hardman&co

genedrive plc

Progressing commercialisation plans

genedrive plc (GDR) is a commercial-stage company focused on point-of-care/need molecular diagnostics and biomarkers. 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 infectious disease diagnosis. Rapid analysis of patient samples greatly aids clinical and public health decision-making, with field testing particularly important in emerging markets. GDR has signed three commercial deals for its Genedrive HCV ID Kit to date, paving the way to accessing the multi-million-dollar market hepatitis C diagnosis market.

- **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 diagnosis of infectious diseases, signing two important commercial agreements with Sysmex, a major global player.

- **Interims:** Sales fell 9% in 1H'18 to £2.63m (£2.88m); however, Genedrive-related income increased 8% to £1.29m (£1.24m), helped by early completion of the Department of Defense (DoD) contract. EBIT of -£2.4m (-£2.1m) was 12% better than forecast. Cash at the period-end was £4.6m.

- **Genedrive HCV:** GDR has signed two distribution deals for its HCV ID Kit with Sysmex for Africa and specific countries in SE Asia, and with ARKRAY for India. Sysmex has undertaken an independent verification field study, incorporated systems and processes, generated its first order, and re-ordered the kit.

- **Risks:** The platform technology has been de-risked through the receipt of CE Mark for its first two assays – hepatitis C and tuberculosis. The main risk is commercial, given that it often takes time for new technologies to be adopted. However, partnering with a major global player reduces this risk significantly.

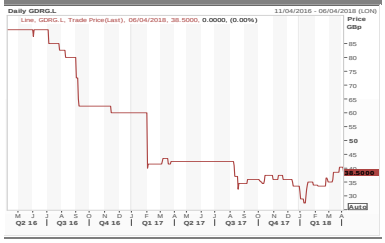
- **Investment summary:** Genedrive technology ticks all the boxes described for an 'ideal' *in vitro* diagnostic that satisfies the need for powerful molecular diagnostics outside the hospital setting. The hepatitis C market is a global opportunity, which is very large, even in developing countries. With strong commercial partners being signed for different territories/countries, early evidence of sales traction would highlight, in our opinion, the significant valuation anomaly that exists.

Financial summary and valuation

Year-end June (£000)	2015	2016	2017	2018E	2019E	2020E
Sales	4,517	5,063	5,785	5,130	5,630	7,950
Underlying EBIT	-3,858	-5,259	-4,812	-5,566	-3,808	-2,716
Reported EBIT	-4,040	-5,426	-7,292	-5,687	-3,966	-2,937
Underlying PBT	-3,242	-6,330	-5,007	-5,972	-4,223	-3,139
Statutory PBT	-3,424	-6,497	-7,487	-6,093	-4,381	-3,360
Underlying EPS (p)	-28.3	-54.6	-21.4	-26.6	-17.4	-10.7
Statutory EPS (p)	-30.1	-56.2	-34.9	-27.3	-18.2	-11.7
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0
Net (debt)/cash	903	-3,877	-70	-3,665	-6,190	-8,176
Capital increases	80	0	6,023	0	1,250	0
P/E (x)	-1.4	-0.7	-1.8	-1.4	-2.2	-3.6
EV/sales (x)	1.8	1.6	1.4	1.6	1.4	1.0

Source: Hardman & Co Life Sciences Research

Pharmaceuticals & Biotechnology



Source: Eikon Thomson Reuters

Market data

EPIC/TKR	**GDR**
Price (p)	38.5
12m High (p)	60.0
12m Low (p)	25.0
Shares (m)	18.7
Mkt Cap (£m)	7.2
EV (£m)	8.1
Free Float*	47%
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/need 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	8.2%
Calculus	16.2%
M&G	13.1%
Odey	12.8%
Hargreave Hale	7.0%
River & Merc.	5.6%

