RNS Number : 1026O
Genedrive PLC
29 November 2024

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

Audited Final Results

genedrive plc (AIM: GDR), the point of care pharmacogenetic testing company, announces its audited Final Results for the year ended 30 June 2024.

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

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 US 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

Gino Miele,CEO of genedrive plc, said:*"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. We made significant progress during the year and 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."*

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About genedrive plc(http://www.genedriveplc.com)

genedrive plc is a pharmacogenetic testing company developing and commercialising a low cost, rapid, versatile and simple to use point of need pharmacogenetic platform for the diagnosis of genetic variants. This helps clinicians to quickly access key genetic information that will aid them make the right choices over the right medicine or dosage to use for an effective treatment, particularly important in time-critical emergency care healthcare paradigms. Based in the UK, the Company is at the forefront of Point of Care pharmacogenetic testing in emergency healthcare. Pharmacogenetics informs on how your individual genetics impact a medicines ability to work for you. Therefore, by using pharmacogenetics, medicine choices can be personalised, made safer and more effective. The Company has launched its two flagship products, the Genedrive® MT-RNR1 ID Kit and the Genedrive® CYP2C19 ID Kit, both developed and validated in collaboration with NHS partners and deployed on its point of care thermocycler platform. Both tests are single-use disposable cartridges which are ambient temperature stable, circumventing the requirement for cold chain logistics. The Directors believe the Genedrive® MT-RNR1 ID Kit is a worlds-first and allows clinicians to make a decision on antibiotic use in neonatal intensive care units within 26 minutes, ensuring vital care is delivered, avoiding adverse effects potentially otherwise encountered and with no negative impact on the patient care pathway. Its CYP2C19 ID Kit which has no comparably positioned competitor currently allows clinicians to make a decision on the use of Clopidogrel in stroke patients in 70 minutes, ensuring that patients who are unlikely to benefit from or suffer adverse effects from Clopidogrel receive an alternative antiplatelet therapeutic in a timely manner, ultimately improving outcomes. Both tests have undergone review by the National Institute for Health and Care Clinical Excellence ("NICE") and have been recommended for use in the UK NHS.

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

Chairman's Statement

Innovative solutions addressing unmet needs

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.

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 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 effort.

Dr Ian Gilham
Chairman

Chief Executive's Review

Pioneering pharmacogenetics

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 an 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

Financial Review

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 announced in May 2024 provided a c.£5.4m net capital injection prior to the year end.

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 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

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	2	**501**	55
Research and development costs		**(4,175)**	(3,924)
Administrative costs		**(1,638)**	(1,355)
Operating loss		**(5,312)**	(5,224)
Finance costs	3	**(2,468)**	(787)
Finance income	3	**30**	30
Loss on ordinary activities before taxation		**(7,750)**	(5,981)
Taxation	4	**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 and diluted	5	**(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		174	392
		174	392
Current assets			
Inventories		**381**	525
Trade and other receivables		**382**	158
Current tax asset		**675**	831
Cash and cash equivalents		**5,188**	2,601
		6,626	4,115
Total assets		**6,800**	4,507
Liabilities			
Current liabilities			
Trade and other payables		**(1,422)**	(935)
Lease liabilities		**(19)**	(222)

Derivative financial instruments	6	**-**	(1,290)
		(1,441)	(2,447)
Non-current liabilities			
Lease liabilities		-	(19)
Total liabilities		**(1,441)**	(2,466)
Net assets		**5,359**	2,041
Equity			
Called-up equity share capital	7	**8,147**	1,485
Other reserves	8	**54,656**	52,777
Accumulated losses		**(57,444)**	(52,221)
Total equity		**5,359**	2,041

Consolidated Statement of Changes in Equity

for the year ended 30 June 2024

	Share capital £'000	Other reserves £'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	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	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		**-**	15
Net cash inflow / (outflow) from investing activities		**1**	(8)
Cash flows from financing activities			
Proceeds from the investment placing agreement	6	**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		**(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 equivalents		**(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		**5,188**	2,601
Net cash		**5,188**	2,601

Notes to the Financial Information

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') is a molecular diagnostics business developing and commercialising a low-cost, rapid, versatile, simple-to-use and robust point-of-need or point-of-care diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications.

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

1. Significant accounting policies

The financial information for the year ended 30 June 2023 has been extracted from the Group's audited statutory financial statements which were approved by the Board of Directors on 28 November 2023 and which have been delivered to the Registrar of Companies for England and Wales. The report of the auditor on these financial statements was unqualified, did not contain a statement under Section 498(2) or Section 498(3) of the Companies Act 2006.

The report of the auditor on the 30 June 2024 statutory financial statements was unqualified, did not contain a statement under Section 498(2) or Section 498(3) of the Companies Act 2006, but did draw attention to the Group's ability to continue as a going concern by way of a material uncertainty paragraph.

The information included in this announcement has been prepared on a going concern basis under the historical cost convention as modified by the revaluation of financial assets and financial liabilities (including derivative instruments) at fair value through profit or loss, and in accordance with UK-adopted International Accounting Standards.

The information in this announcement has been extracted from the audited statutory financial statements for the year ended 30 June 2024 and as such, does not constitute statutory financial statements within the meaning of section 435 of the Companies Act 2006 as it does not contain all the information required to be disclosed in the financial statements prepared in accordance withUK-adoptedInternational Accounting Standards.

This announcement was approved by the board of directors on 29 November 2024 and authorised for issue via RNS.

Going concern

The Group's business activities, market conditions, principal risks and uncertainties along with the Group's financial position are described in the full annual accounts. 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.

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	501	-	501
Operating 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
Operating 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**	Year ended 30 June 2023

	30 June 2024 £'000	£'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. 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)

4. 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 (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.

5. 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:

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

6. 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 8).

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.

7. 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 6.

8. 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 (note 6)	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 (note 6)	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 6.

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.

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