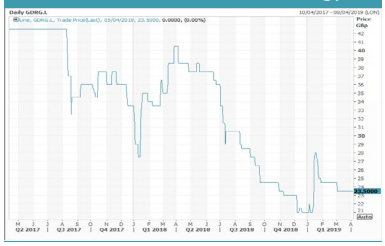
Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data	
EPIC/TKR	GDR
Price (p)	23.5
12m High (p)	42.0
12m Low (p)	18.0
Shares (m)	34.0
Mkt Cap (£m)	8.0
EV (£m)	10.5
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	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

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GENEDRIVE PLC

First commercial sales in new focus area: bio-threats

genedrive plc (GDR) is a commercial-stage company focused on point-of-care (PoC) 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. Strategic progress in 2018 generated the first product sales in hepatitis C and in 1H'19 has delivered the first product sales in the Bio-threat market to the US Department of Defense (DoD).

- **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.

- **Interim results:** The mix of group sales in the period changed significantly vs. 1H'18, with a considerably greater contribution from product sales in 1H'19. 1H'19 was the first reporting period to include commercial product sales from the DoD, and it was the first full period without the Services business.

- **Sales:** Product sales (consisting of Genedrive unit, HCV assay, and DoD sales in 1H'19) contributed £0.8m (£0.0m) to the £1.5m gross income in the six-month period. This included the first, unanticipated, commercial order from the DoD, of $0.9m/£0.7m. Combined, product sales were in line with forecasts.

- **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 Jun (£000)	2016	2017	2018	2019E	2020E	2021E
Group sales	5,063	5,785	1,938	2,529	4,055	7,014
Underlying EBIT	-5,259	-4,812	-5,276	-4,435	-2,979	-205
Reported EBIT	-5,426	-7,292	-7,375	-3,820	-3,010	-247
Underlying PBT	-5,828	-5,316	-5,794	-5,046	-3,867	-1,112
Statutory PBT	-6,497	-7,487	-7,788	-4,107	-3,897	-1,155
Underlying EPS (p)	-49.8	-23.1	-26.9	-14.8	-9.3	-1.5
Statutory EPS (p)	-56.2	-34.9	-31.9	-11.4	-9.4	-1.6
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	-3,877	-70	-2,096	-3,765	-5,922	-5,741
Capital increases	0	6,023	0	3,318	0	0
P/E (x)	-0.5	-1.0	-0.9	-1.6	-2.5	-15.5
EV/sales (x)	2.1	1.8	5.4	4.2	2.6	1.5

Source: Hardman & Co Life Sciences Research

Interim results

Financial highlights

- **Group sales:** As announced by the company in its January trading statement, the total of product sales and grant income grew 15.6% in the six months to December 2019 to £1.49m (£1.29m). 1H'19 was the first period without the Services business, which was divested in June 2018.
- **Product sales:** 1H'19 group sales, at £0.80m (£0.0m), were mostly composed of the first commercial order of $0.9m/£0.7m from the US DoD, which was announced in the January trading update and that we had not forecast. Slower than anticipated growth in product sales relating to HCV brought product sales for the period in line with forecasts.
- **HCV product sales:** In 1H'19, sales of Genedrive units and HCV-ID kits were broadly similar to the £0.13m level reported for the three months following launch late in fiscal 2018. However, whereas the contribution last year benefited from some early pipeline orders, those in 1H'19 were hampered by the unanticipated delays of about nine months in commercialisation processes.
- **EBIT:** Operating losses improved 2.9% in the first half to -£2.0m (-£2.1m) through admin cost savings, partially related to disposal of the services business. R&D costs were 14% above the forecast level, reflecting good progress in grant-funded programmes, including the antibiotic-related hearing loss programme funded by the NIHR and continued investment in Genedrive.
- **Net cash/(debt):** GDR's closing cash position was £5.8m, despite the £1.0m R&D tax credit being delayed to 2H'19, reflecting the debt and equity financing in November 2018 that raised a total of £5.6m (net). Retranslation of the GHIF bond benefited from forex, resulting in a lower-than-forecast net debt of -£2.5m.

