RNS Number : 1411V
Genedrive PLC
30 November 2023

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

Audited Final Results

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces its audited Final Results for the year ended 30 June 2023.

Financial Highlights

- Loss for the year of £5.2m (2022: loss of £4.7m)
- R&D spend of £3.9m (2022: £3.9m)
- Cash at bank of £2.6m (2022: £4.6m)

Operational Highlights

- Genedrive® MT-RNR1 ID Test receives positive final recommendation in NICE's Early Value Assessment programme
- Genedrive® MT-RNR1 commenced rollout in Greater Manchester hospitals
- Commercial distribution agreements for Antibiotic Induced Hearing Loss (AIHL) test in place covering Spain, France, Austria, Greece, Saudi Arabia, Kuwait, Turkey and the Netherlands
- UKCA marking achieved for new Genedrive® CYP2C19 pharmacogenetic test
- Benefiting from £1.2m multi-partner grant awarded for the validation of Genedrive® CYP2C19 ID Kit in time critical NHS settings. The Company is expected to receive c£0.2m directly
- The draft NICE guidance recommends CYP2C19 genotyping for clopidogrel treatment and Genedrive® CYP2C19 ID test modelled to be a clinically and cost-effective option. Final NICE recommendations pending
- Investor Placing Agreement of up to £5m secured with £2.3m drawn down during the year and a further £0.6m drawdown post year end
- Pre-submission process ongoing with the Food and Drug Administration ("FDA") to determine regulatory process and requirements to place AIHL into the American market

James Cheek, CEO of genedrive plc, said: *"I'm excited to be part of a Company that is innovating pharmacogenetic testing by bringing the test closer to the patient thereby making a real difference in patients' lives and helping clinicians make quick insightful decisions that improve patient safety. We continue to develop and create solutions that challenge what is possible and improve patient outcomes."*

For further details please contact:

genedrive plc +44 (0)161 989 0245
James Cheek: CEO / Russ Shaw: CFO

Peel Hunt LLP (Nominated Adviser and Joint Broker)
James Steel / Patrick Birkholm
+44 (0)20 7418 8900

Walbrook PR Ltd (Media & Investor Relations)
Anna Dunphy
+44 (0)20 7933 8780 or genedrive@walbrookpr.com
+44 (0)7876 741 001

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

genedrive plc 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. This helps clinicians to quickly access key genetic information that will help them make the right choices over the right medicine or dosage to use for an effective treatment. Based in the UK, the Company is at the forefront of work on Point of Care pharmacogenetics. Pharmacogenetics looks at how your genetics impacts a medicines ability to work for you. Therefore, by using pharmacogenetics, medicines can be made safer and more effective. The Company has launched its flagship product, the Genedrive® MT-RNR1 ID Kit, which is a single-use disposable cartridge which circumvents the requirement for cold chain logistics by providing temperature stable reagent test kits for use on their proprietary test platform. This test allows clinicians to make a decision on antibiotic use within 26 minutes, ensuring vital care is delivered with no negative impact on the patient pathway.

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

Innovation for better health outcomes

This year has been both challenging and rewarding, the road to commercialisation of groundbreaking innovative products is long and challenging, due to the collection of data required and the sheer size of the NHS and funding complexities of Integrated Care Systems (ICS).

I am very pleased to see our Antibiotic Induced Hearing Loss (AIHL) test in routine use at multiple sites, although initially on a small scale, the Company is well positioned for geographical expansion and I am immensely proud that we have contributed to the prevention of hearing loss in infants, which when considered with the NICE EVA recommendation and the potential to generate significant savings for the NHS, sees us well poised to gain growing commercial traction in the coming year.

Our people have worked relentlessly on the successful development of the Genedrive® CYP2C19 ID test, which is our most complicated assay developed to date and was delivered in the shortest time frame. It was welcoming to see the draft guidance from NICE recommending that CYP2C19 genotyping should be used before clopidogrel administration in the management of ischemic stroke patients and our inclusion in their Diagnostics Assessment Programme is a remarkable achievement. The final NICE recommendation, which had previously been expected in December 2023, has recently been delayed with further details not yet available.

The DEVOTE 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 NICE recommended Genedrive® MT-RNR1 ID Kit. The DEVOTE grant funding will see us benefit from access to the Acute Medicine Unit and reduce clinical validation costs that otherwise would have been fully borne by the Group.

During the year we have consistently advanced our efforts towards transforming the way in which certain personalised medicine can be delivered aiming to enhance health outcomes and bring about health economic benefits.

Governance and People

I was delighted to welcome James Cheek and Gino Miele to the Board both with effect from 11 September 2023. James brings extensive commercial and operational experience at a senior level through a successful career with established diagnostic companies and joined as Chief Executive Officer, replacing David Budd. I would like to thank David for his dedication and leadership over the past seven years and wish him every success for the future. Gino joined the Board as Chief Scientific Officer and has considerable experience in the development of molecular diagnostic technologies and systems and has been the R&D Director at genedrive since 2015 and its predecessor Epistem since 2011.

The Board continues its commitment to maintaining its own efficiency and competence, with an unwavering 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 lifeblood of the Company, and I want to express my gratitude to each and every one of them for their unwavering resilience, innovative spirit, and unyielding determination in both the development and delivery of our products.

