Advancing Pharmacogenetic testing to the point-of-care

Year End Results: 30 June 2024

genedrive plc (LSE: GDR)
2nd December 2024

Executive team

Dr Gino Miele | Chief Executive Officer

- Appointed as CEO August 2024.
- Appointed to board as CSO September 2023.
- Considerable experience in translational genomics and development of molecular diagnostic technologies and systems. Has held position of R&D Director at genedrive since 2015 and its predecessor Epistem since 2011.
- Key driver in the development of the Genedrive® system and the recent menu of pharmacogenetic tests.

Russ Shaw | Chief Financial Officer

- Appointed in April 2022.
- Over 25 years of international experience across multiple sectors including life-sciences, technology and industrials.
- 10 years as Finance Director at Driver Group plc, an AIM quoted company operating in the engineering and construction industry.
- CFO of several private companies and is a qualified Accountant and Treasury professional.

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Agenda

- Our products
- FY'24 Highlights
- Positioning & progress
- Summary financials
- Outlook & future newsflow

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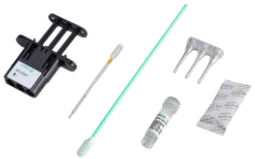
Our Products

SYSTEM

MT-RNR1

CYP2C19



- The Genedrive® system is a low-cost, simple-to-use molecular diagnostic device. Positioned for rapid, clinically actionable pharmacogenetic test results
- We have developed two flagship rapid Point of Care tests for deployment on the Genedrive® system;
- **MT-RNR1 Kit;** the world's first genetic test to help avoid Antibiotic Induced Hearing Loss (AIHL) in neonatal intensive care
- **CYP2C19 Kit;** genetic test to enable more effective management of stroke patients – first point of care product to maximise ethnic inclusivity

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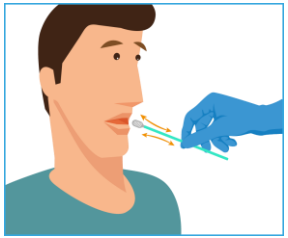
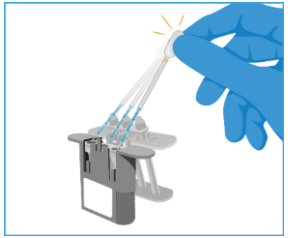
Simplicity & speed to result



- Designed to be used by healthcare professionals in time-critical emergency care settings, enabling rapid clinical decisions on optimal therapeutic prescription



- Simple, minimally invasive adult or neonate cheek swab sample
- Used to reconstitute freeze-dried, ambient temperature stable cartridge test reagents

- Automated genetic test result available to clinician in 26 minutes for MT-RNR1, and 69 minutes for CYP2C19, both being **well within clinically actionable timeframe required.**

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FY 2024 Highlights

OPERATIONAL

MT-RNR1

- Initial orders for new sites in the UK
- Routine clinical use in Royal Sussex County Hospital, Brighton
- NIHR/OLS funding package to collaborators to address NICE evidence gaps in 14 UK hospitals (£500K sales revenue)
- Breakthrough device designation by US FDA
- Agreements with US distributor and Multi-state physician-led organization with broad coverage of US NICU sites.
- Positive assessment by Scottish Health Technology Group (SHTG) for implementation case in Scotland

CYP2C19

- UKCA marking (permitting commercialisation in UK and ME countries recognizing UKCA)
- Completion of clinical studies required for CE-IVD submission, with genedrive PoC test performance superior to laboratory platform.
- Recommendation by NICE as the PoC platform of choice for use in the NHS
- First UK sales (one of the largest Hyperacute stroke centre in NHSE)
- Positive assessment by Scottish Health Technology Group (SHTG) for implementation case in Scotland

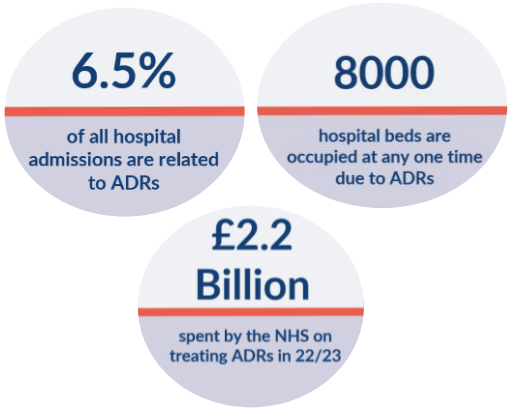
FINANCIAL

- Revenue & other income of £0.5M (2023; £0.06M)
- Successful equity fundraise of £6M (gross) in June 2024, with use of funds focused towards commercial growth initiatives.

