

**genedrive plc**  
**("genedrive" or the "Company")**

**Interim results to 31 December 2024**

genedrive plc (LSE: GDR), the point of care pharmacogenetic testing company, announces unaudited interim results for the six months to 31 December 2024.

**OPERATING HIGHLIGHTS (including post period)**

**Genedrive® CYP2C19**

- First UK commercial sales of the Genedrive® CYP2C19-ID Kit to England's largest Hyperacute Stroke Centre
- North West Anglia Foundation NHS Trusts' Peterborough City Hospital implements the Genedrive® CYP2C19-ID Kit for routine clinical use
- Growing base of initial installations for site verifications expected to lead to subsequent routine clinical use
- Positive value assessment by the Scottish Health Technologies Group (SHTG) following referral by the Accelerated National Adoption (ANIA) pathway group in Scotland, leading to the Scottish Government announcement of investment to support national pharmacogenetic testing of CYP2C19 in Stroke patients, including genedrive's CYP2C19-ID test for rapid genetic testing in Transient Ischaemic Attack (TIA) patients
- NICE recommendation of the Genedrive® CYP2C19-ID Kit as the rapid genetic testing platform of choice for CYP2C19 genotyping strategies for clopidogrel administration in ischaemic stroke (IS) and TIA, with Genedrive's CYP2C19 ID Kit being dominant in cost effectiveness models
- Genedrive® CYP2C19-ID Kit clinical performance published in Journal of Molecular Diagnostics (December 2024), outlining superior performance to laboratory test and alternative available point of care (PoC) platforms with respect to target coverage, speed, accuracy and test fails
- Inclusion in study aimed at understanding how best to deliver CYP2C19 based genotyping at scale throughout the NHS, and accepted on NHS Dynamic Procurement System (DPS), permitting direct procurement by regional NHS trusts
- Market access routes and reimbursement strategies defined in key initial international target countries, including the Middle East region, with well-positioned and aligned in-country distributors, with required regulatory certification (CE-IVD under IVDR) on track for April 2025
- 510(k) route identified for regulatory submission for US market entry, with initial pre-submission engagement with Food and Drug Administration (FDA) held and feedback positive and with regulatory approach confirmed as appropriate

**Genedrive® MT-RNR1**

- Scottish Government announcement of £800k investment to support national phased implementation program of pharmacogenetic testing of MT-RNR1 in newborn babies in NHS Scotland using Genedrive's MT-RNR1 ID Kit
- NIHR and OLS Funding Package of c.£500k to address NICE Real World Evidence Generation Requirements for the Genedrive® MT-RNR1 ID Kit across 14 hospitals across the UK (PALOH-UK). Progressing as planned, with nine Group 1 sites live, with a further five Group 2 sites phased to go-live from May 2025
- 11 babies identified as positive for the MT-RNR1 DNA variant since introduction of the test into Neonatal Intensive Care Units (NICU) in the UK and avoiding lifelong hearing loss resulting from aminoglycoside exposure
- Distributors contracted in key international geographies, with site installations in Italy and Saudi Arabia and additional sites expected near-term
- Accepted on NHS Dynamic Procurement System (DPS), permitting direct procurement by regional NHS trusts
- Breakthrough Device Designation received from the FDA. Progressing as planned, with first-engagement

with FDA under programme initiated

#### **Genedrive**

- Expansion of operational capabilities; onshoring and increased production pipeline of instrumentation, with internalisation of MT-RNR1 and CYP2C19 assay manufacturing to be dual-source supply and complement external vendors scaled-up production capabilities
- Growing base of post-implementation phase "routine clinical user" sites which in turn lead to recurring revenue source for both tests
- Expansion of sales and marketing team, in-country distributors and in-country market access facilitation
- Product Development: focus on on-market product support of CYP2C19 and MT-RNR1, with routine product improvements to further facilitate ease of implementation and usability

#### **FINANCIAL**

- Revenue and other income of £0.35m (H1 2023/4: £0.24m)
- R&D spend of £2.1m (H1 2023/4: £1.9m)
- Operating loss of £2.6m (H1 2023/4: £2.4m)
- Cash of £2.1m as at 31 December 2024 (30 June 2024: £5.2m)
- Cash of £1m as at 20 March 2025
- Equity fundraise of up to £1.25m announced (see separate announcement today)

**Gino Miele, CEO of genedrive plc, commented:**"Thousands of people experience adverse reactions to drugs every year, with medicines being ineffective, or leading to unintended side effects or fatality. This costs the NHS £2.2 billion per year in England alone and it has been estimated that application of PGx could avoid this in approximately 39% of individuals, therefore saving £860 million per year. It is estimated that the value to the NHS of interventional CYP2C19 testing alone if implemented nationally is £160 million per year, equating to one-third of the total savings offered recently by the announcement of the abolishment of NHS England and the accompanying loss of 9,000 jobs. Having expanded our UK sales team, our international commercialisation partners and distribution network we are now seeing clear signs of commercial traction, where following significant preceding phases several sites are becoming routine clinical users, presenting a recurring source of revenue to the company. We are confident that this will continue to grow both in our domestic and international markets, with routine clinical use and growing revenue and pipeline opportunities evidencing clinical need and market fit for our novel products. The UK NHS has a huge opportunity to lead the way in precision medicine and indeed, organisations such as NHS Scotland have approached this in an integrated, forward thinking entrepreneurial manner with the pending deployment of MT-RNR1 and CYP2C19 testing at national scale. I am proud that our company is a key part of this and confident about our future commercial prospects in our markets."

