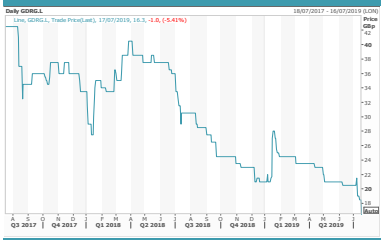
Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data	
EPIC/TKR	GDR
Price (p)	18.5
12m High (p)	31.9
12m Low (p)	16.3
Shares (m)	34.0
Mkt Cap (£m)	6.3
EV (£m)	9.7
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
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	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 prequalification
Oct'19	Fiscal 2019 results

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GENEDRIVE PLC

Hepatitis C market frustrations

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 in the diagnosis of infectious diseases. Rapid analysis of patient samples greatly aids clinical and public health decision-making, particularly in remote areas of developing countries. However, despite the clear utility of the HCV-ID kit for diagnosis of hepatitis C virus (HCV) infections, the frustrating nature of the HCV market has led to little HCV-ID sales growth in 2019.

- **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, tuberculosis, Bio-threats, and Antibiotic-Induced Hearing Loss (AIHL), divesting its Services unit in June 2018.
- **Trading update:** Group sales grew 25.6% to £2.4m (£1.9m) in the 12 months to June, the first full year without the services business. The mix of group sales was considerably more balanced than the prior period, with product sales of ca.£1.0m (£0.1m), which included ca.£0.9m from the US Department of Defense (DoD).
- **HCV product:** Management has been very open on the difficulties encountered in commercialisation of the HCV-ID kit. The process for obtaining in-country registrations has been slower than anticipated, and uptake in registered countries has been frustrated by low demand due to a lack of funding for HCV drugs.
- **Risks:** Genedrive platform technology has been validated by the CE marking of its assay for detection of HCV infection and by recurrent work from the US DoD. The main risks are commercial, given that it often takes time for new technologies to be adopted. 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 should market factors improve, the HCV-ID test has excellent potential. With strong partners being signed for different countries, such as the NHS (UK), and several product lines in development, GDR has a solid growth strategy in place.

Financial summary and valuation

Year-end Jun (£000)	2016	2017	2018	2019E	2020E	2021E
Group sales	5,063	5,785	1,938	2,434	3,040	5,089
Underlying EBIT	-5,259	-4,812	-5,276	-4,559	-4,177	-1,871
Reported EBIT	-5,426	-7,292	-7,375	-3,944	-4,207	-1,914
Underlying PBT	-5,828	-5,316	-5,794	-5,171	-5,019	-2,737
Statutory PBT	-6,497	-7,487	-7,788	-4,232	-5,050	-2,780
Underlying EPS (p)	-49.8	-23.1	-26.9	-16.3	-13.0	-6.6
Statutory EPS (p)	-56.2	-34.9	-31.9	-12.9	-13.1	-6.7
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	-3,877	-70	-2,096	-3,370	-6,740	-8,033
Capital increases	0	6,023	0	3,318	0	0
P/E (x)	-0.4	-0.8	-0.7	-1.1	-1.4	-2.8
EV/sales (x)	1.9	1.7	5.0	4.0	3.2	1.9

Source: Hardman & Co Life Sciences Research

Trading statement

Operational progress

HCV commercialisation frustrated by external factors

Despite the clear unmet need for a rapid and accurate point-of-care 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 South Africa in 4Q'18, GDR has achieved registrations in 12 countries - a shortfall on the target of 30 registrations by fiscal 2019 year-end. Despite the HCV-ID kit's CE mark status, individual countries have required tailored registration dossiers that include data specific to national HCV epidemiology and healthcare systems. As a result, GDR's launch strategy is around 12 months behind schedule.

In addition, uptake, once registered, has been slow. The initial focus has been the private laboratory market, with Sysmex covering selected countries in Africa and SE Asia. However, with a lack of funding for antiviral drugs for HCV patients in many regions, demand for HCV diagnostics has also been limited. Discussions for inclusion of HCV-ID in government and other not-for-profit programmes are ongoing, but these can be notoriously slow to deliver.

In time, both registrations and uptake should be boosted by World Health Organisation (WHO) pre-qualification, which GDR is expected to achieve in the current half-year period. The WHO Prequalification of Medicines Programme (PQP) authorises a list of priority products, used by procurement agencies (e.g. UNITAID) and countries, to guide bulk purchase. There has been a delay to the clinical trial part of this process due to a lack of availability of the low viral load samples specified by the protocol (for measurement of sensitivity). The protocol has now been revised to include samples more reflective of the real-world situation.