What is Pharmacogenetics (PGx) ?

The study of DNA variations relating to patient responses to drugs

- 90% of medications work only in 30-50% of people, with DNA variation affecting patient responses (ineffective or adverse responses)
- Adverse Drug Reactions account for 6.5% of hospital admissions



- **30%** of ADRs may be **preventable by PGx testing**

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What is Pharmacogenetics (PGx) ?

The study of DNA variations relating to patient responses to drugs

- **Availability of an individual's genetic information to a clinician**;
  - ✓ helps address ineffective medication and adverse events
  - ✓ better informs medicine selection and dosing
  - ✓ improves patient outcomes
  - ✓ reduces healthcare costs

- PGx testing is mainly performed in centralised laboratories on expensive equipment and typically **cannot address emergency care requirements** where **rapid bedside result is required**.
- Actionable pharmacogenetics in **emergency care requires test results quicker** than laboratory-based testing can currently provide.
- **genedrive provides the solutions to this**

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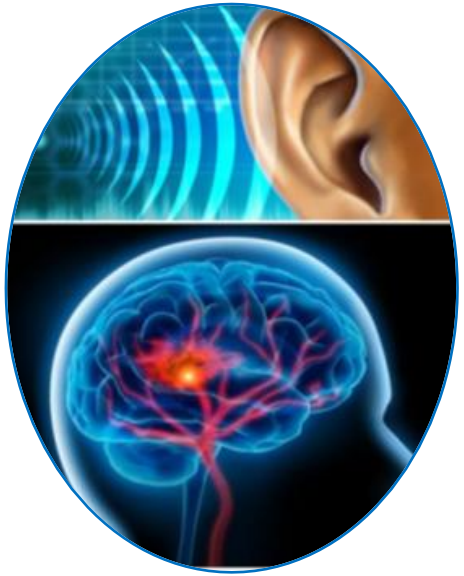
Our potential

Whilst PGx testing in emergency care is an emerging clinical paradigm, with a high barrier regulatory framework & complex market access and reimbursement frameworks.....

- Both of our PGx tests have **clear unmet clinical need globally**, and have been developed **with the NHS for the NHS**.
- Our tests offer **significant benefits to patients and healthcare systems**, and are **recommended by NICE** for use in the UK NHS
- Our Markets are significant relative to our size – **global opportunity** estimated at over **£300M p.a**.
- There is **no current comparably positioned competition** to our point of care tests in emergency care paradigms
- We are actively **in commercialisation phase -** D2C strategy in UK and focused distributor network internationally



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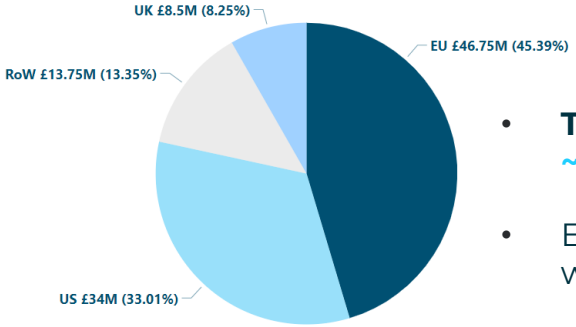
Antibiotic Induced Hearing Loss (AIHL)

MT-RNR1

- ~1 in 7 babies born are admitted to Neonatal Units (~100K in UK pa), with a significant proportion requiring antibiotics
- Antibiotics required within 1hr ("Golden Hour") of decision to treat for suspected sepsis.
- ~1 in 500 of these will carry a variant in the MT-RNR1 gene DNA that places them at high risk of AIHL (profound, bilateral and irreversible hearing loss, requiring cochlear implants).
- **genedrive's MT-RNR1 test identifies those individuals prior to administration of antibiotics, reducing risk of AIHL.**
- **World's first** point of care pharmacogenetic test for AIHL in Neonatal Intensive Care Unit settings (CE-IVD)



- **Total annual addressable market estimate = ~£100M p.a.**[1]
- Estimated to save NHS England ~£5M / year as well as avoiding AIHL in these babies.

