genedrive plc
Annual Report and Accounts 2024
Company Number: 06108621

PGx ➔ PoC

Advancing pharmacogenetics (PGx) to the Point-of-Care (PoC)

Contents

Who We Are

Advancing pharmacogenetics to the Point-of-Care

What is PGx

Pharmacogenetics (PGx) is the study of how the variation in genetic information of individuals can affect the body's response to medications, leading to ineffective response or Adverse Drug Reactions (ADRs).

This information can be used in personalised medicine to allow clinicians to provide medication that is tailored to a person's genetic makeup and optimise their ability to respond to certain drugs, or avoid ADRs.

ADRs are unwanted or harmful reactions that occur after the administration of medication. Evidence suggests that drug interventions are only effective in 30%-60% of patients because of the difference in how individuals respond to medication. ADRs constitute a significant burden on global healthcare systems such as the NHS, where it is estimated to cost more than £2.2bn each year.

What we do

The Genedrive® system is a low cost, versatile, simple to use and robust thermocycling platform designed for near-patient use, enabling rapid molecular diagnostic results in diverse healthcare paradigms such as pharmacogenetics in emergency care. This helps clinicians to quickly access key genetic information that will help them optimise drug prescribing and make the right choices for the right drug for the patient in the timeframe required.

Genedrive has developed two ground-breaking innovative Point-of-Care (PoC) pharmacogenetic tests in collaboration with the UK NHS to address significant global unmet clinical need, improving patient safety and outcomes and substantially reducing the financial burden on global healthcare systems.

- **Genedrive® MT-RNR1 ID Kit;** the world's first genetic test to help avoid Antibiotic Induced Hearing Loss (AIHL) in neonates in neonatal intensive care units (CE-IVD certified).

- **Genedrive® CYP2C19 ID Kit;** UKCA certified test 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

The National Institute for Health and Care Excellence (NICE) have recommended both of our interventional tests for use in the UK NHS, recognising their innovation, potential to significantly improve patient outcomes and make significant cost savings to the NHS, estimated to be over £160m per year.

The Company is at the forefront of the emerging field of emergency care clinical pharmacogenetics , enabling rapid patient stratification for genotype-guided therapies in time-critical scenarios. Notably, this has led to a worlds-first point of care test for pre-emptive testing of variants in the MT-RNR1 gene for avoidance of Antibiotic Induced Hearing Loss of patients in neonatal care, and a similarly positioned emergency care rapid test for rapid identification of DNA variants in the CYP2C19 gene underpinning response to antiplatelet therapies in stroke medicine.

Our team have previously designed and developed innovative molecular tests and devices for the detection of a number of targets, including HCV (Hepatitis C), mTB (Mycobacterium tuberculosis), COVID-19 and pathogen detection of biological threats for military. Genedrive has built on our experiences in these paradigms and positioned ourselves into a rapid point-of-care test provider focussed on delivering near-patient molecular diagnostic solutions for time critical settings.

What next?
Our focus is on the implementation of our pharmacogenetic testing at the point-of-care and we are the forefront of this clinical shift in time critical emergency healthcare paradigms, to ultimately significantly improve individuals' health outcomes whilst also delivering positive health economic benefits to healthcare systems.

The power of pharmacogenetics in personalised medicine is well established, but currently restricted to clinical paradigms which do not require rapid pre-emptive testing and can be addressed by use of centralised diagnostic genomic laboratories where results take days/weeks to be available to the clinician. However, there are scenarios where actionable genetic information to drive drug prescription is required in a rapid timeframe, but are unaddressed due to lack of suitable technology solutions. We aim to disrupt this and deliver these clinically impactful solutions directly into the hands of the emergency healthcare provider.

With a strong *in vitro* diagnostic and genomic research and development capability at the core of our Company, genedrive continually strives to grow its innovative product offering by leveraging our extensive knowledge in developing novel rapid *in-vitro* diagnostic products aligned to unmet clinical need, and we are strategically well positioned to capitalise on time-critical clinical pharmacogenetics.

Genedrive is passionate about the opportunity to play an important role in emergency care molecular diagnostics and has a clear commercial strategy focused on accelerating growth through maximising in-market sales, geographic and portfolio expansion.

Acronyms used throughout this document:

AIHL	Antibiotic Induced Hearing Loss
ADR	Adverse Drug Reactions
ANIA	Accelerated National Innovation Adoption
CPIC	Clinical Pharmacogenetics Implementation Consortium
CYP2C19	Cytochrome P450 2C19
DEVOTE	The Development and Validation of Technology for Time Critical Genomic Testing
FDA	U.S. Food & Drug Administration
IVD	*In vitro* Diagnostic (meaning: in glass)
IVDR	*In vitro* Diagnostic Regulation
MFT	Manchester University NHS Foundation Trust
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OLS	Office of Life Sciences
PCR	Polymerase Chain Reaction
PGx	Pharmacogenomics
POC	Point-of-Care
RFID	Radio Frequency Identification
RNR1	Mitochondrially encoded 12S ribosomal RNA
SHTG	Scottish Health Technology Group
TIA	Transient Ischaemic Attack
UKCA	UK Conformity Assessment
UoM	University of Manchester

Strategic Report

Our Performance

Operational Highlights ((including post period end)

Genedrive® MT-RNR1

- Initial orders of the Genedrive MT-RNR1 Products for new sites in the UK
- Initial overseas orders of the Genedrive® MT-RNR1 ID Kit
- Royal Sussex County Hospital, Brighton adopts the Genedrive® MT-RNR1 ID Kit for routine use
- Entered into a Clinical Trial Agreement with a leading multi-state physician organisation for clinical research studies of the Genedrive® MT-RNR1 Product Range in the USA as part of planned FDA submission
- Breakthrough Device Designation received from the FDA
- 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
- Positive value assessment by the Scottish Health Technology Group following referral by the Accelerated National Innovation Adoption pathway group in Scotland

Genedrive® CYP2C19

- Genedrive® CYP2C19 achieved UKCA marking
- Key CYP2C19-ID test performance milestone achieved, with Genedrive CYP2C19 ID kit outperforming the reference laboratory test platform
- NICE recommends the Genedrive® CYP2C19-ID Kit as the platform of choice for CYP2C19 genotyping strategies for clopidogrel administration in ischaemic stroke and transient ischaemic attack
- First UK commercial sales of the Genedrive® CYP2C19-ID Kit
- Positive value assessment by the Scottish Health Technology Group following referral by the Accelerated National Innovation Adoption pathway group in Scotland

Financial Highlights

- Revenue and other income £0.5m (2023: £0.06m)
- Operating loss for the year of £5.3m (2023: loss of £5.2m)
- R&D spend of £4.2m (2023: £3.9m) focused on near-commercialisation product development
- Successful equity fundraise of £6m (gross) announced in June 2024
- Cash at bank of £5.2m at 30 June 2024 (2023: £2.6m) and debt free

Genedrive® System

PGx ➔ PoC

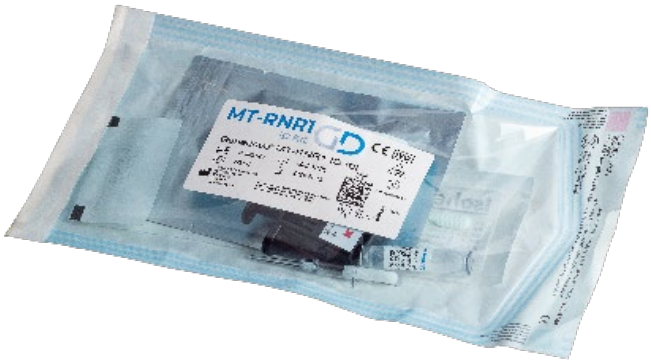
Advancing pharmacogenetics to the Point-of-Care

The Genedrive® System is a rapid nucleic acid thermocycler and fluorescence signal detection system for target discrimination, enabling both PCR and isothermal based amplification techniques, such as loop-mediated isothermal amplification (LAMP). It is a semi-automated system used for qualitative *in vitro* molecular diagnostic tests, and allows trained healthcare professionals to perform complex genetic tests at the point of care without any requirement for data interpretation, view and export test results and is easily operated via the integrated touch screen. Features include:

- Inexpensive, compact benchtop design allowing it to be placed in near-patient or laboratory settings
- Easy to operate touch screen with barcode scanning functionality
- RFID enabled reagent lock out to prevent use of expired tests
- Enabling rapid automated results in clinically actionable timeframes
- Designed to be used in time critical emergency healthcare, ahead of prescribing decisions
- Electronic result and test metadata export
- Flexible connectivity to external systems via middleware to hospital patient record systems
- Optional Bluetooth printer for label printing

Antibiotic Induced Hearing Loss and the Genedrive® MT-RNR1 ID Kit:

MT-RNR1



Genedrive® MT-RNR1-ID Kit is the world's first point-of-care genetic test used to influence neonatal clinical management in an acute setting and reduce aminoglycoside antibiotic induced hearing loss

Unmet clinical need

Ototoxicity (toxicity in the ear) is an example of an Adverse Drug Reaction (ADR), in this case where aminoglycoside antibiotics are toxic to cells in the inner ear and can lead to profound and irreversible Antibiotic Induced Hearing Loss (AIHL), which can potentially occur from as little as one dose of broad-spectrum aminoglycoside antibiotics such as gentamicin.

Individuals with the MT-RNR1 m.1555A>G gene variant develop profound irreversible hearing loss if exposed to aminoglycosides (such as gentamicin), and population based studies estimate a prevalence of the variant of 1:500 (0.2%) (Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for MT-RNR1 and Aminoglycosides (May 2021)).

Antibiotic Induced Hearing Loss (AIHL) resulting from exposure of these individuals is a global, but preventable health problem.

In the UK there are over 100,000 babies admitted to Neonatal Intensive Care Units (NICUs) every year, the vast majority receiving antibiotics for the treatment of infection from life threatening conditions such as sepsis.

Clinical guidance requires the administration of the antibiotic within 1 hour of the decision to treat those at risk of infection, this concept being known as the golden hour.

The solution for use in acute, time-critical settings

Clearly, the risk of sepsis outweighs the risk of hearing loss, but risk of AIHL can now be reduced by use of our intervention in advance of antibiotic prescribing decisions and electing for an alternative treatment where appropriate within the required clinical timeframe.

Genedrive developed the MT-RNR1 PGx test to be administered at the point-of-care (patient's bedside) in neonatal emergency care, taking 26 minutes and allowing for a safer alternative prescription of aminoglycosides in patients that are found to have the variant. It is used on the Genedrive® System to provide an automated result of an individual's MT-RNR1 m.1555A>G variant status to inform the clinician ahead of antibiotic treatment decisions.

It is the first point-of-care genetic test used to influence neonatal management in an acute, time-sensitive setting, gaining competitive advantage from being the first to market and extensive collaborative development and validation with the NHS.

Implementing the Genedrive® MT-RNR1 ID Kit into routine clinical practice allows clinicians to prescribe an alternative antibiotic. For example, cephalosporin antibiotics might be prescribed (alternatively to aminoglycoside antibiotics) to those patients who have tested positive for the MT-RNR1 m.1555A>G variant, using the Genedrive® System. Clinicians can therefore reduce the risk of antibiotic induced hearing loss (AIHL). This enables patients to get the right treatment at the right time, tailored to their genetic results.

With a time to result of 26 minutes, the Genedrive® MT-RNR1 ID Kit allows clinicians to make informed treatment decisions within the so-called "golden hour" (time available from decision to treat to antibiotic administration), without disrupting normal standard of care.

This is a shining example of what can be achieved when SMEs such as genedrive work in collaboration with the NHS to adopt innovative technologies with potential to improve patient outcomes and provide long term financial savings to healthcare systems.

Not only does the intervention present the opportunity to save the hearing of thousands of people across the world, but it also has the potential to have a net positive financial outcome for health care systems. The NHS estimated a £5m annual saving, as the cost of cochlear implants and life-long care otherwise required would be avoided.

Considering the wider societal costs and implications (such as the major impact on the quality of life of children and their families) the case for implementation of the intervention is compelling and represents excellent value for healthcare financial systems worldwide.

The Genedrive® MT-RNR1 ID kit is CE-IVD certified, permitting commercialisation in those countries recognising CE-IVD.

The Genedrive® MT-RNR1 ID kit, was developed in collaboration with the UK NHS and: has the following features and benefits

- **An *in vitro* diagnostic point-of-care genetic test** designed to be used in time critical situations, prior to aminoglycoside antibiotic treatment prescription
- **Reduces the risk** of aminoglycoside induced hearing loss (AIHL) by detecting a variant in the MT-RNR1 gene (m.1555A>G)
- **Is a non-invasive test** using buccal swabs to collect samples
- **Simple to use** test kits, with sealed, single use cartridges that are stable at room temperature, not requiring cold chain storage logistics.
- **Provides Rapid results** to clinicians within the required 'golden hour' period from decision to treat
- **Easy adoption** into existing neonatal admissions process without disrupting normal standard of care

NICE EVA for MedTech: "panning for nuggets of innovation gold"
The National Institute for Health and Care Excellence (NICE) provides national guidance and advice that is designed to improve the quality of health and social care and help the NHS make efficient, cost-effective and consistent decisions about adopting new medicines and technologies, supporting innovation and improving healthcare delivery.

NICE introduced a new process (Early Value Assessment (EVA) for MedTech) offering a rapid assessment of medical devices and diagnostics for clinical effectiveness and value for money, and in March 2023, the Genedrive® MT-RNR1 ID Kit received a conditional recommendation from NICE for use in the NHS whilst further evidence was generated, and subsequently publication of an evidence generation plan, which details the evidence generation requirements. The aim of the EVA evidence generation process is to address evidence gaps inherent with new innovative devices to support transition from conditional to full recommendation.

Progress:

- Genedrive® System developed and CE-marked (European Conformity) for Antibiotic Induced Hearing Loss (AIHL)
- NICE EVA conditional recommendation for use in the NHS in March 2023
- Currently in routine clinical use at 9 UK hospitals
- Breakthrough Device Designation received from the U.S. FDA
- Clinical Trial Agreement with a leading multi-state physician organisation for clinical research studies in the U.S.
- NIHR and OLS Funding Package of c.£500k to address NICE Real World Evidence Generation will see the implementation of the test in a further 5 hospitals and provide the required evidence to NICE to transition the recommendation from conditional to full.
- Initial overseas sales invoices
- Positive value assessment by the Scottish Health Technology group (SHTG) following referral from the Accelerated Innovation Adoption pathway (ANIA) in Scotland, concluding with consideration for roll out in Scotland.

Genedrive® MT-RNR1 ID Test "conditional" recommendation by NICE under the Early Value Assessment programme & path to national implementation.
The UK's National Institute for Health and Care Excellence (NICE) has ratified and finalised its recommendation following a public consultation process that the Genedrive® MT-RNR1 ID Kit can be used by the NHS. The review was conducted through NICE's Early Value Assessment (EVA) programme, which was designed to select and recommend new technologies that will make a real difference to patients and provide the financial value for the NHS.

The positive outcome, published in March 2023, was based on a number of key conclusions, including that the Genedrive® MT-RNR1 ID Kit can quickly and accurately identify babies with the MT-RNR1 genetic variant who may be at risk of hearing loss if given aminoglycoside antibiotics, and that no other test is available to provide results quickly enough to inform decisions on antibiotic prescribing in emergency care.

Being a novel innovative and disruptive intervention in emergency care clinical medicine, the NICE EVA is a process whereby technologies such as this can be adopted under "conditional" recommendation whilst further evidence generation is in progress. With publication of NICEs evidence generation requirements, NIHR and the government Office for Life Sciences have implemented a new mechanism to permit funding of evidence generation activities for technologies recommended under the EVA, with the aim of closing evidence gaps and transitioning from conditional to full recommendation, and with the expectation of subsequently unlocking national commissioning for the test.

The demand to implement the system in many NHS hospitals is clear and national commissioning would see the test funded effectively at a national level, through the regional Integrated Care Systems (ICS). This process takes time in an underfunded NHS despite the very positive health economic case the Genedrive MT-RNR1 ID test provides. In the interim, each hospital needs to make its own business case to secure the necessary funding for the capital equipment and tests.

Clinical academic collaborators have been successfully awarded funding under the NIHR/OLS Real World Evidence Generation programme to implement the Genedrive MT-RNR1 ID kit in 14 hospitals throughout the UK, to address NICE evidence generation requirements. This is scheduled to be conducted over 18 months and in NICUs of varying size. However, the team can submit to NICE when it believes that sufficient data has been generated to address the evidence generation requirements.

FDA Breakthrough Device Designation
The U.S. Food and Drug Administration (FDA) Breakthrough Devices Program is for medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is intended to provide patients and health care providers with timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorisation and is reflective of the FDA commitment to device innovation and protecting the public health.

Genedrive said: "*We are delighted to receive FDA designation of our MT-RNR1 point of care pharmacogenetic test and corresponding recognition of the potential benefits to U.S. patients. The U.S. is an attractive market for this unique test given the potential to save hundreds of individuals from life-long deafness and reduce litigation costs relating to the unwanted side effects from antibiotic use on those carrying the gene variant, and given its size, birth rates, use of diagnostic testing and reimbursement structure. The FDA Breakthrough Device Designation process will be invaluable in mitigating study design risks associated with bringing a novel test such as this to the U.S. market where no predicate device exists with which to align study designs to. Together with our in-place partnership with a multi-state physician led clinical partner with neonatal services expertise covering the majority of U.S. states we look forward to affordable, collaborative and timely progress through the FDA De novo process*".

Clinical Trial Agreement with a leading multi-state physician organisation for clinical research studies in the U.S.

We have partnered with a large physician-led network in the US to support in-country clinical studies to facilitate our strategy to enter the US market via the FDA *de novo* route.

Dr Gino Miele, CEO of genedrive plc "*I am delighted with this agreement to progress our aim of introduction of our MT-RNR1 point of care pharmacogenetic test to the U.S. The U.S. is a particularly attractive market for this unique test given the potential to save hundreds of individuals from life-long deafness and reduce litigation costs relating to the unwanted side effects from antibiotic use on those carrying the gene variant. Additionally, the U.S. Market is potentially the most attractive market given its size, birth rates, use of diagnostic testing and reimbursement structure.*"

ANIA Referral and Scottish Health Technology Group assessment
In response to a referral from the Accelerated National Innovation Adoption (ANIA) collaborative the Scottish Health Technologies Group (SHTG) has carried out a technology assessment focused on the Genedrive® MT-RNR1 ID Kit, and concludes that genetic testing will be considered for national rollout to hospital wards that care for newborn babies. https://shtg.scot/our-advice/genotype-testing-to-guide-antibiotic-use-and-prevent-hearing-loss-in-babies/

Clopidogrel resistance and the Genedrive® CYP2C19 ID Kit:

Rapid PGx test to inform clinicians on an individual's CYP2C19 genotype and CPIC-coded metaboliser status to support antiplatelet therapy prescription in stroke patients.

Unmet clinical need

CYP2C19 is an important gene that codes for a liver enzyme responsible for metabolism of several commonly prescribed drugs. One of these is Clopidogrel, an anti-platelet therapy prescribed to stroke patients. Clopidogrel is a pro-drug, requiring metabolism by CYP2C19 to break it down into its active form. Many of us carry genetic variants which influence our response to clopidogrel, and in those individuals with "loss of function" variants clopidogrel will be less effective. There is a clear global unmet clinical need for an easy to use and rapid molecular point-of-care test for the detection of CYP2C19 in emergency settings and departments where prescribing takes place. Such genotype-guided prescribing can provide tailored treatment and significantly improve patient outcomes whilst providing significant financial benefits to the healthcare provider.

Stroke is the second largest cause of death worldwide and according to the World Stroke Organization, there are over 77 million people globally who currently have experienced ischaemic stroke, with an estimated 113,000 strokes in the UK each year[1], with these figures estimated to increase by 60% to 2035.

Globally, one in four people over the age of 25 will have a stroke in their lifetime, and there are 1.3 million stroke survivors at any time in the UK, with current costs of care of approximately £26 billion per annum and expected to rise to £75 billion per annum by 2035[1]. Societal costs are expected to increase 250% over the period to 2035 unless measures are successfully developed and implemented to prevent strokes and risk of recurrence and reduce the disabling effects of strokes.