Diary

Jul-18	Trading update
Oct-18	Finals

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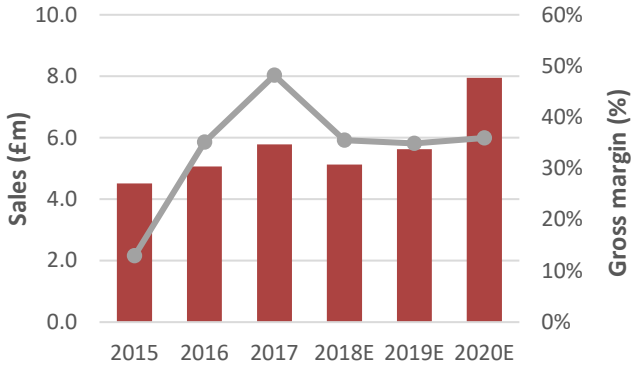
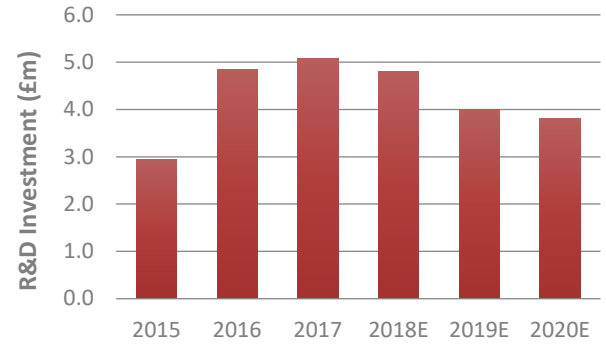
Sales and gross margin



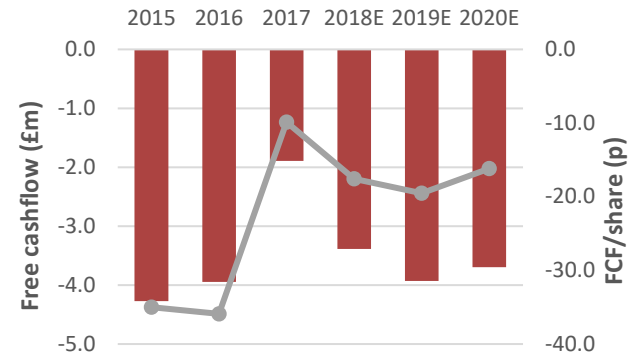
- Historical sales are for non-core operations and Genedrive-related grant income
- Over the forecast period, Genedrive sales more than offset the reducing DoD grant income
- The Genedrive grant income is a relatively high-margin activity
- Margins on Genedrive units and disposable cartridges will increase with rising volumes

R&D investment



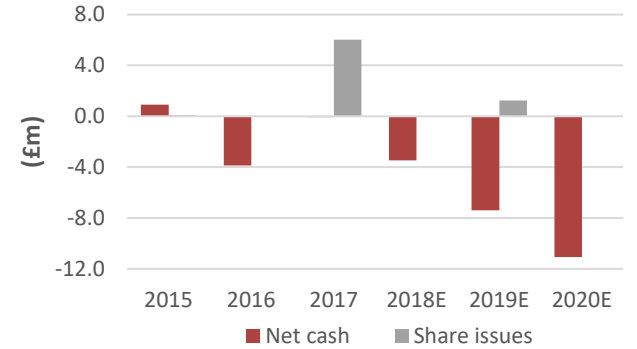
- R&D investment is written off in the year in which it is incurred
- To date, an estimated ca.£20m has been spent on R&D by the company since incorporation (although not spent exclusively on diagnostics)
- Further investment is planned over the next three years to add more tests onto the Genedrive platform
- Future investment will be largely dependent on the commercial success of the HCV test

Free cashflow and FCF per share



- The non-core services segment is profitable and cash generative; a disposal would provide a cash injection
- The Services business is valued at around £2m – a discount reflecting the >1year duration during which a disposal has been sought
- During the investment phase for the Genedrive launch, GDR is burning £3m-£4m cash p.a.
- Forecasts are dependent on Genedrive gaining early sales traction and generating recurring disposable revenues

Net cash/ Share issues



- To date, GDR has raised only ca.£20m 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 GHIF Convertible Bond ($8m) is out-of-the money and should be considered as long-term debt
- There remains a possibility that non-core services will be disposed, generating cash for working capital purposes and boosting the balance sheet

Source: Company data; Hardman & Co Life Sciences Research

Interim results

Key features

The announcement of the interim results provided management with the opportunity to update the market on the meaningful strides that have been made over the last six months. Headline financial information – sales and cash position – was reported to the market in the January trading statement, but overall underlying operating losses were 12% lower than forecast.

Operational highlights

- **Genedrive:** The most significant event in 1H'18 was the receipt of CE Marking for the Genedrive HCV ID kit, which represents a significant endorsement of the technology.
- **Distribution:** GDR has signed exclusive distribution deals with Sysmex, a major global player in diagnostic instruments, reagents and related software, initially covering Africa and a number of countries in SE Asia.
- **Services:** Following the strategic decision to dispose of its Services division, enacting this has taken longer than expected. However, management has disclosed that it is in a period of exclusivity with a potential purchaser.

