

genedrive plc

Interim results to 31 December 2023

Advancing pharmacogenetic testing to the point-of-care

OPERATING HIGHLIGHTS (including post period)

- Food and Drug Administration (“FDA”) progress for the Genedrive[®] MT-RNR1 pharmacogenetic test (Antibiotic Induced Hearing Loss). The Company is in advanced stages of negotiating a collaboration with a USA-based Medical Group to support a highly cost-effective pathway for the necessary clinical trials
- Distributor agreement in place to support the FDA study and support future sales in the United States
- NIHR i4i & OLS Real World Evidence Programme funding application to address NICE EVA evidence generation requirements for the Genedrive[®] MT-RNR1 kit, in partnership with lead partners at Manchester University NHS Foundation Trust and 14 hospitals throughout the UK
- Strategic decision to sell Genedrive[®] MT-RNR1 kit direct in the UK and Ireland in 2024 following addition of increased internal sales capability
- Royal Sussex County Hospital, Brighton adopts the Genedrive[®] MT-RNR1 ID Kit for routine use and ongoing discussions with other hospitals in the UK and Ireland with further near-term adoption anticipated
- Initial international sales of the Genedrive[®] MT-RNR1 ID Kit received from France, Austria, Greece, Saudi Arabia, Turkey and the Netherlands
- UK Conformity Assessed (“UKCA”) marking achieved for new Genedrive[®] CYP2C19 pharmacogenetic test (stroke treatment selection)
- £1.2m (of which the Company is expected to receive c£0.2m directly) multi-partner grant awarded and in progress for the validation of Genedrive[®] CYP2C19 ID Kit in time critical NHS settings
- The draft NICE guidance recommends CYP2C19 genotyping for clopidogrel treatment and Genedrive[®] CYP2C19 ID test modelled to be a clinically and most dominant cost-effective option. The second consultation on the draft guidance is scheduled to commence on 3 April 2024 and the final NICE recommendations are expected to be published in July 2024

FINANCIAL HIGHLIGHTS

- Revenue and other income of £0.24m (H1 2022/3: £0.02m)
- R&D spend of £1.9m (H1 2022/3: £2.0m)
- Operating loss of £2.4m (H1 2022/3: £2.7m)
- Cash of £1.2m as at 31 December 2023 (30 June 2023: £2.6m)
- Cash of £1.2m as at 20 March 2024 following recent receipt of R&D tax credit of £0.8m

CHIEF EXECUTIVE OFFICER'S AND CHAIRMAN'S REPORT

The Company continues to make significant steps in revolutionising the delivery of personalised medicine, enhancing health outcomes and generating health economic benefits. There has been a renewed focus on our commercial team leading to changes in personnel and structure. This has allowed us to go direct in the UK and Ireland, enhance our digital marketing offering and increase our distributor network worldwide.

Antibiotic Induced Hearing Loss (AIHL) - Genedrive® MT-RNR1-ID Kit

Our MT-RNR1 ID kit is the world's first point-of-care genetic test to reduce the risk of antibiotic induced hearing loss ("AIHL"). Following detection of the MT-RNR1 variant an alternative antibiotic treatment can be prescribed. Our test has the potential to save thousands of children from lifelong hearing loss, whilst providing a net positive financial outcome case to global healthcare systems.

In March 2023, the Genedrive® MT-RNR1-ID Kit received a recommendation for use in the UK by the National Institute for Health and Care Excellence ("NICE") under its Early Value Assessment Programme ("EVA"). The EVA was introduced to allow rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money, so that the NHS and patients can benefit from these promising technologies sooner. The recommendation is conditional on further evidence being generated and the Company is a partner with clinical colleagues at Manchester University NHS Foundation Trust ("MFT") who have recently applied for funding to address the NICE EVA evidence generation recommendations, which are required for progressing the NICE conditional recommendation into a full recommendation at the earliest opportunity. The NIHR i4i & OLS Real World Evidence Programme is intended to address each eligible EVA, is being led by Office for Life Sciences ("OLS") as part of the UK Government's Life Sciences Vision and is backed by £10m of government funding and is expected to commence in October 2024.

Royal Sussex County Hospital, Brighton has adopted the Genedrive® MT-RNR1 ID Kit for routine use. This was a significant milestone, as it's the first adopter outside of Greater Manchester and plans are being put into place to roll out the test in the wider Kent, Surrey and Sussex region.

