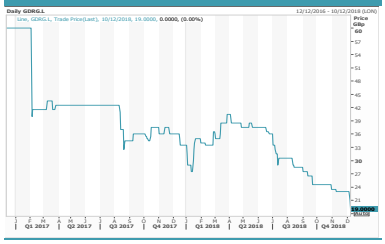
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	GDR
Price (p)	21.0
12m High (p)	42.0
12m Low (p)	18.0
Shares (m)	34.0
Mkt Cap (£m)	7.1
EV (£m)	7.0
Free Float*	52%
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/near-patient 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	0.5%
Calculus	19.4%
M&G	15.2%
BGF	12.8%
Odey	5.5%
River & Merc.	3.1%
C. Booth	3.0%

Diary

31 Dec	2018 AGM
1H'19	First regulatory approvals
1H'20	WHO decision on HCV-ID

Analysts

Martin Hall 020 7194 7632
mh@hardmanandco.com
Dorothea Hill 020 7194 7626
dmh@hardmanandco.com
Grégoire Pavé 020 7194 7628
gp@hardmanandco.com

GENEDRIVE PLC

Accelerating into fiscal 2019 with first sales

genedrive plc (GDR) is a commercial-stage company focused on point-of-care molecular diagnostics. 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 the diagnosis of infectious diseases. Rapid analysis of patient samples greatly aids clinical and public health decision-making, with field testing particularly important in emerging markets. The 2018 fiscal year saw solid operational progress to generate first commercial sales. CE marking of the assay for hepatitis C virus (HCV) detection was awarded, and three commercial partnerships were agreed.

- **Strategy:** Now that the Genedrive technology platform has received CE marking, the new management team has completely re-focused the company onto the commercialisation pathway for gene-based diagnostics, signing three important commercial agreements, and divesting its Services Business unit.

- **Full-year results:** FY'18 was the first reporting period to include commercial product sales. Genedrive and HCV assay revenues contributed £0.13m to the £1.94m total for the Diagnostics Business (£2.62m). The Services Business was divested towards the end of the period, contributing £0.96m in net proceeds.

- **Post-period fundraise:** GDR has raised a total of £6.0m through a mix of debt and equity: a Placing of 15.2m shares @ 23p to raise £3.5m (gross), coupled with a loan note for £2.5m from the British Growth Fund. On completion (10 December), this boosted GDR's cash position to an estimated £8.0m.

- **Risks:** The platform technology has been de-risked through the receipt of CE marking for its assay for detection of HCV infection. The main risk is commercial, given that it often takes time for new technologies to be adopted. However, partnering with major global and local experts reduces this risk.

- **Investment summary:** Genedrive technology ticks all the boxes of an 'ideal' *in vitro* diagnostic that satisfies the need for powerful molecular diagnostics at the point of care/need. The hepatitis C market is a very large global opportunity, and the HCV-ID test has excellent potential, even in developing countries. With strong partners being signed for different countries, such as the NHS in the UK, and evidence of early sales traction, GDR is at a very interesting inflection point.

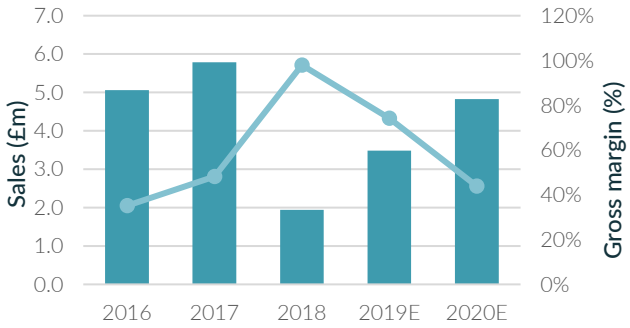
Financial summary and valuation

Year-end June (£000)	2016	2017	2018	2019E	2020E	2021E
Sales	5,063	5,785	1,938	3,480	4,826	7,055
Underlying EBIT	-5,259	-4,812	-5,276	-3,656	-2,887	-2,986
Reported EBIT	-5,426	-7,292	-7,375	-3,677	-2,918	-3,028
Underlying PBT	-5,828	-5,316	-5,794	-4,262	-3,499	-3,624
Statutory PBT	-6,497	-7,487	-7,788	-4,282	-3,530	-3,667
Underlying EPS (p)	-49.8	-23.1	-26.9	-11.9	-7.4	-7.8
Statutory EPS (p)	-56.2	-34.9	-31.9	-12.0	-7.4	-7.9
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	-3,877	-70	-2,096	-4,010	-5,798	-8,386
Capital increases	0	6,023	0	4,547	0	0
P/E (x)	-0.4	-0.9	-0.8	-1.8	-2.8	-2.7
EV/sales (x)	1.4	1.2	3.6	2.0	1.4	1.0

Source: Hardman & Co Life Sciences Research

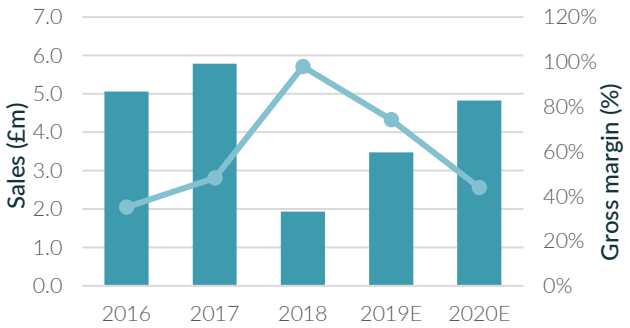
Disclaimer: Attention of readers is drawn to important disclaimers printed at the end of this document