Clopidogrel is an antiplatelet drug used in clinical management of stroke. It is metabolised into its active form by an enzyme encoded by the CYP2C19 gene which in some people has DNA variations that reduce the enzyme's function which means that clopidogrel does not work as well in these people (Loss of Function). Suboptimal response to clopidogrel is common, affecting up to 30% of patients in the general population, which increases to approximately 50%-60% in certain ethnic groups. As a consequence, Clopidogrel has reduced impact on lowering the risk of a further stroke in these individuals.

For dual antiplatelet therapy including clopidogrel, the UK National Clinical Guidelines for Stroke states that his should be considered in patients presenting within 24 hours of TIA and minor stroke.

[1] Stroke Association - Current, future and avoidable costs of stroke in the UK Report

The solution: A rapid Point-of-Care test for CYP2C19 genotyping in time critical settings

Genedrive's CYP2C19 ID Kit is also used on the Genedrive System® and from a simple buccal cheek swab identifies key DNA variants in the CYP2C19 gene that lead to loss of function and therefore ineffective response to clopidogrel. Within approximately 70 minutes the clinician is able to determine whether clopidogrel is suited to stroke patients in their care. It is the only point-of-care genetic test to target DNA variant alleles *2, *3, *4, *8, *17 and *35, some of which are prevalent at a significantly higher incidence in certain under-represented ethnic groups, which is important in ensuring equitable access to healthcare and addressing of healthcare inequalities.

Not only does the intervention present the opportunity to significantly improve clinical outcomes for thousands of stroke patients across the world, but it also has the potential to have a significant net positive financial outcome for health care systems, with approximately £160m financial savings to the NHS per year estimated in health economic modelling.

Considering the wider societal costs and implications (such as the major impact on the quality of life of patients and their families) the case for implementation of the intervention is compelling and represents excellent value for healthcare financial worldwide.

The Genedrive® CYP2C19 ID kit is currently UKCA certified, permitting commercialisation in those countries recognising UKCA (UK and Middle East), it was developed in collaboration with the UK NHS and has the following features and benefits:

- **Point of care genetic test to be used in time critical situations,** to guide therapeutics that are metabolised by Cytochrome P450 2C19 (CYP2C19)
- **Allows personalised treatment for drugs metabolised by CYP2C19**, including the antiplatelet Clopidogrel
- **Non-invasive test**, test performed using a single buccal swab sample from the inner cheek
- **Simple workflow** with automated interpretation of patient CYP2C19 status
- **Rapid actionable results in approximately 69 minutes** including diplotype and metaboliser status
- **Easy adoption** into existing workflows
- **Ready to Use -** ambient temperature-stable reagents for immediate use without requirement for cold-chain storage logistics
- **Comprehensive variant coverage** identifying clinically relevant alleles of CYP2C19 Loss of Function (*2, *3, *4, *8, *35) and gain of function (*17) & therefore maximal ethnic coverage.

NICE recommendation

On the 31 July 2024 NICE recommended in its final guidance that CYP2C19 genotyping should be used to guide clopidogrel use after Ischaemic Stroke (IS) or Transient Ischaemic Attack (TIA), and that the Genedrive® CYP2C19-ID test should be used as the test of choice for point-of-care interventional strategies. Notably, the Genedrive CYP2C19 ID kit, whilst primarily positioned for near-patient testing, can equally be implemented in traditional laboratory paradigms if required.

In addition to being dominant in cost effectiveness models, NICE recommends the Genedrive® as the point-of-care platform of choice for CYP2C19 genotyping strategies in the NHS. The decision was based on several differentiating features of the Genedrive® technology; (1) its greater coverage of genetic variants compared to the other point-of-care system assessed, permitting increased equitable access to healthcare across ethnic populations, (2) no requirement for cold-chain storage logistics, (3) its ability to integrate with patient electronic healthcare systems.

Genedrive, said: *"We are delighted with this final guidance from NICE recommending implementation of CYP2C19 genotype-guided use of Clopidogrel in IS and TIA patients in the NHS to reduce risk of recurrent strokes, and recommendation of our CYP2C19 ID-kit as the point-of-care interventional platform of choice. This represents a key milestone in our commercialisation plans for the product, and further solidifies our business strategy of leading provision of cost-effective solutions for pharmacogenetics in time critical emergency healthcare situations. We are proud to be at the forefront of the emergence of near-patient genetic testing in emergency healthcare to facilitate optimal personalised therapeutic choices and ultimately improve patient outcomes*."

Professor Bill Newman, Professor of Translational Genomic Medicine at the University of Manchester and Lead of the NHSE Network of Excellence in Pharmacogenetics and Medicines Optimisation at Manchester University NHS Foundation Trust, said: "*To ensure that patients receive the correct treatment to reduce the risk of them having a further stroke after an initial episode, we need to use a rapid genetic test. The development of this new point-of-care diagnostic has the potential to significantly improve care for tens of thousands of patients after a stroke. As part of the DEVOTE project we have been delighted to have worked with genedrive to generate the evidence for this test to become available to patients*."

Progress:

- UKCA marking achieved in September 2023
- NICE recommends the Genedrive® CYP2C19-ID Kit in final guidance in July 2024
- First UK commercial sales of the Genedrive® CYP2C19-ID Kit in August 2024
- DEVOTE grant funding and collaboration with UoM for validation to enable CE-IVD registration
- Key CYP2C19-ID test performance milestone achieved 100% accuracy/outperforming reference test
- Completion of DEVOTE activity, with clinical study evidencing superior performance in comparison to a significantly more expensive and time-consuming laboratory platform
- Positive value assessment by the Scottish Health Technology group (SHTG) following referral from the Accelerated Innovation Adoption pathway (ANIA) in Scotland, estimating c£18m savings to NHS Scotland and prevention of 961 recurrent strokes over a five year period, concluding with consideration for roll out in Scotland
- On track for CE-IVD certification in late-Q1 2025

DEVOTE Programme
The Development and Validation of Technology for Time Critical Genomic Testing (DEVOTE)

Genedrive® CYP2C19 ID Kit

DEVOTE is an all-comer study in which CYP2C19 DNA variants in patients presenting in the acute emergency care setting are tested with the Genedrive® CYP2C19-ID test and results compared with those obtained by reference laboratory platform testing, with testing on a third laboratory platform in instances where there is disagreement in test results. In the tests run to date the Genedrive® CYP2C19-ID test has out-performed the reference laboratory-based test with respect to coverage of LoF variants and accuracy (correct identification of variant).

The DEVOTE programme, through its lead partner the University of Manchester ("UoM"), has supported the Company's requirement for assessing performance in acute care patients and provided valuable supporting infrastructure to assess the real-world clinical performance of time-critical clinical tests in NHS settings. The study addresses clinical requirements of the In Vitro Diagnostic Medical Devices Regulation (IVDR) for CE-IVD submission and subsequent commercialisation in those countries recognising CE-IVD, in addition to current UKCA certification allowing UK commercialisation.

The Genedrive® CYP2C19-ID point of care genetic test is UK Conformity Assessed (UKCA) certified, uses a single, non-invasive cheek swab sample, and rapidly identifies several important genetic variants of the CYP2C19 gene (Loss Of Function (LoF)), which are instrumental in an individual's response to the drug clopidogrel which can be prescribed in Ischemic Stroke (IS) and Transient Ischaemic Attack (TIA). The test automatically interprets the CYP2C19 DNA variant information for the clinician and allows for prompt administration of an alternative treatment plan for the circa 30% of individuals that are less likely to respond favourably to clopidogrel.

Approximately 30% of patients in the cohort harboured CYP2C19 LoF variants as expected. The Genedrive® CYP2C19 test outperformed the laboratory test with respect to accuracy of identification of LoF alleles, and broader inclusion of LoF alleles. Genedrive® CYP2C19-ID test results are available in ~70 minutes.
The UK's National Institute for Health and Care Excellence (NICE) has recommended in draft guidance, that the Genedrive® CYP2C19-ID test should be used as the point-of-care test of choice in the NHS before clopidogrel administration in the management of IS and TIA patients
(https://www.nice.org.uk/guidance/indevelopment/gid-dg10054/documents).

Genedrive, said: "This study has been invaluable in progressing our requirements for CE-IVD certification to complement our existing UKCA certification. Our CYP2C19 test is the only one we are aware of that can deliver clinically actionable results for these DNA variants in the CYP2C19 gene in a rapid timeframe in emergency care settings at the point of care. We are excited that the availability of this intervention has the potential to make a difference to patients' lives and we look forward to working with UK stroke networks in the NHS to bring this vital test into day-to-day use."

Professor Bill Newman, Professor of Translational Genomic Medicine at the University of Manchester and Lead of the NHSE Network of Excellence in Pharmacogenetics and Medicines Optimisation at Manchester University NHS Foundation Trust, said: "It has been very positive working with genedrive as part of the Innovate UK funded DEVOTE project to test clinical samples and determine how well the assay performs in this setting. It is clear that the test will offer an effective rapid solution to doctors and pharmacists to guide effective prescribing for patients with stroke."

Professor Ben Bridgewater, Chief Executive at Health Innovation Manchester, said: "This is a great example of how the GM Health Innovation Accelerator programme is supporting development of our innovation ecosystem specifically in this case through validation of a novel and valuable rapid diagnostics test. Congratulations to genedrive for this achievement as they continue to collaborate with academic strengths in the city region to develop products to improve the health of our local population and address inequalities in care."

First UK commercial sales of the CYP2C19-ID Kit:

Following the final published guidance by NICE that CYP2C19 genotyping should be used to guide clopidogrel use after Ischaemic Stroke ("IS") or Transient Ischaemic Attack ("TIA"), and that the Genedrive® CYP2C19-ID test should be used as the test of choice for point of care strategies[1], genedrive were pleased to announce shortly after an initial order for the CYP2C19-ID Kit and instruments to support an implementation assessment at Greater Manchester's Comprehensive Stroke Centre (CSC).

Hyperacute Stroke Units (HASU) are part of the UK's Integrated Stroke Delivery Network, where care typically covers the first 72 hours after admission, with the aim that every patient with acute stroke should gain rapid access to a stroke unit in under four hours and receive an early multidisciplinary assessment. Greater Manchester CSC is the largest and busiest HASU in England with more than 2,000 stroke patient admissions per annum and is situated within the Manchester Centre for Clinical Neurosciences (MCCN) at Salford Royal Hospital, part of Northern Care Alliance NHS Foundation Trust. The implementation assessment's aim is to establish the benefit for patients across Greater Manchester.

UK NICE guidance recommends laboratory CYP2C19 genotyping, and where not available or possible to implement point of care strategies, using the Genedrive® CYP2C19-ID test as the platform of choice. Whilst positioned primarily for enabling near-patient point of care testing, the Genedrive® System is also suitable for traditional laboratory testing paradigms as a more affordable alternative to more expensive laboratory platforms where sample throughput requirements do not necessitate high-scale batch processing.

Dr Gino Miele, CEO of genedrive plc, said: "*With recent NICE guidance recommending CYP2C19 genotyping strategies in the UK NHS for IS and TIA patients in the NHS who are eligible for receiving the antiplatelet Clopidogrel, and recommending our test as the point-of-care platform of choice, these initial first-sales of our CYP2C19 ID-kit in the UK to one of the largest stroke centres nationally is a key initial milestone in our CYP2C19 commercialisation strategy, and further strengthens our pharmacogenetic positioning strategy in emergency care more broadly. We look forward to increasing implementation of our CYP2C19 test in the UK NHS and internationally to the benefit of both healthcare systems financially and improvement of patient outcomes*."

ANIA Referral and Scottish Health Technology Group assessment

In response to a referral from the Accelerated National Innovation Adoption ("ANIA") collaborative the Scottish Health Technologies Group (SHTG) has carried out a technology value assessment which included the Genedrive® CYP2C19 ID Kit.

The Genedrive® CYP2C19 ID Kit is included in the Technology Assessment "Genotype testing to guide clopidogrel use after an ischaemic stroke or transient ischaemic attack (TIA)" which will be used to form an ANIA value case and will inform decision making on the roll out of CYP2C19 genotype testing in NHS Scotland. The report is available at https://shtg.scot/our-advice/clopidogrel-genotype-testing-after-ischaemic-stroke-or-transient-ischaemic-attack-tia/

Key conclusions of the SHTG assessment relevant to the Genedrive® CYP2C19 ID kit were as follows:

- Using the Genedrive® CYP2C19 ID Kit to identify clopidogrel resistance was resource saving from year two onwards and would also prevent 961 recurrent strokes over a 5-year period and save NHS Scotland approximately £18 million;
- The benefits of antiplatelet therapy are maximised when the patient is started on treatment within 24 hours of the initial stroke or TIA. Laboratory-based testing, which can take up to one week to provide results, could result in patient harm if treatment is delayed until the test results are available and many patients could be discharged from hospital by the time laboratory test results are available;
- Smaller hospitals serving remote and rural areas would experience problems accessing laboratory-based genotype testing;

- There are four regional genetic testing centres in Scotland and they are under pressure to deliver urgent cancer genetic testing priorities. There was concern that using regional genetic testing centres would result in inequalities in care across Scotland; and
- The Genedrive® CYP2C19 ID Kit had low test failure rate and can identify more targets, which is a crucial consideration for the inclusion of more patients from a wider range of ethnic backgrounds and therefore aids addressing inequalities in healthcare.

Dr Gino Miele, CEO of genedrive plc, said: "*Following positive recommendations by The National Institute for Clinical Care and Excellence (NICE) for both our MT-RNR1 and CYP2C19 ID products, we are delighted with these additional positive independent assessments of the SHTG, and look forward to further decisions of ANIA regarding potential national rollout plans in Scotland. We are proud to be at the forefront of near-patient pharmacogenetic testing and of the potential for our products to be significantly impactful in delivering improved patient outcomes in these vulnerable groups as well as offering significant savings to healthcare systems*."

[1.] Lee C.R. et al 2022 CPIC Guideline for CYP2C19 Genotype and Clopidogrel Therapy: 2022 Update

Business Model

Dedicated to creating value for shareholders by pushing the boundaries of innovation and delivering pharmacogenetics to the point-of-care

Who we are

A dynamic and competitive pharmacogenetic (PGx) testing company dedicated to developing and commercialising simple-to-use, versatile, rapid and robust molecular solutions for PGx testing in emergency care settings.

We are passionate about the opportunity to not only build a sustainable business around PGx, but to play an important role in providing cost-effective, accurate and timely diagnostics, at the point of need.

We develop and manufacture innovative, molecular devices and tests designed to identify individuals with genetic variations linked to drug response or adverse events within a clinically actionable timeframe prior to the prescription of treatment. The assays are performed using single-use disposable cartridges on our patented Genedrive® technology to rapidly amplify and detect nucleic acid sequences without the requirement for up-front nucleic acid isolation, or the requirement for test result interpretation by the user.

How we create value

genedrive adds value through rapidly developing tests that lever the unique properties of the Genedrive® system.

- Differentiated and competitive technology
- Deep instrument and molecular expertise
- Highly skilled people
- Entrepreneurial culture
- Experienced management team

Who benefits

Our people

- Reward and recognition
- Employee wellbeing
- Personal development in an entrepreneurial work environment

Our partners

- Quality and innovation
- Rapid development of new products addressing unmet clinical need
- Contribution to healthcare & improving patient outcomes
- Positively impacting healthcare costs

Our patients

- First-to-market solutions
- Better health outcomes

Our shareholders

Underpinned by our values

Long-term delivery and growth underpinned by a set of values and frameworks that protect from unnecessary risk.

Robust risk management framework

- Appropriate risk management structure
- Risk managed to ensure the Group delivers its objectives
- Integrated approach to risk

Effective governance structure

- High standard of corporate governance that aligns with the needs of the Company and shareholders
- Experienced and knowledgeable Board
- A desire to out-perform in terms of controls, processes and governance

Innovative solutions addressing unmet needs

"Robust research and development is at the heart of our Company, by applying our deep expertise in developing cutting-edge in-vitro pharmacogenetic assays we are able to provide innovative solutions to address global unmet needs and facilitate better patient outcomes".
Ian Gilham, Ph.D.
Chairman

Dear Shareholders

We entered the year with a clear understanding of the obstacles and opportunities that we faced as a small business operating at the forefront of the groundbreaking and emerging field of pharmacogenetic testing and I am delighted to report on a year that marks successive achievements in product development and implementation, a second NICE recommendation, positive assessments of our products by the Scottish Health Technology Group, FDA breakthrough device designation and early stage market momentum.

The strategic decision to focus on enabling pharmacogenetic testing to the point of need is showing the promise that we believed it would. This is evidenced by NICE recommending both our MT-RNR1 and CYP2C19 products, recognising their significant clinical impact and value for money for the NHS.

Our activities in the DEVOTE programme collaboration has been an outstanding success, verifying and validating our CYP2C19 test, with remarkable results outperforming the laboratory based reference test and I extend my gratitude to our long-standing valued colleagues at the Manchester University NHS Foundation Trust and Health Innovation Manchester for their unwavering support.

Our tests contribute towards optimising the efficacy and safety of patient care and during a time of unprecedented pressure on the NHS, we offer a substantial cost-saving opportunity with our interventions by reducing the burden of avoidable adverse drug reactions, such as the need for cochlear implants for AIHL and the avoidance of ineffective treatment of approximately 30% of stroke patients.

Governance and People

On 6 August 2024 James Cheek left the Company and was succeeded as CEO by Dr. Gino Miele PhD.
Gino has been with the Company since 2011, serving as R&D Director and since September 2023 as Chief Scientific Officer and an Executive Board Director. On behalf of the board, I would like to thank James for his contributions at genedrive and wish him well for the future.

The Board continues its commitment to maintaining its own efficiency and competence, with a dedication to ensuring that our governance framework, internal controls, values, and culture are all in harmony with our strategic goals and the Company's objectives. This can be reviewed in our Corporate Governance Report on pages 35-37.

Our people are the core of our business and the driving force behind the Company. I want to extend my heartfelt appreciation to each of them for their steadfast resilience, innovative mindset, and relentless determination in both the creation and delivery of our product, and navigation of complex healthcare market access and reimbursement routes.

Funding
In my report last year, it was made very clear that given the limitations of the cash runway the Company needed to raise funds to support the operational, commercialisation and growth plans of the business.

We completed an equity fund raise in June 2024 and the net proceeds of £5.4m extended our cash runway materially. The Group's operating expenses are currently running at around £0.5m per month and are expected to be maintained at around this level pending increased commercial traction. To help achieve this we have increased our commercial team in the UK and distribution network in the Middle East and we are generating have revenues from routine use of our tests on a small scale, but have a pipeline of opportunities that, if converted, would see a significant step up in revenues during calendar year 2025 and a reduction in the level of cash burn.

Outlook
Gino was instrumental to our product development, successful NICE recommendations, FDA breakthrough designation, DEVOTE program outcomes, and is a world leading expert in near-patient pharmacogenetics. With his commercial insights aligned to clinical decision maker needs, we are delighted to have him at the helm as we commercialise our products.

Robust research and development is at the heart of our Company, by applying our deep expertise in developing cutting-edge *in-vitro* pharmacogenetic assays we are able to provide innovative solutions to address global unmet needs and facilitate better patient outcomes.

In closing, I would like to extend my sincere gratitude to you, our valued shareholders, especially for the considerable financial support shown at the time of our financing, along with our dedicated staff and collaboration partners, for your continued support.

Dr Ian Gilham
Chairman
28 November 2024

Pioneering pharmacogenetics

Our AIHL and CYP2C19 interventional tests are at the forefront of the emerging realisation of pharmacogenetic testing at the point of care, enabling better health outcomes and improved safety for patients, whilst offering significant health economic benefits to global healthcare systems.

Gino Miele, Ph.D.
Chief Executive Officer

Overview

I am pleased to report on the significant progress that has been made across all aspects of the Group this year and offer my sincere thanks to our entrepreneurial people at genedrive past and present that have worked tirelessly in order to position our company at the forefront of the emerging area of near patient pharmacogenetic (PGx) testing.

Being first to market and pioneering in the field of near-patient pharmacogenetics is a demanding mission, operating in a very heavily regulated field with no precedence or predicate, and with the funding and reimbursement complexity of the overburdened NHS making our domestic market challenging to penetrate quickly.

PGx implementation into clinical practice at scale is an emerging field, and particularly so when positioned near-patient, with many development, regulatory, and clinical implementation challenges being addressed and solved for the first time. With our deep accruing expertise in this paradigm we are uniquely positioned to capitalise on the opportunities our innovative and disruptive interventional products offer.