Financial highlights

- **Sales:** As indicated in the January trading statement, reported sales fell 9% in 1H'18 to £2.63m (£2.88m). More importantly, Genedrive-related income increased 8% to £1.29m (£1.24m), helped by early completion of the DoD contract. Non-core services sales declined 18% to £1.35m from an unusually high £1.65m in 1H'17.
- **Costs:** Overall costs for delivering the services emerged somewhat lower than expected at -£1.29m (-£1.84m), due largely to a turnaround in the pre-clinical research services business.
- **R&D:** Timing on R&D spend is always difficult to predict; however, the overall investment was 7% lower than forecast at £2.23m (-£2.36m).
- **Net cash/(debt):** GDR had already indicated its closing cash position at £4.55m, helped by receipt of a £1.2m 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 -£5.28m.

Interim results – actual vs. forecasts

Year-end June (£000)	1H'17 actual	1H'18 actual	1H'18 forecast	Delta Δ
Sales	2,882	2,633	2,580	+53
Costs	-1,837	-1,286	-1,460	+174
SG&A	-1,074	-1,200	-1,105	-95
R&D	-2,360	-2,233	-2,400	+167
EBIT (underlying)	**-2,389**	**-2,086**	**-2,385**	**+299**
Pre-tax profit	-3,003	-2,157	-2,395	+238
EPS (p)	-14.71	-8.76	-10.25	+15%
Net cash/(debt)	209	-726	-750	+24

Numbers may not add up precisely due to rounding
Source: Hardman & Co Life Sciences Research

Operational update

Commercial opportunity

The sensitivity and specificity of molecular diagnostics has greatly improved the diagnosis of many conditions. However, improvements in these tests have come through increased volumes being performed on large-scale equipment in a laboratory/hospital. The goal of GDR is to offer a technology platform with all the advantages of molecular diagnosis, which can be used outside the hospital/laboratory setting. CE Marking of its Genedrive HCV ID kit makes GDR the first company to reach the market with a non-laboratory-based molecular test for hepatitis C. This adds to the CE Marking achieved already with its tuberculosis (mTB) test. The next step is to make the test available in appropriate markets through distribution deals.

Meanwhile, GDR is looking to expand its menu of tests and to make further enhancements to its existing tests. For example, 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 plasma separation consumable device that will support the future use of GDR's HCV ID Kit closer to a point-of-care setting. The aim of this is to increase the level of diagnosis in people infected with HCV from the current level of about 20%, enabling more of them to get treatment.

In addition, GDR has received a conditional offer of £1.1m from Innovate to part-fund the development of improved sample preparation for its mTB test.

Sysmex

In order to maximise the opportunity ahead, GDR is looking to sign up large distribution partners in appropriate territories. To that end, it has signed two deals with Sysmex Corporation, a Tokyo-listed multi-national capitalised at about $13bn with annual sales of $2.2bn, covering EMEA and Asia Pacific (excluding India). Sysmex is ranked #8 globally in *in vitro* diagnostics (IVD), with a very strong presence in haematology, where it is ranked world #1.

Field evaluation study

As part of the transition to a commercially available product, Sysmex recommended local validation of the Genedrive HCV ID system. Results from a successful field study, independently carried out at the privately-held Lancet Laboratories, were released to the market on 16th January 2018 and published in the BMJ *Gut* on 11th April 2018[1], Sysmex led the support and training of customers, while Lancet Laboratories is well regarded in the field and has operations across the African continent.

- **Accuracy:** Sensitivity and selectivity of the test when performed by a third party.
- **Local samples:** Successful use of patient samples stored and processed under local conditions.
- **Genotypes:** Test further the accurate diagnosis of samples of the HCV genotypes (strains) found particularly in central and southern African countries.

A total of 130 clinical samples from more than six African countries were tested using Genedrive. The Abbott M2000 HCV Real-Time system was used as a reference.

[1] Peer-reviewed publication – see page 11 for details

- **Results:** Sensitivity and specificity for detection of GCV were 100%.
- **Genotypes distinguished:** The samples contained HCV genotypes 1-5, and their subtypes were successfully detected using the system.
- **Efficiency:** 95.4% of test results were achieved on the first attempt, despite many samples being haemolysed (which can be the result of undesirable sampling techniques).