Sales and gross margin



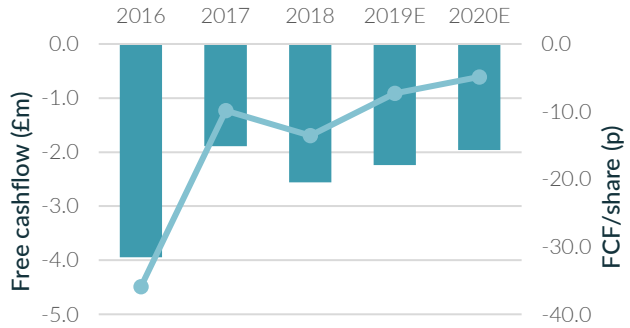
- Historical sales relate to the Services Business and Genedrive-related grant income; forecasts are for the Diagnostics division
- The main driver going forward will be sales of devices and related consumables (tests)
- Group margins are high during the initial HCV assay build-up period and influenced by the mix of DoD revenues
- Margins on Genedrive units and disposable cartridges will start to increase with rising volumes

R&D investment



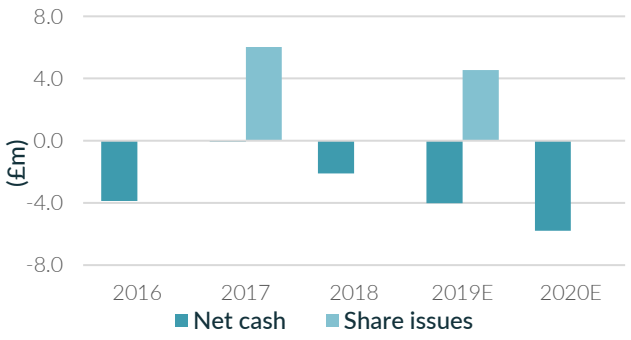
- R&D investment is written off in the year in which it is incurred
- To date, an estimated ca.£23m has been spent on R&D by the company since incorporation (although not spent exclusively on diagnostics)
- Investment in the next three years will add more tests onto the Genedrive platform
- Future investment will be largely dependent on the commercial success of the HCV test

Free cashflow and FCF per share



- Disposal of the non-core Services segment has provided a cash injection, providing a modest profit contribution and cash generation
- During the investment phase for Genedrive and HCV-ID assay launches, GDR is burning £2m-£3m cash p.a.
- Forecasts are dependent on Genedrive gaining early sales traction and generating recurring disposable revenues

Net cash/(debt)/share issues



- To date, GDR has raised only ca.£18.3m of capital and has received a modest level of non-equity grant funding (note that the funding has not been used solely to develop the Genedrive device)
- The Global Health Investment Fund (GHIF) Convertible Bond ($8m) is out-of-the money and should be considered as long-term debt
- The BGF Convertible Loan Note (£2.5m) is also long-term debt, with interest rolled up for three years, and maturation not until 2025

Source: Company data, Hardman & Co Life Sciences Research

Full-year results

Key features

Operational highlights

CE marking achieved for the Genedrive HCV-ID kit…

…plus three commercial partnerships agreed

- **CE marking:** The most significant event in FY'18 was the receipt of CE marking for the Genedrive HCV-ID kit, which represents a significant endorsement of the technology and has paved the way to first commercial sales.
- **Distribution:** GDR has signed exclusive distribution deals with Sysmex, a major global player in diagnostic instruments, reagents and related software, initially covering certain countries in Africa and SE Asia. It has also signed an agreement with Arkray for distribution in India.
- **Launch:** The HCV-ID kit was launched in October 2017 in South Africa by Sysmex Corporation, with first sales following in March 2018.
- **Services Business:** Following the strategic decision to dispose of its Services division in May 2018, this disposal was completed in June 2018 for an initial consideration of £1.15m and up to £0.75m for R&D credits in the three years post-disposal.
- **Post-period event:** Following successful completion of the development and validation phase, the US DoD made its first deployment order for Genedrive units and tests to the company.

Financial highlights

First commercial product sales achieved

Group sales almost £2m, excluding divested Services Business

- **Sales:** FY'18 group sales, at £1.94m, came in 6% below forecasts for the 12 months to June 2018. This was due entirely to lower-than-anticipated income from grants and funded development programmes.
- **Genedrive:** The first sales of Genedrive units and HCV-ID kits were 15% better than expected, reaching £0.13m in the three months of sales between the first orders and the year-end in June.
- **EBIT:** Control of costs resulted in SG&A being 14% below our forecasts, to -£1.99m (-£2.51m). However, R&D costs were 9% above the forecast level due to CE marking and extending the stability claims on HCV-ID, at -£5.18m (-£5.09m). As a result, the group's underlying EBIT loss was 6% greater than anticipated, at £5.28m (£4.81m loss).
- **Net cash/(debt):** GDR's closing cash position was £3.53m, helped by receipt of a £1.20m R&D tax credit. Retranslation of the GHIF bond benefited from currency, offsetting the interest charge, which is being rolled up. The period-end loan was in line with forecasts, at -£5.63m.

Operational progress in 2018

Refined strategy

Re-focused group strategy…

…now a pure-play gene-based diagnostics biotech

In the 2018 fiscal year, GDR has transitioned from a diagnostics service provider with assays under development to a focused developer of molecular diagnostics with first commercial sales. It is in the process of commercialising and developing a menu of diagnostic assays that can be performed in point-of-care (PoC) settings on its Genedrive device, which received CE marking in September 2017.