#### **genedrive plc**

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#### **About genedrive plc (<http://www.genedriveplc.com>).**

genedrive plc is a pharmacogenetic testing company developing and commercialising a low cost, rapid, versatile and simple to use point of need pharmacogenetic platform for the diagnosis of genetic variants. This helps clinicians to quickly access key genetic information that will aid them make the right choices over the right medicine or dosage to use for an effective treatment, particularly important in time-critical emergency care healthcare paradigms. Based in the UK, the Company is at the forefront of Point of Care pharmacogenetic testing in emergency healthcare. Pharmacogenetics informs on how your individual genetics impact a medicines ability to work for you. Therefore, by using pharmacogenetics, medicine choices can be personalised, made safer and more effective. The Company has launched its two flagship products, the Genedrive® MT-RNR1 ID Kit and the Genedrive® CYP2C19 ID Kit, both developed and validated in collaboration with NHS partners and deployed on its point of care, therapeutic platform. Both tests are

collaboration with NHS partners and deployed on its point of care thermocycler platform. Both tests are single-use disposable cartridges which are ambient temperature stable, circumventing the requirement for cold chain logistics. The Directors believe the Genedrive® MT-RNR1 ID Kit is a world's-first and allows clinicians to make a decision on antibiotic use in neonatal intensive care units within 26 minutes, ensuring vital care is delivered, avoiding adverse effects potentially otherwise encountered and with no negative impact on the patient care pathway. Its CYP2C19 ID Kit which has no comparably positioned competitor currently allows clinicians to make a decision on the use of Clopidogrel in stroke patients in 70 minutes, ensuring that patients who are unlikely to benefit from or suffer adverse effects from Clopidogrel receive an alternative antiplatelet therapeutic in a timely manner, ultimately improving outcomes. Both tests have undergone review by the National Institute for Health and Care Clinical Excellence ("NICE") and have been recommended for use in the UK NHS.

The Company has a clear commercial strategy focused on accelerating growth through maximising in-market sales, geographic and portfolio expansion and strategic M&A, and operates out of its facilities in Manchester.

## **CHIEF EXECUTIVE OFFICER'S AND CHAIRMAN'S REPORT**

During the period genedrive maintained a strong focus on executing its commercial strategy in rapid genetic testing, establishing a solid foundation for continued sustainable growth. Thousands of people experience adverse reactions to drugs every year, with medicines being ineffective, or leading to unintended side effects or fatality. This costs the NHS £2.2 billion per year in England alone and it has been estimated that the application of pharmacogenetics (PGx) could avoid this in approximately 39% of individuals, therefore saving approximately £860 million per year<sup>1</sup>. In addition to the avoidable costs to the NHS, there are wider costs to society such as loss of productivity and cost of social care. With an increasing shift from treatment to prevention, and the need for speedier diagnosis, we are well positioned to provide solutions to this, enabling substantially improved patient outcomes whilst at the same time offering significant financial savings and freeing of resources to pressured healthcare systems.

Our focus on positioning the Company at the forefront of near-patient rapid genetic testing is substantiated by recent government strategy announcements throughout the UK, with particular traction in Scotland, where the strategic outlook is to implement PGx within NHS Scotland at national scale, and the genedrive products have an important role in this strategy. This is especially the case in the avoidance of hearing loss in neonates in Neonatal Intensive Care Units (NICU), but also in the rapid genetic testing of CYP2C19 in Transient Ischaemic Attack (TIA) stroke patients, where timely prescription of antiplatelet drugs for pre-emptive prediction of response is critical.

Stroke has a particularly significant financial burden on healthcare systems. The Stroke Association estimate the aggregate cost of stroke in the UK, could reach £75 billion per annum by 2035. The estimated annual saving is £160m for the interventional CYP2C19 testing alone<sup>2</sup> and equates to one-third of the total savings offered recently by the UK government announcement of the biggest structural reform of the NHS in over a decade. We are encouraged by the new Government's focus on driving efficiencies within the NHS and we envisage broader and more rapid adoption of PGx testing as a way of helping to achieve this, both saving money and improving patient outcomes.

There is undoubtedly a clear need for operational and strategic reform that can contribute to mitigating these avoidable outcomes and improve efficient use of resources to lead to "better care, smarter care" for patients, with preventative healthcare as a core strategy essential relative to increasing budgetary allocations to address the impact. Support for development of innovations in the UK is high, but reimbursement routes for implementation are poorly defined in the NHS, particularly in NHS England. A striking example of this is seen with our MT-RNR1 interventional test, where budget for dealing with the avoidable impact of antibiotic induced hearing loss is available to audiology via national commissioning (bilateral cochlear implants) but the savings enabled are not yet available at the upstream location of intervention, with an additional budgetary pressure on Neonatology. Similarly, whilst savings of approximately £160 million annually are estimated for implementation of CYP2C19 testing, these are effected downstream from where the additional cost for intervention is required. Whilst these are current challenges at national level within the NHS we remain confident that they can be resolved, particularly given the approach by the Scottish Government to address shared implementation centrally via provision of funding for the ANA pathway.

phased implementation centrally via provision of funding for the ANIA pathway.