Actual vs. our forecasts

Interim sales performance was as expected given the trading statement in January (which provided group sales and cash position results). The product mix was different to expectations because of the first commercial order from the DoD for $0.9m/£0.7m, but it was counterbalanced by slower-than-anticipated in-country launch processes.

Grant income was lighter than anticipated, which, combined with R&D spend above forecasts, dropped through to generate an EBIT loss that was 9% greater than expected.

1H'19 results – actual vs. forecasts

Year-end Jun 000s	1H'18 actual	1H'19 actual	Growth %	1H'19 forecast	Delta Δ
Product sales	0	798	N/A	837	-5%
Grants income	1,287	690	-46.4%	663	4%
Discontinued ops.	1,346	0	N/A	0	N/A
Group sales	2,633	1,488	N/A	1500*	-1%
COGS	-1,286	-150	-88.3%	-300	-100%
R&D	-2,233	-2,496	11.8%	-2150	14%
SG&A	-1,200	-868	-27.7%	-900	-4%
EBIT (underlying)	-2,086	-2,026	-2.9%	-1850	9%
Pre-tax profit	-2,158	-2,501	15.9%	-2229	11%
EPS (p)	-8.8	-10.7	22.0%	-8	21%
Net cash/(debt)	-726	-2,510	245.7%	-2613	-4%

**As reported in January trading statement, along with cash position*
Source: Hardman & Co Life Sciences Research

Operational progress

Following the transition in fiscal 2018 from a diagnostics service provider to a focused developer of molecular diagnostics with first commercial sales, GDR is in the commercialisation phase for its HCV and Bio-threats assays. It is also developing a menu of additional diagnostic assays that can be performed in PoC settings on its Genedrive device, which received CE marking in September 2017. GDR's foremost aim is to deliver its three priority assays to the market in the medium term, which we estimate to be on a three-year time horizon. This would suggest not only an established commercial footprint, but also material revenues and delivery of shareholder value, by 2022. We provide full detail in our report '*Accelerating into fiscal 2019 with first sales*', published 10 December 2018[1], summarising the progress in the six months to December 2018 in this note.

Key features

HCV-ID kits

For initial market entry, GDR is focusing on private laboratories. To this end, the company is engaging with distributors that specialise in relevant markets and have existing relationships with KOLS. It successfully signed exclusive distribution deals with Sysmex covering selected countries in Africa and SE Asia, and with Arkray for India, during 2018. Following the initial launch in South Africa by Sysmex, the first orders were received in 2H'18.

GDR's stated aim is to achieve registration/approval in 30 countries by the end of the current fiscal year, and it successfully achieved four of these in 1H'19, including two priority countries. Unfortunately, however, the registration and evaluation processes have been slower, by approximately nine months, than anticipated in 1H'19, which has negatively affected revenue growth in the period. Many territories are requiring in-country studies to demonstrate accuracy and reliability in specific settings, an unexpected requirement for full registration. This follows separate delays to some in-country registrations in 2018 that were caused by the disposal of the Services division, and which required a change in the name of GDR's trading entity.

The existing distribution agreements, registrations and dialogue with public health bodies for national registrations is encouraging, representing good progress towards accessing the multi-million-dollar HCV diagnosis market on a revised timeline.

DoD commercialisation phase

Following successful completion of the development phase of the Bio-threat programme with the DoD in FY'18 (a funded development programme allocated to 'grants' in our model), the collaboration has advanced to a commercial phase. The first commercial order was placed and invoiced in 2Q'19 (allocated to product sales), which is excellent validation of the work undertaken and is encouraging for future orders. This order was unforeseen, and future orders could be lumpy. However, another order has been received post-period, in 2H1'9, and therefore GDR management is confident of future orders as the product is adopted by customers within the DoD.