[1] International assumptions are based on extrapolation from population sizes, birth rates & UK NICU admission rates & based on direct business model

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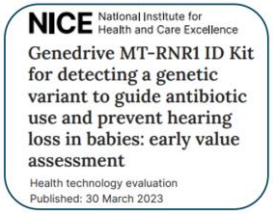
Progress: AIHL

MT-RNR1

- Direct sales model in UK and focused distributor network internationally



- Recommended by NICE for use in NHS England (whilst further performance evidence is gathered) & positive assessment from SHTG for use in NHS Scotland (Oct.2024).
- NIHR / OLS Funding package to collaborators to address evidence gaps required by NICE (£500K revenue over 18mths) to transition to full recommendation (14 hospitals across UK nations).
- Growing commercial traction
  - *Routine clinical use in 9 hospitals in UK, with further 5 committed.*
  - **Recurring revenue** business model ***~4,000 babies / year currently (4% of UK market)*** *(~10 saved from AIHL).*
  - *Initial international traction via distributor network (live sites in Europe and ME)*

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Progress: AIHL

MT-RNR1

- Awarded Breakthrough Device Designation by US FDA (July '24), facilitating regulatory submission route.

  "formal identification by the US FDA that a device in development should be expedited for patient access because ..... of providing more effective treatment than the standard of care for the treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."

- *International Biomedical – US distributor*
- *US Clinical research partner – wide multistate coverage of US NICUs.*
- *Consultation phase with FDA on study requirements (internal and inc. clinical)*
- *~12 months for studies /~1 year review by FDA under program (late 2026) – on track with previously communicated timelines*
- *Expediting where possible (e.g. seeking to use PALOH-UK clinical evidence)*

[1] International assumptions based on extrapolation from population sizes, birth rates & UK NICU admission rates & based on direct business model

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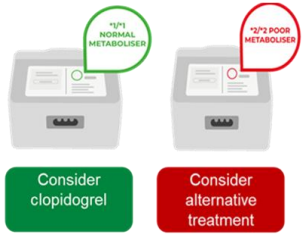
CYP2C19 & Stroke Management

- There are >100,000 strokes p.a in the UK (12M p.a globally and rising)
- ~100M people globally living with effect of stroke (cost of $451Bn in 2017)
- Stroke is treated with antiplatelet drugs, such as Clopidogrel, with stroke guidance recommending administration **within 24 hours**.

- Clopidogrel needs to be broken down by CYP2C19 to become active but variants in CYP2C19 can impair this (e.g. *2, *3, *4, *8, *35), leading to poorer patient outcomes.

CYP2C19

- Rapid Point of care pharmacogenetic test for DNA variants in the *CYP2C19* gene (UKCA)
- The only PoC test with coverage of 5 key variants which underpin stroke patient response to the commonly prescribed antiplatelet Clopidogrel



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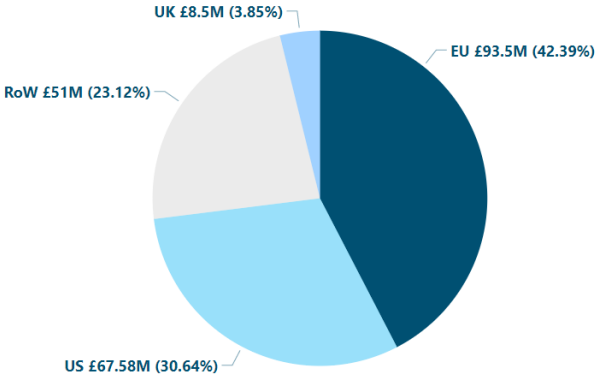
CYP2C19 & Stroke Management

~30% of people carry variants in CYP2C19 known to impair efficacy of Clopidogrel (**50%** in certain ethnic groups). **The genedrive CYP2C19 test identifies five of these, with results available to the clinician in ~70 mins.**

Interventional CYP2C19 testing to optimise antiplatelet therapy in stroke is estimated to **save NHS England ~£160M annually & offer better patient outcomes**.



- **Total annual addressable Market estimate = £220M p.a**[1]
- Middle East & US are key international markets
- Stroke incidence in Middle East is high and age of onset is in younger age group (50% under 45yrs in UAE).
- US entry will be pursued via 510(k) route

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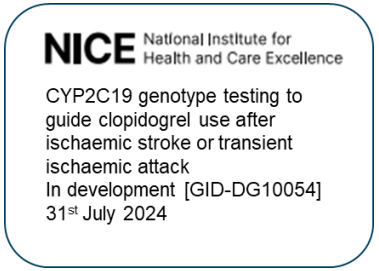
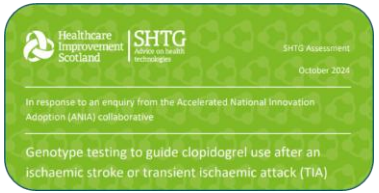
Progress

CYP2C19

- Direct sales model in UK and distributor network (tbd) internationally





- UKCA, with CE-IVD anticipated end-Q1 2024.
- Recommended by NICE as PoC test of choice for NHSE
- Positive value assessment by SHTG for use in Scotland.
- "DEVOTE" clinical study demonstrated superior performance relative to centralised laboratory reference test (speed, accuracy, successful tests & target coverage).