GDR's foremost aim is to deliver its three priority assays (see below) to the market in the medium term, which we estimate to be on a three- to four-year time horizon. This would suggest not only an established commercial footprint, but also material revenues and delivery of shareholder value, by 2022.

Expert partners

Teaming with experts…

…including Sysmex Corporation

A large part of GDR's commercialisation strategy appears to be the engagement of partners with expertise in product engineering and industrial design, following errors in the deployment of the mTB test in India in 2016, and also those with expertise in the distribution and sales of public health in developing countries. We discuss the latter in more detail below. The company made excellent progress in completing agreements with specialist distributers in FY'18 and in acquiring funding from government bodies and specialist venture capital funds in FY'18/early FY'19. These partners should de-risk significantly GDR's product commercialisation going forward.

Divestment of Services Business

In line with the re-focusing of the business, the Services division was divested on 8 June for up to £1.95m to a consortium of (now former) directors of the company. The proceeds will go towards funding the Genedrive development programmes.

Development of three assays

HCV assay: commercialisation under way

First sales of HCV-ID kits…

…in-country registration applications under way

First sales achieved

Perhaps the most notable progress in FY'18 was the achievement of the company's first commercial product sales. Following the CE marking of the Genedrive device in September, and after independent validation at Institut Pasteur, Paris, and Queen's Medical Centre, Newcastle, as well as the launch of the hepatitis C virus (HCV) assay in South Africa in October 2018, the first orders were received in March. The positioning of GDR's HCV assay within the market, and its high sales potential, will be key to its success.

PoC HCV diagnosis: unmet need

Accurate and timely identification of HCV infection is essential for early intervention that disrupts the transmission chain and results in better outcomes for the patient. Due to its prevalence in under-resourced populations and the lack of symptoms in acute infection, HCV infection is widely under-diagnosed. In addition, conventional serological and molecular diagnostic approaches are inconvenient in the field, and the more accurate molecular diagnostics require expert centralised facilities.

Genedrive HCV-ID commercialisation strategy

As the first low-cost, qualitative molecular decentralised testing product on the market, the company has first-mover advantage with the Genedrive HCV-ID Kit®, essential in a competitive market where the top line is driven by high volume sales.

The system detects HCV RNA in human blood samples using real-time PCR technology within a handheld device, delivering diagnosis within 50-90 minutes. It has been designed to overcome potential environmental and technical (e.g. power failure) setbacks when trying to deliver accurate and efficient diagnosis in the field. Currently, however, it still requires a mains electricity supply and, in the short term, Genedrive is being targeted to small and medium-sized laboratories. For initial market entry, GDR is focusing on private laboratories (particularly widespread in resource-poor healthcare systems), and its reputations with Key Opinion Leaders (KOLs) will be key to success. To this end, GDR is engaging with distributers, such as Sysmex, that specialise in the relevant markets and that have existing relationships.

Distributor agreements and global launches

Three commercial partnerships agreed…

…for countries across EMEA and APAC

Shortly after achieving CE marking, GDR agreed partnerships with Sysmex Corporation for distribution in specific countries in Africa and South East Asia (Bangladesh, Pakistan and Malaysia), followed by a similar agreement with Arkray for India in 1H'18. This represents significant progress towards accessing the multi-million-dollar market HCV diagnosis market. As such, following the first launch in South Africa by Sysmex, the first orders (for approximately 50 Genedrive units and 13 HCV-ID kits) were received, providing the validation crucial to KOL engagement and leading to data to support registrations in new territories. This will include engagement with government healthcare decision makers, aiding market access to public healthcare systems in the longer term. These initial product sales have been subsequently repeated in early FY'19.

Specific in-country registrations were, however, delayed during the year, as the disposal of the Services division required a change in the name of GDR's trading entity. This has set the company's commercialisation timetable back by up to six months. However, the delay has allowed GDR to complete some additional stability studies (testing the kit's shelf life under certain temperature and humidity conditions) and has permitted it to extend the stability claims on the HCV-ID kit.

Successful launch in South Africa

HCV-ID kit launch in South Africa…

…followed by successful field evaluation study

As part of a phased launch programme, Sysmex made the first launch of the Genedrive HCV-ID kit in October 2017 at the International Federation of Clinical Chemistry (IFCC) WorldLab congress held in Durban, South Africa. The initial focus for rollout is on countries with existing screening programmes, established funding policies, and with drugs for HCV infection available. South Africa has a well-established public health system, including the National Institute for Communicable Diseases, that carries out molecular surveillance for clinical diagnosis and patient management across the African continent. As HCV is a category 2 notifiable medical condition in the region, there is a legal requirement to report new cases within seven days of diagnosis, providing an excellent opportunity for Genedrive HCV-ID to add value to the system.

Successful field evaluation study

Diagnostics are of little value if they are not used in the clinic for decision-making, and specific in-market data are very useful to underpin registrations. FY'18 saw successful local validation of the Genedrive HCV-ID system in South Africa, independently carried out by the privately-held Lancet Laboratories, a well-regarded organisation in the infectious diseases field. The results released in January 2018 demonstrated:

- **Test accuracy:** high sensitivity and selectivity of the test when performed by a third party.
- **Efficacy in local samples:** successful use of patient samples that had been stored and processed under local conditions.
- **Genotype coverage:** accurate diagnosis in samples containing the HCV genotypes (strains) particular to more than six central and southern African countries.

