Pharmaceuticals & Biotechnology

Source: Refinitiv

Market data	
EPIC/TKR	GDR
Price (p)	7.0
12m High (p)	30.0
12m Low (p)	7.5
Shares (m)	34.9
Mkt Cap (£m)	2.4
EV (£m)	8.2
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

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www.genedriveplc.com

Key shareholders

Directors	1.8%
Calculus	18.9%
M&G	14.8%
BGF	12.5%
Odey	5.4%
River & Merc.	5.2%

Diary

2H'20	WHO decision on HCV-ID pre-qualification

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GENEDRIVE PLC

Western market progress but developing markets difficult

Genedrive plc (GDR) is a commercial-stage biotech focused on point-of-care molecular diagnostics. Its Genedrive® molecular diagnostic platform offers low-cost, simple-to-use devices for highly sensitive and specific testing. The 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, with its hepatitis C virus (HCV) and biothreat assays already on the market. The HCV diagnostics market is proving challenging due to a lack of access to HCV drugs, but biothreat revenue should support GDR in fiscal 2020.

- **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, biothreat pathogen detection and Antibiotic-Induced Hearing Loss (AIHL).

- **Interims:** Ongoing challenges with commercialisation of the HCV-ID kit and delays in delivering orders to the Department of Defense (DoD) have combined with expiry of grant-funded programmes to deliver group sales of £0.6m (£1.5m) in 1H'20. Product sales were ca£0.33m (£0.78m), the majority from the DoD.

- **Operational progress:** Regulatory approval for HCV-ID was achieved in India at the end of 1H'20; however, although the WHO pre-qualification assessment is still ongoing, expected completion is now further delayed. Crucially, the DoD increased its framework contract for pathogen detection by $2.0m/£1.5m.

- **Risks:** The Genedrive platform has been validated by CE marking of the HCV-ID and RNR1 kits, 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.

- **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. The next 12 months will be indicative of GDR's ability to deliver traction across two assays.

Financial summary and valuation

Year-end Jun (£000)	2017	2018	2019	2020E	2021E	2022E
Group sales	5,785	1,938	2,362	2,741	4,455	8,346
Underlying EBIT	-4,913	-5,264	-4,449	-3,172	-1,783	216
Reported EBIT	-7,292	-7,375	-4,010	-3,172	-1,783	216
Underlying PBT	-5,417	-5,782	-5,002	-4,958	-2,830	-605
Statutory PBT	-7,487	-7,788	-4,518	-4,677	-2,830	-605
Underlying EPS (p)	-23.6	-26.9	-15.8	-12.0	-6.2	-0.2
Statutory EPS (p)	-34.9	-31.9	-14.0	-11.2	-6.2	-0.2
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	-70	-2,096	-3,334	-5,834	-6,931	-5,479
Capital increases	6,023	0	3,243	183	105	0
P/E (x)	-0.3	-0.3	-0.4	-0.6	-1.1	-44.2
EV/sales (x)	1.4	4.2	3.5	3.0	1.8	1.0

Source: Hardman & Co Life Sciences Research

Interim results

The first half of fiscal 2020 (six months ending December 2019) represents the start of a transitional period for GDR that will shape its future performance. Its operational progress in the period underpins movement towards sustainable sales from developed healthcare systems within two years and delivery on its investment in the HCV-ID assay in developing markets. These will be instrumental for repayment or restructuring of its debt by 2022. In the meantime, orders from the DoD are supporting the top line.