In the interim to national commissioning, Integrated Care Boards (ICBs), trusts, Health Innovation Networks (HiNs) and clinicians are able to procure via existing locally available budgets and we are pleased to report adoption at several sites for both of our tests in the UK. Implementation leading to routine clinical use is preceded by several stages in addition to securing of finances, including verification by local Point of Care Test teams. Once implemented as a routine clinical service, these sites become sources of recurring revenue generation for genedrive.

The period saw significant advancement operationally, in particular with our tests receiving positive assessments in addition to NICE by the SHTG, ultimately leading to strategic planning for phased implementation throughout Scotland. Funding provision to collaborators being made available by the National Institute for Health and Care Research (NIHR) and the Office for Life Sciences (OLS) enabling data generation across the UK nations to address evidence gaps required by NICE to transition from the highest "conditional recommendation" under the Early Value Assessment (EVA) programme and permitting use in the NHS, to full recommendation. It is heartening to note that since introduction of our test, eleven babies cared for in NICUs in the UK have avoided lifelong deafness that might otherwise have been caused by exposure to aminoglycoside antibiotics. Our team is working tirelessly with our distribution network to enable this same change in paradigm of care internationally, with traction beginning to be realised with installations in Italy and Saudi Arabia.

We have invested significantly in development and pre-commercialisation requirements for enabling our CYP2C19-ID test as a pre-emptive step in management of stroke patients and prescription of the antiplatelet clopidogrel. With NICE recommendation as the point-of-care platform of choice, highly impactful health economic cases, clear and valuable differentiation to current incumbent comparator technology, we are pleased to report early traction with implementation at two Hyper Acute Stroke Centres, one being the largest in NHS England, and look forward to reporting further as these routine user sites grow. Unlike our MT-RNR1 test currently, there is a private Canadian based company that offers a CYP2C19 point of care platform. Whilst we believe, as outlined by NICE, that the valuable differentiators of our CYP2C19 platform are significant, we intend to be mindful of balancing our desire to rightly keep our shareholders up to date with operational progress against seeking to maintain a competitive edge over any emerging competition.

#### **Genedrive® MT-RNR1-ID Kit**

The Genedrive® MT-RNR1 kit is the world's first rapid point-of-care test to screen infants in an urgent care setting for a genetic variant that can cause life-long hearing loss when carriers of the variant are given certain antibiotics. Those infants identified by the Genedrive® MT-RNR1 ID kit as carrying the variant can then be given alternative antibiotics. It has the potential to save thousands of children from lifelong hearing loss, whilst providing a net positive financial outcome case to global healthcare systems. The test is CE-IVD certified, permitting registration and sales to the EU and other countries that are accepting of the CE mark.

NICE developed a new Early Value Assessment (EVA) approach to assess the technologies that are most needed and in demand, allowing rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money, so that the NHS and patients can benefit from these promising technologies sooner. NICE recommended the Genedrive® MT-RNR1 kit for use in the NHS England and Wales through its EVA in March 2023, with the (highest) recommendation for use in the NHS being conditional on further evidence being generated. Subsequently, NIHR in collaboration with the OLS awarded £0.5m of funding to the PALOH-UK program to address evidence generation requirements of the NICE EVA.

PALOH-UK commenced in November 2024 and has a maximum duration of 18 months, with sites phased into two groups: Group 1, consisting of the nine sites currently using the test and Group 2, the remaining five sites, with phased go-live from May 25.

The U.S. is a key strategic market, given the estimated number of positive patient outcomes and the associated cost savings that our test offer, which are substantially exemplified by the litigious nature of the U.S. FDA Breakthrough Device Designation was received in July 2024, offering the opportunity to interact with FDA experts and a prioritised review of our submission. We are progressing as planned, with first-engagement with the FDA under programme reviewing plans for evidencing test performance required. The U.S. clinical studies are expected to take 12-18 months from first patient recruitment and the FDA Breakthrough programme can expediate the regulatory review, so that it takes less than 300 days. The

performance data generated during the EVA programme is also expected to contribute towards clinical performance data requirements for FDA.

### **Genedrive® CYP2C19-ID Kit**

The Genedrive® CYP2C19-ID Kit tests for identification of individuals unlikely to respond to the commonly prescribed antiplatelet drug Clopidogrel, enabling more effective management of stroke patient treatment, and which is the only PoC test offering additional coverage of several DNA variants enriched in certain ethnic groups. It is currently UKCA certified and the Company remains on track for CE-IVD certification in April 2025.

NICE recommended genedrive as the PoC instrument of choice in July 2024, this was quickly followed by the first commercial order from NHS England's largest Hyperacute Stroke Centre in Salford. The subsequent clinical interest and engagement has been positive, with Peterborough City Hospital being the first hospital to adopt the test outside of the implementation study and we are seeing a growing base of initial installations for site verifications leading to expected routine clinical use.

