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.

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**Financial summary and valuation**

<table>
<thead>
<tr>
<th>Year-end Jun (£000)</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020E</th>
<th>2021E</th>
<th>2022E</th>
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<tbody>
<tr>
<td>Group sales</td>
<td>5,785</td>
<td>1,938</td>
<td>2,362</td>
<td>2,992</td>
<td>4,923</td>
<td>9,215</td>
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<tr>
<td>Underlying EBIT</td>
<td>-4,913</td>
<td>-5,264</td>
<td>-4,449</td>
<td>-4,271</td>
<td>-1,928</td>
<td>665</td>
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<tr>
<td>Reported EBIT</td>
<td>-7,292</td>
<td>-7,375</td>
<td>-4,010</td>
<td>-4,271</td>
<td>-1,928</td>
<td>665</td>
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<td>Underlying PBT</td>
<td>-5,417</td>
<td>-5,782</td>
<td>-5,002</td>
<td>-5,001</td>
<td>-2,683</td>
<td>-98</td>
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<td>Statutory PBT</td>
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<td>-7,788</td>
<td>-4,518</td>
<td>-5,001</td>
<td>-2,683</td>
<td>-98</td>
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<td>Underlying EPS (p)</td>
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<td>-26.9</td>
<td>-15.8</td>
<td>-12.4</td>
<td>-5.9</td>
<td>1.3</td>
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<td>Statutory EPS (p)</td>
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<td>-31.9</td>
<td>-14.0</td>
<td>-12.4</td>
<td>-5.9</td>
<td>1.3</td>
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<td>DPS (p)</td>
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<td>0.0</td>
<td>0.0</td>
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<td>Net (debt)/cash</td>
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<td>-6,948</td>
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<td>Capital increases</td>
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<td>3,243</td>
<td>165</td>
<td>95</td>
<td>0</td>
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<td>P/E (x)</td>
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<td>-1.5</td>
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<td>EV/sales (x)</td>
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<td>5.1</td>
<td>4.1</td>
<td>3.3</td>
<td>2.0</td>
<td>11.1</td>
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</table>

Source: Hardman & Co Life Sciences Research
Commercial strategy on track

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 expects to launch this product in 2021.

**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**

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 gene. 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.

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.

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