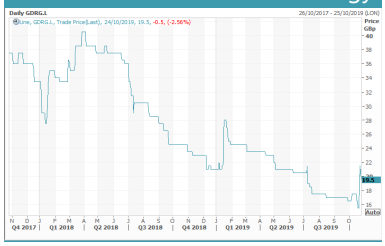
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	GDR
Price (p)	16.0
12m High (p)	30.0
12m Low (p)	13.0
Shares (m)	34.0
Mkt Cap (£m)	5.4
EV (£m)	8.8
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 point-of-care/near-patient settings with a low-cost device offering fast and accurate results. It focuses on diagnostics for acute hospital settings and for serious infectious diseases such as hepatitis C and tuberculosis.

Company information

CEO	David Budd
CFO	Matthew Fowler
Chairman	Ian Gilham

+44 161 989 0245
www.genedriveplc.com

Key shareholders

Directors	1.7%
Calculus	19.4%
M&G	15.2%
BGF	12.8%
Odey	5.5%
River & Merc.	5.4%

Diary

1H'20	WHO decision on HCV-ID pre-qualification
1H'20	Launch of HCV sample device

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GENEDRIVE PLC

Acceleration of news flow expected

genedrive plc (GDR) is a commercial-stage company focused on point-of-care molecular diagnostics. Its Genedrive® molecular diagnostic platform is at the forefront of this technology, offering a rapid, low-cost, simple-to-use device with high sensitivity and specificity. Rapid analysis of samples aids real-time decision-making, whether in clinical, public health or biothreat applications. GDR is developing a portfolio of assays for the Genedrive device. Its hepatitis C virus (HCV) and pathogen detection assays are already on the market, and products for tuberculosis (TB) and screening against adverse reactions to antibiotics are in development.

- **Strategy:** Now that the Genedrive technology platform has received CE marking, management has completely re-focused the company onto the commercialisation pathway for gene-based diagnostics in Hepatitis C, TB, bio-threats and Antibiotic-Induced Hearing Loss (AIHL).

- **2019 results:** Reported group sales increased 21.9% to £2.4m (£1.9m) in the 12 months to June 2019. Product sales of £0.9m from the US Department of Defense (DoD) and £0.5m from customers in Europe contributed to a more balanced income, the remainder being grant income.

- **Interesting period:** Management has been very open on the frustrations encountered in developing HCV markets. However, GDR is in an interesting transition, with HCV-ID kit "real-world" data being collected in global clinical settings and a study under way for AIHL in the UK.

- **Risks:** The Genedrive platform has been validated by CE marking of the HCV-ID kit, repeat orders from the US DoD, and funding from Innovate UK and the NIHR. The key risks are commercialisation in undeveloped global health markets and funding for anti-viral or anti-microbial drugs. Partnering tempers these risks.

- **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 large global opportunity – should market factors improve, the HCV-ID test has excellent potential. With strong partners, e.g. the NHS, being signed in both developed and developing markets, and several product lines in development, GDR has a solid growth strategy.

Financial summary and valuation

Year-end Jun (£000)	2017	2018	2019	2020E	2021E	2022E
Group sales	5,785	1,938	2,362	2,992	4,923	9,215
Underlying EBIT	-4,913	-5,264	-4,449	-4,271	-1,928	665
Reported EBIT	-7,292	-7,375	-4,010	-4,271	-1,928	665
Underlying PBT	-5,417	-5,782	-5,002	-5,001	-2,683	-98
Statutory PBT	-7,487	-7,788	-4,518	-5,001	-2,683	-98
Underlying EPS (p)	-23.6	-26.9	-15.8	-12.4	-5.9	1.3
Statutory EPS (p)	-34.9	-31.9	-14.0	-12.4	-5.9	1.3
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	-70	-2,096	-3,334	-6,948	-8,228	-6,660
Capital increases	6,023	0	3,243	130	75	0
P/E (x)	-0.6	-0.6	-0.9	-1.2	-2.5	11.6
EV/sales (x)	1.5	4.4	3.6	2.8	1.7	0.9

Source: Hardman & Co Life Sciences Research

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

2019 full-year results

Group sales grew 21.9% to £2.4m in 12 months to June 2019…

Following release of the trading statement in July 2019, we discussed the drivers of top-line fiscal 2019 results in our note, *Hepatitis C market frustrations*[1]. In this note, we summarise the full set of 2019 numbers announced in October 2019, introduce our 2022 forecasts for the first time, and update the market on pending news flow.