We continue to pursue all avenues to ensure we achieve specialist commissioning before the current timescale of April 2025. In line with specialist commissioning being devolved to the Integrated Care Boards ("ICBs"), our initial discussions have been with the Manchester ICB to obtain funding from April 2024 for the live sites across the Greater Manchester region.

In December 2023, following product registration and language translations, the first international sales of the Genedrive® MT-RNR1 ID Kit were achieved in France, Austria, Greece, Saudi Arabia, Turkey and the Netherlands and we have recently signed new distributors in Italy and the UAE.

The Company is at advanced stages in agreeing a partnership with a key strategic USA-based Medical Group with broad coverage of neonatal intensive care units nationally to progress our aim of introduction of our MT-RNR1 point of care pharmacogenetic test to the USA (subject to regulatory approval). If the partnership is secured it would provide the Company with a highly cost-effective pathway for the required regulatory studies for potentially attaining approval in the USA which would be a key element of the use of proceeds for the Company's proposed equity financing.

The USA is a particularly attractive market for this unique test, given its high birth rates, use of diagnostic testing and reimbursement structure and therefore has the potential to save many children from life-long deafness. In 2021, 3.7m babies were born in the USA, with approximately 10.5% born prematurely. It was estimated that malpractice litigation settlements in cases related to deafness caused by the use of aminoglycosides average over US\$1.1m per case, further adding to the positive health economic case of providing accurate and timely testing to reduce unwanted side effects of gentamicin usage and reduce potential litigation costs.

A distributor agreement is in place with International Biomedical, Ltd. to support the FDA study and future sales in the United States. International Biomedical has over 45 years' experience in the design, manufacture and distribution of neonatal and perinatal products and solutions, covering the entire USA.

Genedrive® CYP2C19 ID Kit

Genedrive® CYP2C19 ID Kit achieved UKCA marking registration in September 2023. It is a point of care pharmacogenomic test that can differentiate between patients that could respond to clopidogrel treatment and those that will not, allowing more effective drug treatment to be prescribed on a personalised basis. The test can be performed at the bedside or in a ward and can deliver a clinically actionable result in just over one hour.

Suboptimal response to clopidogrel following stroke is common, as reported by the NHS it is affecting up to 30% of patients in the general population, which increases to approximately 50%-60% in certain ethnic groups. In the UK, the National Institute for Health and Care Excellence (“NICE”) recommended in May 2023 draft guidance that people who have had an ischaemic stroke or transient ischaemic attack (“TIA”) should have a CYP2C19 genetic test prior to treatment. According to the World Stroke Organization, globally there are over 77 million people currently living who have experienced ischaemic stroke. It’s estimated by the Stroke Association that there are 100,000 strokes in the UK each year.

The Genedrive® CYP2C19 test uses a single, non-invasive cheek swab sample, and rapidly identifies six important genetic variants of the CYP2C19 gene, which are instrumental in the loss of metabolism function and poor activation of clopidogrel in a patient. The Genedrive® system automatically interprets the information for the clinician, allowing prompt administration of an optimised treatment plan. Like all genedrive products, the tests are presented in a room-temperature stable, freeze-dried format, allowing testing to be performed by healthcare workers, away from laboratory locations. In its performance evaluations, the test achieved 100% accuracy in detecting the variants that underpin loss of metabolism function.

The Development and Validation of Technology for Time Critical Genomic Testing (“DEVOTE”) grant is providing acute care patient access and supporting infrastructure for the Company to assess the real-world clinical performance of time-critical clinical tests in an NHS setting. The programme, led by the University of Manchester (“UoM”), builds on the model of the previous successful UoM/genedrive partnership with the PALOH programme, which supported the development and evaluation of the Genedrive® MT-RNR1 ID Kit. The Company is expected to receive circa £0.2m directly with the £1m balance funding the costs of a clinical trial that would otherwise have been incurred in full.

Our participation in the DEVOTE programme is well underway and is generating additional performance data in an acute care setting. This expanded dataset is required to drive our CE-IVD submission, which will allow for subsequent commercialisation in the EU. Submission is achievable in the second half of 2024 once genedrive’s engagement with DEVOTE has completed. With an approximate seven-month regulatory review process, we anticipate CE-IVD certification in early 2025. Whilst already UKCA marked, our commercialisation efforts in the UK will commence following successful completion of the DEVOTE clinical performance study at end of May 2024.