[1] https://www.hardmanandco.com/research/corporate-research/accelerating-into-fiscal-2019-with-first-sales/

Financials and investment case

Changes to forecasts

Expected news flow – updated

Aforementioned delays to the registration process, including the unanticipated need for in-country studies, has delayed the commercialisation of HCV-ID. We have updated the table below, published in our FY'18 note, to reflect the operating performance in 1H'19.

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'19e	Dec'18 – Jun'19	Target to reach regulatory approvals in 18 additional new countries
FY'19e	Dec'18 – Jun'19	Additional distributer agreements expected
2H'19 – 1H'20e	Jan'19 – Oct'19	WHO decision on HCV-ID prequalification
2H'19 – 1H'20e	Jan'19 – Oct'19	Top-line results from 'intended setting' studies
FY'19e		HCV-ID launch in India
FY'19/FY'20e	2019	First release and launch of Genedrive Connect app.
2H'21e	2021	Data from REACH trial

** Updated since the FY'18 results*

Source: Hardman & Co Life Sciences Research

Revised numbers

We have reduced our sales forecasts for 2019 and 2020 to reflect the nine-month delay to commercialisation of the HCV-ID test. Private sales of the HCV-ID kit are not now expected until 1H'20, but solid growth of 27% in group sales is expected in FY'19.

Grant income is reimbursed as GDR provides invoices against development programmes, and is thus difficult to accurately forecast; however, we expect that the bulk of the £2.25m from existing NIHR and Innovate UK grants will be received in FY'19.

Changes to forecasts

Year-end Jun	2019E			2020E			2021E		
£000	Old	New	Δ	Old	New	Δ	Old	New	Δ
Product sales	1,617	1,015	-37%	4,063	3,119	-23%	7,005	6,948	-1%
Grants	1,864	1,515	-19%	752	936	25%	57	67	17%
Group Sales	3,481	2,529	-27%	4,814	4,055	-16%	7,062	7,014	-1%
COGS	-830	-400	-52%	-2,640	-1,950	-26%	-4,615	-2,455	-47%
R&D	-4,150	-4,800	16%	-3,796	-3,300	-13%	-3,416	-2,835	-17%
SG&A	-2,088	-1,764	-16%	-1,204	-1,784	48%	-1,942	-1,929	-1%
Underlying EBIT	-3,587	-4,435	24%	-2,825	-2,979	5%	-2,912	-205	-93%
Pre-tax profit	-4,193	-5,046	20%	-3,436	-3,867	13%	-3,548	-1,112	-69%
EPS (p)	-11.9	-14.8	25%	-7.3	-9.3	27%	-7.8	-1.5	-80%
Net cash/(debt)	-3,941	-3,765	-4%	-5,597	-5,922	6%	-8,061	-5,741	-29%