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

First launch

In addition to the field evaluation study, standard procedures have been undertaken to integrate processes/information into Sysmex's systems. Sysmex intends to have a phased launch programme. The focus of initial launches will be in countries that have screening programmes, an established funding policy, and where drugs for the treatment of hepatitis C are available and affordable.

In Africa, Sysmex consists of a group of 29 distributors covering 46 sub-Saharan African countries. The regulatory team is working on local processes on a country-by-country basis. To date, GDR management is pleased with the high level of engagement with the Sysmex team.

GDR signed a separate deal, with Sysmex Asia Pacific Pte Ltd, covering the Asia Pacific Region, including the key countries of Bangladesh, Pakistan and Malaysia, in November 2017.

ARKRAY Healthcare

Highlighting GDR's approach to try and operate with the most appropriate partner in each country, in March 2018, management signed a commercial agreement with ARKRAY for its Genedrive HCV ID kit in India. Under the agreement, GDR is retaining responsibility for product development, quality assurance, and manufacturing, while ARKRAY will be responsible for sales, marketing, customer support and distribution. Initially, the companies will work together to secure regulatory approval in India. The product is expected to be launched during fiscal 2019.

mTB test

Although its tuberculosis test was the first test to receive CE Marking using the Genedrive technology platform, its commercialisation in India did not go according to plan. There is still an enormous push to replace the traditional smear microscopy with more accurate molecular diagnostics, which also provides information about drug resistance. Therefore, GDR has renewed its efforts to develop a next-generation test, with a greater focus on improving sample handling and reducing the manufacturing costs, so that it becomes a more affordable, as well as more convenient and efficient, option.

GDR secured a £1.1m conditional grant from Innovate towards improving sample preparation with a new 'modular' solution. The company anticipates that more information on these developments will be available in fiscal 2019.

Financial forecasts

Profit & Loss

- **Sales:** Fluctuations in the sales forecasts are due to the DoD contract tailing off over the next two years, offset by the build-up of Genedrive sales. The non-core services business has stable sales of ca.£3m p.a.
- **Gross margin:** During the build-up phase for the HCV test, coupled with lower DoD income, gross margins for the Genedrive test are expected to be stable at around 31%-32%, compared with reported gross margins including Services.
- **SG&A:** Expected to be stable around current levels, as a large part of the marketing costs for tests will be borne by distribution partners.

Profit & Loss account

Year-end June (£000)	2015	2016	2017	2018E	2019E	2020E
Genedrive	814	1,906	2,619	2,000	2,562	4,905
Services	3,703	3,157	3,166	3,130	3,068	3,045
Sales	**4,517**	**5,063**	**5,785**	**5,130**	**5,630**	**7,950**
COGS	-3,933	-3,285	-2,998	-3,530	-3,180	-4,200
Gross profit	**584**	**1,778**	**2,787**	**1,600**	**2,450**	**3,750**
Gross margin	12.9%	35.1%	48.2%	31.2%	43.5%	47.2%
R&D	-2,942	-4,836	-5,086	-4,800	-4,000	-3,800
SG&A	-1,500	-2,201	-2,513	-2,516	-2,592	-2,666
EBITDA	**-4,243**	**-6,433**	**-3,740**	**-4,650**	**-2,892**	**-1,800**
Depreciation	-241	-240	-216	-216	-216	-216
Amortisation	-144	-934	-856	-700	-700	-700
Other income	0	0	0	150	334	0
Underlying EBIT	**-3,858**	**-5,259**	**-4,812**	**-5,566**	**-3,808**	**-2,716**
Share-based costs	-182	-167	-101	-121	-158	-221
Statutory EBIT	-4,040	-5,426	-7,292	-5,687	-3,966	0
Net financials	616	-1,071	-195	-406	-415	-423
Pre-tax profit	**-3,242**	**-6,330**	**-5,007**	**-5,972**	**-4,223**	**-3,139**
Exceptional items	0	0	0	0	0	0
Reported pre-tax	-3,424	-6,497	-7,487	-6,093	-4,381	-3,360
Tax payable/credit	399	582	1,051	992	827	785
Tax rate	12%	9%	14%	16%	19%	23%
Minorities	0	0	0	0	0	0
Underlying net income	**-2,843**	**-5,748**	**-3,956**	**-4,980**	**-3,397**	**-2,354**
Statutory net income	-3,025	-5,915	-6,436	-5,101	-3,554	-2,574
Ordinary 1.5p shares						
Period-end (m)	10,564	10,565	18,689	18,689	21,936	21,936
Weighted average (m)	10,048	10,532	18,466	18,689	19,501	21,936
Fully-diluted (m)	11,869	12,490	20,527	24,222	21,562	23,997
Underlying basic EPS (p)	**-28.3**	**-54.6**	**-21.4**	**-26.6**	**-17.4**	**-10.7**
Statutory basic EPS (p)	-30.1	-56.2	-34.9	-27.3	-18.2	-11.7
U/l fully-diluted EPS (p)	**-24.0**	**-46.0**	**-19.3**	**-20.6**	**-15.8**	**-9.8**
Stat. fully-diluted EPS (p)	-25.5	-47.4	-31.4	-21.1	-16.5	-10.7
DPS (p)	0.0	0.0	0.0	0.0	0.0	0.0