Key financials

- **Group sales:** The total of product sales and grant income grew 21.9% in the 12 months to June 2019, to £2.36m (£1.94m). Fiscal 2019 was the first full year without the Services business, which was divested in June 2018, and it was also the first full year with a commercialised test – Genedrive and HCV-ID sales were £0.13m in the final three months of fiscal 2018 following launch.
- **Product sales:** Good growth in sales of the Genedrive device and DoD assays took 2019 product sales to £0.96m (£0.13m). The majority, $1.18m/£0.91m, was contributed by the first commercial order from the US DoD, with small product sales to partners in Europe and the UK. The weakness of sterling benefited the top line, with underlying growth of 20.3%.
- **HCV product sales:** In 2019, sales of HCV-ID kits were broadly similar to the £0.13m level reported for the three months following launch late in fiscal 2018. Whereas the contribution in 2018 benefited from some early pipeline orders, those for 2019 were hampered by unanticipated delays of about nine months in commercialisation processes.
- **Grant income:** The National Institute for Health Research (NIHR) and Innovate grants are being recognised between 2018 and 2020 as costs are incurred. In 2019, grant income totalled £1.40m, associated with good progress in development of the AIHL and TB products.
- **Gross margins:** Selling costs are reported within administration costs by GDR. With the product mix underpinning COGS, we estimate that COGS totalled -£0.18m, representing a blended gross margin on product sales of 82%.
- **EBIT:** Operating losses improved 15.5% to -£4.44m (-£5.26m), related partially to the disposal of the Services business in 2018 and tight control of overheads in 2019. R&D spend fell 5.8% to -£4.88m, reflecting a change in the mix of development programmes.
- **Financing:** In November 2018, GDR increased funding through a combination of debt and equity, raising a total £5.6m (net). The British Growth Fund (BGF) contributed to the total via a convertible loan note of £2.5m and a £1.0m equity stake in the Placing.
- **Net cash/(debt):** The closing net debt was -£3.33m, comprising gross cash of £5.18m and debt of -£8.52m from the BGF and Global Health Investment Fund (GHIF) convertible bonds. The gross cash position had reduced to £3.9m by the end of September 2019.

2019: actuals versus forecasts

The trading statement, published on 9 July, provided sales numbers and the cash position for the year. Group sales in the 12 months to June 2019 were 4% lighter than pre-trading statement forecasts, at £2.4m, due partly to the delay in fulfilling the

[1] *https://www.hardmanandco.com/research/corporate-research/hepatitis-c-market-frustrations/*

second DoD order because of (now largely resolved) supplier issues. The greater resolution on income components in the full set of results showed product sales to be 8% below post-trading statement forecasts.

At the time of the trading statement, the closing cash position of £5.2m was 8% above our expectations, which we assumed at the time, was largely the result of improved control of working capital. However, while working capital was tightly controlled, there was a better-than-anticipated (+£0.11m) operating loss, both of which contributed to the gross cash position of £5.18m. The actual allocation of operating costs was also slightly different from that forecast, with higher-than-expected gross margins, due to product mix and tighter control of SG&A.

2019 results summary – actual vs. forecasts

Year-end Jun (£000)	2018 actual	2019 actual	Growth %	2019 forecast	Delta Δ
Product sales	127	961	657%	1,034	-73
Grants	1,811	1,401	-23%	1,400	+1
Group sales*	**1,938**	**2,362**	**22%**	**2,434**	**-72**
COGS	-55	-177	222%	-385	+208
R&D	-5,180	-4,877	-6%	-4,800	-77
SG&A	-1,979	-1,708	-14%	-1,808	+100
Underlying EBIT	**-5,264**	**-4,449**	**-15%**	**-4,559**	**+110**
Underlying PBT	-5,782	-5,002	-13%	-5,171	+169
Working capital	-27	-16	-41%	-16	-
Cash*	3,529	5,184	47%	5,208	-
Net cash/(debt)	**-2,096**	**-3,334**	**59%**	**-3,370**	**+36**

**Reported in July trading statement. Forecasts updated following the trading statement.*
***Now includes share-based payments*
Source: Hardman & Co Life Sciences Research

2019 operational progress – recap

CE marking of AIHL test likely by end of this calendar year

Although GDR's historical focus is infectious disease diagnostics for undeveloped markets, recent trading periods have seen increased activity towards generating a route into developed markets. Global health markets are traditionally underfunded and unpredictable, and the commercialisation of Genedrive AIHL in the UK, Europe and, potentially, in the US, generates a dual strategy towards generation of significant sales. Genedrive technology has been validated by the US DoD, by expert distribution partners and by successful development of three tests, with CE marking of the AIHL test likely by the end of this calendar year.

Commercialisation

New registrations slower to achieve than anticipated

Despite being quick to sign distribution agreements with Sysmex and Arkray for India, uptake of the HCV diagnostic in registered countries was low in fiscal 2019, and new registrations were slower to achieve than anticipated. This was the subject of our note after the July trading statement and is summarised below.