Key operating features

- **HCV-ID kit:** Achieved registration in India, a key growth market for this product, bringing the total registered countries to 14. Assessment of its pre-qualification status by the WHO is still ongoing, with the timelines now out of the hands of GDR. Sales in registered countries have been minimal, impacted by the lack of funding for/access to HCV drugs in developing markets. See our recent note for more detail[1].
- **Pathogen detection:** The DoD framework contract has been extended by $2.0m – this is good validation of the Genedrive platform, although there is no guarantee that the DoD will utilise the full amount. Supplier issues delayed two orders made in FY'19 – these have been rectified by a second supply agreement, and should be delivered by the end of FY'20.
- **RNR-1:** GDR and its partners at Liverpool Women's and Manchester University NHS Foundation Trusts have delivered strong progress with clinical studies of the RNR-1 assay for AIHL, and with implementation studies beginning in 1H'20. GDR successfully achieved CE marking for RNR-1 in November 2019[2].
- **TB:** Development of a "simple-to-use" sample preparation companion module also continued in 1H'20, with the design and development phase now complete. This was funded by one of the Innovate UK grants – the remaining development and manufacturing work will be funded by GDR.

Key financial features

- **Product sales:** Sales of device and assay (HCV-ID and DoD product) were significantly below forecasts (by -£0.52m, due in part to the delay in fulfilling the DoD order) at ca.£0.3m and represented a 58% decrease on the comparable period last year. The majority of the £0.3m was composed of DoD sales, meaning that there has been little to no growth in HCV-ID sales.
- **Grant income:** Grant income of £0.3m (including £0.2m associated with TB development work) was slightly below forecasts, but the decline on the prior period was anticipated, as the grant-funded TB and RNR-1 development programmes move towards completion.
- **Administration costs:** In line with the decline in product sales and tight control of costs, administration costs (COGS and SGA) were below forecasts by £0.36m at -£0.90m.
- **Net cash/(debt):** Underlying operating profit fell 27% on the prior period to -£2.57m (-£2.02m). Combined with an unexpected working capital requirement, GDR ended the period with cash of £3.5m, which was below forecasts by -£1.3m. Debt in the form of convertible bonds is now being carried at £9.3m, resulting in a net debt position of -£5.8m on 31 December 2019.

[1] https://www.hardmanandco.com/research/corporate-research/acceleration-of-news-flow-expected/
[2] https://www.hardmanandco.com/research/corporate-research/regulatory-hurdle-leaped-hearing-loss-assay/

- **Finance costs:** Net costs of £0.77m, which included £0.81m associated with unwinding the discount to the GHIF and BGF convertible bonds, under IFRS accounting, were greater than anticipated.

1H'20 results – actual vs. forecasts					
Year-end Jun (£000)	1H'19 actual	1H'20 actual	Growth %	1H'20 forecast	Delta Δ
Product sales	787	327	-58%	849	-522
Grant income	701	300	-57%	422	-122
Group sales	**1,488**	**627**	**-58%**	**1,271**	**-644**
R&D	-2,496	-2,293	-8.1%	-2,618	+325
Administrative costs	-868	-901	3.8%	-1,262	+361
EBIT (underlying)	**-2,017**	**-2,567**	**27.3%**	**-2,470**	**-97**
Net interest	-475	-1,046	120%	-730	-316
Pre-tax profit	-2,492	-3,613	45.0%	-3,028	-585
EPS (p)	-10.7	-9.7	+8.6%	-7.2	-3
Net cash/(debt)	**-2,510**	**-5,794**	**-**	**-4,121**	**-1,673**

Source: Hardman & Co Life Sciences Research

Changes to forecasts

- **Product sales:** In accordance with the difficult trading environment for HCV diagnostics, we have reduced top-line forecasts for the next three years. FY'20 product sales forecasts are dependent on DoD income, with 2021 being improved by growth in the HCV-ID kit and by first commercial RNR-1 sales.
- **Administration costs:** COGS are difficult to forecast, with GDR gross margin dependent on product mix and the timing of DoD orders uncertain. We have reduced our administration cost forecasts for FY'20 in line with our expectations for an increased proportion of higher-margin DoD sales and tight control of costs.
- **Operating profit:** The cost savings fall through to better EBIT forecasts for 2020 and 2021. Our 2022 profit forecasts are more cautious than previously published.

