hardman&co

# genedrive plc

## Preventing hearing loss in newborns

**genedrive plc (GDR) is a commercial-stage company focused on point-of-care molecular diagnostics. 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 been awarded a £550k grant from the UK's National Institute for Health Research (NIHR) to develop a diagnostic to prevent hearing loss resulting from adverse reactions to gentamicin.**

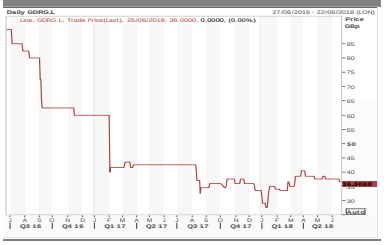
- **Strategy:** Now that the Genedrive technology platform has received CE Marking, the new management team has completely re-focused the company onto the commercialisation pathway for diagnosis of infectious diseases, signing two important commercial agreements with Sysmex, a major global player.
- **Hearing loss in newborns:** There is a major unmet need in developed countries to prevent the adverse reactions that occur in a small minority of patients in the course of life-saving antibiotic treatment. Reactions can be severe, and lead to irreversible and complete hearing loss. Current testing technology is too slow.
- **NIHR grant:** As part of a collaboration with the NHS, GDR will develop a rapid diagnostic for mutations in the (human) mitochondrial gene, RNR1. It will run on the portable, point-of-care Genedrive technology device. Clinically actionable results will be available within the one hour required for treatment.
- **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 major global and local players reduces this risk.
- **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 partners being signed for different countries, such as the NHS in the UK, and evidence of early sales traction, there is, in our opinion, a valuation anomaly existing.

**Financial summary and valuation**

| Year-end June (£000) | 2015 | 2016 | 2017 | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| Sales | 4,517 | 5,063 | 5,785 | 4,869 | 3,447 | 4,826 |
| Underlying EBIT | -3,858 | -5,259 | -4,812 | -4,664 | -3,681 | -2,709 |
| Reported EBIT | -4,040 | -5,426 | -7,292 | -4,784 | -3,837 | -2,927 |
| Underlying PBT | -3,242 | -6,330 | -5,007 | -4,994 | -4,146 | -3,180 |
| Statutory PBT | -3,424 | -6,497 | -7,487 | -5,114 | -4,302 | -3,399 |
| Underlying EPS (p) | -28.3 | -54.6 | -21.4 | -21.5 | -16.4 | -10.1 |
| Statutory EPS (p) | -30.1 | -56.2 | -34.9 | -22.2 | -17.1 | -11.0 |
| DPS (p) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net (debt)/cash | 903 | -3,877 | -70 | -2,362 | -5,175 | -6,947 |
| Capital increases | 80 | 0 | 6,023 | 0 | 1,250 | 0 |
| P/E (x) | -1.3 | -0.7 | -1.7 | -1.7 | -2.2 | -3.6 |
| EV/sales (x) | 2.0 | 1.8 | 1.6 | 1.9 | 2.7 | 1.9 |

*Source: Hardman & Co Life Sciences Research*

**Pharmaceuticals & Biotechnology**



*Source: Eikon Thomson Reuters*

**Market data**

| | |
|---|---|
| EPIC/TKR | **GDR** |
| Price (p) | 36.4 |
| 12m High (p) | 42.5 |
| 12m Low (p) | 25.0 |
| Shares (m) | 18.9 |
| Mkt Cap (£m) | 6.9 |
| EV (£m) | 9.2 |
| Free Float* | 48% |
| 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 | 8.1% |
| Calculus | 16.1% |
| M&G | 13.0% |
| Odey | 12.7% |
| Hargreave Hale | 6.9% |
| River & Merc. | 5.6% |

**Diary**

| | |
|---|---|
| Jul-18 | Trading update |
| Oct-18 | Finals |

**Analysts**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# Diagnostic to prevent hearing loss

## Key features

- A £550k grant awarded to GDR by the NIHR for development of a genetic diagnostic test for prevention of antibiotic-related hearing loss in newborns.
- Two-year development and trial project in an NHS point-of-care (PoC) setting.
- Potentially accelerates GDR to high-income emergency care settings, expanding beyond the low- and middle-income markets targeted with its TB and HCV tests.
- Gentamicin reactions - significant unmet need worldwide, which is impacted by the restricted choice of antibiotics resulting from growing antibiotic resistance.

### *Gentamicin and hearing loss*

Due to the genetic similarity of a mitochondrial gene (RNR1) variant to genetic sequences in bacteria, a small proportion of people experience toxicities that can lead to severe hearing loss when treated with aminoglycoside antibiotics, such as gentamicin. Gentamicin is routinely used in emergency treatment of severe bacterial infections, such as those causing sepsis, and particularly in newborn children, within an hour of admission to intensive care. Currently, detection of RNR1 variants in patients is carried out using standard laboratory tests; unfortunately, results cannot be delivered within the one-hour timeframe, and, therefore, some children experience life-altering reactions in the course of lifesaving gentamycin treatment.

### *Market potential*

Around 90,000 babies are treated per year in the UK with gentamycin. The prevalence of the most common RNR1 variant associated with adverse gentamicin reactions (m.1555A>G) is around 0.2% in Caucasian populations, meaning that, on average, 18 babies could be affected each year in the UK alone. While routine screening of all newborns may not be practicable, a rapid PoC diagnosis of those infants clinically recommended for gentamicin treatment would be cost-effective.