Source: Hardman & Co Life Sciences Research

Profit & Loss

- **Genedrive sales:** The rate of growth in our sales forecasts is being driven by the DoD in the near term, and by Genedrive and infectious disease assay sales in the mid to long term. Our assumptions include a time lag of up to 12 months from launch of HCV-ID in new countries to sales impact.
- **Other programmes:** Because of the lack of visibility on the future of the DoD partnership, we have assumed that this revenue stream will continue at similar levels to FY'19. As the AIHL project is in its initial development phase, we have not included this revenue stream in forecasts. Sales forecasts, therefore, are conservative.
- **Gross margin:** With the increasing contribution of Genedrive sales in the near term, gross margins are expected to narrow. However, as Genedrive volumes increase beyond the initial forecast period, margins will pick up rapidly.
- **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 Jun (£000)	2016	2017	2018	2019E	2020E	2021E
Product sales	0	0	127	1,015	3,119	6,948
Grants/Grant-funded services	1,906	2,619	1,811	1,515	936	67
Discontinued ops.	3,157	3,166	0	0	0	0
Sales	**5,063**	**5,785**	**1,938**	**2,529**	**4,055**	**7,014**
COGS	-3,285	-2,998	-55	-400	-1,950	-2,455
Gross profit	1,778	2,787	1,883	2,129	2,105	4,559
Gross margin	35.1%	48.2%	97.2%	84.2%	51.9%	65.0%
SG&A	-2,201	-2,513	-1,979	-1,764	-1,784	-1,929
R&D	-4,836	-5,086	-5,180	-4,800	-3,300	-2,835
Licensing/Royalties	0	0	0	0	0	0
EBITDA	-6,433	-3,740	-4,197	-4,380	-2,924	-150
Depreciation	-240	-216	-182	-55	-55	-55
Amortisation	-934	-856	-897	0	0	0
Underlying EBIT	**-5,259**	**-4,812**	**-5,276**	**-4,435**	**-2,979**	**-205**
Share-based costs	-167	-101	12	-20	-31	-43
Exceptional items	0	-2,379	-2,111	635	0	0
Statutory EBIT	-5,426	-7,292	-7,375	-3,820	-3,010	-247
Net financials	-1,071	-195	-413	-287	-887	-907
Underlying pre-tax profit	**-5,828**	**-5,316**	**-5,794**	**-5,046**	**-3,867**	**-1,112**
Extraordinary items	0	0	0	0	0	0
Reported pre-tax profit	-6,497	-7,487	-7,788	-4,107	-3,897	-1,155
Tax liability/credit	582	1,051	758	1,008	693	595
Tax rate	9%	14%	10%	25%	18%	52%
Discontinued ops.	0	0	1,063	0	0	0
Underlying net income	**-5,246**	**-4,265**	**-5,036**	**-4,038**	**-3,174**	**-516**
Statutory net income	-5,915	-6,436	-5,967	-3,099	-3,204	-559
Ordinary 1.5p shares:						
Period-end (m)	10.57	18.69	18.78	34.00	34.00	34.00
Weighted average (m)	10.53	18.47	18.69	27.28	34.00	34.00
Fully-diluted (m)	12.49	20.53	20.63	29.22	35.94	35.94
Underlying basic EPS (p)	**-49.8**	**-23.1**	**-26.9**	**-14.8**	**-9.3**	**-1.5**
Statutory basic EPS (p)	-56.2	-34.9	-31.9	-11.4	-9.4	-1.6
Underlying fully-dil. EPS (p)	-42.0	-20.8	-24.4	-13.8	-8.8	-1.4
Statutory fully-dil. EPS (p)	-47.4	-31.4	-28.9	-10.6	-8.9	-1.6
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

Balance sheet

Total £6.0m raised in early 1H'19…

…through a Placing and debt funding

- **Net cash:** The net cash/(debt) position at 31 December 2018 was -£2.5m, composed of cash of £5.8m, offset by long-term debt (convertible bond) of £8.4m. Working capital requirements and accrual of the finance costs result in forecast net debt of -£3.8m at the end of June 2019.
- **Tax credits:** Some of GDR's R&D investment attracts tax credits from HMRC. In FY'18, R&D tax credits were £1.0m, which are due to be received in 2H'19. 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 £0.34m is currently sitting on 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 Global Health Investment Fund (GHIF) is treated as long-term debt.
- **Loan note:** £2.5m unsecured convertible loan issued by BGF as part of the November financing (see below) is also treated as long-term debt.
- **1H'19 financing**: In November, the company increased its funding through a combination of debt and equity, raising a total of £5.6m (net). The British Growth Fund (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.