In the UK, the Company will be selling the product through its direct sales team, and momentum for adoption is expected to be influenced by positive final NICE recommendations for CYP2C19 testing. The draft NICE guidance recommends CYP2C19 genotyping for clopidogrel treatment and Genedrive® CYP2C19 ID test modelled to be a clinically and most dominant cost-effective option. The second consultation on the draft guidance is scheduled to commence on 3 April 2024 and the final NICE recommendations are expected to be published in July 2024.

Antiplatelet therapies such as Clopidogrel are recommended by NICE to prevent occlusive vascular events for people who have had an ischaemic stroke, who have peripheral arterial disease or multivesicular disease, or for people who have had a myocardial infarction only if aspirin is contraindicated or not tolerated. Other antiplatelet drugs can be used where clopidogrel is contraindicated or not tolerated. Other antiplatelet therapies have a higher risk of bleeding, although equivalent efficiency if preceded by CYP2C19 genotype guided therapy, and so in ischaemic stroke, current draft guidance from NICE states that CYP2C19 genotyping should be conducted in advance of Clopidogrel administration within 24 hours for ischaemic stroke. It is likely that this pathway will be adopted for other indications requiring clopidogrel, for example, in cardiovascular indications.

FINANCIAL RESULTS

Revenue and other income in the period was £0.24m (H1 2022/3: £0.02m).

Research and development costs continued at similar levels, being £1.9m (H1 2022/3: £2.0m) as the Company focused on near-commercialisation product development. Administration costs continue to be controlled at £721k (H1 2022/3: £713k). The trading loss for the period was £2.4m (H1 2022/3: £2.7m). Finance costs in the period of £30k (H1 2022/3: £11k).

After financing costs, the loss before taxation was £2.4m (H1 2022/3: £2.7m loss before taxations). The loss after taxation decreases to £2.0m (H1 2022/3: £2.2m loss after taxation) after estimating the six-month taxation credit as £0.35m (H1 2022/3: £0.5m). The basic loss per share was 2.0p (H1 2022/3: 2.4p basic loss per share).

Cash Resources

The operating loss for the period was £2.4m (H1 2022/3: £2.7m) and working capital reduced by £0.2m (H1 2022/3: £0.1m). Net cash out-flow from operations was £2.4m (H1 2022.3: £2.4m) and as the R&D tax credit was not received in the period the net cash flow from operating activities was also £2.4m.

Cash flows from financing activities consisted of lease liability repayments of £112k (H1 2022/3: £81k) and there was £1.2m of proceeds from the Investor Placing Agreement (H1 2022/3: £nil).

Closing cash was £1.2m (31 December 2022: £2.21m). The cash balance on 21 March 2024 was £1.2m with £0.8m received from the R&D tax credit post period end; the current burn rate without any material revenues and assuming current levels of expenditure is circa £0.4m per month.

Balance Sheet

Balance sheet net assets at 31 December 2023 were £1.5m (30 June 2023: £2m; 31 December 2022: £3.5m) and the consolidated loss of the period was £2m (H1 2022/3: £2.2m). As at 31 December 2023 the amount outstanding from the investor placing agreement was £1m (30 June 2023: £1.3m) and £0.1m on 21 March 2024.

PRINCIPAL RISKS AND UNCERTAINTIES

There are a number of potential risks and uncertainties which could have a material impact on the Company's performance over the remaining six months of the financial year and could cause actual results to differ materially from expected and historical results. The Directors do not consider that these principal risks and uncertainties have changed materially since publication of the annual report for the year ended 30 June 2023; a more detailed explanation of the risks for the Company can be found on page 20 of the annual report.

Going Concern

At the current burn rate, the Company has a cash runway through May 2024. We are confident that we will continue to gain commercial traction and securing significant revenues, but due to the time required to achieve this, as we have already stated, we will require additional funding. As described in the accounting policies, we continue to adopt a going concern basis for the preparation of the accounts, but the above condition represents a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern. As set out above, the Company is actively pursuing further equity funding to provide the necessary resources to execute the Company's growth strategy.

OUTLOOK

The Board is pleased with the tangible progress the Group is generating, with a clear focus on pharmacogenetic testing and the commercialisation of our two innovative products. This fuels the Board's optimism for future success, as we strive to generate value for our shareholders while positively impacting individuals' lives.