The Innovate UK funded DEVOTE programme concluded the validation and verification and in December 2024 the clinical performance was published in Journal of Molecular Diagnostics, outlining superior performance to the reference laboratory test with respect to target coverage, speed, accuracy and test fails, and by definition superior to the comparator PoC platform with respect to target coverage.

Ahead of CE-IVD certification we have invested significant resources in defining the market access and reimbursement routes in target European & Middle East countries, onboarding of qualified distributors and are progressing through early stages of customer adoption sites, inclusive of conversion of distributors and users considering using the comparator PoC test to ours. In addition to Europe and the Middle East region, the U.S. is a key target market, where CYP2C19 genotype-guided prescription of Clopidogrel has been recommended by the American Heart Association for cardiovascular indications as well as IS/TIA. We have had initial pre-submission engagement with FDA, receiving positive feedback and confirmation of our strategy, with the 510(k) route being identified for regulatory submission for U.S. market entry. We look forward to updating shareholders on progress in due course.

### **People**

Strategic changes were made to the composition of the Board and senior leadership, with the associated cost savings beginning in H2 of FY25. We have exceptionally talented and highly skilled people and during the period we increased headcount from 43 to 50, to drive forward our commercial efforts and to support our international regulatory requirements.

### **FINANCIAL RESULTS**

Revenue and other income in the period was £0.35m (H1 2023/4: £0.24m).

Research and development costs were £2.1m (H1 2023/4: £1.9m) as the key focus was validation and verification of CYP2C19 and associated regulatory costs. Administration costs at £862k (H1 2023/4: £721k) have increased due to business development, marketing and support team expansion in the UK, EU and the Middle East. The operating loss for the period was £2.6m (H1 2023/4: £2.4m) with finance income in the period of £41k (H1 2023/4: net finance costs of £30k).

After financing costs, the loss before taxation was £2.5m (H1 2023/4: £2.4m). The loss after taxation decreases to £2.3m (H1 2023/4: £2.0m) after estimating the six-month taxation credit as £0.2m (H1 2023/4: £0.35m). The basic loss per share was 0.4p (H1 2023/4: 2.0p).

### **Cash Resources**

The operating loss for the period was £2.6m (H1 2023/4: £2.4m) and working capital reduced by £0.6m (H1 2023/4: £0.2m). Net cash out-flow from operations was £3.1m (H1 2023/4: £2.4m) and as the R&D tax credit was not received in the period the net cash flow from operating activities was also £3.1m.

Cash flows from financing activities consisted of lease liability repayments of £19k (H1 2023/4: £112k) and

there are no proceeds from the financing activities (H1 2023/4: £1.2m).

Closing cash was £2.1m (31 December 2023: £1.2m). The cash balance on 20 March 2025 was £1m with the FY24 R&D tax credit expected in the coming weeks. The current levels of operating expenditure is circa £0.5m per month, revenue and grant funding when received reducing the rate of cash burn. The Company has today announced an equity fundraise of up to £1.25m, the net proceeds of which will provide additional working capital as the Company actively pursues a broad range of growing commercial opportunities in the UK and internationally at the present time.

### **Balance Sheet**

Balance sheet net assets at 31 December 2024 were £3.1m (30 June 2024: £5.4m; 31 December 2023: £1.5m) and the consolidated loss of the period was £2.3m (H1 2023/4: £2m).

### **PRINCIPAL RISKS AND UNCERTAINTIES**

There are a number of potential risks and uncertainties which could have a material impact on the Company's performance over the remaining six months of the financial year and could cause actual results to differ materially from expected and historical results. The Directors do not consider that these principal risks and uncertainties have changed materially since publication of the annual report for the year ended 30 June 2024; a more detailed explanation of the risks for the Company can be found on page 30 of the annual report.

### **Going Concern**

We have increased visibility of our sales pipeline and are beginning to see opportunities come into fruition, we remain reasonably confident of securing more significant revenues, but the timing of them remains unclear. As described in the accounting policies, we continue to adopt a going concern basis for the preparation of the accounts, but the above condition represents a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern.

### **OUTLOOK**

Innovation is the key focus of the NHS Long Term Plan and we are immensely proud of the development of our tests with the NHS for the NHS. As outlined in the recent Scottish Government announcement, approximately £0.8m will fund a programme for testing newborn babies with genedrive's MT-RNR-ID kit, in a phased national roll out over 18 months with first clinical testing beginning in October 2025. Once fully implemented it is expected that over 3,000 babies per year will receive the MT-RNR1-ID test throughout Scotland. A further £1.1m will support interventional CYP2C19 testing in recent stroke patients and whilst primarily focused on laboratory-based testing with substantially slower turnaround times, the Genedrive® CYP2C19-ID kit will be included for assessment against laboratory testing pathways in Transient Ischaemic Attack (TIA) clinics.

We are actively pursuing a broad range of growing commercial opportunities in the UK and internationally at the present time, including both commercial sales and potential non-dilutive grant income. CE-IVD certification for our CYP2C19 test will also enable in-country registration and subsequently sales of the test to commence outside of the UK and we are particularly encouraged by opportunities presented in the Middle East region, where we have focused significant efforts and expenditure to understand market access and reimbursement routes as well as identification of primary target hospitals, opinion leaders and healthcare organisations and will update further in due course as opportunities are converted as appropriate. The additional funding we have announced today provides the Company with an extended cash runway to seek to close a number of the commercial and other opportunities in front of us and further drive shareholder value. The Board continues to assess longer term financing options in the meantime.