Balance sheet						
@31 Jun (£000)	2016	2017	2018	2019E	2020E	2021E
Shareholders' funds	3,753	3,441	-2,437	-1,818	-5,022	-5,581
Cumulated goodwill	0	0	0	0	0	0
Total equity	3,753	3,441	-2,437	-1,818	-5,022	-5,581
Share capital	158	280	282	510	510	510
Reserves	3,595	3,161	-2,719	-2,328	-5,532	-6,091
Provisions/liabilities	1,250	1,250	1,250	0	0	0
	0	0	0	0	0	0
Long-term loans	4,991	5,199	5,625	8,552	9,481	10,247
Short-term debt	0	0	0	0	0	0
less: Cash	1,114	5,129	3,529	4,788	3,559	4,506
less: Deposits	0	0	0	0	0	0
less: Non-core invests.	0	0	512	340	340	340
Invested capital	**8,880**	**4,761**	**397**	**1,607**	**561**	**-181**
Fixed assets	713	568	165	210	280	381
Intangible assets	6,273	3,038	0	0	0	0
Inventories	202	444	171	373	448	485
Trade debtors	*2,290*	*1,376*	*182*	*238*	*381*	*659*
Other debtors	*507*	*278*	*369*	*376*	*384*	*403*
Tax credit/liability	*757*	*1,213*	*980*	*1,008*	*693*	*595*
Trade creditors	*-914*	*-816*	*-392*	*-400*	*-460*	*-529*
Other creditors	*-948*	*-1,340*	*-1,078*	*-198*	*-1,165*	*-2,176*
Debtors less creditors	1,692	711	61	1,024	-168	-1,047
Invested capital	**8,880**	**4,761**	**397**	**1,607**	**561**	**-181**
Net cash/(debt)	**-3,877**	**-70**	**-2,096**	**-3,765**	**-5,922**	**-5,741**

Source: Hardman & Co Life Sciences Research

Cashflow

- **Cash burn:** The current monthly cash burn is ca.£300k. Despite increased R&D expenditure associated with the need to perform in-country studies, tight control of costs is forecast to see this ease back to just below £170k pcm in fiscal 2020.
- **Deferred consideration:** In 1H'19, a deferred consideration of £1.25m, payable in shares, became due as a result of the acquisition of Visible Genomics Ltd in 2010. In 1H'19, 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 Jun (£000)	2016	2017	2018	2019E	2020E	2021E
Underlying EBIT	-5,259	-4,812	-5,276	-4,435	-2,979	-205
Depreciation	240	216	182	55	55	55
Amortisation	934	856	897	0	0	0
Inventories	*-39*	*-242*	*241*	*-202*	*-75*	*-37*
Receivables	*-606*	*1,266*	*4*	*-56*	*-143*	*-278*
Payables	*689*	*284*	*-547*	*-142*	*60*	*69*
Change in working capital	44	1,308	-302	-400	-158	-246
Exceptionals/provisions	0	0	0	172	0	0
Gain/loss on disposals	0	0	864	0	0	0
Other	-151	-162	-132	-134	0	0
Company op. cashflow	**-4,192**	**-2,594**	**-3,767**	**-4,913**	**-3,083**	**-396**
Net interest	-280	14	13	29	42	40
Tax paid/received	691	757	1,220	980	1,008	693
Operational cashflow	**-3,781**	**-1,823**	**-2,534**	**-3,904**	**-2,033**	**338**
Capital expenditure	-164	-70	-24	-100	-125	-156
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	**-3,945**	**-1,893**	**-2,558**	**-4,004**	**-2,158**	**181**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	-300	0	0
Disposals	0	0	957	172	0	0
Other investments	0	0	0	0	0	0
Cashflow after invests.	**-3,945**	**-1,893**	**-1,601**	**-4,132**	**-2,158**	**181**
Share repurchases	-44	0	0	0	0	0
Capital increase	0	6,023	0	3,318	0	0
Currency effect	-791	-323	-425	0	0	0
Cash/(debt) acquired	0	0	0	-854	0	0
Change in net debt	**-4,780**	**3,807**	**-2,026**	**-1,668**	**-2,158**	**181**
Hardman FCF/share (p)	-35.9	-9.9	-13.6	-14.3	-6.0	1.0
Opening net cash/(debt)	903	-3,877	-70	-2,096	-3,764	-5,922
Closing net cash/(debt)	**-3,877**	**-70**	**-2,096**	**-3,764**	**-5,922**	**-5,741**

Source: Hardman & Co Life Sciences Research

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