- **~4%** of patients unlikely to respond to clopidogrel **would not be identified by focus on *2/*3 alone (e.g. comparator POC test or some lab tests.**
- Our test increases ethnic inclusivity and facilitates **equitable access to healthcare.**

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Progress

CYP2C19

Initial commercial focus is on regions recognising UKCA (UK, ME) followed by regions recognising CE-IVD & US FDA.

UK:

Ongoing NHSE “pilot” to establish development of an accessible and efficient model for incorporating CYP2C19 genetic testing into stroke and TIA care in NHSE

- expected to conclude April 2025, with further UK business model clarity subsequently
- First sales to largest Hyper Acute Stroke Centre in NHSE & several other stroke centres expected to implement in advance of NHSE pilot concluding

Europe & ME:

Focus on ME (UKCA) and subsequently Europe with CE-IVD.

US:

Pursual of US market via 510(k) route.

FY24 Summary Financials

Income statement	FY24 £'000	FY23 £'000	
Revenue and other income	501	55	Revenue - RNR1 in routine use and grant income received
R&D costs	(4,175)	(3,924)	£0.25m increase, includes the DEVOTE programme costs
Admin costs	(1,638)	(1,355)	£0.3m increase due to enhanced sales and support efforts
Operating loss	(5,312)	(5,224)	
Finance costs	(2,468)	(787)	£1.9m non-cash fair value adjustment and £0.6m transaction costs
Finance income	30	30	
Loss before tax	(7,750)	(5,981)	
Tax	675	831	Reflects reduction in HMRC R&D tax relief rates
Loss after tax	(7,075)	(5,150)	

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FY24 Cashflow

Cashflow	FY24 £'000	FY23 £'000	
Operating loss before changes in working capital	(5,006)	(4,874)	Slight increase from the prior year
Working capital	407	113	£0.3m higher than FY23 mainly due to creditors
Taxation	831	956	£0.8m receipt from HMRC R&D tax credit scheme
Net cashflow from operations	(3,768)	(3,805)	
Proceeds from investment funding	7,200	2,300	Fund raise of £5.4m (net) announced in June 2024
Transaction costs - investment funding	(614)	(283)	
Repayment of lease liabilities	(222)	(193)	
Other	(9)	(7)	
Net cash flow	2,587	(1,988)	
Cash at beginning of year	2,601	4,589	
Cash at end of year	**5,188**	**2,601**	Unaudited cash at 21 November 2024 of £3m

Underlying monthly burn rate:	FY24 £'000	FY23 £'000	
Gross	(403)	(413)	Underlying cash consumption of £0.4m pcm
Adjusted for taxation	(333)	(334)	Monthly rate reduces to £0.33m

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Summary & Outlook

- **Genedrive are well positioned to capitalise on the emerging paradigm of near-patient pharmacogenetic testing**
- **Two world-leading genetic tests for use in near-patient, time critical emergency care settings;**

  - ✓ With clear global unmet clinical need & recommended by NICE
  - ✓ Underpinned by positive clinical guidance recommendations & value assessments
  - ✓ Strong health economic cases (patient & financial)
  - ✓ Global addressable market of ~£320M p.a.
  - ✓ No competitors currently similarly positioned with equivalent offering
  - ✓ On-track regulatory & registration processes for target regions
  - ✓ Growing domestic and international commercial traction

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Newsflow – what to expect

Near term

- Implementation plans for MT-RNR1 in Scotland
- Implementation plans for CYP2C19 in Scotland
- CYP2C19 ID Kit performance against laboratory platform
- CYP2C19 CE-IVD certification progress
- Commercial progress for both products domestically & internationally (when significant), throughout FYs.

Medium to longer term

- Product development
- US FDA 510(k) submission progress for CYP2C19

Longer term

- PALOH-UK and NICE evidence gap closure progress.
- US FDA *de novo* submission progress under Breakthrough Device Program.

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Mission & Values

At genedrive, we are;

- Innovative, entrepreneurial & commercially focused individuals with deep expertise in pioneering near patient molecular diagnostic solutions into complex healthcare systems.
- Passionate about our disruptive products, enabling better patient outcomes, and addressing health inequalities whilst offering significant financial savings to healthcare systems.
- Committed to growing our company to be a world leader in near patient pharmacogenetic testing & delivering value for our shareholders & stakeholders.

Q&A

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