The progress we have made this year has been significant. To have two recommendations by the highly respected and influential NICE body is remarkable for a healthcare company of our size and low-cost base operating in this space, and we are well aligned with the recent recommendations of Lord Darzi's report on the NHS to the UK Secretary of State for Health and Social Care with respect to an increased focus on prevention as opposed to treatment.

Both our MT-RNR1 and CYP2C19 products have the potential to prevent harm to, and significantly improve the lives of thousands of patients worldwide, some of those at the most vulnerable and early stage of their lives, whilst at the same time offering significant financial benefits to funding-pressured healthcare systems, and I am extremely proud of our team at genedrive and visionary collaborators in bringing these products to the market. Our CYP2C19 genotyping intervention can rapidly identify stroke patients who would otherwise be prescribed medication potentially ineffective for them at a time in their lives when optimal therapeutic management is critical, and at the same time being estimated to offer the NHS approximately £160m of financial savings per year. "Spend to save" is a mantra at the heart of our commercialisation efforts.

Our products, whilst offering significant financial and patient benefits, are robust and highly accurate compared to platforms several-fold more expensive, time-consuming and costly to operate. Our DEVOTE study exemplified this, where the genedrive CYP2C19 test outperformed the laboratory reference test with respect to speed, accuracy and target coverage, with the latter being exceptionally important with respect to improving inequalities in healthcare.

Our MT-RNR1 interventional test enables clinicians within the required timeframe to avoid prescription of aminoglycoside antibiotics to individuals who would otherwise potentially suffer from hearing loss. This is particularly significant in vulnerable newborns in neonatal intensive care settings and is a known adverse event risk which can now be reduced. The NIHR i4i and Office for Life Sciences OLS funding programme is aimed specifically at technologies which have been recommended for use in the NHS by NICE via the EVA, with the goal of NIHR and the Government's Office for Life Sciences via this programme being to drive adoption and implementation of innovative technologies such as ours into the UK's NHS, to the positive benefit of healthcare economies and ultimately significantly improving patient outcomes.

We are delighted that our clinical collaborators have been successfully awarded a funding package under this programme for our MT-RNR1 product, and it represents a key step in enabling generation of real world evidence data requirements of NICE and which will run in parallel to our continued expansion of domestic and international sales strategies.

Performance

Whilst healthcare institutions move slowly, with market access and reimbursement routes convoluted, particularly in the UK NHS and for first-time innovative products, commercialisation efforts are beginning to be realised, with revenue and other income of £0.5m being a credible increase from the prior year. Importantly, we have a pipeline of opportunities for both products and, once implemented, each site becomes a source of recurring revenue. Key to this for both our tests in the UK will be NHS budget provision and commissioning at national level, with inclusion of specific test codes within the NHS for point of care genetic testing, and/or procedural changes to permit reallocation of budgetary requirements for procurement from further down the patient care pathway at the point of addressing the effect (harm) to the point of the intervention, inevitably involving separate departments.

MT-RNR1 is now in routine use in the NHS at 9 hospitals and the NICE EVA programme via NIHR will see this increase to 14, throughout the UK nations. I have a deep sense of pride in our achievements to date of preventing profound, irreversible and lifelong hearing loss in babies in NICUs using our test, and we are making every effort to ensure that the rest of the country can rightly expect to receive the same equality of care.

NICE recommendation for use in the UK NHS and Breakthrough Device Designation by the US FDA underpin recognition of the positive benefits our MT-RNR1 ID kit provides, and positive value assessments by the Scottish Health Technology Group, leading to considerations of phased roll out at national level in Scotland is a significant achievement.

Likewise, full recommendation of our CYP2C19 ID kit and the need for interventional CYP2C19 genotyping in ischaemic stroke and transient ischaemic attack by NICE and positive value assessment by the Scottish Health Technology Group, with health economics estimated to be in the order of £160m financial savings to NHS England per year are powerful drivers of anticipated uptake. Performance of our CYP2C19 ID kit in clinical studies under the DEVOTE program was exceptional, with our device outperforming the laboratory platform costing approximately 20X more with respect to speed of time to result, accuracy and target coverage. Whilst positioned primarily for near-patient testing, our CYP2C19 test with its clear advantages is equally at home in traditional laboratory settings.

Outlook

With our innovative products directly addressing a current unmet clinical need in a cost-effective manner to healthcare systems, I am optimistic about what the future holds for your Company.

Being at the forefront of the realisation of this emerging field, we are under no illusions of the scale of the challenge that we face, but we have the determination, requisite skills and commitment to achieving improvements in healthcare, and as such we are continuing to forge the required relationships to surmount these obstacles.

Our near-term focus is executing on our commercial growth strategy, by navigating the reimbursement complexities of the NHS and other countries, expanding the number of sites using our tests in the UK and making targeted efforts to initiate in-country live sites in our prioritised international markets.

The unmet clinical needs are clear and ratified by national guidance, our solutions are proven in real-world settings and with similar applicability globally. To have two products recommended by NICE for their clinical and financial benefit is a very significant achievement for a company of our size.

The US represents a significant market opportunity for both our products, and I was delighted when we received the FDA breakthrough device designation in recognition of our MT-RNR1 ID kit being in the best interests of patients, offering a potentially quicker and more cost effective route to the US market. We remain on track for design and initiation of required studies and are in discussions with FDA under the Breakthrough Device Program relating to these. In addition, we are hopeful that the performance data generated under the PALOH-UK (NIHR/OLS) programme will contribute significantly to clinical evidence generation requirements of the FDA, potentially reducing or removing the need for in-country clinical studies. It is not possible to forecast exact timings, but our expectation is that approximately 12 months are required for completion of these studies followed by the subsequent FDA review period, potentially expedited under the Breakthrough Program, of 1 year.

Whilst there is a comparable CYP2C19 genotyping test which has been cleared via the 510(k) route in the US, our CYP2C19 ID kit offers several differentiating advantages, and as such we are actively pursuing access to the US market via a route that otherwise would potentially be more time-consuming and costly.

CYP2C19 recommendation from NICE differs from MT-RNR1 in that NICE recommend CYP2C19 genotype guided prescription of clopidogrel, with our CYP2C19 ID kit as the platform of choice for point of care strategies. Unlike MT-RNR1 assessed under the NICE EVA route for our product specifically, there is no requirement to generate additional evidence. With a high prevalence of the CYP2C19 genotype in patients from otherwise underrepresented ethnic groups (c30% in the UK general population, which rises to up to 60% in certain ethnicities) our intervention aligns with goals to address and improve equitable access to healthcare. Our first UK sales for CYP2C19 in the largest hyper acute stroke centre in NHS England is testament to the emerging “pull” from key clinical decision makers in adopting and implementing our product in UK stroke centres.

Our CYP2C19 ID Kit is currently UKCA certified, permitting commercialisation in the UK and we continue with the submission for CE-IVD, which will permit similar efforts throughout Europe. UKCA is also accepted in certain Middle Eastern countries, and we are actively pursuing opportunities for commercialisation in advance of CE-IVD in these regions.

Lastly, the US remains an important target market for our CYP2C19 product, with recent recommendations published by key opinion leaders in the American Heart Association highlighting the need for CYP2C19-genotype guided prescription of Clopidogrel in cardiovascular indications, and we will progress the process for attaining regulatory approval there in the future.

Dr Gino Miele
Chief Executive Officer
28 November 2024

Engaging With Our Stakeholders

Section 172 ('S172') of the Companies Act 2006 requires a director of a company to act in the way he or she considers, in good faith, would most likely promote the success of the company for the benefit of its members as a whole. In doing this, with respect to genedrive, S172 requires a Director to have regard, among other matters, to the:

- likely consequences of any decisions in the long term;
- interests of the Group's employees;
- need to foster the Group's business relationships with suppliers, customers and other stakeholders;
- impact of the Group's operations on the community and environment;
- desirability of the Group maintaining a reputation for high standards of business conduct; and
- need to act fairly as between members of the Group.

In discharging its S172 duties, the Board has had regard to the factors set out above. The Chief Executive's Review on pages 21-23 describes the Group's activities, strategy and future performance, including the considerations for long-term decision making. In its decision making the Board gives appropriate regard to these factors and considers information from across the organisation to help it understand the impact of the Group's operations, and the interests and views of our key stakeholders. The Board also reviews strategy, financial and operational performance, as well as information covering areas such as key risks, and legal and regulatory compliance.

The principal decisions taken by the Board that may have a material impact on the Group's strategy can be grouped as follows:

- Financial results and the impacts on employees and shareholders
- Development expenditure and the impact on future products and commercial launches
- Strategy review and the effect on revenues, suppliers and employees
- Funding opportunities, such as the Investor Placing Agreement entered into in March 2023 and the considerations of existing shareholders

Further details on the decision making of the Board and the consideration of these matters can be found within the Corporate Governance section on pages 31-57.

The Board does not believe that the Group has a significant impact on the communities and environment in which it operates. The Board recognises that the Group has a duty to minimise harm to the environment and to contribute as far as possible to the local community in which it operates.

The Board recognises the importance of maintaining high standards of business conduct with customers, suppliers and other business partners. The Group operates appropriate policies on business ethics and provides mechanisms for whistle blowing and complaints in accordance with s172 by providing access to an independent whistleblowing organisation.

Shareholders

We aim to create value for shareholders by delivering sustainable growth. We engage regularly with shareholders through a planned programme of investor relations activities to ensure that our strategy and market trends are clearly understood. Shareholder feedback along with details of movements in our shareholder base are regularly reported to and discussed by the Board and forms part of its decision-making.

Why we engage

- We want to ensure that our strategy and market trends are clearly understood
- To explain how we aim to grow and create shareholder value

How we engage

- Corporate website investor relations section
- AGM, Annual Report, trading updates and results presentations
- Press releases
- Specialist IR communication partner for private investors
- Investor roadshows with current and prospective institutional shareholders
- Meetings/consultation with shareholders on relevant matters

---

Stakeholder areas of interest

- Governance and transparency of Company vision and our strategy for growth

---

Customers	Suppliers	Employees
We are a diagnostics group that innovate, design and manufacture diagnostics tests for customers worldwide. We engage with our customers, strengthening our understanding of their needs and the core markets we serve. We use our wealth of expertise and knowledge to support their requirements today and tomorrow. Updates and feedback from customers are regularly reported to the Board. This provides the Board with specific and general market intelligence, together with any potential impact or opportunities for the business.	Our network of innovative, reliable and quality-focused suppliers is critical to ensuring we can meet the needs of our customers. We work with our suppliers to balance economical requirements with environmental, social and ethical considerations. Information relating to the Group's supply chain is used by the Board to ensure that, in addition to business needs, social and ethical requirements are also being met.	Creating value for our customers relies on the quality of the services and products that we provide, and the skills and knowledge of our employees. We appreciate the value of diversity and recognise the resilience, focus and innovation that our employees demonstrate, and have a desire to keep them safe, well trained and successful. A regular CEO Town Hall programme was maintained during the year.
Why we engage ◅ To understand and exceed customer expectations – delivering focused solutions that can meet the diverse and changing requirements of our global base ◅ To drive continuous improvement in customer service, by responding to feedback and changes in the wider industrial and healthcare markets we serve	**Why we engage** ◅ To meet the needs of our customers, ensuring and maintaining high-quality materials and resources ◅ To ensure high supplier standards, both ethical and otherwise ◅ To develop mutually beneficial and lasting partnerships	**Why we engage** ◅ To ensure alignment of our culture and strategy ◅ To create a diverse and inclusive workplace where every employee can demonstrate entrepreneurship and help build our business ◅ To ensure we deliver and make the right business decisions ◅ To keep our staff safe and well trained
How we engage ◅ Regular one-to-one interactions and meetings ◅ Industry exhibitions, customer site tours and presentations ◅ Company website ◅ LinkedIn communications ◅ Digital marketing	**How we engage** ◅ Regular communication ◅ Regular evaluation of quality, service and performance using onsite and offsite audits	**How we engage** ◅ Company communications, town hall programmes, briefings, news bulletins ◅ Training and development ◅ Employee performance reviews
Stakeholder areas of interest ◅ Customer service/quality standards and compliance ◅ Research and development opportunities	**Stakeholder areas of interest** ◅ Quality and accreditations ◅ Sustainability ◅ Satisfaction/reputation ◅ Corporate social responsibility expectations	**Stakeholder areas of interest** ◅ Reward and recognition ◅ Internal communication ◅ Diversity and inclusion ◅ Personal development and sense of belonging ◅ Transparency of information ◅ Reputation management

The equity fund raise provided a c£5.4m net capital injection

Russ Shaw
Chief Financial Officer

The financial results have been prepared under UK-adopted International Accounting Standards and the Group's accounting policies are set out on pages 58-61.

Revenue and other income for the year was £0.5m (2023: £0.06m) as hospitals begin to adopt our technology. The MT-RNR1 test is in routine use in Greater Manchester and elsewhere and the NICE EVA evidence generation will see the test adopted in a total of 14 sites during FY25.

Research and development costs were £4.2m (2023: £3.9m) focussing on the near commercialisation product development, validation and verification of CYP2C19 in preparation for regulatory approval. Administration costs were £1.6m (2023: £1.4m) increasing due to employment costs as we enhanced our sales and support efforts. The operating loss for the year was £5.3m (2023: £5.2m).

Financing costs and income

Financing costs were £2.5m (2023: £0.79m) and included a non-cash fair value adjustment in respect of the derivative financial instrument of £1.85m (2023: £0.76m) and the transaction costs relating to the share issue of £0.57m (2023: £nil). Financing income was consistent in both years at £0.03m (2023: £0.03m).

Taxation

The tax credit for the year was £0.7m (2023: £0.8m). The Group investment in R&D falls within the UK Government's R&D tax relief scheme for small and medium sized companies where it meets the qualifying criteria and as the Group did not make a profit in the year it is collected in cash following submission of tax returns. The £0.7m is a receivable on the balance sheet at the year end and is lower than in the previous year due to reductions in the enhanced relief available from April 2023.

Cash resources

Net cash outflow from operating activities before taxation was £4.6m (2023: £4.8m). The operating loss cashflows were £5m (2023: £4.9m) with a working capital inflow of £0.4m (2023: £0.1m) mainly due to the movement in trade and other payables.

The tax credit received was £0.8m (2023: £1m) and relates to cash received under the UK Government's R&D tax relief scheme.

Capital expenditure in the period was £0.03m (2023: £0.05m) and the proceeds from investment funding, net of transaction costs were £6.6m (2023: £2.0m). The increase in cash for the year was £2.6m (2023: £2.0m decrease) meaning a closing cash position of £5.2m (2023: £2.6m).

Funding

The equity fund raise provided a c£5.4m net capital injection in June 2024.
During the year the Company drew down £1.2m from the Investor Placing Agreement dated 31 March 2023, which has been fully converted into equity resulting in a debt free balance sheet by the year end (2023: £1.3m). Further details can be found in note 18.

The Company also continues to actively seek non-dilutive funding and participation in the DEVOTE programme saw the Company receive c£0.2m and avoid a further c£1.0m of costs that would otherwise have been absorbed by the Company for the successful validation and verification of our CYP2C19 product.

Balance sheet

Fixed assets were £0.2m (2023: £0.4m) and include right to use lease assets of £0.02m (2023: £0.2m).

Current assets of £6.6m (2023: £4.1m) included cash of £5.2m (2023: £2.6m). Inventories of £0.4m (2023: £0.5m), consisted mainly of finished goods raw materials used in manufacturing and R&D. The remainder of current asset values were in receivables of £0.4m (2023: £0.2m) and tax. The tax receivable was £0.7m (2023: £0.8m) for the current year Corporation Tax Research and Development tax claim.

Current liabilities were £1.4m (2023: £2.4m) and the prior year include a derivative financial instrument of £1.3m resulting from the Investor Placing Agreement, as set out in note 18.

The shares to be issued reserve of £0.7m (2023: £0.5m) relates to the warrants issued as part of the Investor Placing Agreement.

Net assets closed at £5.4m (2023: £2.0m) and the movement in the accumulated losses reserve for the year was £5.2m (2023: £5.2m).

Going concern

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 is expected to see over £0.5m of revenue commencing in November 2024.

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 first sale 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 various forecast scenarios that were considered by the Board, identify costs mitigations that could extend the cash runway, and the Directors have reasonable confidence in their ability to raise additional financing if required 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.

As described in the accounting policies, we continue to adopt a going concern basis for the preparation of the accounts, but the combination of the above factors represent a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern.

Russ Shaw
Chief Financial Officer
28 November 2024

Key Performance Indicators

The Group has a small set of financial KPIs that are reviewed and discussed as part of the management of the business. These metrics are currently the most important to the business in its current stage of growth, i.e. managing cash, revenue and expenditures is vital to the business. These metrics are expected to change as the business grows and evolves.

Cash reserves
£5.2m (2023: £2.6m) (2022: £4.6m)
Cash reserves boosted by an equity fund raise in June 2024

Revenue and other income
£0.5m (2023: £0.06m) (2022: £0.05m)
Due to initial commercial traction

Research and development costs
£4.2m (2023: £3.9m) (2022: £3.9m)
Research and development costs increased due to near commercialisation product development

Administration costs
£1.6m (2023: £1.4m) (2022: £1.8m)
Administration costs increased due to commercialisation focus

Operating loss
£5.3m (2023: £5.2m) (2022: £5.6m)
Trading result before exceptionals, tax, interest and finance costs

The Group's non-financial KPIs focussed on the milestone achievements on the CYP2C19 test and progress relating to the NICE assessments of both MT-RNR1 and CYP2C19 and the FDA Breakthrough Designation.

Principal Risks and Uncertainties

for the year ended 30 June 2024

The Group's strategic objectives can only be achieved if certain risks are taken and managed effectively. It is important for us to identify and understand the key risks in our business and we have listed below the most significant risks that may affect our business. genedrive records risks using the following risk management model that is centred around a corporate risk register. The Board has overall responsibility for ensuring that genedrive has an effective risk management framework which is aligned to our objectives. The Executive Team, Audit and Risk Committee and Board review risks which could affect the Group throughout the year. Risk and issue tracking systems are reviewed on a regular basis, to ensure that the framework is in line with good practice in risk management and that agreed mitigation plans are being followed. In determining the relative importance of risks in our business, we use a scoring mechanism to identify the likelihood of a risk crystallising and the impact this would have on the achievement of our strategic objectives, assuming that no controls are in place (inherent risk score).
The table below outlines the principal risks and uncertainties which the Group faces together with relevant key controls and mitigating factors. The list does not constitute a list of all risks faced by the Group and is not presented in priority order.

Risk	Impact	Mitigation	Risk movement
Economic and political uncertainty, trade negotiations, and inflation, which affect market and financial stability	Negative impact on long-term prospects	Distributors appointed for geographical diversification Authorised key operators in place for key regulatory matters	No change
Business strategy The Board develops the wrong strategy or fails to implement strategy effectively	Negative impact on long-term prospects	Focused strategy on PGx and emergency care. Progress of strategy clear in KPIs and reporting and Board reviews regularly.	Reduce
Competitor entry Entry to the market of better performing or cheaper products remains a key risk	Loss of first-to-market advantage and reduction of potential market share	MT-RNR1 is the first to market in UK, therefore incoming competitor unlikely in the short-term Product improvement projects to differentiate and protect Genedrive® Cost programmes in place to support future price-down strategies Constant market monitoring and competitor analysis	Increase
Regulatory approval Transition from the EU's existing In Vitro Diagnostic Directive ("IVDD") to the new In Vitro Diagnostic Regulation ("IVDR")	Delays in product approval could impact ability to trade	In-house Quality and Regulatory specialists Engagement with notified bodies and regulatory organisations	No change
AIHL sales slower than expected Delays in the uptake of the test owing to lack of funding from NHS or slow speed to get the test written into clinical guidance	Loss of revenue and profit Loss of reputation	Building relationships with government bodies such as the Office for Life Sciences Expanding business development team in place to promote and progress product adoption Close monitoring and reporting to the Board	Increase
Supply chain The Company is reliant on certain key suppliers of raw materials and components including microchips that are currently under long lead time supply	Inability to fulfil demand Loss of revenue and profit	Contractual arrangements exist where possible Secondary suppliers scoped and in place Selective forward buying of key components	Reduce
Financial position The Company is loss-making and will continue to have going concern challenges until it builds a portfolio of profitable diagnostics assays	Negative impact on Company's prospects	The Company successfully completed a £6m gross fundraise in June 2024 Cash consumption is a key Board metric and the Board continuously assess the funding requirements	No change

This Strategic Report was approved by the Board of Directors on 28 November 2024 and signed on its behalf by R J Shaw.