The news that funding is to be made available from the government's Office for Life Sciences via NIHR for the real world evidence generation required by NICE for our Genedrive[®] MT-RNR1 ID Kit is very welcome, affording the potential for it to move from a conditional recommendation to a full recommendation with NICE which would accelerate the adoption of the test in the NHS. Genedrive is a technical partner in an application from a consortia of 14 hospitals throughout the UK regions, led by our clinical partners at MFT.

Our equity funding plans are being advanced and the intention will be to raise sufficient funding to complete the clinical trials and regulatory approval process in the USA for the AIHL test whilst also providing sufficient funding to cover the Company's operating costs for an appropriate period of time. The Board intends to provide a mechanism for retail shareholders to participate in any equity financing and a further announcement will be made in due course.

Securing further funding is key to the execution of our strategy as is finalising our partnership in the USA for MT-RNR1 studies required for future *de novo* submission route for FDA approval. As a direct result of our collaboration with clinical colleagues under the DEVOTE programme for CYP2C19, we should also achieve IVDR approval for CYP2C19 by the end of 2024/early 2025 allowing us to sell the product into Europe and further afield. With both these products, with strong unmet need, clear market potential and defined NICE recommendations, genedrive has significant potential but we will also pursue new developments, partnerships and opportunities for Pharmacogenetic testing. We believe we are in the right place at the right time, with the right products, with little competition in the field of point of care pharmacogenetic testing.

James Cheek
Chief Executive Officer

Dr Ian Gilham
Chairman

28 March 2024

UNAUDITED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the six months ended 31 December 2023

		Six months ended 31 December 2023	Six months ended 31 December 2022	Year ended 30 June 2023
	<i>Note</i>	Unaudited £000	Unaudited £000	Audited £000
Revenue and other income	(4)	238	21	55
Research and development costs		(1,876)	(1,988)	(3,924)
Administrative costs		(721)	(713)	(1,355)
Operating loss	(4)	(2,359)	(2,680)	(5,224)
Finance costs	(5)	(30)	(11)	(757)
Loss on ordinary activities before taxation		(2,389)	(2,691)	(5,981)
Taxation		350	500	831
Loss for the financial period		(2,039)	(2,191)	(5,150)
Total comprehensive expense for the period		(2,039)	(2,191)	(5,150)
Loss per share (pence)				
-Basic		(2.0)p	(2.4)p	(5.5)p
-Diluted		(2.0)p	(2.4)p	(5.5)p

UNAUDITED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
For the six months ended 31 December 2023

	Share Capital (unaudited) £000	Other Reserves (unaudited) £000	Accumulated Losses (unaudited) £000	Total (unaudited) £000
At 30 June 2022	1,388	51,294	(47,071)	5,611
Equity –settled share-based payments	-	34	-	34
Transactions settled directly in equity	-	34	-	34
Total comprehensive loss for the period	-	-	(2,191)	(2,191)
At 31 December 2022	1,388	51,328	(49,262)	3,454
Share issue	-	2	-	2
Investment funding arrangement, net of costs	97	1,385	-	1,482
Equity –settled share-based payments	-	62	-	62
Transactions settled directly in equity	97	1,449	-	1,546
Total comprehensive loss for the period	-	-	(2,959)	(2,959)
At 30 June 2023	1,485	52,777	(52,221)	2,041
Investment funding arrangement, net of costs	351	1,113	-	1,464
Equity –settled share-based payments	-	40	-	40
Transactions settled directly in equity	351	1,153	-	1,504
Total comprehensive loss for the period	-	-	(2,039)	(2,039)
At 31 December 2023	1,836	53,930	(54,260)	1,506