The U.S. remains a significant opportunity for both of our tests. Whilst we are in the early stages of interaction with FDA under Breakthrough Device Designation status awarded for our MT-RNR1 test, progression is as to plan and previously reported, but with complexities to navigate that are inherent to planning for FDA-required evidencing of safety and performance for a novel diagnostic test such as ours, particularly in a vulnerable and challenging to access patient group. For CYP2C19 pre-emptive testing, the American Heart Association published clear scientific statement that this should be conducted for Cardiovascular indications in addition to neurologic stroke and we expect CYP2C19 rapid genotyping to grow

cardiovascular indications in addition to neurologic stroke, and we expect CYP2C19 rapid genotyping to grow significantly in importance and placement in patient healthcare pathways. Regulatory clearance for our CYP2C19-ID test in the USA is central to our commercialisation strategy.

Our deep understanding of clinical PGx testing requirements and user needs, and expertise in PGx *in vitro* diagnostic test development lends itself well to product development offerings complementary to near-patient rapid PGx and we look forward to updating shareholders in due course as these consolidate.

On behalf of ourselves and the board, we would like to thank our employees, partners, collaborators and shareholders for their support and we look forward to our growing commercial traction and patient impact.

Dr Gino Miele  
Chief Executive Officer

Dr Ian Gilham  
Chairman

27 March 2025

<sup>1</sup> Osanlou R, Walker L, Hughes DA, et al BMJ Open 2022;12:e055551. doi: 10.1136/bmjopen-2021-055551

<sup>2</sup> [Manchester leads implementation of lifesaving genetic bedside stroke test - Manchester University NHS Foundation Trust](#)

**UNAUDITED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**  
**For the six months ended 31 December 2024**

		Six months ended 31 December 2024	Six months ended 31 December 2023	Year ended 30 June 2024 Audited
	<i>Note</i>	Unaudited £000	Unaudited £000	£000
Revenue and other income	(3)	350	238	501
Research and development costs		(2,058)	(1,876)	(4,175)
Administrative costs		(862)	(721)	(1,638)
<b>Operating loss</b>	(4)	<b>(2,570)</b>	<b>(2,359)</b>	<b>(5,312)</b>
Finance costs	(5)	-	(48)	(2,468)
Finance income	(5)	41	18	30
<b>Loss on ordinary activities before taxation</b>		<b>(2,529)</b>	<b>(2,389)</b>	<b>(7,750)</b>
Taxation		200	350	675
<b>Loss for the financial period</b>		<b>(2,329)</b>	<b>(2,039)</b>	<b>(7,075)</b>
<b>Total comprehensive expense for the period</b>		<b>(2,329)</b>	<b>(2,039)</b>	<b>(7,075)</b>
Loss per share (pence)				
-Basic		(0.4)p	(2.4)p	(4.7)p
-Diluted		(0.4)p	(2.4)p	(4.7)p

## UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the six months ended 31 December 2024

	Share Capital (unaudited) £000	Other Reserves (unaudited) £000	Accumulated Losses (unaudited) £000	Total (unaudited) £000
<b>At 30 June 2023</b>	<b>1,485</b>	<b>52,777</b>	<b>(52,221)</b>	<b>2,041</b>
Investment funding arrangement, net of costs	351	1,113	-	1,464
Equity -settled share-based payments	-	40	-	40
Transactions settled directly in equity	351	1,153	-	1,504
Total comprehensive loss for the period	-	-	(2,039)	(2,039)
<b>At 31 December 2023</b>	<b>1,836</b>	<b>53,930</b>	<b>(54,260)</b>	<b>1,506</b>
Share issue: January 2024	4	13	-	17
Share issue: June 2024	6,000	-	-	6,000
Investment funding arrangement, net of costs	307	711	-	1,018
Equity -settled share-based payments	-	2	-	2
Transactions settled directly in equity	6,311	726	-	7,037
Total comprehensive loss for the period	-	-	(5,036)	(5,036)
Settlement of Financial Derivative Liability	-	-	1,852	1,852
<b>At 30 June 2024</b>	<b>8,147</b>	<b>54,656</b>	<b>(57,444)</b>	<b>5,359</b>
Equity -settled share-based payments	-	40	-	40
Transactions settled directly in equity	-	40	-	40
Total comprehensive loss for the period	-	-	(2,329)	(2,329)
<b>At 31 December 2024</b>	<b>8,147</b>	<b>54,696</b>	<b>(59,773)</b>	<b>3,070</b>

## UNAUDITED CONSOLIDATED BALANCE SHEET

As at 31 December 2024

	Note	31 December 2024 (unaudited) £000	31 December 2023 (unaudited) £000	30 June 2024 (audited) £000
<b>Non-current assets</b>				