HCV commercialisation frustrated by external factors

Despite the clear unmet need for a rapid and accurate point-of-care (PoC) HCV diagnostic, GDR's commercialisation of the HCV-ID kit has been frustrated by factors associated with HCV markets in developing countries. Since its initial launch in 4Q'18, GDR has achieved registrations in 12 countries – a shortfall on the initial target of 30 registrations by fiscal 2019 year-end. This target was revised to 18 by the end of fiscal 2020, at the time of the trading statement, but seems to be less key than focusing on registration in key geographies, such as India, certain African countries and South East Asia. One reason for the delay is that, despite the HCV-ID kit's CE marking status, individual countries have required tailored registration dossiers that include data

specific to national HCV epidemiology and healthcare systems, and that may also require in-country studies. As a result, GDR's initial launch strategy is now around 12 months behind schedule. Furthermore, uptake, once registered, has also been slow, with the lack of funding for antiviral drugs affecting demand. Discussions for inclusion of HCV-ID in government and other not-for-profit programmes are ongoing, but these are notoriously slow to conclude.

In time, both registrations and uptake should be boosted by World Health Organisation (WHO) pre-qualification (PQ). Management remains confident of achieving this around the end of calendar 2019, following a successful site quality audit in January 2019. There has been a delay to the clinical trial part of this process during 2019 due to a lack of availability of the low viral load samples specified by the protocol (for sensitivity measurements). The protocol has now been revised to include samples more reflective of the real-world situation.

Bio-hazard pathogen detection

Source: genedrive plc

DoD

GDR received its first commercial orders of product related to the US DoD in the first half of fiscal 2019 – excellent validation of GDR's capabilities in gene-based diagnostics outside the infectious diseases area. Some isolated supplier issues (now resolved) meant that the fulfilment of the second order has been delayed into the current year. GDR has now arranged dual supply of reagents to prevent further issues.

Development activities

R&D progressed well in the period, with delivery of the Innovate UK-funded HCV plasma separation device and TB assay on track for commercialisation at the end of calendars 2019 and 2020, respectively.

TB sample preparation device

Source: genedrive plc

Being a large and well-understood market, diagnosis of mTB infection remains a vital part of GDR's strategy to material revenue by 2022. Fiscal 2019 saw the following progress in product development:

- completion of reformulation of the mTB assay;
- finished design phase of the mTB sample preparation companion module – automates extraction and concentration of mTB DNA from patient samples (covered by the £1.1m Innovate grant); and
- Engaged Sagentia (Cambridge, UK, part of Science Group (SAG.L)) to drive development of a sample prep consumable and companion module.

Results within 30 minutes

Source: genedrive plc

The sample module is particularly important for mTB, with patient sputum samples being unsafe to handle (e.g. during conventional smear microscopy). The *M. tuberculosis* bacteria are killed within the cartridge, allowing for biosafe handling and safer disposal of patient specimens.

AIHL screening assay – RNR1 – funded by NIHR grant

Development of the assay for screening against AIHL, part-funded by the NIHR, also progressed well in FY'19, with GDR completing the development phase of the programme. Test results are now achieved more rapidly than originally expected – within 30 minutes of taking a sample (buccal swab). This is an exciting achievement, given that time is of the essence in clinical decision-making for newborns with conditions such as acute sepsis.

GDR is progressing well towards full CE marking in FY'19 and is ready for the implementation phase of the project. Initiation of in-hospital evaluations should start imminently. Being high-margin with an easily defined customer base and no commercial competitors, significant revenue should still be achieved in 2022.

Accelerating pace of development

Management strategy: to deliver material revenues from three assays by 2022

GDR appears to be in a transition period in terms of the pace of development. Multiple HCV-ID studies have been completed since launch, others are ongoing, and the large evaluation of the AIHL product is due to initiate with the NHS next month. Accelerated news flow is expected from clinical and product development of each of the HCV, AIHL and mTB products in the current fiscal year, towards management's strategy to deliver material revenues from three assays by 2022.

HCV-ID: multiple studies

The HCV-ID kit successfully received CE marking in September 2017, with distribution deals with Sysmex Corporation (Sysmex Europe and Sysmex Asia Pacific Pte Ltd) being agreed by GDR in the following months. With the initial focus for commercialisation being African countries, Genedrive HCV was formally launched by Sysmex at the International Federation of Clinical Chemistry (IFCC) WorldLab congress held in Durban, South Africa, in October 2017.

Although GDR has achieved registrations in 12 additional countries since this time, commercialisation has been frustrated by i) unexpected requirements by certain healthcare systems for country-specific validation studies prior to sales, and ii) lack of funding for antiviral medicines, affecting demand in the market.

Overview of HCV genotypes

Geno-type	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[2]

Overcoming the former is within the control of GDR and its partners. Validation of the Genedrive HCV ID platform on local samples, in terms of specificity and sensitivity, is important for the following reasons:

- **Epidemiology:** Circulating HCV genotypes vary among and within countries – for example, genotypes 1-4 are particularly prevalent across African countries.
- **Genotyping:** In addition to diagnosis of infection, genotype identification is clinically relevant, as genotyping affects the progression of disease and the choice of treatment, and also permits outbreak analysis.