UNAUDITED CONSOLIDATED BALANCE SHEET
As at 31 December 2023

		31 December 2023 (unaudited) £000	31 December 2022 (unaudited) £000	30 June 2023 (audited) £000
	Note			
Non-current assets				
Intangible assets		-	-	-
Plant and equipment		279	503	392
		279	503	392
Current assets				
Inventories		539	665	525
Trade and other receivables		214	126	158
Current tax asset	(6)	1,181	1,456	831
Cash and cash equivalents		1,226	2,083	2,601
		3,160	4,330	4,115
Liabilities				
Current liabilities				
Trade and other payables		(788)	(1,066)	(935)
Lease liabilities		(129)	(221)	(222)
Derivative financial instruments		(1,016)	-	(1,290)
		(1,933)	(1,287)	(2,447)
Non-current liabilities				
Lease liabilities		-	(92)	(19)
Total liabilities		(1,933)	(92)	(2,466)
Net assets				
		1,506	3,454	2,041
Capital and reserves				
Called-up equity share capital	(8)	1,836	1,388	1,485
Other reserves	(9)	53,930	51,328	52,777
Accumulated losses		(54,260)	(49,262)	(52,221)
Total shareholder equity		1,506	3,454	2,041

UNAUDITED CONSOLIDATED CASH FLOW STATEMENT
For the six months ended 31 December 2023

	31 December 2023 (unaudited) £'000	31 December 2022 (unaudited) £'000	30 June 2023 (audited) £'000
Cash flows from operating activities			
Operating loss for the period	(2,359)	(2,680)	(5,224)
Depreciation and amortisation on non-leased assets	28	32	61
Depreciation on right-of-use assets	90	81	193
Share – based payment	40	34	96
Operating loss before changes in working capital and provisions	(2,201)	(2,533)	(4,874)
Increase/ (decrease) in inventories	(14)	83	223
(Increase)/ decrease in trade and other receivables	(56)	(19)	(51)
Decrease/ (increase) in trade and other payables	(147)	62	(59)
Net cash outflow from operations	(2,418)	(2,407)	(4,761)
Tax received	-	-	956
Net cash outflow from operating activities	(2,418)	(2,407)	(3,805)
Cash flows from investing activities			
Finance income	18	5	29
Finance costs	(10)	(16)	-
Proceeds from disposal of discontinued operations	-	14	15
Acquisition of plant and equipment and intangible assets	(5)	(21)	(52)
Net cash inflow/ (outflow) from investing activities	3	(18)	(8)
Cash flows from financing activities			
Proceeds from the investment placing agreement	1,200	-	2,300
Transaction costs relating to investment placing agreement	(48)	-	(283)
Repayment of lease liabilities	(112)	(81)	(193)
Net inflow/ (outflow) from financing activities	1,040	(81)	1,824
Net decrease in cash equivalents	(1,375)	(2,506)	(1,989)
Effects of exchange rate changes on cash and cash equivalents	-	-	1
Cash and cash equivalents at beginning of period	2,601	4,589	4,589
Cash and cash equivalents at end of period	1,226	2,083	2,601
Analysis of net funds			
Cash at bank and in hand	1,226	2,083	2,601

NOTES TO THE UNAUDITED INTERIM FINANCIAL STATEMENTS

1. General information

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

The financial information for the period ended 31 December 2023 and similarly the period ended 31 December 2022 has been neither audited nor reviewed by the auditor. The financial information for the year ended 30 June 2023 has been based on information in the audited financial statements for that period. The interim financial statements for the period ended 31 December 2023 do not constitute statutory accounts as defined in section 434 of the Companies Act 2006. A copy of the statutory accounts for the year ended 30 June 2023 has been delivered to the Registrar of Companies, the accounts had an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006 but did include a reference to a material uncertainty that might cast significant doubt over the Group's ability to continue as a going concern, to which the auditor drew attention by way of emphasis.

These interim financial statements were approved by the Board of Directors on 28 March 2024.

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

2. Significant accounting policies

Basis of accounting

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

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

The accounting policies used in the preparation of the financial information for the six months ended 31 December 2023 are in accordance with the recognition and measurement criteria of UK adopted international accounting standards and are consistent with those which will be adopted in the annual financial statements for the year ending 30 June 2024. Whilst the financial information included has been prepared in accordance with the recognition and measurement criteria of international accounting standards, the financial information does not contain sufficient information to comply with international accounting standards. The Group has not applied IAS 34, Interim Financial Reporting, which is not mandatory for UK AIM listed Groups, in the preparation of this interim financial report.

Going concern

The Directors have concluded that it is necessary to draw attention to the revenue and cost forecasts in the business plans during the period to June 2025. The Group and Company does not currently have sufficient cash resources to continue as a going concern during the forecast period due to the time expected to be needed to gain commercial traction in its revenues. Therefore, the Company will need to raise further equity, or other funding, in the near term in order to continue as a going concern. The forecasts prepared by the Directors include a plan to raise additional funds from equity investors or debt providers to allow the Company to continue as a going concern.