Maintenance of good Corporate Governance

As a board we fully acknowledge the importance of Corporate Governance and the expectations of stakeholders.

Dr Ian Gilham
Chairman

The statement of corporate governance practices set out on pages 31-42, including the reports of Board Committees, and information incorporated by reference, constitutes the Corporate Governance Report of genedrive plc.

genedrive plc's Corporate Governance Report for the year ended 30 June 2024 is presented here on behalf of the Board.

Dear Shareholders,

We have been applying the principles of good governance as set down in the Quoted Companies Alliance Corporate Governance Code (the "QCA Code") since 2019. As a board we fully acknowledge the importance of Corporate Governance and the expectations of stakeholders and this report seeks to provide shareholders and stakeholders with a clear understanding of how we discharge our governance duties. How we meet the principles and where further information can be found is covered as follows:

We have a clear and well-established strategy that can be read in our business model and strategic review.

We embed effective risk management in our business and maintain a fit for purpose governance structure. The business has a structure of risk registers, control frameworks and policies that are appropriate to our size and to the healthcare sector we work within. The top corporate level risks can be viewed within the Strategic Report and the Board gets assurance that the risks are under management by reviewing the risks and plans for each risk on a regular basis.

We maintain a well-functioning Board, with appropriate skills and frequent evaluations. We review the Board effectiveness annually, through an internal process using confidential questionnaires developed by each Committee Chair, the Company Secretary and myself. The review was a productive exercise and I am pleased to confirm that the review found that the Board and its Committees continue to perform effectively. In addition to the effectiveness, during the year the composition of the Board was reviewed to ensure we have the right skill set to achieve our strategic objectives. We believe that the Board has the appropriate mix of skills and as we progress through these periods of rapid change Board stability will remain a benefit to the Group. Further details on the role of the board, its composition and its operation are described on pages 33-37.

We promote an ethical culture and take account of wider stakeholder and social responsibilities. We adhere to high ethical standards as demanded by the Healthcare markets in some of our territories, ensuring appropriate training is provided to meet the required regulatory requirements.

Our engagement with our key stakeholders, shareholders, customers, suppliers, employees and our impact on the environment and communities, is described in our s172 statement on pages 24-26.

We aim to understand and meet shareholder needs and communicate how the Group is governed and maintain dialogues with relevant shareholders. Our investor relations strategy is appropriate to our size and we attempt to use innovative platforms to reach a wider investor base. Further information regarding our engagement with shareholders is provided on page 24.

Please see our website for further information on Corporate Governance: www.genedriveplc.com/investor-relations/corporate-governance.php

In line with our historical practice all Directors will be proposed for re-election at the Annual General Meeting of the Company to be held on 30 December 2024. Details of how shareholders may submit questions into the AGM will be issued as part of the AGM notices. We look forward to hearing from you.

Dr Ian Gilham
Chairman
28 November 2024

Board of Directors

Skills and experience suited to our business

Ian Gilham Ph.D. 1 2*3*
Non-Executive Chairman

Ian was appointed a Director on 24 November 2014 and as Non-Executive Chairman on 11 May 2015. He is currently Chair of Trustees for LifeArc, a philanthropic fund looking to invest £1.3 billion making life science life changing; Non-Executive Chairman of at Pelago Bioscience AB, a Life Science tools business based in Stockholm; and Non-Executive Chairman of RevoNA Bio Ltd, a University of Portsmouth spinout Life Science tools company. Dr Gilham was formerly Chief Executive Officer of Axis-Shield Plc.

Gino Miele Ph.D.
Chief Executive Officer and Chief Scientific Officer

Gino was appointed Chief Executive Officer on 6 August 2024 and a Director and Chief Scientific Officer on 11 September 2023. He has considerable experience in the development of molecular diagnostic technologies and instrumentation, and has been the R&D Director at genedrive since 2015 and its predecessor Epistem since 2011. Prior to that Gino served as Associate Director for clinical translational genomics at Wyeth and Pfizer. Gino has been a key driver in the development of the genedrive® system and positioning of point of care pharmacogenetic testing in emergency healthcare.

Russ Shaw
Chief Financial Officer

Russ was appointed Chief Financial Officer and Company Secretary on 7 April 2022. He has over 25 years of international experience across multiple sectors including life sciences, technology and the industrials. Prior to joining genedrive, he spent 10 years as Finance Director at Driver Group plc, an AIM-quoted company operating in the engineering and construction industry. Russ has been CFO of several private companies and is a qualified Accountant and Treasury professional.

Tom Lindsay 1 2 3
Non-Executive Director

Tom was appointed to the Board on 9 April 2018. He has 35 years of global sales and marketing experience in the diagnostics sector. He is currently Non-Executive Director of Trinity Biotech plc . Tom most recently worked for Alere Inc. in Africa, where he held a range of executive posts including President of Africa, President Commercial Operations Africa and Business Development Director for Africa. Prior to Alere, Tom held senior commercial roles at Trinity Biotech (Ireland) including Marketing and Sales Director (Global) and Business Development Director for Africa, Middle East and India. Tom studied microbiology at Glasgow Caledonian University and completed a national diploma in microbiology at the South African Institute of Medical Research in Johannesburg, South Africa.

Chris Yates 1* 2 3
Non-Executive Director

Chris was appointed to the Board on 22 August 2018. He is CEO of Abingdon Health plc, a position he has held since July 2015. Chris co-founded Abingdon in 2008 and was a Non-Executive of the Company prior to his appointment as CEO. Chris has over 20 years' experience of working in listed environments and prior to working at Abingdon, was CFO at Immunodiagnostic Systems Holdings PLC and Cozart plc. Chris is a Chartered Accountant and has a degree in economics from Cambridge University.

Committee Membership

1 Audit and Risk Committee
2 Remuneration Committee
3 Nominations Committee
* Denotes Committee Chair

Corporate Governance

The Board has delegated certain responsibilities to the following Board Committees:

the Audit and Risk Committee
the Nominations Committee
the Remuneration Committee

The reports of the Audit and Risk Committee and Remuneration Committee are set out on pages 27-37. There is no separate report provided for the Nominations Committee.

Each Committee operates under clearly defined Terms of Reference. Each Committee provides update reports to the Board via the Chairman of the Committee. Each Committee has sufficient resources to undertake their duties, including access to the Company Secretary and external advisers, where appropriate.

Audit and Risk Committee

The Audit and Risk Committee's main responsibilities are to monitor the integrity of the Group's financial statements, to review internal and external audit activity and to monitor the effectiveness of risk management and internal controls.

Remuneration Committee

The Remuneration Committee is responsible for determining all elements of remuneration for the Executive Directors and Executive Team and for reviewing the appropriateness and relevance of the Group's remuneration policy.

Nominations Committee

The Nominations Committee is responsible for Board recruitment and succession planning, to ensure that the Board is balanced and comprises the correct skill sets.

Leadership

The role of the Board

The Board is responsible for the long-term success of the Group and is ultimately accountable for the Group's strategy, risk management and performance. The Board's primary roles are: to provide leadership to the Group within a framework of prudent and effective control which enables risk to be assessed and managed; to set the Group's strategic objectives; and to ensure that the necessary resources are made available so that those objectives can be met. The Board also sets the Group's values and standards and is responsible for ensuring that its obligations to shareholders and other stakeholders, including employees, suppliers, customers and the community, are understood and met.

The Board has adopted an annual programme ensuring that key matters are routinely considered in addition to non-standard items.

The annual programme includes:

- approval of the annual budget;
- review of performance of the Company against the approved budget;
- review of key advisers;
- review of cashflows and funding opportunities;
- review of accounting for the Investor Placing Agreement;
- review of insurance premiums and coverage;
- review of governance issues affecting the Company; and
- assessment of the corporate risk register.

The Board currently comprises two Executive Directors, a Non-Executive Chairman and two Non-Executive Directors. The names, biographical details and Committee memberships of the current Board members are set out on pages 33-34 of this report. Given the size and strategy of the Company, the Board believes that two Non-Executive Directors as well as a Non-Executive Chairman is an appropriate structure going forwards.

Division of responsibilities of the Chairman and Chief Executive

There is a clear division of responsibilities between the Chairman and the Chief Executive. Each role has its own formal written description of specific responsibilities.

The Chairman's principal responsibility is to lead the Board in the determination of its strategy, setting its objectives and monitoring the achievement of those objectives.

The Chairman is responsible for organising the business of the Board, ensuring its effectiveness by facilitating full and constructive contributions to the development and determination of the Group's strategy and its overall commercial objectives from each member of the Board.

The Chief Executive is directly responsible for all executive management matters affecting the Group. His principal responsibility is ensuring achievement of the agreed strategic objectives and leadership of the business on a day-to-day basis. The Chief Executive is accountable to the Board for the financial and operational performance of the Group.

The role of the Non-Executive Directors

The Non-Executive Directors bring independence and a wide range of experience to the Board. Their role is to help develop strategy and to promote constructive debate and challenge in Board discussions. The Non-Executive Directors ensure that the financial controls and systems of risk management are robust and defensible.

The role of the Company Secretary

The Company Secretary advises the Board through the Chairman on all governance matters. All Directors have access to the services of the Company Secretary and may take independent professional advice at the Company's expense in conducting their duties.

Operation of the Board

The Board held 10 Board meetings during the year to 30 June 2024. The normal pattern of meetings is to hold six main in-person meetings every other month, with a video conference meeting in between, with no meetings scheduled in August and December. The provision of relevant, up-to-date information is fundamental to the effective leadership delivered by the Board. Reports from the Executive Directors, which focus on major operational matters, are circulated in advance of every Board meeting. To ensure that the Board is kept fully informed on the status of the business, reports and presentations are also produced by key Executive management. Attendance at each meeting is set out below. The Board evaluates its performance annually in a formal review and via a performance questionnaire.

Attendance at meetings

The following table sets out the attendance of each Director at Board and Committee meetings held during the year, along with the maximum number of meetings that it was possible to attend:

	Board	Audit and Risk Committee	Remuneration Committee [a]	Nominations Committee
Ian Gilham	10/10	3/3	2/2	1/1
Tom Lindsay	10/10	3/3	2/2	1/1
Chris Yates	10/10	3/3	2/2	1/1
Gino Miele [a]	9/9	3/3	1/1[a]	1/1
Russ Shaw [a]	10/10	3/3	1/1[a]	1/1
James Cheek [a]	9/9	1/1	n/a	1/1
David Budd [a]	1/1	n/a	n/a	n/a

a Attendance via invite.

Although not members of the Committees, the Executive Directors attend meetings of the Audit and Risk Committee, Remuneration Committee and Nominations Committee as invited attendees when appropriate.

Key matters considered at each main meeting of the Board during the year included:

July 2023	September 2023	November 2023
Review of cashflows and funding opportunities Commercial presentation Reviewed and approved Annual Budget for 2023/24	Review of R&D projects Risk management and risk Register	Reviewed and approved Annual Report 2022/23 Reviewed auditor's report on the year ending June 2023 Commercial presentation

January 2024	March 2024	June 2024
Review of R&D projects Commercial presentation Review of cashflows and funding opportunities	Approved Investor Placing Agreement Reviewed and approved Interim results Commercial presentation	Annual review of insurance risks Reviewed Board effectiveness and the plan for 2024/25 Review of R&D projects Reviewed controls and policy of the Group

Report of the Audit and Risk Committee

Chris Yates
Non-Executive Director

The Audit and Risk Committee ('the Committee') report for the year ended 30 June 2024 is set out on below through to page 40.

Dear Shareholders,

I am pleased to present the report of the Audit and Risk Committee for the year ended 30 June 2024.

The Committee completed its agenda of work, meeting the scope set out in the audit committee terms of reference, and has continued to play a key role within the Group's governance framework. In this report I have sought to provide genedrive stakeholders, including investors and prospective investors, with an understanding of the approach we have taken to provide assurance on the integrity of the 2023/24 Annual Report and financial statements, and how we have supported the Board in matters relating to financial reporting, internal control and risk management. In terms of the work performed in the year, I can confirm that there are no matters to bring to your attention.

Looking forwards we will continue to provide meaningful disclosure of the Committee's activities in line with our Terms of Reference, which are set out in the Corporate Governance section of our website, and on ensuring that the Committee's agenda is kept under review in light of internal and external developments. Should there be any questions about the Committee or this Audit and Risk Committee report, I will be available to answer any questions at the Annual General Meeting.

Terms of Reference for the Audit Committee can be found on www.genedrive.com

Aims and objectives

The overall aim of the Committee is to monitor the integrity of the Group's financial statements and announcements, its accounting processes, and the effectiveness of internal controls and risk management.

Main responsibilities of the Committee

- Reviewing the financial statements and the Company's announcements relating to financial performance, including reporting to the Board on the significant issues considered by the Committee in relation to the financial statements and how these were addressed;
- Reviewing the scope and results of the annual audit and reporting to the Board on the effectiveness of the audit process and how the independence and objectivity of the auditors have been safeguarded;
- Reviewing significant legal and regulatory matters;
- Reviewing matters associated with the appointment, terms, remuneration, independence, objectivity and effectiveness of the external audit process and reviewing the scope and results of the audit; and
- Reporting to the Board on how the Committee has discharged its responsibilities as set out in the Committee's Terms of Reference.

At this stage of the Group's size and development the Committee has decided that an internal audit function is not required as the Group's internal controls system in place is appropriate for its size. This will continue to be reviewed on a periodic basis as the Group's operations develop.

Composition

The Audit and Risk Committee is comprised of Ian Gilham, Tom Lindsay and myself. In addition, James Cheek, Gino Miele and Russ Shaw were invited and attended meetings during the year.

All members of the Committee are independent Non-Executive Directors and the Committee as a whole has competence relevant to our sector. Since July 2015 I have been the CEO of Abingdon Health plc, an AIM listed company. Prior to this I served as CFO at two AIM-listed medical diagnostic companies: Immunodiagnostic Systems Holdings PLC and Cozart plc. I am a Fellow of the Institute of Chartered Accountants of England and Wales.

Ian Gilham is Chairman of the trustees at LifeArc and Non-Executive Chairman of Pelago Bioscience AB and RevoNA Bio Ltd. Ian was previously the CEO at Axis Shield Plc as well as having held a number of independent director roles at various life sciences and healthcare businesses.

Tom Lindsay has held a number of senior roles within major diagnostics businesses, with specific focus and knowledge of the Africa region.

This relevant experience allows the members to:

Oversee the relationship with the external auditor;

- understand the risks facing a pre-profit diagnostics business and approaches to managing these risks;
- maintain an oversight of the Group's internal control environment through the internal audit plan and risk management framework;
- review strategic financial management and provide constructive challenge to the reports and assurances given by management, and guide the design and implementation of a suitable assurance framework; and
- provide practical insights on the Group's approach to corporate governance.

Audit and Risk Committee's agenda 2023/24

During the year the Committee met three times and undertook the following activities:

Governance

- Reviewed and revised the Audit and Risk Committee's Terms of Reference;
- Reported to the Board on how it has discharged its responsibilities.
- Checked at each Committee meeting individual directors' conflicts of interest.

Financial statements and reports

- Reviewed and considered the significant issues, including key accounting judgements, in relation to the financial statements and how these have been addressed, including:
- Requirements around going concern and the Group's viability;
- Estimates and judgements relating to the treatment and measurement of the Investor Placing Agreement;
- Advised the Board that, taken as a whole, the Annual Report and accounts are fair, balanced and understandable.
- Reviewed the interim financial statements and related statements and reviewed and considered key accounting judgements.

External auditor and auditor independence

- Reviewed and agreed the statutory audit fee for the year ending 30 June 2024
- Monitored the independence and objectivity of the external auditor.
- Confirmed the independence of the external auditors and recommended to the Board the re-appointment of RSM UK Audit LLP at the upcoming AGM.
- Reviewed and approved the scope and methodology of the external audit strategy for 2023/24

Cash position

- Considered the cash position and forecast spending of the Group.
- Reviewed the potential for equity fund raising.
- Reviewed and considered alternative financing options available to the Group.

Risk management

- Reviewed and approved the key internal controls in the business and the effectiveness of these controls.
- Reviewed and considered the Group's Whistleblowing Arrangements and Anti-Bribery Policy.

Going concern

The Committee reviewed whether it was appropriate to adopt the going concern basis for the preparation of the Annual Report. Consideration was given to the Group's two-year forecasts and the current cash resources. The forecasts were stress tested and factors which impact on risks and uncertainties were properly considered.

Following the Committee's review, it recommended to the Board that it was appropriate to adopt the going concern basis. However, given the uncertainty of the timing of the revenues over the review period, the cost base and funding requirements of the Group the Committee recommended that the disclosures in the Directors' Report and accounting policies identify a material uncertainty that casts significant doubt as to the ability of the Group and Company to continue as a going concern.

External audit

The Committee continues to monitor the external auditor's compliance with applicable guidance and guidelines and considers the independence and objectivity of the external auditor as part of the Committee's duties.

The Committee received and reviewed written confirmation from the external auditor on all relationships that, in their judgement, may bear on their independence. The external auditor has also confirmed that they consider themselves independent within the meaning of UK regulatory and professional requirements.

In all services purchased, the Group selects the provider best placed to deliver the work in terms of quality and cost. As a general principle the external auditor is excluded from consultancy work and other non-audit work except for assurance services. The Group adheres to the Financial Reporting Council Revised Ethical Standard 2019 which prohibits the auditor from providing non-audit services to listed companies except for certain assurance-related services. The external auditors did not undertake any other non-audit services during the year.

Tendering policy and review of auditor effectiveness

Following a tender process undertaken by the Committee the Group appointed RSM UK Audit LLP (RSM) as the Group's and Company's auditors in December 2019. The Committee continues to review the performance and effectiveness of the auditors and has no plans to tender in the forthcoming 12-month period.

Chris Yates
Chairman of the Audit and Risk Committee
28 November 2024

Demonstrated resilience, creativity, and determination

Ian Gilham, Ph.D.
Chairman of the Remuneration Committee

Dear Shareholders, on behalf of the Remuneration Committee I am pleased to introduce the Directors' Remuneration Report for the year ended 30 June 2024. This report sets out the activities of the Remuneration Committee for the year ended 30 June 2024. The report is divided into three sections: this statement, a summary table of our Remuneration Policy and our Annual Report on Remuneration for the year ended 30 June 2024.

As detailed in the Strategic Report, the past year has seen some great achievements in product development and as we outlined in last year's accounts the route to adoption of new clinical tests takes time, healthcare systems are conservative in their nature and face inevitable budgetary constraints. The absence of revenue is a key driver in setting the overall remuneration outcomes for the year to 30 June 2024.

I hope it is clear from the way we have applied our remuneration policy in FY 2023/24 that we continue to take account of the feedback of our shareholders and we look forward to receiving your support for the Directors' Remuneration Report at the upcoming Annual General Meeting. As in previous years I will be available to answer any questions before the Annual General Meeting. The following Remuneration Committee report was approved by the Committee at its meeting held on 28 November 2024.

Our strategy

Our goal is to drive the success of genedrive by adhering to a disciplined strategy to create a focused molecular diagnostics business. We are dedicated to creating new assays to expand our offerings and generate revenue in the near term, addressing the significant market opportunities.

Executive remuneration and link to strategy

Our Remuneration Policy focuses on rewarding sustained performance. It is our belief that Executives should be rewarded on the basis of their individual performance and the value created for shareholders. Variable elements of pay are therefore focused on simple and transparent measures of key strategic objectives, sales, cash and building shareholder value. Bonus and long-term incentive scheme targets are purposely designed to be challenging and drive the long-term success of the Group.

Remuneration outcomes of 2024

Full details of the decisions of the Committee made in 2024 are set out in the Directors' Annual Report on Remuneration on pages 41-47.

The Committee agreed that there would be no increase to the salary of the CEO and that the CFO would receive a 3% increase, which is aligned with the general workforce increase for the same period for the year commencing 1 July 2024.

The annual bonus targets for the Executive Directors and Executive Team were set by the Committee at the beginning of the financial year. The CEO could receive an annual bonus equivalent to 100% of salary and the CFO and CSO receive an annual bonus equivalent to 80% of salary for 2024. Having reviewed the targets, the bonus payment made for this financial year was approximately 45% of entitlement for both the CFO and CSO.

