



Market data

EPIC/TKR	GDR
Price (p)	19.0
12m High (p)	30.0
12m Low (p)	13.0
Shares (m)	34.0
Mkt Cap (£m)	6.5
EV (£m)	9.8
Free Float*	51%
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

Analysts

Martin Hall	020 7194 7632	mh@hardmanandco.com
Dorothea Hill	020 7194 7626	dnh@hardmanandco.com
Grégoire Pavé	020 7194 7628	gp@hardmanandco.com

GENEDRIVE PLC

Regulatory hurdle leaped: hearing loss assay

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, with its hepatitis C virus (HCV) and pathogen detection assays already on the market. Its assay for screening against adverse reactions to antibiotics obtained CE marking this week, allowing progression to the next stage towards commercialisation: an NHS implementation study.

- **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 (TB), bio-threats and Antibiotic-Induced Hearing Loss (AIHL).
- **CE marking:** genedrive's products require CE marking before they can be sold in the EEA. Therefore, obtaining CE marking for the AIHL assay – the Genedrive® MT-RNR1 ID kit – is a necessary hurdle to allow entry into the UK and other European markets, on track to launch in 2020.
- **Large market potential:** Peak sales in the UK could reach £3.6m if the MT-RNR1 assay is adopted for screening of all babies prior to treatment with gentamicin (ca.90k per annum). In the UK alone, this could prevent 180 cases of AIHL each year, saving children from bilateral and irreversible hearing loss.
- **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	165	95	0
P/E (x)	-0.8	-0.7	-1.2	-1.5	-3.2	14.7
EV/sales (x)	1.7	5.1	4.1	3.3	2.0	1.1

Source: Hardman & Co Life Sciences Research

Commercial strategy on track

Strategy to deliver material revenues from three assays by 2022...

...accelerating the news flow

As highlighted in our recent note, *Acceleration of news flow expected*¹, GDR is in a transition period. Management has been reiterating its strategy to deliver material revenues from three assays by 2022, and we have been anticipating accelerated news flow associated with the clinical and product development of the HCV, AIHL and mTB products in the current fiscal year.

Third assay to be commercialised

With the HCV-ID kit already on the market, and the US Department of Defense (DoD) biothreat product receiving repeat (although irregular) commercial orders, the MT-RNR1 ID kit is set to be the third assay commercialised by GDR. It will also be the company's first test commercialised for developed markets, since the biothreat assay is only available to DoD customers. The fourth element of the GDR's assay strategy is mTB; GDR's expects to launch this product in 2021.

Hearing loss screening product...

...developed in collaboration with the NHS and funded by the NIHR

MT-RNR1 ID kit development programme

GDR was awarded a £550k "Invention to Innovation" grant by the UK's National Institute for Health Research (NIHR) in June 2018 for development of a test to screen against AIHL. The two-year project has been structured into a development phase and an initiation phase. Development was relatively straightforward, with only slight modification of the chemistry needed for recognition of variants of the MT-RNR1 gene, and with only minimal sample preparation required – a buccal swab is all that is needed to run the test.

The implementation phase of the project involves more complexity, given that the device will need to be incorporated into existing NHS procedures and infrastructure. However, the collaboration with highly-experienced partners, such as Professor William Newman at the Manchester University NHS Foundation Trust, will facilitate trials. The partners received around the same amount of grant funding for their part in the project, which covers the implementation phase.

CE marking successfully obtained...

...with excellent sensitivity and specificity data

CE marking

A necessary hurdle on the path to commercialisation is obtaining CE marking for the RNR1 assay prior to the implementation stage of the programme and to sales in the UK and other EEA markets. GDR was eligible for self-certification, demonstrating in-house that the assay conforms to the relevant EU safety, health and environmental protection requirements. Sensitivity/specificity data will have been collected with collaborators as part of the development phase of the project. Data have yet to be publicly released, but they should be high given the needs of the customer and the nature of gene-based diagnostics.