Property, plant and equipment	145	279	174
	145	279	174
<b>Current assets</b>			
Inventories	366	539	381
Trade and other receivables	522	214	382
Current tax asset (6)	875	1,181	675
Cash and cash equivalents	2,098	1,226	5,188
	3,861	3,160	6,626
<b>Total assets</b>	<b>4,006</b>	<b>3,439</b>	<b>6,800</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	(936)	(788)	(1,422)
Lease liabilities	-	(129)	(19)
Derivative financial instruments	-	(1,016)	-
	(936)	(1,933)	(1,441)
<b>Non-current liabilities</b>			
Lease liabilities	-	-	-
	(936)		(1,441)
<b>Total liabilities</b>		(1,933)	
<b>Net assets</b>	<b>3,070</b>	<b>1,506</b>	<b>5,359</b>
<b>Capital and reserves</b>			
Called-up equity share capital (8)	8,147	1,836	8,147
Other reserves (9)	54,696	53,930	54,656
Accumulated losses	(59,773)	(54,260)	(57,444)
<b>Total shareholder equity</b>	<b>3,070</b>	<b>1,506</b>	<b>5,359</b>

## UNAUDITED CONSOLIDATED CASH FLOW STATEMENT

For the six months ended 31 December 2024

	31 December 2024 (unaudited)	31 December 2023 (unaudited)	30 June 2024 (audited)
	£000	£000	£000
<b>Cash flows from operating activities</b>			
Operating loss for the period	(2,570)	(2,359)	(5,312)
Depreciation and amortisation on non-leased assets	26	28	54
Depreciation on right-of-use assets	17	90	193
Share - based payment	40	40	59
<b>Operating loss before changes in working capital and provisions</b>	<b>(2,487)</b>	<b>(2,201)</b>	<b>(5,006)</b>
Decrease/ (increase) in inventories	15	(14)	144
Increase in trade and other receivables	(140)	(56)	(224)
(Decrease)/ increase in trade and other payables	(486)	(147)	487
<b>Net cash outflow from operations</b>	<b>(3,098)</b>	<b>(2,418)</b>	<b>(4,599)</b>
Tax received	-	-	831
<b>Net cash outflow from operating activities</b>	<b>(3,098)</b>	<b>(2,418)</b>	<b>(3,768)</b>
<b>Cash flows from investing activities</b>			
Finance income	41	18	30
Finance costs	-	(10)	-
Acquisition of plant and equipment	(14)	(5)	(29)
<b>Net cash inflow from investing activities</b>	<b>27</b>	<b>3</b>	<b>1</b>
<b>Cash flows from financing activities</b>			
Proceeds from the investment placing agreement	-	1,200	1,200
Transaction costs relating to investment placing agreement	-	(40)	(40)

Transaction costs relating to investment placing agreement	-	(48)	(48)
Proceeds from share issue	-	-	6,000
Transaction costs relating to share issue	-	-	(566)
Repayment of lease liabilities	(19)	(112)	(222)
<b>Net (outflow)/ inflow from financing activities</b>	<b>(19)</b>	<b>1,040</b>	<b>6,364</b>
Net (decrease) /increase in cash equivalents	(3,090)	(1,375)	2,597
Effects of exchange rate changes on cash and cash equivalents	-	-	(10)
Cash and cash equivalents at beginning of period	5,188	2,601	2,601
Cash and cash equivalents at end of period	2,098	1,226	5,188
<b>Analysis of net funds</b>			
Cash at bank and in hand	2,098	1,226	5,188

## NOTES TO THE UNAUDITED INTERIM FINANCIAL STATEMENTS

### 1. General information

genedrive plc ('the Company') and its subsidiaries (together 'the Group') is a pharmacogenetic testing company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need pharmacogenetic platform for the diagnosis of genetic variations. The Company is a public limited company incorporated and domiciled in the UK. The address of its registered office is 48 Grafton Street, Manchester, M13 9XX. The Company has its listing on the London Stock Exchange Alternative Investment Market (AIM).

The financial information for the period ended 31 December 2024 and similarly the period ended 31 December 2023 has been neither audited nor reviewed by the auditor. The financial information for the year ended 30 June 2024 has been based on information in the audited financial statements for that period. The interim financial statements for the period ended 31 December 2024 do not constitute statutory accounts as defined in section 434 of the Companies Act 2006. A copy of the statutory accounts for the year ended 30 June 2024 has been delivered to the Registrar of Companies, the accounts had an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006 but did include a reference to a material uncertainty that might cast significant doubt over the Group's ability to continue as a going concern, to which the auditor drew attention by way of emphasis.

These interim financial statements were approved by the Board of Directors on 27 March 2025.

The accounting policies set out below have, unless otherwise stated, been applied consistently to all periods represented in these consolidated financial statements.

### 2. Significant accounting policies

#### ***Basis of accounting***

The consolidated interim financial statements consolidate those of the Company and its subsidiaries (together referred to as the "Group"). They are presented in pounds sterling and all values are rounded to the nearest one thousand pounds (£k) except where otherwise indicated.

Subsidiaries are entities controlled by the Group. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Transactions between Group companies are eliminated on consolidation.