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

mTB assay

New sample prep improvements for tuberculosis assay…

…supported by Innovate UK

This financial year, GDR has also renewed its efforts to develop a next-generation tuberculosis diagnostic, for which there is still an enormous push to replace traditional smear microscopy with more accurate molecular diagnostics. Although GDR's mTB assay was the first to receive CE marking using the Genedrive technology platform, commercialisation in India did not go according to plan, in part due to issues with sample handling in the clinic. In FY'18, the company successfully secured a £1.1m conditional grant from Innovate UK for improvement of sample preparation and reduction of manufacturing costs. Some assay reformulation is also underway to expand the strains detectable to those that are most prevalent in a range of geographies. More information on these developments should be available in fiscal 2019, with the current timeline being 2021 for re-launch of an improved product that has performance characteristics suitable across a wide geographical market.

PoC screen for gentamicin reactions

Expanding into acute care in developed markets…

…with detection of adverse antibiotic reactions in babies

In addition to infectious disease diagnostics, GDR is expanding its menu of tests, leveraging its health economic and speed advantages in acute care settings. In the second half of FY'18, a £550k grant was awarded to the company by the National Institute of Health Research (NIHR) for the development of a gene-based diagnostic for preventing antibiotic-induced hearing loss (AIHL) in newborns. This would allow expansion into developed countries, in addition to global health settings – a new market for GDR. The key features of the programme are:

- **Two-year duration:** development and initial implementation in an NHS PoC setting.
- **Accelerating GDR to new markets:** high-income emergency care settings, beyond the low- and middle-income markets for TB and HCV tests.
- **Significant unmet need:** Gentamicin reaction prevalence worldwide impacted by the restricted choice of antibiotics resulting from growing antibiotic resistance.

Market potential

A diagnostic test that delivers results in real-time to prevent AIHL has a very large market potential across Europe and the US. Due to the genetic similarity of a mitochondrial gene (RNR1) variant to genetic sequences in bacteria, a small proportion of people experience toxicities that can lead to severe hearing loss when treated with aminoglycoside antibiotics such as gentamicin, which is routinely used in emergency treatment of severe bacterial infections in newborn children. Current methods of detection of RNR1 variants cannot deliver results within the timeframe needed.

In the UK alone, around 90,000 babies are admitted to emergency care settings. The vast majority are treated with gentamycin. The prevalence of the most common RNR1 variant associated with adverse gentamicin reactions (m.1555A>G) is around 0.2% in Caucasian populations, meaning that, on average, 18 babies could experience AIHR each year in the UK alone. While routine screening of all newborns may not be practicable, a rapid PoC diagnosis of those infants clinically recommended for gentamicin treatment would be cost-effective.

If successful, the programme would set the stage for expansion to a large European market, and as GDR's first programme to involve a high-income country, should the RNR1 test be successfully implemented at a national level, it would significantly reduce GDR's risk profile. GDR anticipates first launch in 2020, and we would expect significant sales growth from around 2023 if successful in Europe.

Additional commercialisation activities

Product development

The company has been pursuing a number of activities to supplement the long-term commercialisation of the HCV assay. Genedrive is a rapid testing platform designed for detection of DNA or RNA using real-time PCR technology. It is presented as a plug-in cartridge and a Genedrive unit, presenting the opportunity for developing a range of plug-and-play gene-based assays. Furthermore, multiple specimen types, e.g. blood, and sputum, can be used.

To extend adoption in the field, in fiscal 2018 GDR was awarded, together with NHS Tayside and the University of Dundee, a £0.6m grant from Innovate (UK) for the development of a disposable centrifuge-free blood plasma separation consumable device. In addition, the company has been working on its launch of Genedrive Connect, a mobile app for android, to allow wireless data management and integration into a larger network.

Companion diagnostics

Finally, the company has been engaging with pharma companies to discuss the opportunities for the HCV assay as a companion to direct acting antivirals (DAAs) – new drugs for HCV treatment. DAAs are relatively expensive ($54-$147 per patient per 12-week course)[1], so there is a strong health economics case for accurate diagnosis of patients prior to treatment.

Market access studies

Progressing various intended setting studies for Genedrive HCV-ID tests

Studies that illustrate the analytical validity and clinical utility of diagnostic tests in local settings are extremely important for registration and pricing negotiations. For gene-based detection of infectious disease, this is particularly important, due to the geographical variation in the prevalence of strain types. HCV genotypes vary among and within countries (e.g. genotypes 1-4 are particularly prevalent across Africa), and the genotype is clinically relevant, affecting the progression of disease and the choice of treatment. GDR has been progressing various 'intended setting' studies for Genedrive HCV-ID tests in the 2018 fiscal year. The results from two studies, carried out in small clinics in Georgia and Cameroon, can be expected within FY'19. Both are sponsored by FIND, a not-for-profit organisation that supports development and delivery of infectious disease diagnostics in resource-poor settings.

Post-period events

US DoD programme

In 2018, GDR successfully completed the development phase of its programme with the US DoD to develop a 'handheld biohazard identifier' for identification of pathogens. The details of the programme are not disclosed; however, in September 2019, GDR received its first commerical order of units and assays, approximating to $0.9m, which is expected to be shipped and recognised as income in the first half of fiscal 2019. There is likely to be further engagement with the DoD, but this will be lumpy in terms of income, and the company does not have visibility on timing. As a whole, the project is excellent validation of the company's product development capabilities, and it has provided good funding to the group.