DoD

As mentioned at the interim stage, GDR received its first commercial orders of product related to the US DoD in FY'19 - excellent validation of GDR's capabilities in gene-based diagnostics outside the infectious diseases area. Some isolated supplier issues meant that the fulfilment of the second order has been delayed into FY'20. Management remains confident that this has been resolved – and is also confident of further orders.

New products funded by Innovate UK

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

AIHL screening funded by NIHR

Development of the assay for screening against AIHL, funded by the National Institute for Health Research (NIHR), also progressed well in the period, with test results being achieved more rapidly than originally expected. The stated aim at the time the project was initiated was to deliver results within one hour; to be achieving results within one hour is very promising, given that time is of the essence in being able to make clinical decisions for treatment of acute infections in newborns. The process towards CE marking is now underway. The implementation phase of the project, whereby in-hospital trials can be initiated, is therefore expected to start this autumn.

Financials and investment case

The trading statement, published on 9 July, has provided sales and product mix numbers, and the cash position for the year. Group sales in the 12 months to June 2019 were 4% lighter than forecast, at £2.4m, due in part to the delay in fulfilling the second DoD order, but this does represent a solid 25.6% increase on FY'18 sales. We had not expected further revenue from the HCV-ID kit in 2H'19 as a consequence of the interim results; therefore, the additional delays to commercialisation have not impacted our model in 2019.

Grant income of £1.4m in 2019 was as forecast at the interim period, with GDR accruing the NIHR and Innovate UK grants between FY'18 and FY'20. A reallocation of a small portion of DoD income from grants to sales is shown in the table below ('actual vs. forecasts') as the £0.1m difference between forecast and actual grant income in 2019.

FY'19 trading statement – actual vs. forecasts

Year-end June (£000)	2018 actual	2019 actual	Growth %	2019 forecast	Delta Δ
Product sales*	127.0	1,033.9	714.1%	1,015.0	2%
Grants*	1,811.0	1,400.0	-22.7%	1,515.0	-8%
Group sales	**1,938.0**	**2,433.9**	**25.6%**	**2,529.0**	**-4%**
EPS (p)	-26.9	-16.3	-39.4%	-14.8	9%
Cash*	3,529.0	5,208.4	47.6%	4,788.00	8%
Net cash/(debt)	-2,096.0	-3,369.9	60.8%	-3,765.00	-12%

**Reported in July trading statement*
Source: Hardman & Co Life Sciences Research

Changes to forecasts

Changes to forecasts

Year-end Jun	2019E			2020E			2021E		
(£000)	Old	New	Δ	Old	New	Δ	Old	New	Δ
Product sales	1,015	1,034	2%	3,119	2,390	-23%	6,948	5,089	-23%
Grants	1,515	1,400	-8%	936	650	-31%	67	0	-31%
Group sales	2,529	2,434	-4%	4,055	3,040	-25%	7,014	5,089	-25%
COGS	-400	-385	-4%	-1,950	-1,434	-26%	-2,455	-2,035	-26%
R&D	-4,800	-4,800	0%	-3,300	-4,050	23%	-2,835	-3,398	23%
SG&A	-1,764	-1,808	3%	-1,784	-1,733	-3%	-1,929	-1,527	-3%
Underl. EBIT	-4,435	-4,559	3%	-2,979	-4,177	40%	-205	-1,871	40%
Pre-tax profit	-5,046	-5,171	2%	-3,867	-5,019	30%	-1,112	-2,737	30%
Underl. EPS (p)	-14.8	-16.3	10%	-9.3	-13.0	40%	-1.5	-6.6	40%
Ch. working cap	-400	119	-	-158	119	-	-246	52	-
Net cash/(debt)	-3,765	-3,370	-10%	-5,922	-6,740	14%	-5,741	-8,033	14%

Source: Hardman & Co Life Sciences Research

Fiscal 2019

The closing cash position of £5.2m was 8% above our expectations. Without further visibility on the P&L in FY'19, we have assumed that working capital control was primarily responsible for cash preservation in the period; given that the majority of GDR's trade debtors are public organisations and therefore reliable in reimbursement of grant-qualifying costs, we have reduced debtors in our balance sheet model, lifting cash to the reported £5.2m in 2019.

Fiscal 2020-21

We have reduced our sales forecasts for 2020 and 2021 to reflect the 12-month delay to commercialisation of, and for a reduction in demand for, the HCV-ID test. Growth in private sales of the HCV-ID kit is expected to begin in 1H'20, but at a lower rate than previously anticipated. At this point, no revenue from the new HCV

sample preparation device, the TB assay and the AIHL project have been included in our two-year forecasts, which are, therefore, conservative. We have also taken a more conservative view of gross margins in 2021 to reflect the lack of volume from the higher-margin HCV-ID tests. This drops straight through to drive an increase in underlying EBIT losses in 2020 and 2021.