The accounting policies used in the preparation of the financial information for the six months ended 31

December 2024 are in accordance with the recognition and measurement criteria of UK adopted international accounting standards and are consistent with those which will be adopted in the annual financial statements for the year ending 30 June 2025. Whilst the financial information included has been prepared in accordance with the recognition and measurement criteria of international accounting standards, the financial information does not contain sufficient information to comply with international accounting standards. The Group has not applied IAS 34, Interim Financial Reporting, which is not mandatory for UK AIM listed Groups, in the preparation of this interim financial report.

### ***Going concern***

The Directors have concluded that it is necessary to draw attention to the revenue and cost forecasts in the business plans for the period to June 2026. In order for the Company to continue as a going concern, there is a requirement to achieve a certain level of sales. If an adequate sales level cannot be achieved to support the Group and Company, the Directors have the options to reduce ongoing spend and seek additional financing from investors or debt providers.

The Company is confident that given the health benefits and economics that MT-RNR1 will be a commercial success. The NICE EVA (Early Value Assessment) recommendation is testimony to it and the funding for the EVA evidence generation, which commenced in November 2024, will see over £0.5m of revenue.

The huge success of our CYP2C19 product development, offers the NHS an intervention that is estimated to save the NHS £160m every year and improve patient outcomes. This paves the way to a much larger global market than MT-RNR1 with a far less complex route to adoption. The NICE DAP (Diagnostics Assessment Programme) recommendation and the initial sales demonstrates significant progress.

The Company recognises the uncertainty regarding the timing of the associated revenue generation, given we are at the forefront of the emerging pharmacogenetic field and the funding complexities within the NHS are understood. National Commissioning of our products brings significant upside to the sales forecasts, but it is outside of our control and therefore the timing is difficult to predict.

The Directors have reasonable confidence in their ability to raise additional financing to bridge the funding gap to a positive EBITDA position.

While the Board has a successful track record in raising funds, there remains uncertainty as to the amount of funding that could be raised from shareholders or debt providers.

The combination of the above factors represents a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern.

Accordingly, the Directors have concluded that it is appropriate to continue to adopt the going concern basis of accounting in preparing these financial statements. These financial statements do not include the adjustments that would result if the Group and Company were unable to continue as a going concern.

### ***New accounting standards adopted in the period***

There have been no new accounting standards adopted in the period that have had a material impact on the financial statements.

### ***Estimates***

The preparation of interim financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing these interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation were the same as those that applied to the consolidated financial statements for the year ended 30 June 2023, with the exception of changes in estimates that are required in:

- determining the provision for taxation; and
- determining the carrying value for inventory

### ***Revenue recognition***

#### **a. Product sales**

Sales of goods are recognised when all the performance obligations have been completed and when the Group entity has no continuing managerial involvement nor effective control over the goods. The transfer of control of goods can pass at various points depending on the shipping terms of the contract with the customer, they can be at collection from a premises or delivery to the relevant port or customer designated premises. Where items are sold with a right of return, accumulated experience is used to estimate and provide for such returns at the time of sale.

#### **b. Collaboration and licensing revenue**

Contractually agreed upfront payments and similar non-refundable payments in respect of collaboration or licence agreements which are not directly related to ongoing research activity are recorded as deferred income and recognised as revenue over the anticipated duration of the agreement. Where the anticipated duration of the agreement is modified, the period over which revenue is recognised is also modified.

Non-refundable milestone and other payments that are linked to the achievement of significant and substantive technological or regulatory hurdles in the research and development process are recognised as revenue upon the achievement of the specified milestones.

Income which is related to ongoing research activity is recognised as the research activity is undertaken, in accordance with the contract. Activity is measured based on progress and milestones and not cost.

#### **c. Other income - development grant funding**

Income receivable in the form of Government grants to fund product development is recognised as development grant funding over the periods in which the Group recognises, as expenses, the related eligible costs which the grants are intended to compensate and when there is reasonable assurance that the Group will comply with the conditions attaching to them and that the income will be received. Government grants whose primary condition is that the Group should purchase or otherwise acquire non-current assets are recognised as deferred revenue in the Consolidated Balance Sheet and transferred to the Consolidated Statement of Comprehensive Income on a systematic and rational basis over the useful lives of the related assets.

#### **Research and development**

Research expenditure is written off as it is incurred. Development expenditure is written off as it is incurred up to the point of technical and commercial validation. Thereafter, costs that are measurable and attributable to the project are carried forward as intangible assets, subject to having met the following criteria:

- demonstration that the product will generate profitable future economic benefit and of an intention and ability to sell the product;
- assessment of technical feasibility;
- confirmation of the availability of technical, financial and other resources to complete the development;
- management intends to complete the development so the product will be available for use; and
- the expenditure attributable to the development can be reliably measured.

#### **Right-of-use assets (ROU)**

At inception of a contract, the Group assesses whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Leases are recognised as an ROU asset and a corresponding lease liability at the date at which the leased asset is available for use by the Group. At the lease commencement date, a ROU asset is measured at cost comprising the following: the amount of the initial measurement of the lease liability; any lease payments made at or before the commencement date less any lease incentives received; any initial direct costs; and restoration costs to return the asset to its original condition. The ROU asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If ownership of the ROU asset transfers to the Group at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

#### **Foreign currencies**

##### **(a) Functional and presentation currency**

Items included in the financial statements of each of the Group's entities are measured using the currency of

the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in sterling which is the Group's presentation currency.