Good market potential

First to market

This assay is an exciting development. Particularly key to GDR is that the MT-RNR1 ID kit is thought to be the first genetic screening test developed for use in an infant emergency care environment. Although the target population (the m. 1555A>G mutation in the MT-RNR1 gene) is relatively small (ca.0.2% UK prevalence), the assay is initially being positioned for screening of all babies admitted to emergency care who

¹ <https://www.hardmanandco.com/research/corporate-research/acceleration-of-news-flow-expected/>

need rapid treatment with gentamicin (ca.90,000 p.a. in the UK). Widespread adoption by the NHS would be first-class validation of the Genedrive platform and would create a channel for more rapid commercialisation and uptake of similar tests in the future. With ca.210 intensive care units (ICU) in the UK, and assuming one Genedrive unit per ICU, peak sales estimates of £3.6m p.a. in the UK appear reasonable.

Strong health economics

Screening of all babies that require gentamicin antibiotics in acute care also has a strong health economics case. Around 180 patients each year are left profoundly deaf following gentamicin treatment (ototoxicity) due to being carriers of particular variants of the mitochondrial RNR1 gene². Gentamicin is used to treat acute severe bacterial infections such as sepsis, and treatment must be within one hour of admission (NICE guidelines) for the best outcome. However, current approaches to identification of high-risk patients are sub-optimal, with maternal family histories unreliable and centralised laboratory DNA testing taking in the order of days. GDR's MT-RNR1 ID kit can deliver accurate diagnostic results within 30 minutes, well within NICE guidelines, allowing immediate treatment with an alternative, safe antibiotic, should the mutation be detected.

*Potential to prevent severe hearing loss in
180 babies each year in the UK...*

...and to deliver £3.6m in annual sales

Used appropriately, the RNR1 test could prevent AIHL in 180 patients per year. On the basis of both long-term improved patient outcomes and reduced NHS costs (in long-term care for patients suffering from AIHL), the RNR1 test has a strong health economics case that should support good pricing and reimbursement agreements.

Next steps

PALOH study to initiate

The implementation phase – hospital evaluation of the RNR1 assay – is now under way, with recruitment to the NHS “PALOH” study (Pharmacogenetics to Avoid Loss Of Hearing) trial to begin in January 2020. The study will focus primarily on the practical implications of integrating Genedrive into the neonatal emergency admissions process, i.e. the number of neonates identified with the genetic variant and the time to antibiotic treatment. It will also provide insight on the resource impact, e.g. nursing time and the number of Genedrive units required per ICU.

Launches

UK launch of the MT-RNR1 kit is anticipated in the autumn of 2020, with additional European market launches from 2021. Although the m. 1555A>G RNR1 prevalent population is lower in the US (ca.0.09%)³, the EU and US are likely to be larger markets, due to the scale of the European and US populations. We anticipate that GDR will partner with an expert for both marketing and distribution of RNR1 in the UK and Europe, and certainly for US market entry, where achieving 510(k) regulatory approval is expensive.

Conclusions

UK launch and reimbursement of the Genedrive device and RNR1 assay would significantly de-risk GDR for the first time, putting it on track to achieve its strategy of commercialisation of three assays by 2020, and providing its first predictable revenue stream. Our forecasts include RNR1-associated sales from 2020, with a real impact from 2022.

² <https://www.hardmanandco.com/research/corporate-research/preventing-hearing-loss-in-newborns/>

³ Dean L. Gentamicin Therapy and MT-RNR1 Genotype. 2015 Apr 29. In: Pratt V, McLeod H, Rubinstein W, et al., editors. Medical Genetics Summaries [Internet]. Bethesda (MD): National Center for Biotechnology Information (US); 2012-.

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research@hardmanandco.com

35 New Broad Street
London
EC2M 1NH

+44(0)20 7194 7622

www.hardmanandco.com