical decision making specific to the HCV variant and improve understanding of the source of infections, it is not yet practical for field diagnosis in resource-poor and rural locations; not least, blood samples still need to be sent to central laboratories.

Genedrive HCV ID workflow



Source: Llibre et al[1]; genedrive plc

Genedrive HCV ID platform

Genedrive is a rapid point of care molecular testing platform designed for diagnosis by detection of DNA or RNA 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 diagnosis in approximately 50-90 minutes. The technology is a plug-in cartridge and a Genedrive unit, to which Radio-frequency identification (RFID) allows programming of assay metrics; this allows re-configuration for specific assays. Multiple specimen types, e.g. blood, and sputum, can be used. Genedrive HCV ID is fully CE marked following thorough and independent validation at Institut Pasteur and Queen's Medical Centre, Newcastle, on reference material and patient samples.

The Genedrive HCV ID system detects HCV RNA in human blood samples. To our knowledge, the particular sequence of HCV genome that is being detected has not been disclosed. However, the system is able to distinguish among all six major genotypes (genetic variants) of HCV.

Target market

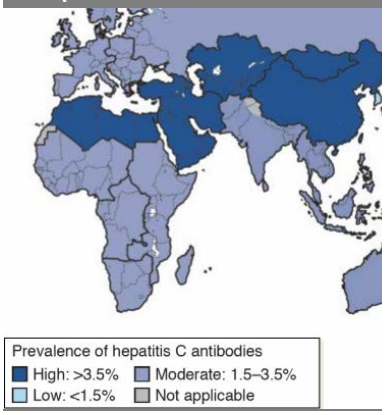
Genedrive has been designed to overcome potential environmental (temperature, humidity) and technical (power failure) setbacks when trying to deliver accurate and efficient diagnosis in these markets. However, it still requires a mains electricity supply and, therefore, in the short to medium term, Genedrive is being targeted to small and medium-sized laboratories at point-of-care in emerging markets. For market entry, the company is focusing initially on private laboratories, which are widespread in healthcare systems particularly in resource-poor territories. Sales traction will build KOL reputations, such as with government healthcare decision makers, and will aid market access to public healthcare systems in the longer term.

Unmet need

HCV causes acute (usually asymptomatic) infection and chronic liver disease. Infection typically results from use of contaminated needles or blood transfusions, but can be sexually transmitted. There are approximately 4m new cases annually, which means that around 3% of the global population carries the virus.

[1] Poster: *Clinical validation of a rapid point-of-need HCV molecular test*. Llibre *et al*. EASL congress 2017

HCV prevalence: Africa & Asia



Source: Thomas[2]

The greatest global HCV burden is found in North Africa and parts of Asia. Many southern African counties also have a moderate burden: South Africa, for example, has around 350,000 chronic infections at any time[2].

The HCV genotype varies among and within country, and therefore it is important to test the Genedrive HCV ID platform on local samples. For example, genotypes 1-4 are particularly prevalent across Africa. The genotype is clinically relevant, affecting the progression of disease and the choice of treatment.

Overview of global HCV genotypes

Genotype	Subtype	Geographical distribution
1	a, b, c	Central Africa, Europe, N. America
2	a, b, c, k	Western Africa
3	a, b, k	Southeast Asia
4	a	Central Africa
5	a	
6	a, b, d, g, h, k	Southeast Asia

Source: Yu and Chiang[3]

Distributor agreement

Following regulatory authorisation of the Genedrive HCV ID Kit, genedrive plc has signed distribution deals with Sysmex Corporation, a major player in clinical laboratory systemisation and solutions, covering EMEA and Asia Pacific (excluding India). Sysmex is listed in Tokyo and is capitalised at about $13bn, with annual sales of $2.2bn. genedrive plc has had to sign separate agreements with subsidiaries of Sysmex for distribution of the Genedrive platform and the Genedrive HCV ID kit: with Sysmex Europe for distribution in the EMEA region, with an initial focus on Africa, signed in October 2017, and with Sysmex Asia Pacific Pte Ltd, for the Asia Pacific Region, signed in November 2017.

Choosing a distributer is extremely important when delivering public health interventions to resource-poor and developing countries. Sysmex has the necessary expertise to ensure that the platform is properly used and suitable for use in local markets; it is ranked #8 globally in *in vitro* diagnostics (IVD), with a very strong presence in haematology, where it is ranked world #1.

Launch in South Africa

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.

South Africa has a well-established public health system, including the National Institute for Communicable Diseases. It carries out molecular surveillance for clinical diagnosis and patient management across the African continent, in addition to South Africa. HCV is a category 2 notable medical condition in the region, meaning that it is a legal requirement to report new cases within seven days of diagnosis. The benefits of an efficient, easy-to-use and accurate diagnostic at the point-of-need are clear when time and financial resources are limited.

[2] *Global control of hepatitis C: where challenge meets opportunity.* Thomas DL. Nat Med (2012) 19(7)
[3] *A new insight into hepatitis C vaccine development.* Yu CI, Chiang B. J Biomed Biotech (2010)

WorldLab 2017

The company officially launched the Genedrive HCV kit in October 2017 at the International Federation of Clinical Chemistry (IFCC) WorldLab congress held in Durban, South Africa. This was organised in cooperation with the African Federation of Clinical Chemistry, a regional society of the IFCC, which guides on the setting of standards for laboratory medicine among other activities, and was focused on highlighting innovative science, particularly that underpinning evidence-based laboratory and personalised medicine.