HCV-ID kit

HCV-ID kit under review from the WHO...

In August 2018, GDR made an application to the World Health Organisation (WHO) for the Genedrive HCV-ID test to be added to the list of prequalified *in vitro* diagnostics. This would make the product eligible for UN and other procurement tenders, and would accelerate further market access and, therefore, commercialisation. A decision is expected in the next six to 12 months, as the product has been granted accelerated review.

...towards increasing market access further

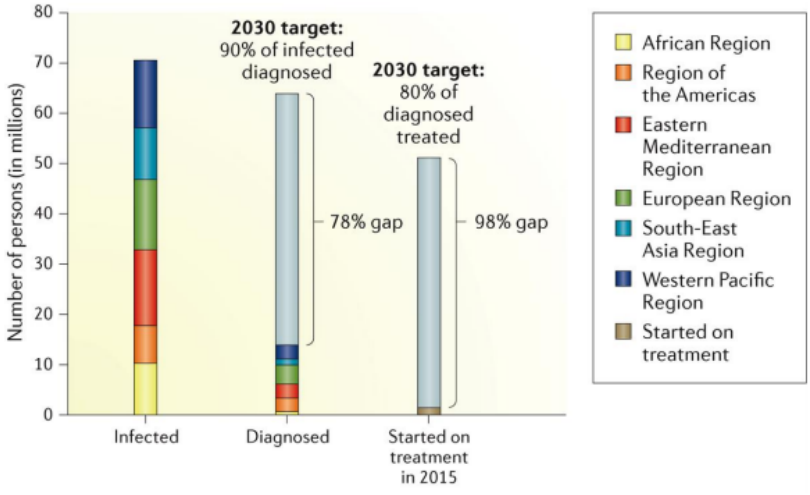
HCV assay REACH study – AbbVie sponsored

A real-world study should provide cost-effectiveness data for submission to payors

Following discussions with pharmaceutical collaborators in fiscal 2018, testing of the HCV assay in the AbbVie sponsored 'REACH' study began in November 2018. The study will examine the PoC advantages of the Genedrive system, whereby a test-and-treat approach in community pharmacies improves the rate of diagnosis, treatment and follow-up to cure of HCV infection in those who are resistant/unable to travel to central testing facilities. The trial will cover up to 40 pharmacies across three sites in Scotland, Wales and Australia, and is anticipated to enrol approximately 140 patients over two years. This is a real-world study that should provide cost-effectiveness data for submission to payors (e.g. NHS and Medicare in Australia).

The target patient population is people who inject drugs (PWID) who are undergoing opiate substitute therapy, e.g. methadone users. Approximately 53%[2] of the PWID global population are HCV antibody-positive – thus improving PWID access to diagnostics is essential in elimination of HCV infection.

Global rates of diagnosis and treatment



Source: Lazarus JV. et al. 2017

Expected news flow

genedrive plc news flow		
Fiscal year	**Calendar year**	**Progress/news**
1H'19	2018	First regulatory approvals
FY'19	Dec 2018 - Jun 2019	Regulatory approvals in approx. 30 countries
FY'19	Dec 2018 - Jun 2019	Additional distributer agreements
2H'19 - 1H'20	Jan 2019 - Oct 2019	WHO decision on HCV-ID prequalification
2H'19 - 1H'20	Jan 2019 - Oct 2019	Top-line results from 'intended setting' studies
FY'19		HCV-ID launch in India
FY'19/FY'20	2019	First release and launch of Genedrive Connect app.
2H'21	2021	Data from REACH trial

Source: Hardman & Co Life Sciences Research

Financials

Full-year 2018 results

Actual vs. our forecasts

GDR group sales, at £1.94m, were 6% below forecasts for the 12 months to June 2018. This was due entirely to lower-than-anticipated income from grants and funded development programmes. Sales of Genedrive units and HCV testing kits were 15% better than expected, reaching £0.13m in the three months of sales between HCV-ID test launch and the year-end in June.

Careful control of administration costs meant that SG&A was 14% below forecasts, at
-£1.99m; however, when combined with increases in R&D, 9% above the forecast level due to CE marking and extending the stability claims on HCV-ID, the group's underlying EBIT loss was 6% greater than anticipated, at £5.28m.

FY'18 results – actual vs. forecasts

Year-end June (£000)	2017 actual	2018 actual	Growth %	2018 forecast	Delta Δ
Product sales	0	127	nm	108	+19
Grant-funded	2,619	1,811	-30.9%	1,941	-130
Discontinued ops.	3,166	2,783	nm	2,820	-
Group sales	5,785	1,938	nm	2,049	-111
COGS	-2,998	-40	nm	*-37	-3
R&D	-5,086	-5,180	1.8%	-4,700	-480
SG&A	-2,513	-1,994	-20.6%	-2,264	+270
EBIT (underlying)	**-4,812**	**-5,276**	**9.6%**	**-4,953**	**-323**
Pre-tax profit	-5,316	-5,794	9.0%	-5,412	-382
EPS (p)	-23.1	-26.9	16.7%	-23.8	-3.1
Net cash/(debt)	**-70**	**-2,096**	**-**	**-1,476**	**-620**

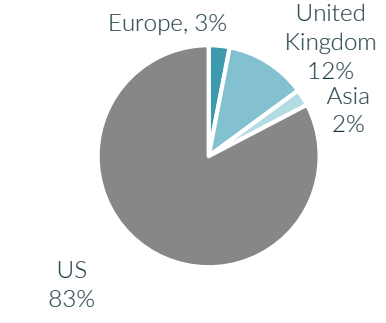
**Adjusted for disposal of Services Business*
Source: Hardman & Co Life Sciences Research

Disposal of Services division

In the table above, we show our updated FY 2018 forecasts (last published in June 2018) for the disposal of the Services Business (reclassified as discontinued operations). The disposal was proposed in May 2018 and completed on 8 June 2018, and our forecasts had included a full year of Services Business operations. For comparison with the actual fiscal 2018 results from continuing operations, forecast sales, COGS, and SGA associated with the Services Business have been removed from our previous forecasts.