In terms of market access following registration, GDR is in the process of securing PQ with the WHO. PQ facilitates market access by validating certain products on the basis of quality, safety and efficacy, providing confidence, or even additional funding mechanisms, to purchasing organisations (e.g. UNITAID). Certain antiviral medications for treatment of HCV are also pre-qualified, such as generic sofosbuvir (Mylan Laboratories Ltd), so achieving PQ for Genedrive and the HCV-ID kit could result in obtaining synergistic orders for both drug and diagnostic, in addition to directly through increased market access.

Finally, going forward, certain countries, such as the UK and the US, will need to see evidence of successful practical integration of Genedrive systems within existing treatment pathways to award reimbursement and recommend them for use.

To this end, six "intended-setting" studies have been completed in the past 18 months, and one by an independent third party (summarised in the table below). While certain countries require performance studies after the registration process, some require a specific intended setting study to secure registration approval. Genedrive has conducted a pre-registration study in India concurrent with the registration process, which should avoid some of the delays encountered previously. Sensitivity and specificity information have been collated across the studies, and will be used in

[2] *A new insight into hepatitis C vaccine development.* Yu CI, Chiang B. J Biomed Biotech (2010)

promotional marketing activities. The full results will be disclosed only once published in a peer-reviewed journal or at a scientific conference.

HCV-ID studies ongoing and performed to date		
Study type	Notes	*Data
Intended setting – South Africa	Independently performed by Lancet Laboratories	**Sensitivity 98.6% Specificity 100% Efficiency 95.4%
Intended settings – x6 studies, multiple locations	x1 registration study x5 in-country performance studies	Sensitivity 96.5%-100% Specificity 100%
WHO pre-qualification study	Ongoing	Expected around 2019
"REACH HCV" real world study Scotland, Wales, Australia	Comparing treatment pathways among methadone users via community pharmacies Collaborators: Public Health Wales, Burnet Institute Sponsor: Abbvie/University of Dundee	Expected autumn 2022 (Study starts Oct'19)

**See explanation of terms below*
***Llibre A. et al (2019)*
Source: Hardman & Co Life Sciences Research

Looking towards developed markets

In yet another HCV-ID study, the real-world REACH HCV trial should provide cost-effectiveness data for submission to payors (e.g. NHS and Medicare in Australia). Due to begin this month (October 2019), it 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 patients 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. The target population is people who inject drugs (PWID) who are undergoing opiate substitute therapy, e.g. methadone, since ca.53% of the PWID global population are HCV antibody-positive. Improving PWID access to diagnostics is essential in elimination of HCV disease.

PALOH – AIHL study

RNR1 assay – 98% specificity, 100% sensitivity

Hospital evaluation of the RNR1 assay for AIHL are due to begin next month (November 2019). The study will focus primarily on the practical implications of integrating Genedrive into the neonatal emergency admissions process, with the official sensitivity/specificity data already collected as part of the CE marking process – specificity was 100%, with sensitivity at 100%.

The NHS "PALOH" study (Pharmacogenetics to Avoid Loss Of Hearing) will provide information for reimbursement materials, such as the number of units needed per NICU (Neonatal Intensive Care Unit) and ease of use of the Genedrive Connect app with nurses' mobile devices. In addition to further information on effectiveness time to results, the information will aid adoption into paediatric care guidelines. Further information on the use of Genedrive Connect will be available once the study concludes in May 2020.

Successful use of the RNR1 assay could prevent permanent hearing loss in as many as 180 neonatal admissions per year in the UK. There is also a potential broader market from bigger populations in Europe and the US. Recent releases have included the first mention of US market entry, with a partnering strategy likely necessary. More detail

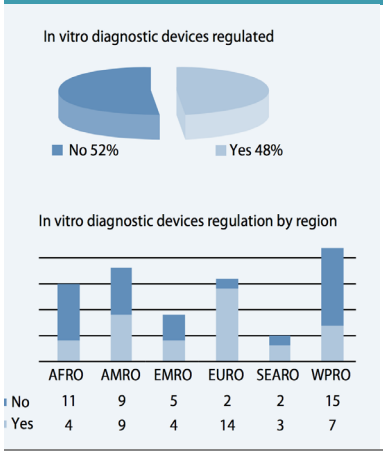
on the mitochondrial gene mutation that results in AIHL following gentamicin treatment is provided in our 2018 note, *Preventing hearing loss in newborns*[3].

Data coming up – evaluating diagnostics

What to look for

More detailed data will be released during the coming 12 months from the HCV-ID studies and the PALOH study. The main considerations when evaluating diagnostics are analytical validity, clinical validity and clinical utility. Clinical validity is straightforward in the case of simple diagnostics based on one or a few genes, like the Genedrive approach. Analytical validity (technical test performance), on the other hand, is key to CE marking or country registrations, and proper studies must be carried out that confirm that the test works in patients and healthy controls. In the US, these requirements are covered by regulatory bodies, such as the Clinical Laboratory Improvement Amendments (CLIA) and the In Vitro Diagnostics Devices Directive, and, in the EU, by ISO/EN 15189:2014. In developing countries, such as the primary markets for GDR's infectious disease assays, there is often a lack of clarity and transparency on the standards required for approval of diagnostics, which is compounded by an absence of regional harmonisation.