Remuneration Committee

The Remuneration Committee is responsible for determining reviews of the scale and structure of the Executive Directors' and senior management's remuneration and the terms of their service contracts. The remuneration and terms of appointment of the Non-Executive Directors are set by the Board. The Remuneration Committee also approves the issue of share options under schemes approved by the Board. None of the Committee members have any personal financial interest (other than as shareholders), conflicts of interest arising from cross-directorships or day-to-day involvement in the running of the business. No Director plays a part in any final decision about his or her own remuneration.

Meeting frequency and attendance

The Committee is scheduled to meet at least twice a year, with other meetings taking place as required; there were two meetings in the year to June 2024. Only members of the Committee have the right to attend Committee meetings. However, other individuals including the Group Chief Executive and external advisers may be invited to attend for all or part of any meetings, as and when appropriate and necessary, at the discretion of the Chair.

Transparency

The Committee seeks to operate in a clear and transparent manner and to demonstrate good practice in Executive remuneration. The Committee's report comprises two sections, namely:

- this statement, which sets out a summary of and explains the major decisions on Directors' remuneration;
- the Directors' Annual Report on Remuneration, which provides details on how the proposed amended Remuneration Policy will operate in the forthcoming year and states the remuneration earned by the Directors in the year to 30 June 2024.

The Directors' Annual Report on Remuneration will be subject to an advisory vote by shareholders at the 2024 Annual General Meeting. As Chairman of the Committee, I will be available to respond to any questions you may wish to raise on any of the Committee's activities.

Dr Ian Gilham
Chairman of the Remuneration Committee
28 November 2024

Remuneration Policy

This report sets out the Company's policy on the remuneration of its Executive Directors and Non-Executive Directors (the 'policy'). The Executive Directors have written terms of engagement with no fixed expiry date. Executive remuneration packages are prudently designed to attract, motivate and retain Directors of the necessary calibre and to reward them for enhancing value to shareholders. The performance measurement of the Executive Directors and key members of senior management and the determination of their annual remuneration package is undertaken by the Remuneration Committee.

Directors' remuneration policy table

Element of remuneration	Purpose and link to strategy	Operation	Maximum	Target
Base Salary	To provide competitive and fixed remuneration. To attract and retain the right calibre of Executive.	Salaries are usually determined by reference to market data and taking into account the responsibilities of the Executive. All increases and changes are at the discretion of the Committee. Salaries are normally reviewed annually in July.	Executive Directors normally receive a salary increase in line with the general workforce.	None
Benefits	To provide market consistent benefits.	Current benefits are: ▪ Life assurance ▪ Group income protection ▪ Private health insurance	There is no maximum and the costs of these benefits can vary year over year. The same benefits are provided to the general workforce.	Not applicable
Pension	To attract and retain the right calibre of Executive. To provide a level of benefits that allow for retirement planning	Executives are offered a contribution into a defined contribution pension scheme A cash allowance in lieu of pension A combination of contribution and cash	The maximum Company pension contribution is 3% - this is consistent with the general workforce	Not applicable
Annual bonus	To incentivise performance against personal objectives and selected KPIs linked to business strategy.	Company and Individual bonus targets are set in July of each year. Achievement of both Company and Individual targets are assessed in the September following the end of the financial year with payment following shortly thereafter.	The current maximum percentages are 100% for the Chief Executive, and 80% for the Chief Financial Officer. A maximum pay-out requires an Executive's personal performance to be maximum and the Company bonus achievement to be maximum as well.	An overall Company achievement is based on financial and operational KPIs. A summary of the current year KPIs is contained on page 29.
Long-term Incentive Plans	Designed to align the strategic objective of delivering sustainable earnings growth over the longer term with the interests of shareholders.	Awards are rights to receive shares in the Company. Each award is measured over at least three years. All awards are issued with an exercise price equal to the prevailing share price on the day prior to the award.	Awards are made annually up to a maximum percentage of 100% of salary. The overall policy allows for up to 200% of salary in exceptional circumstances.	Targets are based on one or more financial and non-financial measures linked to the long-term strategy of the business as deemed appropriate by the Committee.

Service contracts: Executive Directors' service contracts are subject to six months' notice of termination by either party.

External appointments: Executive Directors are entitled to accept appointments outside the Company provided the Board's permission is sought. Gino Miele served as a Non-Executive Director of Cytomos Ltd.

Non-Executive Directors' terms of engagement: The remuneration of the Non-Executive Directors is determined by the Board within limits set out in the Articles of Association. Each Non-Executive Director has specific terms of engagement. In the event that a Non-Executive undertakes additional assignments for the Company, the Non-Executive's fee will be agreed by the Company in respect of each assignment. No additional assignments were performed by the Non-Executive Directors during the year.

Annual Report on Remuneration

As the Company is AIM registered it is not required by company law to prepare a Remuneration Report. The information in this report has been provided on a voluntary basis and has not been audited.

Single figure for total remuneration

The following table sets out the single figure for total remuneration for Directors for the financial years ended 30 June 2024 and 2023 and has not been audited.

		Salary and fees £	Bonus £	Benefits in kind £	Pension £	Total £
Executive						
Gino Miele	**2024**	**127,649**	**25,145**	**1,647**	**18,761**	**173,202**
(appointed 11 September 2023)	2023	–	–	–	–	–
Russ Shaw	**2024**	**157,075**	**26,172**	**1,270**	**30,394**	**214,911**
	2023	152,500	-	1,002	4,575	158,077
James Cheek	**2024**	**161,538**	**-**	**-**	**5,000**	**166,538**
(appointed 11 September 2023)	2023	–	–	–	–	–
David Budd	**2024**	**182,280**	**16,957**	**£2,532**	**£5,573**	**£207,342**
(resigned 11 September 2023)	2023	247,697	-	1,669	7,431	256,797
Non-Executive						
Ian Gilham	**2024**	**65,000**	**–**	**–**	**–**	**65,000**
	2023	65,000	–	–	–	65,000
Tom Lindsay	**2024**	**35,000**	**–**	**–**	**–**	**35,000**
	2023	35,000	–	–	–	35,000
Chris Yates	**2024**	**35,000**	**–**	**–**	**–**	**35,000**
	2023	35,000	–	–	–	35,000

Gino Miele's remuneration relates to the period in which he was a director of the Group.

David Budd's remuneration relates to the period in which he was employed by the Group.

Additional disclosures for single figure of total remuneration to 30 June 2024.

Salary, with effect from the 1 July 2024:

The CEO salary remained at £200,000
The CFO salary was increased 3% to £162,000

The Committee believes that the increase of 3.0% awarded was in line with wage inflation in the market, the performance of the Group and the individual, as well as being entirely consistent with the pay increases awarded to other members of staff.

Annual performance bonus

The 2024 bonus for the Executive Directors and senior management was based on:

- Revenue targets on the sales of Genedrive® units and assays
- The cash position of the Group at 30 June 2024
- The EBITDA result for the year
- Milestone achievements on the CYP2C19 test
- NICE and FDA progress

The specific targets have not been disclosed.

Annual Report on Remuneration continued

Long Term Incentive Plans

Details of the options for Directors who served during the year are as follows:

	Outstanding 30 June 2024	Date granted	Exercised	Lapsed	Exercise price	Earliest exercise date	Expiry date
Executive							
Gino Miele	500,000	06/02/2024	–	–	£0.0600	06/02/2027	06/02/2034
	100,000	21/10/2022	–	–	£0.1225	21/10/2025	21/10/2032
	100,000	03/12/2021	–	–	£0.3100	03/12/2024	03/12/2031
	170,000	06/04/2020	–	–	£0.0900	06/04/2023	06/04/2030
	150,000	05/04/2019	–	–	£0.2350	05/04/2022	05/04/2029
	43,024	30/11/2017	–	–	£0.3600	30/11/2020	30/11/2027
	50,000	04/04/2017	–	–	£0.4300	04/04/2020	04/04/2027
	20,000	01/05/2016	–	–	£0.8200	01/05/2019	01/05/2026
Russ Shaw	500,000	06/02/2024	–	–	£0.0600	06/02/2027	06/02/2034
	100,000	04/04/2022	–	–	£0.3000	04/04/2025	04/04/2032
James Cheek	750,000	06/02/2024	–	–	£0.0600	06/02/2027	06/02/2034

The Company issues long-term incentives under the management incentive plan dated July 2017. The incentive plan has the following key features:

- Executives may be awarded up to 100% of salary per annum in the form of options, with allowance for up to 200% in exceptional circumstances.
- The exercise price of options will not be below market price.
- Awards vest over three years subject to performance criteria being met.
- The Board retains the right to scale back or reduce to zero the size of vesting awards if they are not satisfied that the status and performance of the business is sufficient or the individual has not met an acceptable level of personal performance.

The Company has a policy to issue awards to the Executive Directors and other senior management annually.

Directors and their interests in shares

The Directors of the Company who held office throughout the year, unless otherwise stated, and their interests in the share capital of the Company, including family and pension scheme trust interests, were as follows:

	30 June 2024	30 June 2023
Executive		
Gino Miele	1,066,979	n/a
Russ Shaw	1,700,000	-
James Cheek	666,666	n/a
David Budd	n/a	293,710
Non-Executive		
Ian Gilham	1,280,961	614,295
Tom Lindsay	929,383	262,717
Chris Yates	267,554	67,554

Share Investment Plan

The details of the Epistem Share Investment Plan ('SIP') are outlined in note 19 to the financial statements. None of the Directors serving during the year participated in the SIP.

Advice received by the Committee

The Committee has access to advice when it considers it appropriate. In the current year the Committee did not receive any external advice on remuneration.

This Remuneration Report was approved by a duly authorised Committee of the Board of Directors on 28 November 2024 and was signed on its behalf by:

Dr Ian Gilham
Chairman of the Remuneration Committee
28 November 2024

Directors' Report

The Directors present their Annual Report for genedrive plc ('the Company') and its subsidiaries (together 'Genedrive' or 'the Group') for the year ended 30 June 2024.

Principal activities and business review

genedrive plc is the holding company for a group operating in the design, development and manufacture of molecular diagnostics testing equipment for applications in the Healthcare and other markets. A review of the performance and future development of the Group's business is contained on pages 3-30 and forms part of this report.

Results

The trading results for the year and the Group's financial position at the end of the financial year are shown in the financial statements on pages 58-61 of this report. The Directors do not recommend paying a dividend, (2023: £nil).

Going concern

The Group's business activities and market conditions are described on pages 5-23. The principal risks and uncertainties are shown on page 30 while the Group's financial position is described on pages 27 and 28. The Group funds its day-to-day cash requirements from existing cash reserves, revenue generation and other income. These matters have been considered by the Directors in forming their assessment of 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 will see over £0.5m of revenue commencing in November 2024.

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 first sale 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 if required 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.

Annual General Meeting

The Annual General Meeting will be held on 30 December 2024 at 46 Grafton Street, Manchester M13 9XX. Details of the business to be considered at the Annual General Meeting and the Notice of Meeting are included in a separate document.

Share capital

Details of the issued share capital, together with details of movements in the Company's issued share capital during the year, are shown in note 22 to the Company's financial statements on page 81. The Company has one class of ordinary share which carries the right to one vote at General Meetings of the Company. The nature of the Directors' holdings is disclosed on page 46. No person has any special rights of control over the Company's share capital and all issued shares are fully paid. Subject to the provisions of the Company's Articles of Association and the Companies Act 2006, at a General Meeting of the Company the Directors may request authority to allot shares and the power to disapply pre-emption rights and the authority for the Company to purchase its own ordinary shares in the market.
The Board requests such authority at each Annual General Meeting. Details of the authorities to be sought are set out in the Notice of Annual General Meeting.

Share options and warrants

Details of the Company's share capital and options over the Company's shares under the Company's employee share plans, given in notes 19 and 22.

Significant agreements

All of the Company's share plans contain provisions relating to a change of control. On a change of control, outstanding awards would normally vest and become exercisable, subject to the satisfaction of any performance criteria. There are no agreements between the Company and its Directors or employees that provide for compensation for loss of office on a change of control.

Board of Directors

The names of the present Directors and their biographical details are shown on pages 33-34. Post period end James Cheek resigned as a Director on 6 August 2024. At the Annual General Meeting, to be held on 30 December 2024, all the Directors will offer themselves for re-election.

The Company has entered into Directors and Officers liability insurance for the benefit of all of its Directors in a form and scope which comply with the requirements of the Companies Act 2006.

Significant shareholdings

In addition to the Directors' holdings, the Company has been advised of that there are no interests of over 5% of the issued ordinary shares at 30 June 2024.

Research and development

During the year ended 30 June 2024 the Group has incurred research and development costs of £4.2m (2023: £3.9m). Expenditure on Intangible Assets (relating to research and development activities) was £nil (2023: £nil). A review of this expenditure is included within the Strategic Report on pages 5-30.

Strategic Report

The information required by schedule 7 of the Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 has been included in the separate Strategic Report in accordance with section 414C (11) of the Companies Act 2006 (Strategic Report and Directors' Reports) Regulations 2013. It has done so in respect of likely future developments, activities related to research and development and the business's relationship with suppliers, customers and other stakeholders.

Financial risk management

The Company's use of financial instruments and its approach to managing financial risk is covered in note 20 to the financial statements.

Provision of information to auditors

The Directors who were members of the Board at the time of approving the Directors' Report are listed on pages 33-34. Having made enquiries of fellow Directors each of these Directors confirms that:

to the best of each Director's knowledge and belief, there is no relevant audit information (that is, information needed by the Group's auditors in connection with preparing their report) of which the Group's auditors are unaware; and

each Director has taken all the steps that a Director might reasonably be expected to take to be aware of relevant audit information and to establish that the Group's auditors are aware of that information.

Independent auditors

The independent auditors, RSM UK Audit LLP, have indicated their willingness to continue in office and a resolution that they be reappointed will be proposed at the 2024 Annual General Meeting.

Statement of Directors' responsibilities in respect of the financial statements

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulation.

Company law requires the Directors to prepare Group and Company financial statements for each financial year.

The Directors have elected under company law and are required by the AIM Rules of the London Stock Exchange to prepare the Group financial statements in accordance with UK-adopted International Accounting Standards and have elected under company law to prepare the Company financial statements in accordance with UK-adopted International Accounting Standards and applicable law.

The Group and Company financial statements are required by law and UK-adopted International Accounting Standards to present fairly the financial position of the Group and Company and the financial performance of the Group. The Companies Act 2006 provides in relation to such financial statements that references in the relevant part of that Act to financial statements giving a true and fair view are references to their achieving a fair presentation.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and Company and of the profit or loss of the Group and Company for that period. In preparing the Group and Company financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- state whether they have been prepared in accordance with UK-adopted International Accounting Standards;
- make judgements and accounting estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group and Company will continue in business.

The Directors are also responsible for safeguarding the assets of the Group and Company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group and Company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and Company and enable them to ensure that the financial statements comply with the Companies Act 2006.

Directors' statement pursuant to the Disclosure and Transparency Rules

Each of the directors, whose names and functions are listed in Board of Directors section confirm that, to the best of each person's knowledge:

a) the financial statements, prepared in accordance with the applicable set of accounting standards, give a true and fair view of the assets, liabilities, financial position and loss of the company and the undertakings included in the consolidation taken as a whole; and

b) the Strategic Report contained in the Annual Report includes a fair review of the development and performance of the business and the position of the company and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the genedrive plc website.

Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

By order of the Board,

Russ Shaw
Company Secretary
28 November 2024

Independent Auditor's Report to the members of genedrive plc

Report on the audit of the financial statements

Opinion

We have audited the financial statements of Genedrive plc (the 'parent company') and its subsidiaries (the 'group') for the year ended 30 June 2024 which comprise the consolidated statement of comprehensive income, consolidated and company balance sheets, consolidated and company statements of changes in equity, consolidated and company cashflow statements, and notes to the financial statements, including significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and UK-adopted International Accounting Standards and, as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 30 June 2024 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with UK-adopted International Accounting Standards;
- the parent company financial statements have been properly prepared in accordance with UK-adopted International Accounting Standards and as applied in accordance with the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the group and parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Summary of our audit approach

Key audit matters	• Going Concern
Materiality	• Overall materiality: £264,000 (2023: £265,000) • Performance materiality: £198,000 (2023: £198,000)
Scope	Our audit procedures covered 100% of revenue and costs, 100% of total assets and 100% of loss before tax.

Key audit matters

Except for the matter described in the Material uncertainty related to going concern section we have determined that there are no other key audit matters to communicate in our report.

Our application of materiality

When establishing our overall audit strategy, we set certain thresholds which help us to determine the nature, timing and extent of our audit procedures. When evaluating whether the effects of misstatements, both individually and on the financial statements as a whole, could reasonably influence the economic decisions of the users we take into account the qualitative nature and the size of the misstatements. Based on our professional judgement, we determined materiality as follows:

	Group	Parent company
Overall materiality	£264,000 (2023: £265,000)	£132,000 (2023: £75,900)
Basis for determining overall materiality	3.4% of loss before tax	2.6% of total assets
Rationale for benchmark applied	We believe that loss before tax is an important measure of performance and is consistent with the expectations of the users of the financial statements of an AIM listed entity.	We believe that total assets is an important measure in assessing the performance of the parent in its primary role as a holding company.
Performance materiality	£198,000 (2023: £198,000)	£99,000 (2023: £56,200)
Basis for determining performance materiality	75% of overall materiality	75% of overall materiality
Reporting of misstatements to the Audit Committee	Misstatements in excess of £13,200 and misstatements below that threshold that, in our view, warranted reporting on qualitative grounds.	Misstatements in excess of £6,600 and misstatements below that threshold that, in our view, warranted reporting on qualitative grounds.

An overview of the scope of our audit

The group consists of 2 components, both of which are based in the UK. The coverage achieved by our full scope audit procedures was 100% of revenue and costs, 100% loss before tax and 100% of net assets. No work was undertaken by component auditors.

Material uncertainty relating to going concern

We draw attention to note 1 on going concern in the financial statements concerning the group and parent company's ability to continue as a going concern. Having prepared financial forecasts to 30 June 26, the directors have concluded that they have a reasonable expectation of having sufficient cash to meet their liabilities as they fall due throughout that period, however, in reaching that conclusion, the directors recognise that it is reliant on inherent uncertainties relating to the group's ability to generate revenue and raise additional funding from shareholders or debt providers. As stated in note 1 on going concern, these events or conditions indicate that a material uncertainty exists which may cast significant doubt on the group and parent company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the group and company's ability to continue to adopt the going concern basis of accounting included:

- Testing the mathematical accuracy of the cash flow and profit forecasts prepared by the directors, including sensitivity of those forecasts to changes in assumptions relating to revenues, costs and plans regarding any additional sources of funding;
- Assessing whether the forecasts and sensitivity analysis have been prepared on a reasonable and appropriate basis and performing our own stress testing of the forecasts;
- Reviewing and challenging available evidence drawing upon knowledge obtained during the course of our audit to corroborate or contradict the assumptions that underpin the forecasts;
- Evaluating whether the mitigating actions identified by management in the event that forecast revenues are not achieved are feasible operationally, are within the control of management and can be actioned within the assumed timeframe;
- Comparing the budgeted results for the year ended 30 June 2024 to the actual outturn to inform our assessment regarding the accuracy of forecasts and management's ability to control costs; and
- Reviewing performance since the year end date and how this compares to the forecasts.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report

Other information

The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the course of the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Strategic Report and the Directors' Report have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

In the light of the knowledge and understanding of the group and the parent company and their environment obtained in the course of the audit, we have not identified material misstatements in the Strategic Report or the Directors' Report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Responsibilities of directors

As explained more fully in the directors' responsibilities statement set out on page 48 the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

The extent to which the audit was considered capable of detecting irregularities, including fraud

Irregularities are instances of non-compliance with laws and regulations. The objectives of our audit are to obtain sufficient appropriate audit evidence regarding compliance with laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements, to perform audit procedures to help identify instances of non-compliance with other laws and regulations that may have a material effect on the financial statements, and to respond appropriately to identified or suspected non-compliance with laws and regulations identified during the audit.

In relation to fraud, the objectives of our audit are to identify and assess the risk of material misstatement of the financial statements due to fraud, to obtain sufficient appropriate audit evidence regarding the assessed risks of material misstatement due to fraud through designing and implementing appropriate responses and to respond appropriately to fraud or suspected fraud identified during the audit.