The initial consideration from the disposal was £1.15m. Up to a £0.75m deferred consideration is due, based on R&D tax credits earned in the three years post-disposal. Cash proceeds were £0.96m, which represented a gain on disposal of £0.6m.

Group 2018 sales



Source: Hardman & Co Life Sciences Research

Sales

Group sales, excluding those of the now disposed Services Business (pharmacogenomics and pre-clinical research), were £1.94m in the 12 months to June 2018. This was the first year to include product sales, following successful CE marking of the HCV-ID kit in October 2017 and first sales in March 2018. These sales were composed of approximately £0.18m of Genedrive units and £4,500 of HCV-ID kits across EMEA, APAC and India, where the company has distribution relationships with Sysmex and Arkray.

GDR also reports government- and grant-funded programmes as sales, which totalled £1.81m (£2.62m), and represented a 31% decline on the previous year, due largely to the completion of the development phase of the US DoD drawing to a successful close.

Net debt

The group's net debt position increased from -£0.07m to -£2.10m during the year, largely the result of the increased R&D investment. The GHIF debt on the balance sheet totalled £5.63m (£5.20m) due to the interest charge roll-up, offset by a currency benefit. The cash position was £3.53m (£5.13m) at 30 June 2018.

Post-period financing

Total £6.0m raised in early FY'19…

…through a Placing and debt funding

In November, the company announced an increase in funding to be raised through a combination of debt and equity to raise a total of £5.6m (net), as outlined in the table below. The British Growth Fund (BGF) contributed £2.5m to the total via a loan of £2.5m and by taking a £1.0m equity stake through the Placing. Up to a further £0.5m shares were available via a broker option until 6 December; none were issued under this option. The Placing shares were admitted to AIM on 10 December 2018.

GDR fundraising, November 2018

Financing type	Investor(s)	Proceeds		Notes
		Gross	Net	
Placing	New and existing	£3.5m	*£3.3m	Issued 10 Dec
Loan notes	BGF	£2.5m	*£2.3m	Subscribed 19 Nov
Sub-total		**£6.0m**	**£5.6m**	
Broker option	Potentially new and existing	£0.5m	nc	Closed 6 Dec
Total		**£6.5m**	nc	Potential total

**Estimate*

Source: Hardman & Co Life Sciences Research

Placing

On 16 November, GDR undertook a Placing of 15,217,391 new Ordinary 1.5p shares by way of an accelerated book build at a price of 23p per share – the closing middle market price on 15 November. It raised £3.5m with existing and new shareholders. The new shares represent 45% of the enlarged share capital and were admitted to AIM on 10 December 2018 following approval at a General Meeting. Only those institutions listed below have declared their resulting holdings.

Changes in major shareholdings

Shareholder	Pre-Placing		Number of Placing shares	Post-Placing	
	Number of shares	%		Number of shares	%
Calculus Capital	3,031,250	16.1%		6,588,032	19.4%
M&G	2,448,490	13.0%		5,178,143	15.2%
BGF	0	0%		4,347,826	12.8%
Odey AM	1,997,254	10.6%		1,880,266	5.5%
Total number of shares	**18,783,115**		**15,217,391**	**34,000,506**	

Source: Genedrive, Hardman & Co Life Sciences Research

Broker option

An additional 2,173,913 new Ordinary shares were available via a broker option, on the same terms as the Placing shares, to raise up to a further £0.5m from investors. The broker option remained open until 6 December 2018 – together with the

Placing shares, they would have represented approximately 42.1% of the enlarged share capital. However, the bookrunners (Peel Hunt and Stanford Capital) were under no obligation to release the shares, and none were issued.

Shares qualify for EIS relief

GDR has received assurance from HMRC that its Ordinary shares qualify for Enterprise Investment Scheme (EIS) tax relief and are a qualifying investment for a Venture Capital Trust (VCT).

BGF convertible loan notes

GDR has also taken on a £2.5m unsecured convertible loan issued by BGF. BGF has also invested £1.0m (4,347,826 new Ordinary shares) in GDR, which was conditional on GDR successfully raising an additional £2.5m in the Placing. Key terms of the loan are outlined below:

- **Loan notes to be issued:** on or around 10 December 2018.
- **Coupon:** 7%, to be rolled up for the first three years, payable on 31 December 2021.
- **Conversion of loan note:** principal convertible at 125% of the Placing price (28.75p per share, equivalent to 8,695652 shares). Cannot be converted within six months of issue. Conversion price may be adjusted downwards in certain circumstances. Maximum shares in issue to BGF on conversion capped at 29.9% of issued share capital.
- **Maturity date:** 30 June 2025.