Regulation, developing countries



WHO regions
Source: TDR, 2002, from Peeling R. and McNerney R. 2011

Diagnostic performance in clinical decision-making

Studies evaluating the performance of diagnostics in patients in a clinical setting are needed to demonstrate analytical validity (e.g. intended setting studies) and clinical utility (e.g. PALOH and REACH studies) to the regulators. Analytical validity is measured by several statistics, summarised in the table below.

Accuracy of diagnostics – the proportion of patients correctly identified as having, or not having, the disease/gene in question[4] – is key. This can be refined by its positive predictive value (PPV), which describes the proportion of patients in the sample with a positive result who truly have the disease. The PPV captures the reliability of positive test results. However, because the prevalence of the disease/gene in the sample population is a factor of the PPV and NPV, these values should be assessed in a variety of different patient populations, and this is particularly important for identification of diverse pathogens that vary by geography.

Evaluating the performance of diagnostics

	Performance measure	Description	Note
Analytical validity	Sensitivity	$Sensitivity = \frac{number\ true\ positives}{number\ true\ positives + number\ false\ negatives}$	True positive rate
	Specificity	$Specificity = \frac{number\ true\ negatives}{number\ true\ negatives + number\ false\ positives}$	True negative rate
	Positive predictive value	$PPV = \frac{number\ true\ positives}{positive\ test\ results}$	Depends on prevalence of condition in sample
	Negative predictive value	$NPV = \frac{number\ true\ negatives}{negative\ test\ results}$	
Clinical validity		How well the test is able to identify and predict the disorder of interest. This is underpinned by how well the genetic variant, or other marker, is associated with presence/absence/risk of the disease.	
Clinical utility		How well the test aids clinical decision-making – diagnosis, treatment, management, or prevention of a disease – and its ability to improve clinical outcomes.	

Source: Hardman & Co Life Sciences Research

[3] https://www.hardmanandco.com/research/corporate-research/preventing-hearing-loss-in-newborns/
[4] Eisenberg M. J. (1995). Accuracy and predictive values in clinical decision making. *Cleveland Clinic Journal of Medicine* 62;5

The sensitivity and specificity of a test depend less on the prevalence of the disease in question and can be thought of as characteristic of the test alone. These should be calculated using samples representative of the population of interest.

Limit of detection

Sample preparation and prevention of contamination are equally important to the test itself in allowing detection of a small number of target DNA (RNA in the case of HCV-ID) fragments among an abundance of non-target DNA fragments (the "noise") with high sensitivity and specificity. One of the greatest challenges in diagnostic development is the limit of detection (LoD). This is a particular challenge for methods that hunt for single nucleotide polymorphisms (SNPs) or other small sequence variants. Since the LoD is the lowest quantity of DNA that is still detectable and analysable at a specified precision by the test, the smaller the concentration of the target variant in a sample, the lower the LoD must be.

The Genedrive approach

Being based on PCR, GDR's assays are a practical solution to the lack of availability of point-of-need nucleotide sequencing in low- and middle-income countries. With soon-to-launch advanced sample preparation cartridges, and with marketing of separate Genedrive devices for each assay, the risk of contamination is somewhat mitigated.

The evidence so far is that both the AIHL and HCV-ID assays have very high sensitivity and specificity. The reason for the 96.5% accuracy reported in the top-line data from the intended setting studies should be reported in the next 12 months, but this could have resulted from just a few false negatives or false positives.

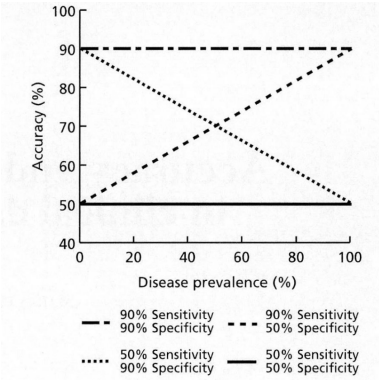
The HCV-ID kit's LoD (around 2362 IU/mL)[5] is sufficient for the HCV-ID kit's primary purpose (diagnosis of chronic HCV infection in pre-treated patients and identification of major HCV genotypes), and is within the WHO guidelines of an LoD 3000 IU/mL or lower being acceptable and sufficient to identify 95% of patients with viremia. It could, however, limit adoption by customers preferring a low LoD closer to central laboratory capabilities.

Diagnostic test performance

a.

	Disease present	Disease absent	
Positive test result	True positive (TP)	False positive (FP)	TP+FP
Negative test result	False negative (FN)	True negative (TN)	FN+TN
	TP+FN	FP+TN	Total

b.