1H'20 results – actual vs. forecasts									
Year-end Jun	2020E			2021E			2022E		
(£000)	Old	New	Δ	Old	New	Δ	Old	New	Δ
Product sales	2,343	2,092	-12%	4,923	4,455	-10.5%	9,215	8,346	-10.4%
Grants	649	649	0%	0	0	0.0%	0	0	0.0%
Group sales	**2,992**	**2,741**	**-9%**	**4,923**	**4,455**	**-10.5%**	**9,215**	**8,346**	**-10.4%**
Administration costs	-3,142	-1,861	-69%	-3,348	-2,807	-19.3%	-4,895	-5,008	2.2%
R&D	-4,048	-4,003	-1%	-3,400	-3,363	-1.1%	-3,060	-3,026	-1.1%
Underlying EBIT	**-4,271**	**-3,172**	**-35%**	**-1,928**	**-1,783**	**-8.1%**	**665**	**216**	**-207.9%**
Pre-tax profit	-5,001	-4,958	-1%	-2,683	-2,830	5.2%	-98	-605	83.8%
Underlying EPS (p)	-12	-12	-3%	-6	-6	4.4%	1	0	920.3%
Change in working cap	-30	0	7972%	200	264	24.3%	234	567	58.8%
Cash	**2,046**	**3,157**	**35%**	**1,269**	**2,558**	**50.4%**	**1,122**	**2,296**	**51.1%**
Net cash/(debt)	-6,948	-5,834	-19%	-8,228	-6,931	-19%	-6,660	-5,479	-22%

Source: Hardman & Co Life Sciences Research

Outlook

The next 12 to 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. The most significant events for the company's outlook will be launch of the HCV-ID kit in India and the initial market response, and UK launch of the MT-RNR1 assay for AIHL – both this calendar year.

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
1H'20	**2019**	**CE marking expected for AIHL product**
1H'20	Oct'19	HCV REACH study starts recruiting
FY'20	Nov'19	Initiation of PALOH study: Genedrive MT-RNR1 assay
FY'20E	2020	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
2H'20E	**Feb'20**	**HCV-ID launch in India**
2H'20E	**Jul'19-Jun'20**	**WHO decision on HCV-ID prequalification***
2H'20E	Jul'19-Jun'20	Top-line results from "intended setting" studies*
2H'20E	**Jul'19-Jun'20**	**Additional distributer agreements expected**
FY'20E	2019-2020	First release and launch of Genedrive Connect app
FY'20E	Jul'19-Jun'20	Data from AIHL study
FY'21E	**Autumn 2020**	**UK launch of AIHL (Genedrive MT-RNR1) assay**
2H'21E	2021	Data from REACH trial
FY'22E	**2021-2022**	**Launch of TB product**

** Delayed since last results publication (28 October 2019)*
Source: Hardman & Co Life Sciences Research

Forecast summary

- **Product sales:** The rate of growth in sales forecasts is being driven by estimated changes in the DoD, HCV-ID, AIHL and TB product mix.
- **Gross margin:** In 2020 and 2021, margins should pick up rapidly, with growing sales of lower-margin assays pushing down the gross margin in 2022.
- **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 the underlying R&D cost (ca.£3.0m) should be maintained in the forecast period.
- **Finance costs:** Interest is being accrued on the GHIF and BGF loans, until repayment of all interest in 2022.