The availability of an accurate, point-of-need diagnostic remains the first step in tackling HCV infection, which causes disease in an estimated 71 million people globally. Despite the existence of curative antiviral drugs, lack of diagnosis and poor access to these medicines results in annual mortality rates of almost 1% of those infected. HCV-ID remains a very valuable product, and being the first-to-market point-of-need test, management seems reasonable in its expectation of an increase in demand going forward, subject to funding for treatment becoming available in the market. Forecasts will be revisited with the full set of numbers in October.

genedrive plc news flow – updated timelines

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	Jul'19–Jun'20	*Target to reach regulatory approvals in 18 additional new countries
FY'20E	Jul'19–Jun'20	*Additional distributer agreements expected
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
FY'20E		*HCV-ID launch in India
FY'20E	2019-2020	*First release and launch of Genedrive Connect app.
2H'21E	2021	Data from REACH trial

** Updated since 1H'19 results*

Source: Hardman & Co Life Sciences Research

Financial summary

- **Product sales:** The rate of growth in our two-year sales forecasts is being driven by the DoD, Genedrive and HCV-ID. Our assumptions include a time lag of up to 12 months from launch of HCV-ID in new countries to sales impact.
- **Gross margin:** Beyond the forecast period, gross margins should pick up rapidly as HCV-ID volumes increase.
- **R&D spend:** Grant income is received as development costs are incurred. The balance of underlying R&D costs (ca.£3.4m) is expected to be maintained in the near term.
- **1H'19 financing**: In November, 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 loan of £2.5m and a £1.0m equity stake in the Placing.
- **Net cash:** The net cash/(debt) position at 30 June 2019 was ca.-£3.4m, composed of cash of £5.2m and offset by estimated long-term debt (including convertible bond and accrual of finance costs) of £8.6m.

Financial summary

Year-end Jun (£000)	2016	2017	2018	2019E	2020E	2021E
Profit & Loss						
Product sales	0	0	127	1,034	2,390	5,089
Grants	1,906	2,619	1,811	1,400	650	0
Discontinued ops.	3,157	3,166	0	0	0	0
Group sales	**5,063**	**5,785**	**1,938**	**2,434**	**3,040**	**5,089**
COGS	-3,285	-2,998	-55	-385	-1,434	-2,035
SG&A	-2,201	-2,513	-1,979	-1,808	-1,733	-1,527
R&D	-4,836	-5,086	-5,180	-4,800	-4,050	-3,398
Underlying EBIT	-5,259	-4,812	-5,276	-4,559	-4,177	-1,871
Share-based costs	-167	-101	12	-20	-31	-43
Reported EBIT	-5,426	-7,292	-7,375	-3,944	-4,207	-1,914
Net financials	-1,071	-195	-413	-287	-843	-866
Underlying PBT	-5,828	-5,316	-5,794	-5,171	-5,019	-2,737
Exceptionals	0	0	0	0	0	0
Tax payable/credit	582	1,051	758	720	608	510
Underlying net income	-5,246	-4,265	-5,036	-4,451	-4,412	-2,227
Underlying basic EPS (p)	-49.81	-23.10	-26.9	-16.3	-13.0	-6.6
Statutory basic EPS (p)	-56.16	-34.85	-31.9	-12.9	-13.1	-6.7
Balance sheet						
Share capital	158	280	282	510	510	510
Reserves	3,595	3,161	-2,719	-3,141	-7,583	-9,853
Provisions/liabilities	1,250	1,250	1,250	0	0	0
Debt	4,991	5,199	5,625	8,578	9,059	9,593
less: Cash	1,114	5,129	3,529	5,208	2,319	1,560
Invested capital	8,880	4,761	397	399	-674	-1,650
Net cash/(debt)	**-3,877**	**-70**	**-2,096**	**-3,370**	**-6,740**	**-8,033**
Cashflow						
Underlying EBIT	-5,259	-4,812	-5,276	-4,559	-4,177	-1,871
Change in working capital	44	1,308	-302	119	119	52
Company op. cashflow	-4,192	-2,594	-3,767	-4,519	-4,002	-1,764
Capital expenditure	-164	-70	-24	-100	-125	-156
Capital increase	0	6,023	0	3,318	0	0
Change in net debt	-4,780	3,807	-2,026	-1,274	-3,370	-1,293
OCFPS (p)	-35.9	-9.9	-13.6	-12.9	-9.5	-3.3

OCFPS: Operating Cash Flow Per Share
Source: Hardman & Co Life Sciences Research

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