Source: Eisenberg M. J. (1995)

Upcoming news flow

Aside from a slight delay to the HCV REACH trial, there have been no further updates to the timelines estimated by the company since the trading statement. The next 12-18 months look set to be a very busy period for news flow, with the most important events and associated RNS announcements detailed in the following table.

genedrive plc news flow

Fiscal year	Calendar year	Progress/news
2H'18	2018	First launch of HCV-ID kits – in South Africa
1H'19	2018	First regulatory approvals – four approvals achieved
2H'19	2019	Eight additional approvals, incl. two priority countries
FY'20E	2019	HCV plasma separation device launch
FY'20E	Jul'19-Jun'20	Target to reach regulatory approvals in 18 additional new countries by Jun'20, incl. India by Jan'20
1H'20E	**Sep'19-Dec'19**	**WHO decision on HCV-ID prequalification**
1H'20E	Jul'19-Dec'19	Top-line results from "intended setting" studies
1H'20E	**2019**	**CE marking expected for AIHL product**
1H'20E	Oct'19	HCV REACH study starts recruiting
FY'20E	Nov'19	Initiation of PALOH study: Genedrive MT-RNR1 assay
2H20E	Jul'19-Jun'20	Additional distributer agreements expected
2H'20E	**Feb'20**	**HCV-ID launch in India**
FY'20E	2019-2020	First release and launch of Genedrive Connect app

[5] Llibre A. et al (2018) Development and clinical validation of the Genedrive point-of-care test for qualitative detection of hepatitis C virus

FY'20E	May'20	Data PALOH study
FY'21E	Autumn 2020	UK launch of Genedrive MT-RNR1 assay
2H'21E	2021	Data from REACH trial
FY'22E	2021-2022	Launch of TB product

Source: Hardman & Co Life Sciences Research

Financials and investment case

Changes to forecasts

Changes to forecasts

Year-end Jun	2020E			2021E		
(£000)	Old	New	Δ	Old	New	Δ
Product sales	2,390	2,343	-2%	5,089	4,923	-3.4%
Grants	650	649	0%	0	0	0.0%
Group sales	3,040	2,992	-2%	5,089	4,923	-3.4%
COGS	-1,434	-1,434	0%	-2,035	-1,871	-8.8%
R&D	-4,050	-4,048	0%	-3,398	-3,400	0.1%
SG&A	-1,733	-1,708	-1%	-1,527	-1,477	-3.4%
Underl. EBIT	-4,177	-4,271	2%	-1,871	-1,928	2.9%
Underl. PBT	-5,019	-5,001	0%	-2,737	-2,683	-2.0%
Underl. EPS (p)	-13	-12	-5%	-7	-6	-12.1%
Ch. working cap	119	-30	496%	52	200	74.0%
Cash	2,319	2,368	2%	1,560	1,732	9.9%
Net cash/(debt)	-6,740	-6,948	3%	-8,033	-8,228	2%

Source: Hardman & Co Life Sciences Research

Fiscal 2020-21

We have refined our sales model following the additional timelines on the progress of each of HCV-ID, mTB and RNR1 assays provided along with the 2019 results. Orders from the DoD are hard to forecast, so we are holding them constant YoY, with the expectation of two orders fulfilled in 2020. We have reduced slightly our expectations for HCV-ID sales in both 2020 and 2021.

We have also taken a more optimistic view of gross margins in 2021 to reflect the start of revenue from the higher-margin AIHL products. This drops straight through to drive a decrease in underlying EBIT losses in 2021. Margins are hard to forecast due to a changing product mix and customer base.

Fiscal 2022

We introduce our 2022 forecasts in the detailed tables below. GDR expects material revenues across three assays by 2022, which will be complemented by the new HCV sample preparation device launch around this time.

Profit and loss

- **Product sales:** The rate of growth in our two-year sales forecasts is being driven by estimated growth in Genedrive units and the DoD, AIHL and HCV-ID assays.
- **Gross margin:** In 2021 and 2022, gross margins should pick up rapidly, with sales of the higher-margin AIHL assay.
- **R&D spend:** Grant income is received as development costs are incurred. We anticipate FY'20 to include the final portion of the Innovate grants. The balance of underlying R&D costs (ca.£3.0m) is expected to be maintained in the forecast period.
- **Finance costs:** Interest is being accrued on the GHIF and BGF loans, until repayment of all interest in FY'22.