First field evaluation study

As part of the transition to a commercially available product, Sysmex recommended that there was local validation of the Genedrive HCV ID system. The results of the successful field study were released on 16th January 2017, independently carried out at the privately-held Lancet Laboratories. Sysmex led the support and training of the customer. Lancet Laboratories is well regarded in the field and has operations across the African continent. The study demonstrated:

- **Accuracy:** Sensitivity and selectivity of the test when performed by a third party.
- **Local samples:** Successful use of patient samples stored and processed under local conditions.
- **Genotypes:** Test further the accurate diagnosis of samples of the HCV genotypes (strains) found particularly in central and southern African countries.

A total of 130 clinical samples from more than six African countries were tested using Genedrive. The Abbott M2000 HCV Real-time system was used as a reference.

- **Results:** Sensitivity and specificity for detection of GCV were 100%.
- **Genotypes distinguished:** The samples contained HCV genotypes 1-5, and their subtypes were successfully detected using the system.
- **Efficiency:** 95.4% of test results were achieved on the first attempt, despite many samples being haemolysed (which can be the result of undesirable sampling techniques).

Unlike the Abbott system, Genedrive HCV was found to be fast, no/low maintenance, and have a low laboratory footprint. The study demonstrated clearly the potential for the system to decentralise clinical diagnosis and management of HCV infection, meaning that HCV public health interventions may be expanded to rural areas of resource-poor countries.

Financial summary

- **Forecasts:** Although there might be a slight rebalancing of the sales mix, there is unlikely to be any change to our full-year forecasts.
- **Detailed analysis:** Full financial forecasts were presented in our initiation report published on 13th December 2017 entitled: '*Remodelled for growth*', which can be downloaded free of charge from our website:

http://www.hardmanandco.com/docs/default-source/company-docs/genedrive-plc-documents/13.12.17-remodelled-for-growth.pdf

Forecast summary						
Year-end June (£000)	**2015**	**2016**	**2017**	**2018E**	**2019E**	**2020E**
Profit & Loss						
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
SG&A	-1,500	-2,201	-2,513	-2,516	-2,592	-2,666
Underlying EBIT	**-4,243**	**-6,433**	**-3,740**	**-4,650**	**-2,892**	**-1,800**
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**
Exceptionals	**0**	**0**	**0**	**0**	**0**	**0**
Tax payable/credit	399	582	1,051	992	827	785
Underlying net income	-2,843	-5,748	-3,956	-4,980	-3,397	-2,354
Underlying Basic EPS (p)	**-28.30**	**-54.58**	**-21.42**	**-26.6**	**-17.3**	**-10.4**
Statutory Basic EPS (p)	-30.11	-56.16	-34.85	-27.3	-18.1	-11.4
Balance sheet						
Share capital	158	158	280	280	336	336
Reserves	9,387	3,595	3,161	-1,940	-4,301	-6,875
Provisions/liabilities	0	1,250	1,250	1,250	0	0
Debt	4,025	4,991	5,199	5,473	5,761	6,064
less: Cash	4,928	1,114	5,129	1,808	-430	-2,112
Invested capital	**8,612**	**8,880**	**4,761**	**3,255**	**2,226**	**1,637**
Cashflow						
Underlying EBIT	-3,858	-5,259	-4,812	-5,566	-3,808	-2,716
Change in working capital	-1,122	44	1,308	181	-369	-571
Company op cashflow	**-4,833**	**-4,192**	**-2,594**	**-4,742**	**-3,261**	**-2,371**
Capital expenditure	-758	-164	-70	-100	-115	-132
Capital increase	80	0	6,023	0	1,250	0
Change in net debt	**-3,335**	**-4,780**	**3,807**	**-3,595**	**-2,526**	**-1,985**
Hardman FCF/share (p)	-35.0	-35.9	-9.9	-18.7	-12.3	-8.3

Source: genedrive plc, Hardman & Co Life Sciences Research

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(Disclaimer Version 4 – Effective from January 2018)

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Some professional investors, who are subject to the new MiFID II rules from 3rd January, may be unclear about the status of Hardman research and, specifically, whether it can be accepted without a commercial arrangement. Hardman's company research is paid for by the companies about which we write and, as such, falls within the scope of 'minor non-monetary benefits', as defined in the Markets in Financial Instruments Directive II.

In particular, Article 12(3) of the Directive states: 'The following benefits shall qualify as acceptable minor non-monetary benefits only if they are' (b) 'written material from a third party that is commissioned and paid for by an[sic] corporate issuer or potential issuer to promote a new issuance by the company, or where the third party firm is contractually engaged and paid by the issuer to produce such material on an ongoing basis, provided that the relationship is clearly disclosed in the material and that the material is made available at the same time to any investment firms wishing to receive it or to the general public;'

The fact that we are commissioned to write the research is disclosed in the disclaimer, and the research is widely available.

The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf

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