### *The development programme*

The UK's NIHR has awarded a £550k 'Invention to Innovation' grant to GDR for the two-year project, which is expected to begin immediately. Development of the new test is likely to be straightforward, with only slight modification of the chemistry needed for recognition of the new target gene. As with the TB and HCV tests, there will be minimal sample preparation required – a buccal swab will be all that is needed to run the test. The implementation phase of the project will involve more complexity, given that the device will need to be incorporated into existing NHS procedures and infrastructure; however, a strong collaboration has been formed with Professor William Newman at the Manchester University NHS Foundation Trust, and, therefore, it should not be unduly problematic. GDR's partners are expected to receive around the same amount of grant funding for their part in the project.

### *Impact on GDR*

This programme, if successful, would set the stage for expansion to a very large European market. It is the first programme for GDR that involves a high-income country and, should the RNR1 test be successfully implemented at a national level in the UK, it would reduce significantly the company's risk profile. We anticipate strong growth in sales of the device and testing cartridges from around 2023, as full UK market penetration is achieved and the technology is adopted by European healthcare providers.

# Summary financials

- **Services:** Grant-funded services include the NIHR grant, which is expected to be accrued in 2019 and 2020 with a weighting of around £0.4m in 2020. Grant-funded services include also the Innovate grants and income from the US DoD.
- **Discontinued ops.:** In May 2018, GDR completed the disposal of its services business for a £1.9m cash consideration, a small part of which will be deferred into 2019. Loss of income in June 2018 was around £0.3m.
- **RNR1 programme costs:** The costs have been accounted across 2019 and 2020 in proportion with the income, with no associated margin.
- **Forecasts:** Apart from the NIHR and other new grants, we have not altered our forecasts at this time (last updated for the disposal, in our June monthly publication). Our sales model of the RNR1 diagnostic impacts GDR from 2021.

**Profit & Loss account**

| Year-end June (£000) | 2015 | 2016 | 2017 | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| **Profit & Loss** | | | | | | |
| Genedrive + services | 814 | 1,906 | 2,619 | 2,049 | 3,447 | 4,826 |
| Discontinued ops. | 3,703 | 3,157 | 3,166 | 2,820 | 0 | 0 |
| **Sales** | **4,517** | **5,063** | **5,785** | **4,869** | **3,447** | **4,826** |
| COGS | -3,933 | -3,285 | -2,998 | -2,496 | -911 | -2,580 |
| SG&A | -1,500 | -2,201 | -2,513 | -2,337 | -2,068 | -1,158 |
| R&D | -2,942 | -4,836 | -5,086 | -4,700 | -4,149 | -3,796 |
| Other income | 0 | 0 | 0 | 0 | 0 | 0 |
| **Underlying EBIT** | **-3,858** | **-5,259** | **-4,812** | **-4,664** | **-3,681** | **-2,709** |
| Share based costs | -182 | -167 | -101 | -120 | -156 | -219 |
| Statutory EBIT | -4,040 | -5,426 | -7,292 | -4,784 | -3,837 | -2,927 |
| Net financials | 616 | -1,071 | -195 | -330 | -465 | -472 |
| **Pre-tax profit** | **-3,242** | **-6,330** | **-5,007** | **-4,994** | **-4,146** | **-3,180** |
| Exceptionals | **0** | **0** | **0** | **0** | **0** | **0** |
| Tax payable/credit | 399 | 582 | 1,051 | 971 | 857 | 784 |
| Underlying net income | -2,843 | -5,748 | -3,956 | -4,022 | -3,288 | -2,396 |
| **Underlying Basic EPS (p)** | **-28.30** | **-54.58** | **-21.42** | **-21.5** | **-16.4** | **-10.1** |
| Statutory Basic EPS (p) | -30.11 | -56.16 | -34.85 | -22.2 | -17.1 | -11.0 |
| | | | | | | |
| **Balance sheet** | | | | | | |
| Share capital | 158 | 158 | 280 | 283 | 357 | 357 |
| Reserves | 9,387 | 3,595 | 3,161 | -985 | -3,253 | -5,868 |
| Provisions/liabilities | 0 | 1,250 | 1,250 | 1,800 | 400 | 0 |
| Debt | 4,025 | 4,991 | 5,199 | 5,671 | 6,144 | 6,619 |
| less: Cash | 4,928 | 1,114 | 5,129 | 3,308 | 968 | -328 |
| **Invested capital** | **8,612** | **8,880** | **4,761** | **3,461** | **2,679** | **1,437** |
| | | | | | | |
| **Cashflow** | | | | | | |
| Underlying EBIT | -3,858 | -5,259 | -4,812 | -4,664 | -3,681 | -2,709 |
| Change in working capital | -1,122 | 44 | 1,308 | -398 | -440 | 134 |
| **Company op cashflow** | **-4,833** | **-4,192** | **-2,594** | **-4,068** | **-3,105** | **-1,559** |
| Capital expenditure | -758 | -164 | -70 | -100 | -125 | -156 |
| Capital increase | 80 | 0 | 6,023 | 0 | 1,250 | 0 |
| **Change in net debt** | **-3,335** | **-4,780** | **3,807** | **-2,104** | **-2,340** | **-1,297** |
| Hardman FCF/share (p) | -35.0 | -35.9 | -9.9 | -15.2 | -11.8 | -4.2 |

*Source: Hardman & Co Life Sciences Research*

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*The full detail is on page 26 of the full directive, which can be accessed here: http://ec.europa.eu/finance/docs/level-2-measures/mifid-delegated-regulation-2016-2031.pdf*

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