Source: Hardman & Co Life Sciences Research

- **R&D:** Investment in new tests, initially HIV, will be dictated by the success of the HCV assay. There remains some flexibility about both the quantum and timing of investment into additional tests.
- **Services business:** Sales of ca.£3m p.a. are expected, with small cash and profit contributions.
- **Tax:** Modest tax credits on R&D spend are expected over the forecast period, but these will be at lower levels than seen historically.

Balance sheet

- **Net cash:** The net cash/(debt) position at 30th June 2017 was -£70k, comprising cash of £5.1m offset by long-term debt (convertible bond) of £5.2m. Cashflow suggests that the company will have net debt of -£3.7m by the end of June 2018.
- **Tax credits:** Some of its R&D investment attracted tax credits from HMRC. Going forward, the R&D tax credit is expected to approach £1m p.a.
- **Working capital:** Given that the company will be selling to a large distributor and the non-core business is relatively stable, Genedrive is not expected to have significant working capital requirements during its growth phase.
- **Convertible bond:** The collaborative funding agreement for a total of $8.0m initiated in July 2014, and revised in July 2016, with the Global Health Investment Fund (GHIF) is treated as long-term debt.

Balance sheet

@30th June (£000)	2015	2016	2017	2018E	2019E	2020E
Shareholders' funds	9,545	3,753	3,441	-1,660	-3,964	-6,539
Cumulated goodwill	0	0	0	0	0	0
Total equity	9,545	3,753	3,441	-1,660	-3,964	-6,539
Share capital	158	158	280	280	332	332
Reserves	9,387	3,595	3,161	-1,940	-4,297	-6,871
Provisions/liabilities	0	1,250	1,250	1,250	0	0
Deferred tax	-30	0	0	0	0	0
Long-term loans	4,025	4,991	5,199	5,473	5,761	6,064
Short-term debt	0	0	0	0	0	0
less: Cash	4,928	1,114	5,129	1,808	-430	-2,112
less: Deposits	0	0	0	0	0	0
less: Non-core invests.	0	0	0	0	0	0
Invested capital	**8,612**	**8,880**	**4,761**	**3,255**	**2,226**	**1,637**
Fixed assets	805	713	568	452	351	267
Intangible assets	7,191	6,273	3,038	2,338	1,638	938
Inventories	163	202	444	564	719	1,015
Trade debtors	*1,725*	*2,290*	*1,376*	*1,220*	*1,339*	*1,891*
Other debtors	*466*	*507*	*278*	*256*	*261*	*266*
Tax liability/credit	*685*	*757*	*1,213*	*992*	*827*	*785*
Trade creditors	*-696*	*-914*	*-816*	*-961*	*-866*	*-1,143*
Other creditors	*-1,727*	*-948*	*-1,340*	*-1,606*	*-2,042*	*-2,382*
Debtors less creditors	453	1,692	711	-99	-482	-583
Invested capital	**8,612**	**8,880**	**4,761**	**3,255**	**2,226**	**1,637**
Net cash/(debt)	**903**	**-3,877**	**-70**	**-3,665**	**-6,190**	**-8,176**

Source: Hardman & Co Life Sciences Research

Cashflow

- **Cash burn:** The underlying cash burn is forecast to trend downwards after fiscal 2018 to ca. -£2.5m (2019) followed by ca.-£2.0m (2020).
- **Working capital:** Only modest changes in working capital are anticipated, given that the non-core services business is stable and the supply agreement is with a large, well-capitalised distribution partner.
- **R&D tax credit:** Payment of the amount shown in the balance sheet at the end of June 2017 has already been received; management intends to get annual claims submitted to HMRC in a timely manner.
- **Capex:** The company does not have any immediate requirement for significant expenditure for capital investment.