Profit & Loss account						
Year-end Jun (£000)	2017	2018	2019	2020E	2021E	2022E
Product sales	0	127	961	2,343	4,923	9,215
Grant-funded services	2,619	1,811	1,401	649	0	0
Discontinued ops.	3,166	0	0	0	0	0
Sales	5,785	1,938	2,362	2,992	4,923	9,215
COGS	-2,998	-55	-177	-1,434	-1,871	-3,502
Gross profit	2,787	1,883	2,185	1,558	3,052	5,713
Gross margin	48.2%	97.2%	92.5%	52.1%	62.0%	62.0%
SG&A	-2,513	-1,979	-1,708	-1,708	-1,477	-1,843
Share-based costs	-101	12	-49	-74	-103	-144
R&D	-5,086	-5,180	-4,877	-4,048	-3,400	-3,060
Other income	0	0	0	0	0	0
EBITDA	-3,841	-4,185	-4,351	-4,173	-1,830	763
Depreciation	-216	-182	-98	-98	-98	-98
Amortisation	-856	-897	0	0	0	0
Underlying EBIT	-4,913	-5,264	-4,449	-4,271	-1,928	665
Exceptional items	-2,379	-2,111	439	0	0	0
Statutory EBIT	-7,292	-7,375	-4,010	-4,271	-1,928	665
Net financials	-195	-413	-508	-730	-755	-763
Underlying PBT	-5,417	-5,782	-5,002	-5,001	-2,683	-98
Extraordinary items	0	0	0	0	0	0
Reported PBT	-7,487	-7,788	-4,518	-5,001	-2,683	-98
Tax payable/credit	1,051	758	882	732	615	553
Tax rate	14%	10%	20%	15%	23%	567%
Discontinue ops.	0	1,063	0	0	0	0
Underlying net income	-4,366	-5,024	-4,120	-4,269	-2,068	456
Statutory net income	-6,436	-5,967	-3,636	-4,269	-2,068	456
Ordinary 1.5p shares						
Period-end (m)	18.69	18.78	34.00	34.87	35.37	35.37
Weighted average (m)	18.47	18.69	26.04	34.44	35.12	35.37
Fully-diluted (m)	20.53	20.63	26.12	34.52	35.20	35.45
Underlying basic EPS (p)	-23.6	-26.9	-15.8	-12.4	-5.9	1.3
Statutory basic EPS (p)	-34.9	-31.9	-14.0	-12.4	-5.9	1.3
Underlying fully-dil. EPS (p)	-21.3	-24.3	-15.8	-12.4	-5.9	1.3
Statutory fully-dil. EPS (p)	-31.4	-28.9	-13.9	-12.4	-5.9	1.3
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

- **Tax credits**: Some of GDR's R&D investment attracts tax credits from HMRC. The carrying balance of R&D tax credits was £1.0m in fiscal 2019, which is expected to be received in fiscal 2020. Going forward, the tax credit is likely to fall due to a greater mix of non-qualifying costs.
- **Convertible bond:** The collaborative funding agreement for a total of $8.0m initiated in July 2014 (terms amended in July 2016 and November 2018) with GHIF is treated as long-term debt. It is due to mature in December 2023.
- **Convertible loan note:** A £2.5m unsecured convertible loan was issued by BGF as part of the November 2019 financing package, and is also treated as long-term debt. It is due to mature in June 2025.
- **Fiscal 2019 financing:** In November 2018, the company increased its funding through a combination of debt and equity, raising a total of £5.6m (net). BGF contributed to the total via a loan of £2.5m and by taking a £1.0m equity stake through the Placing. The Placing shares were admitted to AIM on 10 December 2018.
- **Net cash:** The net cash/(debt) position is composed of gross cash on the balance sheet, offset by long-term debt of ca.£9.0m from the GHIF and BGF. Working capital requirements, earn-out from the sale of Visible Genomics and accrual of the finance costs result in net debt of -£6.9m at the end of June 2020, on our estimates.

Balance sheet						
@30 Jun (£000)	2017	2018	2019	2020E	2021E	2022E
Shareholders' funds	3,441	-2,437	-2,478	-6,617	-8,609	-8,154
Cumulated goodwill	0	0	0	0	0	0
Total equity	3,441	-2,437	-2,478	-6,617	-8,609	-8,154
Share capital	280	282	510	523	531	531
Reserves	3,161	-2,719	-2,988	-7,140	-9,140	-8,684
Provisions/liabilities	1,250	1,250	0	0	0	0
Deferred tax	0	0	0	0	0	0
Long-term loans	5,199	5,625	8,518	8,994	9,497	7,782
Short-term debt	0	0	0	0	0	0
less: Cash	5,129	3,529	5,184	2,046	1,269	1,122
less: Deposits	0	0	0	0	0	0
less: Non-core invests.	0	512	259	153	0	0
Invested capital	4,761	397	597	178	-381	-1,493
Fixed assets	568	165	164	187	241	332
Intangible assets	3,038	0	0	0	0	0
Inventories	444	171	123	156	-34	-63
Trade debtors	*1,376*	*182*	*65*	*82*	*135*	*54*
Other debtors	*278*	*369*	*491*	*501*	*526*	*552*
Tax liability/credit	*1,213*	*980*	*971*	*732*	*615*	*553*
Trade creditors	*-816*	*-392*	*-402*	*-422*	*-485*	*-609*
Other creditors	*-1,340*	*-1,078*	*-727*	*-1,058*	*-1,379*	*-2,313*
Debtors less creditors	711	61	310	-165	-589	-1,763
Invested capital	4,761	397	597	178	-381	-1,493
Net cash/(debt)	-70	-2,096	-3,334	-6,948	-8,228	-6,660