The Company is confident that given the health benefits and economics that RNR1 will be a commercial success. The NICE EVA (Early Value Assessment) recommendation is testimony to it. Our CYP2C19 product is at validation and verification stage and has a much larger potential market than RNR1 with a far less complex route to market. The Company recognises the uncertainty regarding the timing of the associated revenues, given we are first to market for RNR1 and the funding complexities within the NHS. NICE recommendations and Specialist Commissioning will bring significant upside to our sales forecasts, but they are outside of our control and are therefore uncertain. The Directors have reasonable confidence in their ability to raise additional funds given the progress described above and having made enquiries, have a reasonable expectation that the Group has access to adequate resources to continue in operational existence for the foreseeable future.

While the Board has a successful track record in raising funds, there remains uncertainty as to the amount of funding that could be raised from shareholders or debt providers. The combination of the above factors represents a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern.

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

New accounting standards adopted in the period

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

Estimates

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

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

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

Revenue recognition

a. Product sales

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

b. Collaboration and licensing revenue

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

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

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

c. Other income – development grant funding

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

Research and development

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

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

Right-of-use assets (ROU)

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

Foreign currencies

(a) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in sterling which is the Group's presentation currency.

(b) Transactions and balances

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

3. Revenue

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

4. Operating segments

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

	Diagnostic Segment	Administrative Costs	Total
Six months ended 31 December 2022	£'000	£'000	£'000
Revenue and other income	21	-	21
Operating loss	(1,967)	(713)	(2,680)
Net Finance costs			(11)
Loss on ordinary activities before taxation			(2,691)
Taxation			500
Loss for the financial period			(2,191)

	Diagnostic Segment	Administrative Costs	Total
Twelve months ended 30 June 2023	£'000	£'000	£'000
Revenue and other income	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 period			(5,150)

5. Net Finance costs

	31 December 2023 £000	31 December 2022 £000	30 June 2023 £000
Net interest income on bank deposits	18	5	30
Transaction costs relating to investment placing agreement	(40)	-	(81)
Movement in fair value of derivative financial instrument	-	-	(675)
Finance lease interest costs	(8)	(16)	(31)
	(30)	(11)	(757)

6. Current tax asset

The current tax asset relates to tax owing under the R&D tax credit scheme of £1.2m (H1 2022/3: £1.5m). A payment of £0.8m was received in March 2024. The remaining £0.4m is an estimate of the tax credit for the interim period to December 2023 and this will be received following submission of the tax returns for the 12 months to June 2024, with receipt expected to be in the first quarter of 2025.

7. Earnings per share

The basic earnings per share is calculated by dividing the earnings attributable to ordinary shareholders for the year by the weighted average number of ordinary shares in issue during the period. The weighted average number of shares in issue during the period was 103,900,492 (H1 2022/3: 92,542,446). Potentially dilutive options, after proceeds from conversion, add no shares to basic weighted average number of shares in issue (H1 2022/3: 40,342).

8. Share capital

Allotted, issued and fully paid:

	No	£'000
Balance at 30 June 2022 and 31 December 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	23,390,000	351
Balance at 31 December 2023	122,439,946	1,836

During the financial period the Company issued 23,390,000 shares in genedrive plc as part of the Investor Placing Agreement entered into on 31 March 2023.

9. Other Reserves

	Share Premium Account £000	Shares to be issued £000	Employee Share Incentive Plan Reserve £000	Share Options Reserve £000	Reverse Acquisitions Reserve £000	Total £000
At 30 June 2022	52,426	-	(196)	1,560	(2,496)	51,294
Equity settled share-based payments	-	-	-	34	-	34
At 31 December 2022	52,426	-	(196)	1,594	(2,496)	51,328
Investment funding arrangement	910	477	-	-	-	1,387
Share issue	-	-	-	-	-	-
Equity settled share-based payments	-	-	-	62	-	62
At 30 June 2023	53,336	477	(196)	1,656	(2,496)	52,777
Investment funding arrangement	916	197	-	-	-	1,113
Share issue	-	-	-	-	-	-
Equity settled share-based payments	-	-	-	40	-	40
At 31 December 2023	54,252	674	(196)	1,696	(2,496)	53,390