However, it is the primary responsibility of management, with the oversight of those charged with governance, to ensure that the entity's operations are conducted in accordance with the provisions of laws and regulations and for the prevention and detection of fraud.

In identifying and assessing risks of material misstatement in respect of irregularities, including fraud, the group audit engagement team:

- obtained an understanding of the nature of the industry and sector, including the legal and regulatory framework that the group and parent company operate in and how the group and parent company are complying with the legal and regulatory framework;
- inquired of management, and those charged with governance, about their own identification and assessment of the risks of irregularities, including any known actual, suspected or alleged instances of fraud;
- discussed matters about non-compliance with laws and regulations and how fraud might occur including assessment of how and where the financial statements may be susceptible to fraud

The most significant laws and regulations were determined as follows:

Legislation / Regulation	**Additional audit procedures performed by the audit engagement team included:**
IFRS/UK-adopted IAS, Companies Act 2006 and AIM Rule 19 relating to the preparation of annual accounts	Review of the financial statement disclosures and testing to supporting documentation. Completion of disclosure checklists to identify areas of non-compliance with the financial reporting framework.
Tax compliance regulations relating to R&D tax credits	Inspection of advice received from external tax advisors. Inspection of correspondence with local tax authorities in respect of the R&D tax credits claim for the previous year.

The areas that we identified as being susceptible to material misstatement due to fraud were:

Risk	**Audit procedures performed by the audit engagement team:**
Revenue recognition	Substantively tested the balance by agreeing to contract, invoice and, where applicable, cash. Testing sample of invoices either side of the year end, and agreeing to invoice and dispatch or delivery note.
Management override of controls	Testing the appropriateness of journal entries and other adjustments; Assessing whether the judgements made in making accounting estimates are indicative of a potential bias; and Evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: http://www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Use of our report

This report is made solely to the company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

Charlotte Massey

Charlotte Massey (Senior Statutory Auditor)
For and on behalf of RSM UK Audit LLP, Statutory Auditor
Chartered Accountants
Landmark
St Peter's Square
1 Oxford Street
Manchester
M1 4PB

28 November 2024

Consolidated Statement of Comprehensive Income

for the year ended 30 June 2024

	Note	**Year ended 30 June 2024 £'000**	Year ended 30 June 2023 £'000
Continuing operations			
Revenue and other income	3	**501**	55
Research and development costs	4	**(4,175)**	(3,924)
Administrative costs	4	**(1,638)**	(1,355)
Operating loss	4	**(5,312)**	(5,224)
Finance costs	7	**(2,468)**	(787)
Finance income	7	**30**	30
Loss on ordinary activities before taxation		**(7,750)**	(5,981)
Taxation	8	**675**	831
Loss for the financial year		**(7,075)**	(5,150)
Loss/total comprehensive expense for the financial year		**(7,075)**	(5,150)
Loss per share (pence)			
– Basic	10	**(4.7p)**	(5.5p)
– Diluted	10	**(4.7p)**	(5.5p)

Consolidated Balance Sheet

as at 30 June 2024

	Note	30 June 2024 £'000	30 June 2023 £'000
Assets			
Non-current assets			
Property, plant and equipment	11	**174**	392
		174	392
Current assets			
Inventories	13	**381**	525
Trade and other receivables	14	**382**	158
Current tax asset		**675**	831
Cash and cash equivalents	15	**5,188**	2,601
		6,626	4,115
Total assets		**6,800**	4,507
Liabilities			
Current liabilities			
Trade and other payables	16	**(1,422)**	(935)
Lease liabilities	17	**(19)**	(222)
Derivative financial instruments	18	**-**	(1,290)
		(1,441)	(2,447)
Non-current liabilities			
Lease liabilities	17	**-**	(19)
Total liabilities		**(1,441)**	(2,466)
Net assets		**5,359**	2,041
Equity			
Called-up equity share capital	22	**8,147**	1,485
Other reserves	23	**54,656**	52,777
Accumulated losses		**(57,444)**	(52,221)
Total equity		**5,359**	2,041

The financial statements were approved by the Board of Directors and authorised for issue on 28 November 2024.
They were signed on its behalf by:

Gino Miele
Chief Executive Officer

Russ Shaw
Chief Financial Officer

Company number: 06108621

Consolidated Statement of Changes in Equity

for the year ended 30 June 2024

	Share capital £'000	Other reserves (note 23) £'000	Accumulated losses £'000	Total equity £'000
Balance at 30 June 2022	**1,388**	**51,294**	**(47,071)**	**5,611**
Transactions with owners in their capacity as owners:				
Share issue	-	2	-	2
Investment funding arrangement, net of transaction costs (note 18)	97	1,385	-	1,482
Equity-settled share-based payments	-	96	-	96
Transactions settled directly in equity	**97**	**1,483**	**-**	**1,580**
Total comprehensive loss for the year	-	-	(5,150)	(5,150)
Balance at 30 June 2023	**1,485**	**52,777**	**(52,221)**	**2,041**
Transactions with owners in their capacity as owners:				
Share issue: January 2024	4	13	-	17
Share issue: June 2024	6,000	-	-	6,000
Investment funding arrangement, net of transaction costs (note 18)	658	1,824	-	2,482
Equity-settled share-based payments	-	42	-	42
Transactions settled directly in equity	**6,662**	**1,879**	**-**	**8,541**
Total comprehensive loss for the year	-	-	(7,075)	(7,075)
Settlement of Financial Derivative Liability	-	-	1,852	1,852
Balance at 30 June 2024	**8,147**	**54,656**	**(57,444)**	**5,359**

Consolidated Cash Flow Statement

for the year ended 30 June 2024

	Note	**Year ended 30 June 2024 £'000**	Year ended 30 June 2023 £'000
Cash flows from operating activities			
Operating loss for the year		**(5,312)**	(5,224)
Depreciation, amortisation and impairment		**54**	61
Depreciation, right-of-use assets		**193**	193
Share-based payment		**59**	96
Operating loss before changes in working capital		**(5,006)**	(4,874)
Decrease in inventories		**144**	223
Increase in trade and other receivables		**(224)**	(51)
Increase / (decrease) in trade and other payables		**487**	(59)
Net cash outflow from operating activities before taxation		**(4,599)**	(4,761)
Tax received		**831**	956
Net cash outflow from operating activities		**(3,768)**	(3,805)
Cash flows from investing activities			
Finance income		**30**	29
Acquisition of plant and equipment		**(29)**	(52)
Proceeds from disposal of discontinued operations	12	**-**	15
Net cash inflow / (outflow) from investing activities		**1**	(8)
Cash flows from financing activities			
Proceeds from the investment placing agreement	18	**1,200**	2,300
Transaction costs relating to investment placing agreement		**(48)**	(283)
Proceeds from share issue		**6,000**	-
Transaction costs relating to share issue		**(566)**	-
Repayment of lease liabilities	17	**(222)**	(193)
Net inflow from financing activities		**6,364**	1,824
Net increase / (decrease) in cash equivalents		**2,597**	(1,989)
Effects of exchange rate changes on cash and cash equivalent		**(10)**	1
Cash and cash equivalents at beginning of year		**2,601**	4,589
Cash and cash equivalents at end of year		**5,188**	2,601
Analysis of net funds			
Cash at bank and in hand	15	**5,188**	2,601
Net cash		**5,188**	2,601

Notes to the Consolidated Financial Statements

for the year ended 30 June 2024

General information

genedrive plc ('the Company') is a company incorporated and domiciled in the UK. The registered head office is The CTF Building, Grafton Street, Manchester M13 9XX, United Kingdom.

genedrive plc and its subsidiaries (together, 'the Group') 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.

genedrive plc is a public limited company, whose shares are listed on the London Stock Exchange Alternative Investment Market.

1. Significant accounting policies

This note provides a list of the principal accounting policies adopted in the preparation of these consolidated financial statements to the extent that they have not already been disclosed in the other notes below. The accounting policies set out below have, unless otherwise stated, been applied consistently to all periods represented in these consolidated financial statements.

Basis of accounting

The consolidated financial statements have been prepared in accordance with UK-adopted International Accounting Standards.

The financial statements have been prepared on a historical cost basis as modified by the revaluation of financial assets and financial liabilities (including derivative instruments) at fair value through profit or loss.

The consolidated 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 (£k) except where otherwise indicated.

The Group funds its day-to-day working capital requirements through its bank resources and draw downs from the investor placing agreement (note 18).

Going concern

The Group's business activities and market conditions are described on pages 5-13. The principal risks and uncertainties are shown on page 30 while the Group's financial position is described on pages 27 and 28. The Group funds its day-to-day cash requirements from existing cash reserves, revenue generation and other income. These matters have been considered by the Directors in forming their assessment of 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 will see over £0.5m of revenue commencing in November 2024.

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 first sale 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 if required 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.

Basis of consolidation

Subsidiaries are entities controlled by the Group. Control exists when the Group has the power, directly or indirectly, to govern the financial and operating policies of an entity so as to obtain benefits from its activities. In assessing control, potential voting rights that are currently exercisable or convertible are taken into account. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Inter-company transactions, balances and unrealised gains on transaction between Group companies are eliminated. Unrealised losses are also eliminated. Where necessary, amounts reported by subsidiaries have been adjusted to conform with the Group's accounting policies.

Revenue

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

Revenue recognition

a. Product sales

Sales of goods are recognised when all the performance obligations and transfer of goods 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.

Segment reporting

A segment is a group of assets, liabilities and operations engaged in providing products or services that are subject to risks and returns that are different from those of other parts of the business. Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Board of Directors.

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.

Plant and equipment

Plant and equipment are stated at cost less accumulated depreciation and any accumulated impairment losses. Depreciation is calculated so as to write off the cost of an asset, less its estimated residual value, over the useful economic life of that asset as follows:

- Lab equipment – 25% reducing balance basis
- Fixtures and fittings – straight-line over 48 months
- Other equipment – straight-line over 48 months

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. A lease is 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.

Lease liabilities

A lease liability is recognised at the commencement date of a lease. The lease liability is initially recognised at the present value of the lease payments to be made over the term of the lease, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the consolidated entity's incremental borrowing rate. Lease payments comprise of fixed payments less any lease incentives receivable, variable lease payments that depend on an index or a rate, amounts expected to be paid under residual value guarantees, exercise price of a purchase option when the exercise of the option is reasonably certain to occur, and any anticipated termination penalties. The variable lease payments that do not depend on an index or a rate are expensed in the period in which they are incurred.

Lease liabilities are measured at amortised cost using the effective interest method. The carrying amounts are remeasured if there is a change in the following: future lease payments arising from a change in an index or a rate used; residual guarantee; lease term; certainty of a purchase option; and termination penalties. When a lease liability is remeasured, an adjustment is made to the corresponding right-of use asset, or to profit or loss if the carrying amount of the right-of-use asset is fully written down.

Operating lease agreements

The Group has elected not to recognise right-of-use assets and lease liabilities for short-term leases that have a lease term of 12 months or less and leases of low-value assets, including IT equipment. The Group recognises the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

Impairment of non-financial assets

Assets that are subject to depreciation and amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows (cash-generating units). Prior impairments of non-financial assets are reviewed for possible reversal at each reporting date.

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. The foreign currency risks relating to assets and liabilities are detailed in note 20.

Share-based payments (Group and Parent Company)

The Group issues equity-settled share-based payments to certain employees (including Directors). The fair value of the employee services received in exchange for the grant of the options is calculated using appropriate valuation models and is recognised as an expense over the vesting period.

The total amount to be expensed over the vesting period is determined by reference to the fair value of the options granted. Fair value is measured using the Black-Scholes pricing model. The expected life used in the model has been adjusted, based on management's best estimate, experience and behavioural considerations.

At each balance sheet date, the entity revises its estimates of the number of options that are expected to become exercisable.

It recognises the impact of the revision of original estimates, if any, in the income statement, and a corresponding adjustment to equity, over the remaining vesting period.

The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised.

Share Incentive Plan ('SIP')

The Company operates a SIP scheme and both issues new shares to settle the liability and offers the cash equivalent to employees. The liability to settle the shares accrued under the SIP scheme is thus treated as a cash-settled liability on the balance sheet with the cost of the liability being expensed to the income statement. The balance sheet liability is adjusted periodically to reflect the change in the share price over the life of the scheme with the movement taken to the income statement. Any shares bought in anticipation of settling the SIP scheme are held as a debit in reserves. Where a leaver requests to take shares instead of cash, as permitted under the SIP scheme, the historic cost of shares acquired is moved from reserves to the balance sheet liability.

Pension contributions

Contributions to personal pension plans of employees on a defined contributions basis are charged to the income statement in the period in which they are payable.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is calculated on a first-in and first-out basis and includes bought-in cost and, where appropriate, other direct costs. Net realisable value represents the estimated selling price less applicable selling costs. Where applicable, provision is made for slow-moving and obsolete inventory.

Trade and other receivables

Trade and other debtors are recognised and carried forward at invoiced amounts less provisions for any expected credit losses. Expected credit losses are estimated using reasonable and supportable historic and forward-looking information that is available at the reporting date and the provisions are reviewed until debts are collected.

Cash and cash equivalents (Group and Parent Company)

Cash and cash equivalents are included in the balance sheet at cost. Cash and cash equivalents comprise cash at bank and in hand and short-term deposits with an original maturity of four months or less.

Interest-bearing loans and borrowings (Group and Parent Company)

All loans and borrowings are recognised initially at cost, which is the fair value of the consideration received, net of issue costs associated with the borrowing. After initial recognition, interest-bearing loans and borrowings are measured at amortised cost using the effective interest method. Gains or losses are recognised in the Consolidated Income Statement when liabilities are derecognised or impaired, as well as through the amortisation process.

Taxation

Current tax is provided at amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted, or substantively enacted, by the balance sheet date.

Taxation credits which fall under the category of Above The Line Research & Development credits ("ATL Research credits") as detailed in the Finance Act 2013 are offset against the expenditure to which they relate and, in the statement of profit and loss, are disclosed within administrative and development costs, as appropriate.

Deferred tax is recognised in respect of all temporary differences identified at the balance sheet date, except to the extent that the deferred tax arises from the initial recognition of goodwill (if amortisation of goodwill is not deductible for tax purposes) or the initial recognition of an asset or liability in a transaction which is not a business combination and at the time of the transaction affects neither accounting profit nor taxable profit and loss. Temporary differences are differences between the carrying amount of the Group's assets and liabilities and their tax base.

Deferred tax liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority. Current tax assets and liabilities are offset where an entity has a legally enforceable right to offset and either intends to settle on a net basis, or to realise the asset and settle the liability simultaneously.

Deferred tax is provided on temporary differences arising in subsidiaries, jointly controlled entities and associates, except where the timing of reversal of the temporary difference will not reverse in the foreseeable future. Deferred tax is measured at the average tax rates that are expected to apply in the periods in which the asset is realised or liability settled, based on tax rates and laws that have been enacted or substantially enacted by the balance sheet date. Measurement of deferred tax liabilities and assets reflects the tax consequence expected to fall from the manner in which the asset or liability is recovered or settled.

Financial instruments - including Investor Placing Agreement (Group and Parent Company)

Financial instruments are classified and accounted for, according to the substance of the contractual arrangement, as either financial assets, financial liabilities or equity instruments. An equity instrument is any contract that evidences a residual interest in the assets of the Company after deducting all of its liabilities.

As disclosed in note 18, during the prior year the Company entered into an Investor Placing Agreement, which resulted in the issuances of ordinary shares, share warrants and the recognition of a derivative financial liability.

The ordinary shares meet the definition of an equity instrument, as defined by IAS 32 and the warrants are for a fixed amount of cash for a fixed number of shares are therefore classified as equity, with the initial recognition being recorded at fair value net of issue costs

The liability arising from the outstanding amounts drawn down from the facility met the definition of a derivative financial instrument under IFRS 9 and is initially recognised at fair value with changes in fair value recognised in profit and loss. At each reporting date, the fair value of the derivative financial liability is reassessed by management. Where there is no market for such derivatives, the Company uses option pricing models to measure the fair value.

The fair value movement in the derivative financial liability is disclosed with finance costs detailed in note 7.

Fair value measurement (Group and Parent Company)

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

Fair value is measured using the assumptions that market participants would use when pricing the asset or liability, assuming they act in their economic best interests. For non-financial assets, the fair value measurement is based on its highest and best use. Valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, are used, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

Assets and liabilities measured at fair value are classified into three levels, using a fair value hierarchy that reflects the significance of the inputs used in making the measurements. Classifications are reviewed at each reporting date and transfers between levels are determined based on a reassessment of the lowest level of input that is significant to the fair value measurement.

For recurring and non-recurring fair value measurements, external valuers may be used when internal expertise is either not available or when the valuation is deemed to be significant. External valuers are selected based on market knowledge and reputation. Where there is a significant change in fair value of an asset or liability from one period to another, an analysis is undertaken, which includes a verification of the major inputs applied in the latest valuation and a comparison, where applicable, with external sources of data.

Parent Company assets

The assets of the Parent Company which consist primarily of amounts due from other group undertakings are subject to impairment review in each financial period.

Adoption of new standards and revised standards

The Group has not early adopted any standards in the current or prior year.

New and amended IFRSs that are effective for the future

At the date of these financial statements, there are two new standards and amendments to IFRSs in issue but not yet effective and have therefore not been applied as set out below:

New and amended IFRSs	Effective date
Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current and Non-current and Classification of Liabilities as Current or Non-current	1 January 2024
IFRS 18 Presentation and Disclosure in Financial Statements	1 January 2027

The full impact of IFRS 18 on the financial statements is in the process of being reviewed, however the directors adoption of the statements will not have a material impact on the financial statements of the Group in future periods.

Critical accounting estimates

The preparation of financial statements in conformity with International Accounting Standards requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed below:

- The inventory valuation is stated net of a stock provision of £884k (2023: £801k). The inventory provision is put in place for slow-moving and potentially obsolete inventory as well as damaged and/or out-of-specification product where cost is considered to be higher than the net realisable value. The level of provisioning is an estimate, with judgement required on ageing, customer order profiles, alternative routes to market and the option to reprocess. The estimation of the range of possible outcomes, by flexing key assumptions, is an increase in the value of inventory of £0.3m to an additional decrease of £0.3m, which would be recognised through the income statement.
- R&D tax credit of £0.7m (2023: £0.8m). Determining which components of expenditure fit the definitions of the R&D tax credit regime requires an estimation and interpretation of tax rules on research and development costs. There have been no changes to historic assumptions in the year and there is no expectation of a change in the level of uncertainty within the next financial year. There have been changes made to the way the R&D tax claim is capped, but these changes are unlikely to impact the Group. If the qualifying costs used to calculate the R&D tax credits are 10% higher/lower than estimated then the value of the tax debtors in the balance sheet would increase/(decrease) by £0.07m.

Critical judgements

- Judgement was required in assessing whether warrants issued under the Investor Placing Agreement should be treated as debt or equity. As a financial instrument under IAS 32, warrants are derivative financial instruments as their value changes in response to the Company's share price, however, as the exercise of these warrants results in exchange of fixed amount of cash for fixed number of shares, management concluded that these instruments were equity instruments.
- The Company used judgement in selecting appropriate techniques with which to measure the fair value of the derivative financial liability at the dates of draw down and at the reporting date. The measurement of fair value required use of assumptions regarding the share price volatility and assumes that the investor will seek to achieve the optimal value to settle the outstanding amount. Further detail is provided in note 18.

Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised and in any future periods affected.

The separate financial statements of genedrive plc are presented on pages 83-88.

2. Operating segments

For internal reporting and decision-making, the Group is organised into one segment, Diagnostics. Diagnostics is commercialising the Genedrive® point-of need molecular testing platform. In future periods, and as revenue grows, the Group may review management account information by type of assay and thus split out Diagnostics into segments – however, for now, the single segment is appropriate.

The chief operating decision-maker primarily relies on turnover and operating loss to assess the performance of the Group and make decisions about resources to be allocated to each segment. Geographical factors are reviewed by the chief operating decision-maker, but as substantially all operating activities are undertaken in the UK, geography is not a significant factor for the Group. Accordingly, only sales have been analysed into geographical statements.

The results of the operating division of the Group are detailed below.