Source: Hardman & Co Life Sciences Research

Cashflow

- **Cash burn:** The average monthly cash burn in 2019 was £383k. Within completion of in-country studies and the development phase of the AIHL programme, and with tight control of administration costs, this is forecast to ease back to just below £345k per month in fiscal 2020, and to fall rapidly thereafter.
- **Deferred consideration:** In 2019, GDR settled a deferred consideration of £1.25m, payable in shares, in relation to the acquisition of Visible Genomics Ltd in 2010. As part of the 2019 fund raise, 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 would be receivable as shares 12 months from the share admissions; and 200,000 further shares would be received 36 months from the share admissions. There is approximately £0.3m remaining to be paid.

Cashflow						
Year-end Jun (£000)	2017	2018	2019	2020E	2021E	2022E
Underlying EBIT	-4,913	-5,264	-4,449	-4,271	-1,928	665
Depreciation	216	182	98	98	98	98
Amortisation	856	897	0	0	0	0
Inventories	*-242*	*241*	*-12*	*-33*	*189*	*29*
Receivables	*1,266*	*4*	*148*	*-17*	*-53*	*82*
Payables	*284*	*-547*	*-346*	*20*	*63*	*123*
Change in working capital	1,308	-302	-210	-30	200	234
Exceptionals/provisions	0	0	57	106	153	0
Disposals	0	864	0	0	0	0
Other	-162	-132	-89	0	0	0
Company op. cashflow	-2,594	-3,767	-4,601	-4,130	-1,527	1,142
Net interest	14	13	18	36	17	-1,715
Tax paid/received	757	1,220	980	971	732	615
Operational cashflow	-1,823	-2,534	-3,603	-3,122	-779	42
Capital expenditure	-70	-24	-97	-121	-152	-189
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	-1,893	-2,558	-3,700	-3,244	-930	-147
Dividends	0	0	0	0	0	0
Acquisitions	0	0	-300	-130	-75	0
Disposals	0	957	57	106	153	0
Other investments	0	0	0	0	0	0
Cashflow after invests.	-1,893	-1,601	-3,943	-3,268	-852	-147
Share repurchases	0	0	0	0	0	0
Capital increase	6,023	0	3,243	130	75	0
Currency effect	-323	-425	-2,904	0	0	0
Borrowings acquired	0	0	2,366	-476	-503	1,715
Change in net debt	3,807	-2,026	-1,238	-3,614	-1,280	1,568
Hardman FCF/share (p)	-9.9	-13.6	-13.8	-9.1	-2.2	0.1
Opening net cash	-3,877	-70	-2,096	-3,334	-6,948	-8,228
Closing net cash	-70	-2,096	-3,334	-6,948	-8,228	-6,660

Source: Hardman & Co Life Sciences Research

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

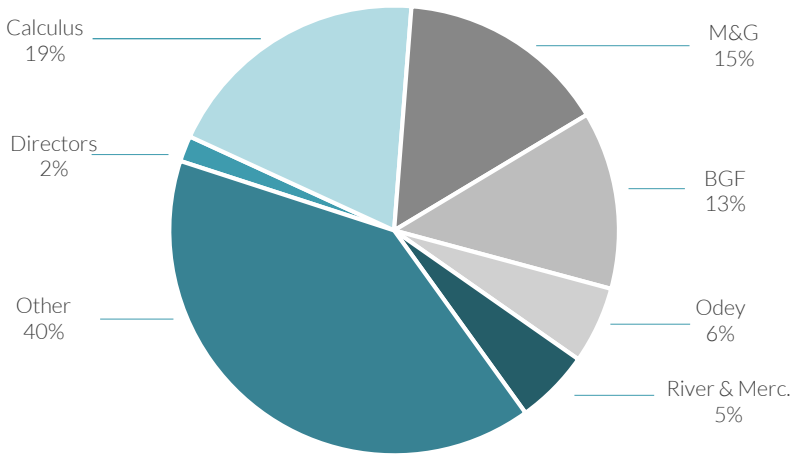
Position	Name	Nominations	Remuneration	Audit
Chairman	Ian Gilham	C	C	C
Chief Executive Officer	David Budd			
Chief Financial Officer	Matthew Fowler			
Non-executive director	Tom Lindsay	M	M	M
Non-executive director	Chris Yates	M	M	M

M = member; C = chair
Source: Company reports

Share capital

On 24 October 2019, there were 34,000,506 Ordinary shares in issue and 1,942,252 share options outstanding.

Shareholders



Source: genedrive plc

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