Cashflow

Year-end June (£000)	2015	2016	2017	2018E	2019E	2020E
Underlying EBIT	-3,858	-5,259	-4,812	-5,566	-3,808	-2,716
Depreciation	241	240	216	216	216	216
Amortisation	144	934	856	700	700	700
Inventories	*-163*	*-39*	*-242*	*-120*	*-155*	*-296*
Receivables	*-1,066*	*-606*	*1,266*	*156*	*-119*	*-552*
Payables	*107*	*689*	*284*	*145*	*-95*	*278*
Change in working capital	-1,122	44	1,308	181	-369	-571
Exceptionals/provisions	-36	0	0	0	0	0
Disposals	0	0	0	0	0	0
Other	-202	-151	-162	-274	0	0
Company op. cashflow	**-4,833**	**-4,192**	**-2,594**	**-4,742**	**-3,261**	**-2,371**
Net interest	-196	-280	14	35	-141	-309
Tax paid/received	1,513	691	757	1,213	992	827
Operational cashflow	**-3,516**	**-3,781**	**-1,823**	-3,495	-2,411	-1,853
Capital expenditure	-758	-164	-70	-100	-115	-132
Sale of fixed assets	0	0	0	0	0	0
Free cashflow	**-4,274**	**-3,945**	**-1,893**	**-3,595**	**-2,526**	**-1,985**
Dividends	0	0	0	0	0	0
Acquisitions	0	0	0	0	-1,250	0
Disposals	0	0	0	0	0	0
Other investments	0	0	0	0	0	0
Cashflow after invests.	**-4,274**	**-3,945**	**-1,893**	**-3,595**	**-3,776**	**-1,985**
Share repurchases	-22	-44	0	0	0	0
Capital increase	80	0	6,023	0	1,250	0
Currency effect	292	-791	-323	0	0	0
Borrowings acquired	589	0	0	0	0	0
Change in net debt	**-3,335**	**-4,780**	**3,807**	**-3,595**	**-2,526**	**-1,985**
Hardman FCF/share (p)	-35	-36	-10	-19	-12	-8
Opening net cash	4,238	903	-3,877	-70	-3,665	-6,190
Closing net cash	**903**	**-3,877**	**-70**	**-3,665**	**-6,190**	**-8,176**

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

GDR announced recently the appointment of Tom Lindsay as a non-executive director. He has considerable sales and marketing experience in the diagnostics sector, working most recently for Alere Inc. in Africa.

Board of Directors

Position	Name	Nominations	Remuneration	Audit
Chairman	Ian Gilham	M	M	M
Chief Executive Officer	David Budd			
Chief Financial Officer	Matthew Fowler			
Managing Director	Dr Catherine Booth			
Non-executive director	Tom Lindsay			
Non-executive director	Roger Lloyd	M	M	M
Non-executive director	Robert Nolan	M	M	M

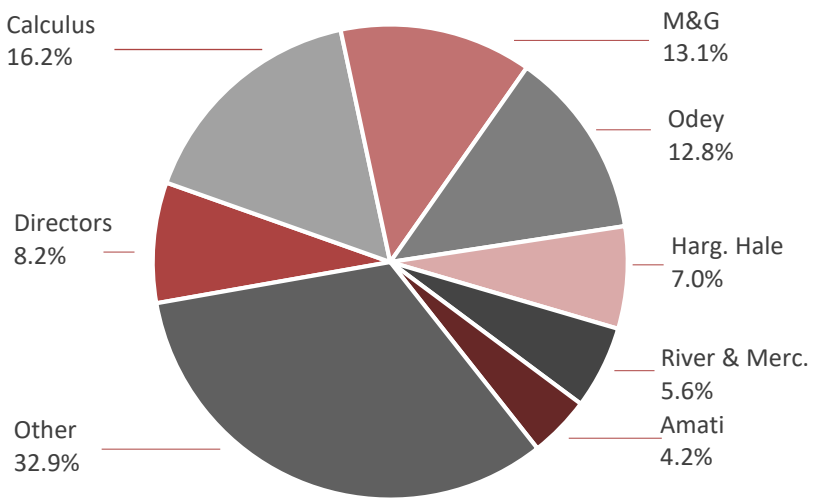
M = member; C = chair

Source: Company reports

Share capital

At 10th April 2017, there were 18,689,446 Ordinary shares in issue, and a further 1,820,000 share options.

Shareholders



Source: Company reports; RNS announcements

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Reference

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