Business segments	Diagnostics segment £'000	Corporate costs £'000	Total £'000
Year ended 30 June 2024			
Revenue and other income	501	–	501
Trading loss	**(3,674)**	**(1,638)**	**(5,312)**
Net finance costs			(2,438)
Loss on ordinary activities before taxation			**(7,750)**
Taxation			675
Loss for the financial year			(7,075)
Total comprehensive expense for the year			**(7,075)**

Business segments	Diagnostics segment £'000	Corporate costs £'000	Total £'000
Year ended 30 June 2023			
Revenue	55	–	55
Trading loss	**(3,869)**	**(1,355)**	**(5,224)**
Net finance costs			(757)
Loss on ordinary activities before taxation			**(5,981)**
Taxation			831
Loss for the financial year			(5,150)
Total comprehensive expense for the year			**(5,150)**

	Diagnostics segment £'000	Corporate costs £'000	Total £'000
Year ended 30 June 2024			
Segment assets	**821**	**5,979**	**6,800**
Segment liabilities	**(886)**	**(555)**	**(1,441)**
Year ended 30 June 2023			
Segment assets	960	3,547	4,507
Segment liabilities	(877)	(1,589)	(2,466)

Additions to non-current assets: Diagnostics segment £23k (2023: £353k) and Corporate costs £6k (2023: £88k).

Geographical segments

The Group's operations are located in the United Kingdom. The following table provides an analysis of the Group's revenue and other income by customer location:

All on continuing operations	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
United Kingdom	**411**	35
Europe	**74**	16
United States of America	**-**	4
Rest of the world	**16**	-
	501	55

Revenues from three customers accounted for more than 10% of total revenue in the current year (2023: three).

3. Revenue and other income

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Revenue from customer contracts	**332**	55
Grant and other income	**169**	-
	501	55

There were no sales with extended payment terms. For both financial years revenue from customers was all related to product sales and recognised at a point in time.

4. Operating loss

The Group operating loss is stated after charging/(crediting):

	Note	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Research and development expenditure (including staff costs)		**4,175**	3,924
Depreciation of owned tangible fixed assets	11	**54**	61
Depreciation of right-of-use assets	11	**193**	193
Share-based payments		**59**	96
Auditors' remuneration, fees payable for:			
– the audit of the Parent Company and consolidated accounts		**82**	59
– the audit of subsidiary accounts		**8**	7

5. Particulars of employees

The average number of staff employed by the Group during the financial year was:

	Year ended 30 June 2024 Number	Year ended 30 June 2023 Number
Research and development	**31**	31
Administration	**12**	12
	43	43

The aggregate employee costs (including Directors) were:

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Wages, salaries and other benefits	**2,998**	2,352
Social security costs	**324**	261
Pension cost-defined contribution plans	**102**	55
	3,424	2,668

6. Remuneration of key management, including directors

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Wages, salaries and other benefits	**1,097**	947
Social security costs	**124**	117
Equity-settled share-based payments	**47**	63
Pension cost-defined contribution plans	**69**	25
	1,337	1,152

The key management of the Company is the senior management team of the Company and comprises Executive Board members plus five (2023: five) members of the senior staff.

Disclosure of individual Directors' remuneration, share interests, share options, long-term incentive schemes, pension contributions and pension entitlements required by the Companies Act 2006 are shown in the tables in the Remuneration Committee report on pages 41-47 and form part of these financial statements.

7. Finance income and costs

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Interest income on bank deposits	**30**	30

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Transaction costs relating to share issue	**(566)**	**-**
Transaction costs relating to investment placing agreement (note 18)	**(38)**	(81)
Movement in fair value of derivative financial instrument (note 18)	**(1,852)**	(675)
Finance charge on leased assets	**(12)**	(31)
Finance costs	**(2,468)**	(787)

8. Taxation

(a) Recognised in the income statement

Current tax:	**Year ended 30 June 2024 £'000**	Year ended 30 June 2023 £'000
Research and development tax credits	**(675)**	(831)
Total tax credit for the year	**(675)**	(831)

(b) Reconciliation of the total tax credit

The tax credit assessed on the loss for the year is lower (2023: lower) than the weighted average applicable tax rate for the year ended 30 June 2024 of 25% (2023: 20.5%). The differences are explained below:

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Loss before taxation on continuing operations	**(7,750)**	(5,981)
Tax using UK corporation tax rate of 25% (2023: 20.5%)	**(1,938)**	(1,226)
Adjustment in respect of R&D tax credit claimed	**(61)**	(295)
Items not deductible / (taxable) for tax purposes – permanent	**603**	140
Items not deductible for tax purposes – temporary	**(2)**	(2)
Deferred tax not recognised	**723**	686
Rate differences	**-**	(134)
Total tax credit for the year	**(675)**	(831)

No deferred tax assets are recognised at 30 June 2024 (2023: £nil). Having reviewed future profitability in the context of trading losses carried, it is not probable that there will be sufficient profits available to set against brought forward losses.

The Group had trading losses, as computed for tax purposes, of approximately £23,942k (2023: £21,676k) available to carry forward to future periods; this excludes management expenses.

9. Loss attributable to members of the Parent Company

genedrive plc has not presented its own statement of comprehensive income as permitted by Section 408 of the Companies Act 2006. The loss dealt with in the accounts of genedrive plc was £6,518k (2023: loss £1,152k).

10. Earnings per share

	2024 £'000	**2023 £'000**
Loss for the year after taxation	**(7,075)**	(5,150)

Group	**2024 Number**	**2023 Number**
Weighted average number of ordinary shares in issue	**151,441,746**	94,165,295
Potentially dilutive ordinary shares	**-**	–
Adjusted weighted average number of ordinary shares in issue	**151,441,746**	94,165,295
Loss per share on continuing operations		
– Basic	**(4.7)p**	(5.5)p
– Diluted	**(4.7)p**	(5.5)p

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 year. As the Company is loss-making, no potentially dilutive options have been added into the EPS calculation. Had the Company made a profit in the period, the conversion into shares of options whose exercise price was below the share price at the reporting date would have increased the number of ordinary shares as follows:

Group	**2024 Number**	2023 Number
Potentially dilutive shares from share options and warrants	**8,616,321**	1,163,817
Potentially dilutive shares within the SIP	**551,835**	339,967
Potentially dilutive ordinary shares	**9,168,156**	1,503,784

11. Property, plant and equipment

	Right of use land & buildings £'000	Lab equipment £'000	Fixtures and fittings £'000	Other equipment £'000	Total £'000
Cost					
At 30 June 2022	389	465	114	256	1,224
Additions	-	26	–	28	54
Modifications	387	–	–	–	387
Disposals	(389)	–	–	(2)	(391)
At 30 June 2023	**387**	**491**	**114**	**282**	**1,274**
Additions	–	–	–	29	29
Modifications	–	–	–	–	–
Disposals	–	–	–	–	–
At 30 June 2024	**387**	**491**	**114**	**311**	**1,303**
Accumulated depreciation					
At 1 July 2022	373	305	114	226	1,018
Charge for the year	193	45	–	16	254
Depreciation on disposed assets	(389)	–	–	(1)	(390)
At 30 June 2023	**177**	**350**	**114**	**241**	**882**
Charge for the year	193	35	–	19	247
Depreciation on disposed assets	–	–	–	–	–
At 30 June 2024	**370**	**385**	**114**	**260**	**1,129**
Net book value					
At 30 June 2022	16	160	–	30	206
At 30 June 2023	210	141	–	41	392
At 30 June 2024	**17**	**106**	**–**	**51**	**174**

The Group leases land and buildings for its offices and laboratories with agreements of two years. On renewal, the terms of the leases are renegotiated.

The Group leases office equipment under agreements of less than two years. These leases are either short-term or low-value, so have been expensed as incurred and not capitalised as right-of-use assets.

12. Contingent consideration receivable

	Greater than 12 months £'000	Less than 12 months £'000	Total £'000
Balance at 30 June 2022	-	15	15
Received in the period	-	(15)	(15)
Balance at 30 June 2023 and 30 June 2024	**-**	**-**	**-**

The amount provided on the balance sheet dated 30 June 2022 of £15k represents contingent consideration held under the sale and purchase agreement for the disposal of the Services business. The amount relates to the remaining six months trading under the agreement and was settled in October 2022.

13. Inventories

	2024 £'000	2023 £'000
Raw materials	**156**	373
Finished goods	**225**	152
	381	525

The inventory valuation at 30 June 2024 is stated net of a provision of £884k (2023: £801k) to write down inventories to their net realisable value. The net charge to the income statement in the year in respect of inventory net realisable value was £83k (2023: £106k).

14. Trade and other receivables

	2024 £'000	2023 £'000
Trade receivables	122	38
Other receivables	3	12
Prepayments	257	108
	382	158

Analysis of trade receivables

	2024 £'000	2023 £'000
Neither impaired nor past due	98	28
Past due but not impaired	24	10
Trade receivables	**122**	38

At the year end, net trade receivables were aged as follows:

	2024 £'000	2023 £'000
Not overdue	98	28
Less than 1 month overdue	24	-
Later than 1 month but less than 3 months overdue	-	10
Later than 3 months overdue	-	-
Total	**122**	38

The Group's credit period generally ranges up to 60 days.

15. Cash and cash equivalents

	2024 £'000	2023 £'000
Cash at bank and in hand	**5,188**	2,601

Cash and cash equivalents comprise current accounts held by the Group with immediate access and short-term bank deposits with a maturity of four months or less. Market rates of interest are earned on such deposits. The credit risk on such funds is limited because the counterparties are banks with high credit ratings assigned by international credit rating agencies.

16. Trade and other payables

Group	2024 £'000	2023 £'000
Trade payables	665	432
Accruals	589	382
Other payables	168	121
	1,422	935

17. Lease liabilities

	2024 £'000	2023 £'000
Lease liabilities falling due within one year	**19**	222
Lease liabilities falling due over one year	**-**	19
Lease liabilities	**19**	241

Lease liabilities relate to land and buildings right-of-use assets as detailed in note 11.

	£'000
Balance at 30 June 2023	**241**
Modifications - lease renewals	-
Interest	12
Repayment of lease liabilities	(234)
Balance at 30 June 2024	**19**

There was a £1k cash outflow in the year relating to short-term and low-value lease payments (2023: £1k).

18. Derivative Financial Instruments

On 31 March 2023, the Company entered into an Investor Placing Agreement for up to £5m with RiverFort Global Opportunities PCC Limited ("Noteholders"). The instrument was entered by way of an initial drawdown in the amount of £2m and related issuance of 6,250,000 shares priced at nominal value of 1.5 pence to be used to facilitate the settlement of amounts advanced under the investment agreement Further drawdowns totalling £1.5m were made and the remaining balance as at the balance sheet date of £1.5m under the Facility is available for the Company to drawdown, at its discretion, but subject to there being no trading Material Adverse Change:

(a) the Share Price falling below 16 pence
(b) the 3 day average volumes traded being less than £100,000
(c) the 10 day average trading volumes being less than £100,000 and
(d) the amount outstanding under the Facility being no more than £700,000;

Any outstanding liability after the disposal by the Noteholder of the shares issued in exchange for each drawdown can be settled at the discretion of the Noteholder by further subscription to the Company's shares. The Company can also elect to settle the outstanding liability with a 10% premium on the balance. As the value of the outstanding amount is expected to move with the Company's share price, the instrument met the definition of a derivative and is initially recognised at fair value with changes in fair value recognised in profit and loss.

There was no outstanding liability as at 30 June 2024 (2023: £1.29m).

Pursuant to the facility, the Noteholders were granted warrants exercisable at 1.5p to subscribe for 8,616,321 shares. All warrants remain outstanding at 30 June 2024 and can be exercised at any time from the date of issue for a period of four years.

The warrants are initially valued using a model which utilised observable market factors such as the share price at the date of the grant, the term of the award, the share price volatility and the risk-free interest rate (Level 2 inputs).

The Company made drawdowns of £1.2m during the financial year (2023: £2.3m), which has all been settled by the issue of equity and received a non-cash fair value adjustment, which can be summarised as follows:

	Derivative financial liability £'000	Finance costs £'000	Equity £'000	Warrants £'000	Total £'000
Proceeds	615	–	1,117	568	2,300
Transaction costs	–	(81)	(191)	(91)	(363)
	615	**(81)**	**926**	**477**	**1,937**
Fair value movement	675				
At 30 June 2023	**1,290**				
Proceeds	947	–	–	253	1,200
Transaction costs	–	(38)	–	(10)	(48)
	947	**(38)**	**–**	**243**	**1,152**
Equity Settlement	(4,091)				
Fair value movement	1,854				
At 30 June 2024	**–**				

In the year to June 2023 the transaction costs include fees of £80,000 payable to the Noteholders that were settled by issue of shares and included in share premium (note 23).

The derivative has been marked to market through profit or loss, immediately prior to conversion, such that the time value of money on the option is captured in the income statement.

19. Share-based payments

(a) Share options outstanding at 30 June 2024

Prior to 28 November 2007, the Company operated a number of HMRC approved and unapproved share option schemes for employees (including Directors). The original options were granted by Epistem Ltd but, following its acquisition in 2007 by Epistem Holdings Plc (the former name of genedrive plc), these were released in exchange for equivalent options over the ordinary shares of Epistem Holdings Plc. On 28 November 2007, the Company established the 2007 Epistem Share Option Scheme. The 2007 Epistem Share Option Scheme was replaced by the 2017 Epistem Share Option Scheme that was adopted at the 2017 AGM.

Share options

Award	Number of awards	Exercise price	Period within which options are exercisable	Fair value per option	Fair value £
2007 Epistem Share Option Scheme	1,000	£3.2500	12 Aug 2017 to 11 Aug 2024	£0.60p	£600
2007 Epistem Share Option Scheme	20,000	£3.2500	20 Sep 2017 to 19 Sep 2024	£0.60p	£12,000
2014 Unapproved Share Options	100,000	£2.7500	17 Dec 2017 to 16 Dec 2024	£0.52p	£52,000
2007 Epistem Share Option Scheme	2,500	£1.2000	20 Sep 2018 to 19 Sep 2025	£0.33p	£825
2007 Epistem Share Option Scheme	1,000	£1.2000	20 Sep 2018 to 19 Sep 2025	£0.33p	£330
Epistem Unapproved Share Options	50,000	£2.7800	07 Apr 2019 to 06 Apr 2026	£0.05p	£2,500
2007 Epistem Share Option Scheme	20,000	£0.8200	02 May 2019 to 01 May 2026	£0.27p	£5,400
2007 Epistem Share Option Scheme	32,000	£0.8000	02 Oct 2019 to 01 Oct 2026	£0.11p	£3,520
Epistem Unapproved Share Option	50,000	£0.4300	05 Apr 2020 to 04 Apr 2027	£0.06p	£3,000
2017 Epistem Share Option Scheme	12,500	£0.3600	29 Nov 2020 to 30 Nov 2027	£0.06p	£750
Epistem Unapproved Share Option	43,024	£0.3600	29 Nov 2020 to 30 Nov 2027	£0.06p	£1,721
Epistem Unapproved Share Option	150,000	£0.2350	05 Apr 2022 to 05 Apr 2029	£0.02p	£3,000
2017 Epistem Share Option Scheme	67,500	£0.2350	05 Apr 2022 to 05 Apr 2029	£0.02p	£1,350
2017 Epistem Share Option Scheme	80,000	£0.2150	10 Nov 2022 to 10 Nov 2029	£0.031p	£2,480
Epistem Unapproved Share Option	170,000	£0.0900	06 Apr 2023 to 06 Apr 2030	£0.013p	£2,210
2017 Epistem Share Option Scheme	52,500	£0.4700	14 Dec 2023 to 14 Dec 2030	£0.234p	£12,285
2017 Epistem Share Option Scheme	125,000	£0.3100	02 Dec 2024 to 02 Dec 2031	£0.19p	£4,183
2017 Epistem Share Option Scheme	200,000	£0.3100	03 Dec 2024 to 03 Dec 2031	£0.098p	£39,160
2017 Epistem Share Option Scheme	100,000	£0.3000	04 Apr 2025 to 04 Apr 2032	£0.098p	£9,790
2017 Epistem Share Option Scheme	70,000	£0.1925	05 Jul 2025 to 05 Jul 2032	£0.0156p	£10,901
2017 Epistem Share Option Scheme	3,570	£0.1800	10 Aug 2025 to 10 Aug 2032	£0.0132p	£470
2017 Epistem Share Option Scheme	363,000	£0.1225	21 Oct 2025 to 21 Oct 2032	£0.0968p	£59,073
2017 Epistem Share Option Scheme	10,000	£0.0875	29 Nov 2025 to 29 Nov 2032	£0.0675p	£675
2017 Epistem Share Option Scheme	10,000	£0.0975	15 Dec 2025 to 15 Dec 2032	£0.0759p	£759
2017 Epistem Share Option Scheme	361,000	£0.0600	06 Feb 2027 to 06 Feb 2034	£0.0372p	£15,470
2017 Epistem Share Option Scheme	2,050,000	£0.0600	06 Feb 2027 to 06 Feb 2034	£0.0372p	£76,235
	4,144,594				

Option valuations

The options were valued using the Black-Scholes option-pricing model. The fair value per option granted and the assumptions used in the calculations are in the table below.

Award	Grant date	Expected term (Note a)	Expected dividend yield % (Note b)	Expected volatility % (Note c)	Risk % rate (Note d)
2007 Epistem Share Option Scheme	12 Aug 2014	5 years	0	43	0.50
2007 Epistem Share Option Scheme	20 Sep 2014	5 years	0	43	0.50
2014 Unapproved Share Options	17 Dec 2014	5 years	0	43	0.50
2007 Epistem Share Option Scheme	20 Sep 2018	5 years	0	36	0.50
Epistem Unapproved Share Option Scheme	07 Apr 2016	5 years	0	36	0.50
2007 Epistem Share Option Scheme	02 May 2016	5 years	0	37	0.50
2007 Epistem Share Option Scheme	01 Oct 2016	3 years	0	19	0.25
2007 Epistem Share Option Scheme	04 Apr 2017	3 years	0	20	0.25
2017 Epistem Share Option Scheme	30 Nov 2017	3 years	0	15	0.50
Epistem Unapproved Share Option	30 Nov 2017	3 years	0	15	0.50
Epistem Unapproved Share Option	05 Apr 2019	3 years	0	16	0.75
2017 Epistem Share Option Scheme	05 Apr 2019	3 years	0	16	0.75
2017 Epistem Share Option Scheme	10 Nov 2019	3 years	0	16	0.75
Epistem Unapproved Share Option	06 Apr 2020	3 years	0	18	0.10
2017 Epistem Share Option Scheme	14 Dec 2020	3 years	0	19	0.10
2017 Epistem Share Option Scheme	02 Dec 2021	3 years	0	57	0.10
2017 Epistem Share Option Scheme	03 Dec 2021	3 years	0	93	0.10
2017 Epistem Share Option Scheme	04 Apr 2022	3 years	0	105	0.75
2017 Epistem Share Option Scheme	05 Jul 2022	3 years	0	115	1.25
2017 Epistem Share Option Scheme	10 Aug 2022	3 years	0	121	1.75
2017 Epistem Share Option Scheme	21 Oct 2022	3 years	0	126	2.25
2017 Epistem Share Option Scheme	29 Nov 2022	3 years	0	130	3.00
2017 Epistem Share Option Scheme	15 Dec 2022	3 years	0	132	3.50
2017 Epistem Share Option Scheme	06 Feb 2024	3 years	0	94	5.25

(a) The expected term used in the model is three to five years and is based upon the Directors' best estimates for the effects of exercise restrictions and behavioural considerations.
(b) The dividend yield of 0% reflects the absence of a history of paying dividends and a clear dividend policy at the relevant grant dates.
(c) The risk-free rate used is based upon the prevailing UK bank base rate at the date of the grant.
(d) These options may be exercised following the third anniversary of grant and are subject to performance criteria which are appropriate to the option holders' role within the Company and which are assessed by the Remuneration Committee.

The number of options and their weighted average exercise prices are as follows:

	Number		Weighted average exercise price		Weighted average remaining contracted life – Years	
	2024	**2023**	**2024**	**2023**	**2024**	**2023**
Outstanding as at 1 July	5,606,746	5,410,417				
Granted during the year	2,411,000	704,070	6p	13p		
Exercised during the year	-	(7,500)	–	22p		
Forfeited during the year	-	-	–	–		
Lapsed during the year	(3,873,152)	(500,241)	24p	35p		
Outstanding as at 30 June	4,144,594	5,606,746	24p	33p	8.1	7.4
Options exercisable at 30 June	852,024	4,228,926	16p	27p	4.2	6.6

No options over shares were exercised in the year ended 30 June 2024 (2023: 7,500). The weighted average market price at exercise was £0.35 in 2023. No Director exercised any options and no options expired during the year.

