

# Advancing **Pharmacogenetic testing** to the **point-of-care**

## Year End Results: 30 June 2024

genedrive plc (LSE: GDR)  
2<sup>nd</sup> December 2024

# Executive team

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## **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.

# Agenda

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

# Our Products

**GD**  
SYSTEM



- The Genedrive® system is a **low-cost, simple-to-use** molecular diagnostic device. Positioned for **rapid, clinically actionable** pharmacogenetic test results

**GD**  
MT-RNR1



- We have developed **two flagship rapid Point of Care tests** for deployment on the Genedrive® system;

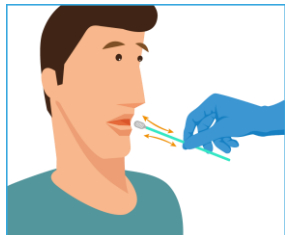
- **MT-RNR1 Kit;** the **world's first** genetic test to help avoid Antibiotic Induced Hearing Loss (AIHL) in neonatal intensive care

**GD**  
CYP2C19

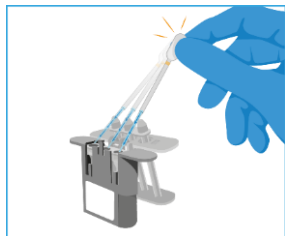


- **CYP2C19 Kit;** genetic test to enable more effective management of stroke patients – **first point of care product to maximise ethnic inclusivity**

# 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.**

# FY 2024 Highlights

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## 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.



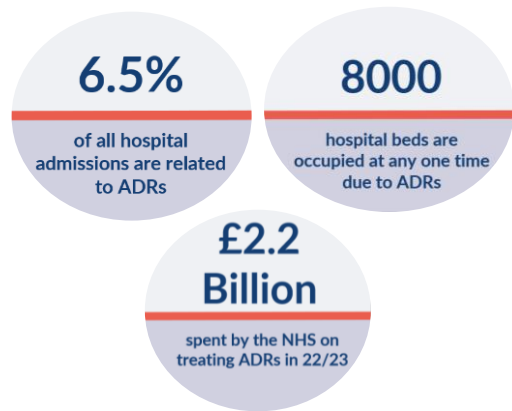
# What is Pharmacogenetics (PGx) ?

*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**



Up to  
**£660 million**  
could be saved

# 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**





# 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.....*

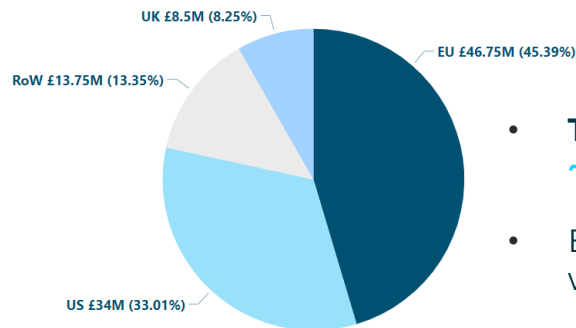
- Both of our PGx tests have **clear unmet clinical need globally**, and have been developed **with the NHS for the NHS**.
- Our tests offer **significant benefits to patients and healthcare systems**, and are **recommended by NICE** for use in the UK NHS
- Our Markets are significant relative to our 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**



# Antibiotic Induced Hearing Loss (AIHL)



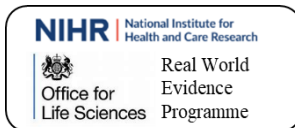
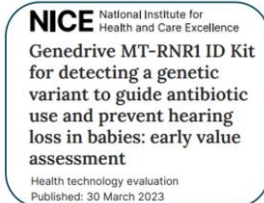
- ~1 in 7 babies born are admitted to Neonatal Units (~100K in UK pa), with a significant proportion requiring antibiotics
- Antibiotics required within 1hr ("Golden Hour") of decision to treat for suspected sepsis.
- ~1 in 500 of these will carry a variant in the MT-RNR1 gene DNA that places them at 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.<sup>1</sup>**
- Estimated to save NHS England ~£5M / year as well as avoiding AIHL in these babies.

# Progress: AIHL

- **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)*



- 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)*

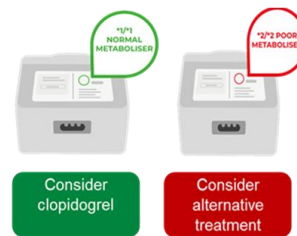
# CYP2C19 & Stroke Management



- 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.



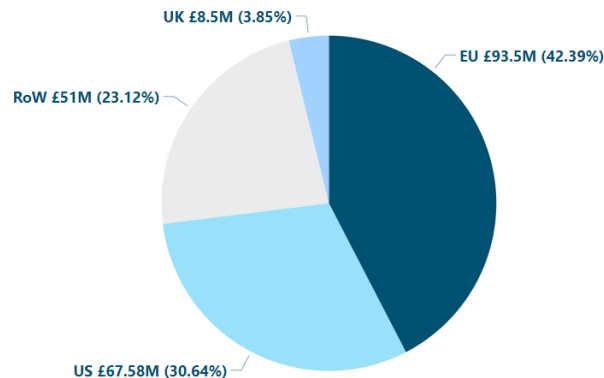
- Rapid Point of care pharmacogenetic test for DNA variants in the CYP2C19 gene (UKCA)
- The only PoC test with coverage of 5 key variants which underpin stroke patient response to the commonly prescribed antiplatelet Clopidogrel



# 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<sup>1</sup>**
- 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

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

## NICE National Institute for Health and Care Excellence

CYP2C19 genotype testing to guide clopidogrel use after ischaemic stroke or transient ischaemic attack  
In development [GID-DG10054]  
31<sup>st</sup> July 2024

- 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).



In response to an enquiry from the Accelerated National Innovation Adoption (ANIA) collaborative

Genotype testing to guide clopidogrel use after an ischaemic stroke or transient ischaemic attack (TIA)

- ~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.**



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 - RNRI 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)	



# 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	<b>5,188</b>	<b>2,601</b>	Unaudited cash at 21 November 2024 of £3m
<b>Underlying monthly burn rate:</b>	<b>FY24 £'000</b>	<b>FY23 £'000</b>	
<b>Gross</b>	(403)	(413)	Underlying cash consumption of £0.4m pcm
<b>Adjusted for taxation</b>	(333)	(334)	Monthly rate reduces to £0.33m



# Summary & Outlook

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- 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

# Newsflow – what to expect

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## 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.

# Mission & Values

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## 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