GHIF convertible bond

GDR also has an existing $8.0m, five-year convertible bond issued to the GHIF. At the time of signing, in June 2016, it was worth £4.7m, at USD1.70. The terms were previously amended alongside genedrive plc's 2017 Placing, with the maturity date being extended by two years to 21 July 2021 and with the bond being split into two tranches.

In parallel with the Placing this November, the terms have been further amended – key changes are listed below:

- **Maturity date extended:** from July 2021 to December 2023.
- **Interest payments:** roll-up extended from January 2019 to 2022.
- **Strike price reduced:** first $2.0m tranche reduced from 150p to 28.75p, in line with BGF conversion price. Remaining $6.0m tranche reduced to 150p from 489p.

Part of the arrangement is for GDR to make its technology platform available for sale in emerging markets under a pricing framework that reflects the needs of those in low- to middle-income countries. GHIF is a social impact investment fund designed to support the advancement of public health interventions; it is backed by the Bill & Melinda Gates foundation, JPMorgan, AXA, and pharmaceuticals companies, including GSK and Pfizer.

Use of proceeds

GDR's priority is to deliver three assays to the market in the medium term (we estimate two to three years), and management believes that the Placing and the two loans provide the flexibility and level of funding needed to deliver this goal. The stated use of proceeds includes projects towards increasing the gross margins of the Genedrive HCV-ID kit and supporting additional in-country launches.

Profit & Loss

- **Genedrive sales:** The rate of growth in our sales forecasts is being driven by Genedrive and infectious disease assay sales in the near term. Our assumptions include a time lag of up to 12 months from launch to sales in new countries.
- **Other programmes:** Because of the lack of visibility on the future of the DoD partnership, we have not made assumptions on this revenue stream. As the AIHL project is in its initial development phase, we have not included this revenue stream either. Sales forecasts are, therefore, conservative.
- **Gross margin:** During the build-up phase, gross margins for the Genedrive HCV-ID test and Genedrive unit are expected to be stable, at around 33%-50%, compared with the higher gross margins reported.
- **SG&A:** Expected to be stable around current levels in the medium term, as a large part of the marketing costs for tests will be borne by distribution partners.

Profit & Loss account						
Year-end June (£000)	**2016**	**2017**	**2018**	**2019E**	**2020E**	**2021E**
Product sales	0	0	127	1,616	4,074	6,997
Grant-funded services	1,906	2,619	1,811	1,864	752	58
Discontinued ops.	3,157	3,166	0	0	0	0
Sales	**5,063**	**5,785**	**1,938**	**3,480**	**4,826**	**7,055**
COGS	-3,285	-2,998	-40	-899	-2,711	-4,684
Gross profit	1,778	2,787	1,898	2,582	2,115	2,371
Gross margin	35.1%	48.2%	97.9%	74.2%	43.8%	33.6%
SG&A	-2,201	-2,513	-1,994	-2,088	-1,206	-1,940
R&D	-4,836	-5,086	-5,180	-4,150	-3,796	-3,416
Licensing/Royalties	0	0	0	0	0	0
EBITDA	-6,433	-3,740	-4,197	-2,704	-1,935	-2,034
Depreciation	-240	-216	-182	-55	-55	-55
Amortisation	-934	-856	-897	-897	-897	-897
Underlying EBIT	**-5,259**	**-4,812**	**-5,276**	**-3,656**	**-2,887**	**-2,986**
Share-based costs	-167	-101	12	-20	-31	-43
Exceptional items	0	-2,379	-2,111	0	0	0
Statutory EBIT	-5,426	-7,292	-7,375	-3,677	-2,918	-3,028
Net financials	-1,071	-195	-413	-605	-612	-639
Underlying pre-tax profit	**-5,828**	**-5,316**	**-5,794**	**-4,262**	**-3,499**	**-3,624**
Extraordinary items	0	0	0	0	0	0
Reported pre-tax profit	-6,497	-7,487	-7,788	-4,282	-3,530	-3,667
Tax liability/credit	582	1,051	758	607	555	500
Tax rate	9%	14%	10%	14%	16%	14%
Discontinued ops.	0	0	1,063	0	0	0
Underlying net income	**-5,246**	**-4,265**	**-5,036**	**-3,655**	**-2,944**	**-3,124**
Statutory net income	-5,915	-6,436	-5,967	-3,675	-2,975	-3,167
Ordinary 1.5p shares:						
Period-end (m)	10.57	18.69	18.78	39.95	39.95	39.95
Weighted average (m)	10.53	18.47	18.69	30.60	39.95	39.95
Fully-diluted (m)	12.49	20.53	20.75	32.66	42.01	42.01
Underlying basic EPS (p)	**-49.8**	**-23.1**	**-26.9**	**-11.9**	**-7.4**	**-7.8**
Statutory basic EPS (p)	-56.2	-34.9	-31.9	-12.0	-7.4	-7.9
Underlying fully-dil. EPS (p)	-42.0	-20.8	-24.3	-11.2	-7.0	-7.4
Statutory fully-dil. EPS (p)	-47.4	-31.4	-28.8	-11.3	-7.1	-7.5
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 30 June 2018 was -£2.10m, composed of cash of £3.53m, offset by long-term debt (convertible bond) of £5.63m. Working capital requirements and accrual of the finance costs result in forecast net debt of -£3.7m at the end of June 2019.
- **Tax credits:** Some of GDR's R&D investment attracts tax credits from HMRC – this year, R&D tax credits were £1.2m, but, going forward, the tax credit is expected to reduce, due to a greater mix of non-qualifying costs.
- **Deferred consideration:** GDR will receive up to £750k from disposal of the Services Business, based on the R&D credits earned by the business in the three years post-disposal. A total of £512k is currently sitting in the balance sheet.
- **Convertible bond:** The collaborative funding agreement for a total of $8.0m initiated in July 2014 (terms revised in July 2016) with GHIF is treated as long-term debt.
- **Loan note:** £2.5m unsecured convertible loan issued by BGF is also treated as long-term debt.