#### (b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the income statement, except when deferred in equity as qualifying net investment hedges. Non-monetary items carried at fair value and denominated in foreign currencies are retranslated at the rates prevailing on the date when fair value is determined.

#### 3. Revenue and other income

Revenue is measured at the fair value of the consideration received or receivable and net of discounts and sales-related taxes.

	31 December December 2024 £'000	31 December December 2023 £'000	30 June 2024 £'000
Revenue from customer contracts	298	123	332
Grant and other income	52	115	169
	<b>350</b>	<b>238</b>	<b>501</b>

#### 4. Operating segments

	Diagnostic Segment £'000	Administrative Costs £'000	Total £'000
<b>Six months ended 31 December 2024</b>			
Revenue and other income	350	-	350
<b>Operating loss</b>	<b>(1,708)</b>	<b>(862)</b>	<b>(2,570)</b>
Finance income			41
<b>Loss on ordinary activities before taxation</b>			<b>(2,529)</b>
Taxation			200
Loss for the financial			
<b>Loss for the financial period</b>			<b>(2,329)</b>

	Diagnostic Segment £'000	Administrative Costs £'000	Total £'000
<b>Six months ended 31 December 2023</b>			
Revenue and other income	238	-	238
<b>Operating loss</b>	<b>(1,638)</b>	<b>(721)</b>	<b>(2,359)</b>
Net Finance costs			(30)
<b>Loss on ordinary activities before taxation</b>			<b>(2,389)</b>
Taxation			350
Loss for the financial			
<b>Loss for the financial period</b>			<b>(2,039)</b>

	Diagnostic Segment £'000	Administrative Costs £'000	Total £'000
<b>Twelve months ended 30 June 2024</b>			
Revenue and other income	501	-	501
<b>Operating loss</b>	<b>(3,674)</b>	<b>(1,638)</b>	<b>(5,312)</b>
Net Finance costs			(2,438)
<b>Loss on ordinary activities before taxation</b>			<b>(7,750)</b>
Taxation			675
Loss for the financial			
<b>Loss for the financial period</b>			<b>(7,075)</b>

## 5. Finance income and costs

	31 December December 2024 £000	31 December December 2023 £000	30 June 2024 £000
Interest income on bank deposits	41	18	30

	31 December December 2024 £000	31 December December 2023 £000	30 June 2024 £000
Transaction costs relating to share issue	-	-	(566)
Transaction costs relating to investment placing agreement	-	(40)	(38)
Movement in fair value of derivative financial instrument	-	-	(1,852)
Finance lease interest costs	-	(8)	(12)
<b>Finance costs</b>	<b>-</b>	<b>(48)</b>	<b>(2,468)</b>

## 6. Current tax asset

The current tax asset relates to the estimate of the refund under the R&D tax credit scheme of £0.9m (H1 2023/4: £1.2m). This includes £0.2m for the interim period to December 2024 that would be received following submission of the tax returns for the 12 months to June 2025, with receipt expected to be in the first quarter of 2026.

## 7. Earnings per share

The basic earnings per share is calculated by dividing the earnings attributable to ordinary shareholders for the year by the weighted average number of ordinary shares in issue during the period. The weighted average number of shares in issue during the period was 543,141,481 (H1 2023/4: 103,900,492). As the Company is loss-making, no potentially dilutive options have been added into the EPS calculation. (H1 2023/4: no shares).

## 8. Share capital

Allotted, issued and fully paid:

	No	£000
<b>Balance at 30 June 2023</b>	<b>99,049,946</b>	<b>1,485</b>
Share issue - equity-settled share-based payments	260,870	4
Share issue	443,830,665	6,658
<b>Balance at 30 June 2024 and 31 December 2024</b>	<b>543,141,481</b>	<b>8,147</b>

## 9. Other Reserves

	Share Premium Account £000	Shares to be issued £000	Employee Share Incentive Plan Reserve £000	Share Options Reserve £000	Reverse Acquisitions Reserve £000	Total £000
<b>At 30 June 2023</b>	<b>53,336</b>	<b>477</b>	<b>(196)</b>	<b>1,656</b>	<b>(2,496)</b>	<b>52,777</b>
Investment funding arrangement	916	197	-	-	-	1,113
Equity settled share-based payments	-	-	-	40	-	40
<b>At 31 December 2023</b>	<b>54,252</b>	<b>674</b>	<b>(196)</b>	<b>1,696</b>	<b>(2,496)</b>	<b>53,930</b>
Investment funding	711	-	-	-	-	711

arrangement	-					
Share issue	13	-	-	-	-	13
Equity settled share-based payments	2	-	-	-	-	2
<b>At 30 June 2024</b>	<b>54,978</b>	<b>674</b>	<b>(196)</b>	<b>1,696</b>	<b>(2,496)</b>	<b>54,656</b>
Equity settled share-based payments	-	-	-	40	-	40
<b>At 31 December 2024</b>	<b>54,978</b>	<b>674</b>	<b>(196)</b>	<b>1,736</b>	<b>(2,496)</b>	<b>54,696</b>

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