Profit & Loss account						
Year-end Jun (£000)	2017	2018	2019	2020E	2021E	2022E
Profit & Loss						
Product sales	0	127	961	2,092	4,455	8,346
Grants	2,619	1,811	1,401	649	0	0
Discontinued ops.	3,166	0	0	0	0	0
Group sales	**5,785**	**1,938**	**2,362**	**2,741**	**4,455**	**8,346**
COGS	-2,998	-55	-177	-628	-1,470	-3,338
SG&A	-2,513	-1,979	-1,708	-1,233	-1,337	-1,669
R&D	-5,086	-5,180	-4,877	-4,003	-3,363	-3,026
Underlying EBIT	-4,913	-5,264	-4,449	-3,172	-1,783	216
Share-based costs	-101	12	-49	-49	-69	-96
Statutory EBIT	-7,292	-7,375	-4,010	-3,172	-1,783	216
Net financials	-195	-413	-508	-1,504	-1,047	-821
Underlying pre-tax profit	-5,417	-5,782	-5,002	-4,958	-2,830	-605
Exceptionals	0	0	0	0	0	0
Tax payable/credit	1,051	758	882	724	608	547
Underlying net income	-4,366	-5,024	-4,120	-4,234	-2,222	-57
Underlying basic EPS (p)	-23.64	-26.9	-15.8	-12.0	-6.2	-0.2
Statutory basic EPS (p)	-34.85	-31.9	-14.0	-11.2	-6.2	-0.2
Balance sheet (@30 Jun)						
Share capital	280	282	510	536	544	544
Reserves	3,161	-2,719	-2,988	-6,784	-8,909	-8,966
Provisions/liabilities	1,250	1,250	0	0	0	0
Debt	5,199	5,625	8,518	8,990	9,490	7,775
less: Cash	5,129	3,529	5,184	3,157	2,558	2,296
Invested capital	4,761	397	597	-567	-1,434	-2,943
Net cash/(debt)	**-70**	**-2,096**	**-3,334**	**-5,834**	**-6,931**	**-5,479**
Cashflow						
Underlying EBIT	-4,913	-5,264	-4,449	-3,172	-1,783	216
Change in working capital	1,308	-302	-210	0	264	567
Company op. cashflow	-2,594	-3,767	-4,601	-3,025	-1,352	977
Capital expenditure	-70	-24	-97	-121	-152	-189
Capital increase	6,023	0	3,243	183	105	0
Change in net debt	3,807	-2,026	-1,238	-2,500	-1,097	1,452
OCFPS (p)	-9.9	-13.6	-13.8	-5.7	-1.7	-0.2

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

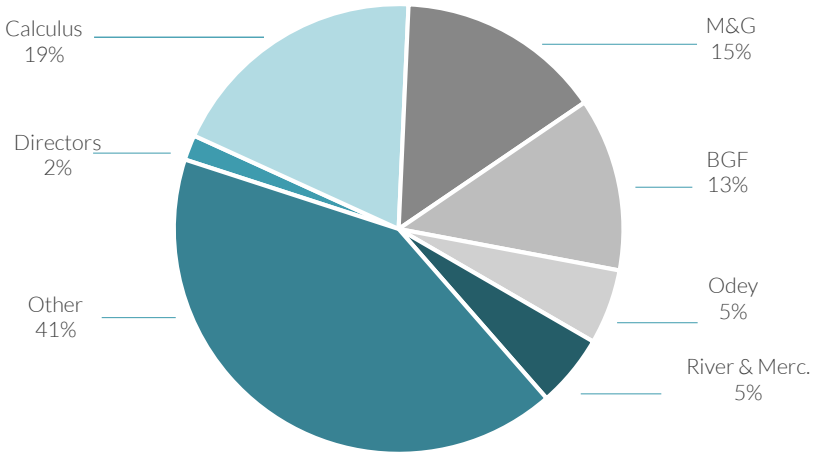
Position	Name	Nominations	Remuneration	Audit
Chairman	Ian Gilham	C	C	C
Chief Executive Officer	David Budd			
Chief Financial Officer	Matthew Fowler			
Non-executive director	Tom Lindsay	M	M	M
Non-executive director	Chris Yates	M	M	M

M = member; C = chair
Source: Company reports

Share capital

On 4 February 2020, there were 34,870,071 Ordinary shares in issue, and, at 30 June 2019, there were 3,488,968 share options outstanding.

Shareholders



Source: genedrive plc

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