Balance sheet						
@31 June (£000)	**2016**	**2017**	**2018**	**2019E**	**2020E**	**2021E**
Shareholders' funds	3,753	3,441	-2,437	-1,565	-4,539	-7,707
Cumulated goodwill	0	0	0	0	0	0
Total equity	3,753	3,441	-2,437	-1,565	-4,539	-7,707
Share capital	158	280	282	599	599	599
Reserves	3,595	3,161	-2,719	-2,164	-5,139	-8,306
Provisions/liabilities	1,250	1,250	1,250	400	0	0
	0	0	0	0	0	0
Long-term loans	4,991	5,199	5,625	8,768	9,423	10,088
Short-term debt	0	0	0	0	0	0
less: Cash	1,114	5,129	3,529	4,759	3,624	1,702
less: Deposits	0	0	0	0	0	0
less: Non-core invests.	0	0	512	0	0	0
Invested capital	**8,880**	**4,761**	**397**	**2,845**	**1,259**	**679**
Fixed assets	713	568	165	140	123	114
Intangible assets	6,273	3,038	0	0	0	0
Inventories	202	444	171	557	772	1,129
Trade debtors	*2,290*	*1,376*	*182*	*327*	*453*	*663*
Other debtors	*507*	*278*	*369*	*376*	*384*	*403*
Tax credit/liability	*757*	*1,213*	*980*	*607*	*555*	*500*
Trade creditors	*-914*	*-816*	*-392*	*-400*	*-106*	*416*
Other creditors	*-948*	*-1,340*	*-1,078*	*-1,263*	*-922*	*-2,546*
Debtors less creditors	1,692	711	61	-352	364	-565
Invested capital	**8,880**	**4,761**	**397**	**2,845**	**1,259**	**679**
Net cash/(debt)	**-3,877**	**-70**	**-2,096**	**-4,010**	**-5,798**	**-8,386**

Source: Hardman & Co Life Sciences Research

Cashflow

- **Disposal:** Proceeds from the disposal of Services were £0.96m in 2018; operating cashflows from Services prior to the disposal were £0.86m.
- **Cashburn:** The underlying net cashburn is forecast to trend downwards after fiscal 2018, to ca.-£3.0m in 2019, as GDR's commercial partners gain sales traction with the Genedrive units and follow-through tests.
- **Deferred consideration payable:** There is a deferred consideration of £1.25m shares due as a result of the acquisition of Visible Genomics Ltd in 2010 to its former owners. These are included in 'capital increase' in the cashflow statement in fiscal 2019. Post period-end, and as part of the fund raising, the company agreed with the beneficiary of the deferred consideration to alter the terms of the agreement: £0.3m would be payable in cash; £0.2m receivable as shares 12 months from the share admissions; and 200,000 further shares to be received 36 months from the share admissions.

Cashflow						
Year-end June (£000)	2016	2017	2018	2019E	2020E	2021E
Underlying EBIT	-5,259	-4,812	-5,276	-3,656	-2,887	-2,986
Depreciation	240	216	182	55	55	55
Amortisation	934	856	897	897	897	897
Inventories	*-39*	*-242*	*241*	*-386*	*-215*	*-357*
Receivables	*-606*	*1,266*	*4*	*-145*	*-126*	*-209*
Payables	*689*	*284*	*-547*	*8*	*-294*	*-523*
Change in working capital	44	1,308	-302	-523	-635	-1,089
Exceptionals/provisions	0	0	0	172	170	0
Gain/loss on disposals	0	0	864	0	0	0
Other	-151	-162	-132	0	0	0
Company op. cashflow	**-4,192**	**-2,594**	**-3,767**	**-3,227**	**-2,570**	**-3,122**
Net interest	-280	14	13	38	42	27
Tax paid/received	691	757	1,220	980	607	555
Operational cashflow	-3,781	-1,823	-2,534	-2,209	-1,921	-2,540
Capital expenditure	-164	-70	-24	-30	-38	-47
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	**-3,945**	**-1,893**	**-2,558**	**-2,239**	**-1,959**	**-2,587**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	-1,250	0	0
Disposals	0	0	957	172	170	0
Other investments	0	0	0	0	0	0
Cashflow after invests.	**-3,945**	**-1,893**	**-1,601**	**-3,317**	**-1,789**	**-2,587**
Share repurchases	-44	0	0	0	0	0
Capital increase	0	6,023	0	4,547	0	0
Currency effect	-791	-323	-425	0	0	0
Cash/(debt) acquired	0	0	0	-3,143	0	0
Change in net debt	**-4,780**	**3,807**	**-2,026**	**-1,914**	**-1,789**	**-2,587**
Hardman FCF/share (p)	-35.9	-9.9	-13.6	-7.2	-4.8	-6.4
Opening net cash/(debt)	903	-3,877	-70	-2,096	-4,010	-5,798
Closing net cash/(debt)	**-3,877**	**-70**	**-2,096**	**-4,010**	**-5,798**	**-8,386**

Source: Hardman & Co Life Sciences Research

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research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com