(b) Share Investment Plan

The Company operates a share investment plan ('SIP'), the Epistem Share Investment Plan, which is open to Directors and employees in accordance with HMRC approved rules. Under the terms of the SIP, Directors and employees may invest up to £150 per month to be invested in ordinary shares ('Partnership Shares') in the Company at the prevailing market price. Participants may withdraw their Matching Shares once their associated Partnership Shares have been held for three years. At the same time as each monthly subscription, a maximum of two Matching Shares for each Partnership Share is accrued by the Company on behalf of the SIP's participants. The Matching Shares vest after three years; if an employee leaves the Company, unvested shares lapse. The monthly cost of the Matching Shares is expensed to the income statement.

At 30 June 2024 the number of Partnership Shares earnt by employees was 166,899 (2023: 96,280). The total number of potential Matching Shares provided for employees at 30 June should all the employees meet the three-year vesting rule was 333,798 (2023: 192,575. Of the 333,798 shares, 105,864 (2023: 98,152) have vested under the three-year service rule. The Company accrues for the value of shares that it expects to be purchased to satisfy the number of shares earnt – this accrual at 30 June 2024, included within trade and other payables, was £8k (2023: £51k).

In order to satisfy the shares accumulated as both Partnership and Matching Shares, Epistem SIP Trustee Ltd, a wholly owned subsidiary of the Company, periodically purchases shares on behalf of the scheme's participants. At the balance sheet date, Epistem SIP Trustee Ltd owned no shares (2023: nil) in the Company. The historic cost of the purchased shares is recorded as a debit in reserves and the movement over the year period is recorded below.

	2024 £'000	2023 £'000
Outstanding at 30 June	**196**	196

(c) Warrants in the period or outstanding

As part of the Investor Placing Agreement entered into with RiverFort Global Opportunities on 31 March 2023, the Company issued 724,998 warrants in July 2023, 1,614,670 warrants in November 2023 and a further 3,093,923 warrants were issued in December 2023 (note 18). The fair value of the warrants issued in the year was £0.2m (2023: £0.48m).

As at 30 June 2024 the Company had 8,616,321 warrants outstanding (2023: 3,182,731).

Each warrant gives the holder the right to subscribe for one new Ordinary Share at a price of 1.5 pence per share at any time for a period of four years.

20. Financial risk management objectives and policies

	Classification	2024 £'000	2023 £'000
Financial assets			
Cash and cash equivalents	Amortised cost	**5,188**	2,601
Trade and other receivables	Amortised cost	**125**	50
Financial liabilities			
Trade and other payables	Amortised cost	**1,489**	938
Lease liabilities	Amortised cost	**19**	241
Derivative financial liability	Fair value	**-**	1,290

The Group holds or issues financial instruments to achieve two main objectives, being:
(a) to finance its operations; and
(b) to manage its exposure to interest and currency risks arising from its operations and from its sources of finance.

In addition, various financial instruments (e.g. trade receivables, trade payables and accruals) arise directly from the Group's and the Company's operations.

Transactions in financial instruments result in the Group assuming or transferring to another party one or more of the financial risks described below.

Interest rate risk

The Group currently finances its operations through reserves of cash and liquid resources. Surplus cash at bank is placed on deposits at variable rates. The Board monitors the financial markets and the Group's own requirements to ensure that the policies are exercised in the Group's best interests.

The following table demonstrates the sensitivity to a possible change in interest rates on the Group's profit before tax through the impact of floating rate cash balances.

	Increase in the basis points	Before tax and equity £'000
2024		
Cash and cash equivalents	**25**	**6**
2023		
Cash and cash equivalents	25	3

A decrease in 25 basis points would have a similar opposite effect.

Capital management

Capital is regarded as total equity, as recognised in the balance sheet, plus net debt. Net debt is calculated as total borrowings less cash and cash equivalents.

The Group's objective in managing its capital is to ensure that the Group has adequate capital to fund its trading operations and ensure the Group's ability to continue as a going concern. In achieving this objective, the Group seeks to maintain an optimal capital structure to reduce its cost of capital and provide returns for shareholders.

In managing its capital, the Group may from time to time issue new shares, sell assets or issue other capital instruments to optimise its capital structure. During the year to 30 June 2024 the Company issued 444,091,535 (2023: 6,500,000) new shares as described in note 22.

Credit risk

The Group monitors credit risk closely and considers that its current policies of credit checks meet its objectives of managing exposure to credit risk.

Liquidity risk

The Board's policy aims to ensure that sufficient funds are held on a short-term basis in order to meet operational needs. The age profile of the Group's gross undiscounted obligations at the balance sheet date is detailed below:

	2024 £'000	**2023 £'000**
Payable within 1 year	**1,508**	1,157
	1,508	1,157

Currency risk

The Group's functional currency is sterling. The exposure to currency risk relates to licence income, those short-term trade receivables which are not invoiced in sterling and foreign denominated cash held in UK banks. There are no significant costs incurred that involve payments in foreign currency. The Group has no forward contracts at the year end (2023: £nil) to manage foreign currency risk.

Balances which are denominated in US dollars are detailed below:

	2024 £'000	2023 £'000
Trade and other receivables	**-**	-
Cash and cash equivalents	7	9
	7	9

The following table demonstrates the sensitivity to a possible change in currency rates on the Group's loss before tax through the impact of sterling weakening against the US dollar.

	Decrease in the currency rate	Effect on equity £'000
2024		
Trade and other receivables	**5%**	**-**
Cash and cash equivalents	**5%**	**-**
2023		
Trade and other receivables	5%	-
Cash and cash equivalents	5%	-

An increase in currency rate of 5% would have a similar opposite effect.

Fair values of financial assets and liabilities

Recognised fair value measurements

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

- Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and trading securities) is based on quoted market prices at the end of the reporting period.
- Level 2: The fair value of financial instruments that are not traded in an active market (for example, over-the-counter derivatives) is determined using valuation techniques that maximise the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value instrument are observable, the instrument is included in Level 2.
- Level 3: If one or more of the significant inputs is not based on observable market data the instrument is included in Level 3.

The derivative financial liabilities are categorised as Level 2 within the fair value hierarchy under IFRS 13. Further information is contained in note 18.

There is no material difference between the book value and the fair value of the Group's other financial assets or liabilities (Level 3), due to the short maturity of the cash, debtors and creditors.

Market risk: The fair value of the derivative financial liability is impacted by changes in the Company's share price although an increase in the share price of 100% would not have a material impact on the fair value at the reporting date.

Changes in liabilities resulting from financing activities

	Derivative financial liability £'000	Lease liability £'000	Total £'000
Balance at 30 June 2022	-	16	**16**
Net cash from / (used) in financing activities			
Proceeds from Investor Placing Agreement	2,300	-	2,300
Transaction costs	(283)	-	(283)
Lease repayments	-	(193)	(193)
	2,017	**(193)**	**1,824**
Other movements			
Lease modifications	-	387	**387**
Equity and warrant components of the Investor Placing Agreement (note 18)	(1,403)	-	**(1,403)**
Transaction costs settled by issue of shares	(80)	-	**(80)**
Finance costs	81	31	**112**
Fair value movement	675	-	**675**
Balance at 30 June 2023	**1,290**	**241**	**1,531**
Net cash from / (used) in financing activities			
Proceeds from Investor Placing Agreement	1,200	-	1,200
Transaction costs	(48)	-	(48)
Lease repayments	-	(234)	(234)
	1,152	**(234)**	**918**
Other movements			
Equity and warrant components of the Investor Placing Agreement (note 18)	(4,334)	-	**(4,334)**
Finance costs	38	12	**50**
Fair value movement	1,854	-	**1,854**
Balance at 30 June 2024	**-**	**19**	**19**

21. Related party transactions

Other than items relating to Directors' remuneration and employment, there were no related party transactions during the year (2023: £nil).

22. Share capital

Allotted, issued and fully paid:

	Number	£'000
Balance at 30 June 2022	**92,542,446**	**1,388**
Share issue – equity-settled share-based payments	7,500	-
Share issue	6,500,000	97
Balance at 30 June 2023	**99,049,946**	**1,485**
Share issue – equity-settled share-based payments	260,870	4
Share issue	443,830,665	6,658
Balance at 30 June 2024	**543,141,481**	**8,147**

Over the months of May and June 2024 the Company issued 400,000,000 shares as part of a placing and open offer to shareholders for net proceeds of £5.434m.

During the year the Company issued 43,830,665 (2023: 6,500,000) shares with a nominal value of £658,000 (2023: £97,000) as part of the Investor Placing Agreement detailed in note 18.

Note 19 to these accounts details the share options that could also be exercised and result in the issue of additional shares.

23. Other reserves

	Share premium account £'000	Shares to be issued £'000	Employee share incentive plan reserve £'000	Share options reserve £'000	Reverse acquisition reserve £'000	Total equity £'000
Balance at 30 June 2022	**52,426**	**–**	**(196)**	**1,560**	**(2,496)**	**51,294**
Investment funding arrangement (note18)	910	477	-	-	-	1,387
Equity-settled share-based payments	-	-	-	96	-	96
Transactions settled directly in equity	**910**	**477**	**-**	**96**	**-**	**1,483**
Balance at 30 June 2023	**53,336**	**477**	**(196)**	**1,656**	**(2,496)**	**52,777**
Investment funding arrangement (note18)	1,581	243	-	-	-	1,824
Equity-settled share-based payments	13	-	-	42	-	55
Transactions settled directly in equity	**1,594**	**243**	**-**	**42**	**-**	**1,879**
Balance at 30 June 2024	**54,930**	**720**	**(196)**	**1,698**	**(2,496)**	**54,656**

Shares to be issued relates to the warrants issued; full details are contained in note 19.

The employee share incentive plan reserve is the historic cost of shares purchased to satisfy share rights under the Share Investment Plan ("SIP") of £196k. The Company no longer buys shares to satisfy the SIP.

The reverse acquisition reserve arises as a difference on consolidation under merger accounting principles and is solely in respect of the merger of the Company and Epistem Ltd, during the year ended 30 June 2007.

Company Balance Sheet

as at 30 June 2024

	Note	30 June 2024 £'000	30 June 2023 £'000
Assets			
Non-current assets			
Investment in subsidiaries	a	**–**	–
Current assets			
Amounts receivable from Group undertakings and other receivables	b	**5,105**	2,520
Cash and cash equivalents	c	**10**	10
		5,115	2,530
Liabilities			
Current liabilities			
Derivative financial instruments	f	**–**	1,290
Non-current liabilities		**–**	–
Net assets		**5,115**	1,240
Capital and reserves			
Called-up equity share capital		**8,147**	1,485
Share premium account		**54,930**	53,336
Share options reserve		**2,032**	1,990
Shares to be issued		**720**	477
Accumulated losses:			
At 1 July		**(56,048)**	(54,896)
Transactions settled directly in equity		**-**	-
Total comprehensive expense for the year		**(6,518)**	(1,152)
Fair value through accumulated losses reserve		**1,852**	-
		(60,714)	(56,048)
Total shareholders' funds equity		**5,115**	1,240

These financial statements were approved by the Directors and authorised for issue on 28 November 2024 and are signed on their behalf by:

Gino Miele
Chief Executive Officer

Russ Shaw
Chief Financial Officer

As permitted by s408 of the Companies Act 2006, the Company has not presented its own profit and loss account and related notes as it has prepared Group accounts. The Company's loss for the year was £6.5m (2023: £1.2m loss).

Company Statement of Changes in Equity

for the year ended 30 June 2024

	Called-up equity share capital £'000	Share premium account £'000	Share options reserve £'000	Shares to be issued £'000	Accumulated losses £'000	Total equity £'000
Balance at 30 June 2022	**1,388**	**52,426**	**1,894**	–	**(54,896)**	**812**
Transactions with owners in their capacity as owners						
Investment funding arrangement (note f)	97	910	–	477	–	1,484
Equity-settled share-based payments	–	–	96	–	–	96
Transactions settled directly in equity	**97**	**910**	**96**	**477**	**–**	**1,580**
Total comprehensive income for the year	–	–	–	–	(1,152)	(1,152)
Balance at 30 June 2023	**1,485**	**53,336**	**1,990**	**477**	**(56,048)**	**1,240**
Transactions with owners in their capacity as owners						
Share issue	6,000	–	–	–	–	6,000
Investment funding arrangement (note f)	658	1,581	–	243	–	2,482
Equity-settled share-based payments	4	13	42	–	–	59
Transactions settled directly in equity	**6,662**	**1,594**	**42**	**243**	**–**	**8,541**
Total comprehensive income for the year	–	–	–	–	(6,518)	(6,518)
Settlement of Financial Derivative Liability	–	–	–	–	1,852	1,852
Balance at 30 June 2024	**8,147**	**54,930**	**2,032**	**720**	**(60,714)**	**5,115**

Company Statement of Cash Flows

for the year ended 30 June 2024

	Year ended 30 June 2024 £'000	Year ended 30 June 2023 £'000
Cash flows from operating activities		
Operating loss for the year	**(4,043)**	(395)
Group undertaking loan impairment	**4,000**	300
Impairment of investment	**42**	96
Operating profit before changes in working capital and provision	**(1)**	1
Increase in amount owed from Group companies	**(6,585)**	(2,820)
Net cash outflow from operating activities	**(6,586)**	(2,819)
Cash flows from financing activities		
Proceeds from the investment placing agreement	**1,200**	2,300
Transaction costs relating to investment placing agreement	**(48)**	(283)
Proceeds from share issue	**6,000**	-
Transaction costs relating to share issue	**(566)**	-
Net inflow from financing activities	**6,586**	2,017
Net (decrease) / increase in cash equivalents	**-**	(802)
Cash and cash equivalents at beginning of year	**10**	812
Cash and cash equivalents at end of year	**10**	10
Analysis of net funds		
Cash at bank and in hand	**10**	10
Net funds	**10**	10

Notes to the Company Financial Statements

for the year ended 30 June 2024

Basis of accounting

The Company financial statements have been prepared in accordance with UK-adopted International Accounting Standards. The financial statements have been prepared on a historical cost basis as modified by the revaluation of financial assets and financial liabilities (including derivative instruments) at fair value through profit or loss.

The principal accounting policies adopted in the preparation of these financial statements are those relating to investments, share options and financial; instruments, and have been disclosed in the notes to the consolidated financial statements of the Group above.

Going concern

The Group's business activities and market conditions are described on pages 5-13 The principal risks and uncertainties are shown on page 30 while the Group's financial position is described on pages 27 and 28. The Group funds its day-to-day cash requirements from existing cash reserves, revenue generation and other income. These matters have been considered by the Directors in forming their assessment of 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 will see over £0.5m of revenue commencing in November 2024.

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 first sale 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 if required 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.

Critical accounting estimates

The preparation of financial statements in conformity with International Accounting Standards requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed below:

- Estimates in the measurement of the expected credit loss relating to amounts due from group undertakings are described in note b.

Critical judgements

- Judgement was required in assessing whether warrants issued under the Investor Placing Agreement should be treated as debt or equity. As a financial instrument under IAS 32, warrants are derivative financial instruments as their value changes in response to the Company's share price, however, as the exercise of these warrants results in exchange of fixed amount of cash for fixed number of shares, management concluded that these instruments were equity instruments.
- The Company used judgement in selecting appropriate techniques with which to measure the fair value of the derivative financial liability at the dates of draw down and at the reporting date. The measurement of fair value required use of assumptions regarding the share price volatility and assumes that the investor will seek to achieve the optimal value to settle the outstanding amount. Further detail is provided in note 18 to the Group's financial statements.

a. Investments

The Company is the holding company of the Group. The Company owns 100% of the issued share capital of Genedrive Diagnostics Ltd (formerly called Epistem Ltd) and Epistem SIP Trustees Ltd. The principal activities of the subsidiary companies are:

- Genedrive Diagnostics Ltd –the provision of services to the medical, biotechnology and pharmaceutical industries; incorporated in England, and with registered address 48 Grafton Street, Manchester, M13 9XX, United Kingdom
- Epistem SIP Trustees Ltd – to act as trustee to the Epistem Share Incentive Plan; incorporated in England and with registered address 48 Grafton Street, Manchester, M13 9XX, United Kingdom

	Investment in subsidiaries £'000
At 30 June 2022	–
Additions in the year	96
Impairment	(96)
At 30 June 2023	–
Additions in the year	**42**
Impairment	**(42)**
At 30 Jun 2024	**–**

Additions in the year ended 30 June 2024 comprised the fair value of the share options issued to employees of the subsidiary undertaking during the year of £42k (2023: £96k). Full details of the share options issued are set out in note 19 to the consolidated financial statements. Following an impairment review, the carrying value of the investments was impaired by £42k (2023: £96k).

b. Amounts receivable from Group undertakings and other receivables

Company	2024 £'000	2023 £'000
Opening amounts receivable from Group undertakings	**2,520**	–
Additions in the year	**6,585**	2,820
Changes in expected credit loss	**(4,000)**	(300)
Closing amounts receivable from Group undertakings	**5,105**	2,520

Amounts receivable from Group undertakings are held in intercompany accounts with no security and no specified repayment terms. The Company has assessed the expected credit loss by reference to the subsidiary's liquid resources at the reporting date that would be available to repay the amounts outstanding if repayment was demanded. Due to uncertainties relating to the company's future revenues, no assumptions have been made regarding any further repayments beyond those that could be made at the reporting date.

c. Cash and cash equivalents

	2024 £'000	2023 £'000
Cash at bank and in hand	**10**	10

Cash and cash equivalents comprise current accounts held by the Company with immediate access and short-term bank deposits with a maturity of three months or less. Market rates of interest are earned on such deposits. The credit risk on such funds is limited because the counterparties are banks with high credit ratings assigned by international credit rating agencies.

d. Related party transactions

All of the employees of the Group are employed by Genedrive Diagnostics Ltd. There are no employees of the Company.

e. Financial risk management

The Company's approach to managing financial risk is covered in note 20 to the Group's financial statements.

	Classification	2024 £'000	2023 £'000
Financial assets			
Cash and cash equivalents	Amortised cost	**10**	10
Amounts due from Group undertakings	Amortised cost	**5,105**	2,520
Financial liabilities			
Derivative financial liability	Fair value	**-**	1,290

Changes in liabilities resulting from financing activities

	Derivative financial liability £'000
Balance at 30 June 2022	-
Net cash from / (used) in financing activities	
Proceeds from Investor Placing Agreement	2,300
Transaction costs	(283)
	2,017
Other movements	
Equity and warrant components of the Investor Placing Agreement (note f)	(1,403)
Transaction costs settled by issue of shares	(80)
Finance costs	81
Fair value movement	675
Balance at 30 June 2023	**1,290**
Net cash from / (used) in financing activities	
Proceeds from Investor Placing Agreement	1,200
Transaction costs	(48)
	1,152
Other movements	
Equity and warrant components of the Investor Placing Agreement (note f)	(4,334)
Finance costs	38
Fair value movement	1,854
Balance at 30 June 2024	**-**

f. Derivative financial instruments

Details of the Investor Placing Agreement are provided in note 18 to the Group's financial statements.

g. Share-based payments

The issuance by the Company of share options to employees of its subsidiary represents additional capital contributions and the fair value of such options and awards is therefore recognised as an increase in the Company's investment in Group undertakings with a corresponding increase in total equity shareholders' funds.

h. Investments

Investments in subsidiaries are stated at cost less any provisions for impairment. An impairment is recognised when the recoverable amount of the investment is less than the carrying amount.

Directors, Secretary and Advisers

Directors
Ian Gilham
Gino Miele
Russ Shaw
Tom Lindsay
Chris Yates

Company Secretary
Russ Shaw

Registrars
Neville Registrars Ltd
Neville House
Steelpark Road
Halesowen
B62 8HD

Legal Advisers
Addleshaw Goddard LLP
Cornerstone
107 West Regent Street
Glasgow
G2 2BA

Registered Office
The Incubator Building
Grafton Street
Manchester
M13 9XX
United Kingdom

Nominated Adviser & Broker
Peel Hunt LLP
100 Liverpool Street
London
EC2M 2AT

Principal Banker
NatWest
1st Floor, 1 Hardman Boulevard
Manchester
M3 3AQ

Independent Auditors
RSM UK Audit LLP
Landmark
St Peter's Square
1 Oxford Street
Manchester
M1 4PB