Funding

The Board continuously assesses the Group's requirements and funding options that would bridge the gap before revenue generation allows us to be self-sufficient. The Investor Placing Agreement entered into on 31 March 2023 provided a committed facility of up to £5m and to date the Group has received £2.9m (£2m initial payment and further payments of £0.3m in June, July and November 2023). Further drawdowns are conditional on meeting certain share trading criteria, which are set out in note 6 and were also set out in the Company's circular issued on 24 April 2023 and therefore further drawdowns cannot be considered as guaranteed. The Board is planning for an equity or debt raise in early 2024 to support the growth and development plans of the business and allow the Group to continue to operate as a going concern. The Group does

expect to receive an R&D tax credit of c£0.8m in Q1 of 2024 which, if received, would extend the cash runway (absent any further funding received) towards the end of Q1 2024 and provide a longer window for our planned financing activities. The Group's current cash runway is limited; unaudited cash as at 23 November 2023 was £1m and further funding will be required in early 2024 in order to continue as a going concern. The further payment of £0.3m pursuant to the Investor Placing Agreement announced on 29 November 2023 is due to be received shortly.

We also remain active in our pursuit of non-dilutive funding, such as the DEVOTE programme and we have pushed ahead with commercial opportunities outside of the UK, appointing eight international distributors and achieving six product registrations. We are continuing to work closely with the NHS to secure specialist commissioning funding for our MT-RNR1 product, as well as finalising our 2024 sales strategy and distribution channel for our new CYP2C19 product. With our commercialisation strategy including the US, we have recently completed a pre-submission exercise with the FDA which has, with no predicate device, clarified what would be expected to fulfil for release in the US of our novel MT-RNR1 test. We are now looking at funding options to take us forward for FDA approval for the MT-RNR1 product, with substantially all of the exploratory groundwork completed we are ready to proceed to the next step. Future funding would also be required to support the ongoing development of the instrumentation allowing us to capitalise on our pharmacogenetic positioning in emergency care and add further tests to our existing menu.

Outlook

Our mission is to leverage our technology to facilitate the improvement of health outcomes and it is encouraging that we are now beginning to bear the fruits of our labour. The Group will need to raise further funds in early 2024 to allow us to continue to operate as a going concern and fulfil our mission.

The Company will remain focused on its strengths, with a strong research and development capability at the core of our company, we will continually strive to grow our innovative product offering by leveraging our extensive knowledge in developing novel in-vitro pharmacogenetic assays.

Our Genedrive® platform is at the forefront, offering efficient and speedy genetic testing solutions and has the capability to address molecular pharmacogenetics in critical care settings. By harnessing our extensive expertise in developing in-vitro molecular diagnostic assays for use in time-critical healthcare settings, coupled with the advantages of our evolving Genedrive® platform, our company is establishing itself as a pioneer in the implementation of pharmacogenetics within emergency care.

We continue to make progress for FDA approval of our MT-RNR1 product, the US represents a very important market opportunity. As there is no predicate product in the US, there is no defined pathway for us to follow. The FDA have been very supportive of our efforts throughout the process to date to bring this test to the US market.

Finally, I want to express my appreciation to you, our valued shareholders, as well as our staff and collaboration partners for your ongoing support.

Dr Ian Gilham
Chairman

Chief Executive's Review

Innovation in Point-of-Care pharmacogenetic diagnostics in Emergency Medicine

Overview

This year has marked significant progress in our efforts to revolutionise the delivery of pharmacogenetic testing and personalised medicine. We continue to seek out and address unmet clinical requirements, capitalising on our proficiency in developing in-vitro pharmacogenetic diagnostic assays.

The UKCA marking of the Genedrive® CYP2C19 test is testimony to this and the use of our point-of-care test will allow patients to be put on an optimised treatment plan much quicker than is currently possible. I would like to take this opportunity to whole heartedly thank the efforts of the entire team here at genedrive for turning this ambitious and challenging vision into a reality in an incredibly short time which is a real testament to the quality, ability and dedication that we have in the organisation.

It is a privilege for the Group to once again collaborate with our esteemed colleagues at the University of Manchester (UoM) and Manchester University NHS Foundation Trust (MFT) in developing time-critical genetic test solutions. The DEVOTE program is an amazing opportunity to engage with the NHS to demonstrate the effectiveness of a new diagnostic approach. Real time access to the Acute Medicine Unit has considerable value to the Group and the grant funding to genedrive and its partners allows us to expediate the ongoing product development and support the pathway to clinical validation of our Genedrive® CYP2C19 ID Kit. This level of clinical input and evaluation is increasingly required by regulatory authorities prior to marketing product especially in the EU.

Our AIHL test is the world's first pharmacogenetic test in an urgent neonatal point-of-care setting. It helps avoid lifelong deafness in infants that are genetically predisposed to the unintended toxic effects in the inner ear from certain antibiotics. The test delivers a diagnostic result in under 30 minutes and allows for alternative treatment selections depending on the genetic variant of the patient.

Last year the Company took the strategic decision of transferring instrument manufacturing operations to the UK and some assay manufacturing in-house, with a view to increase visibility and control of its processes. This cost beneficial action has resulted in elevated transparency and oversight, whilst enhancing the speed and flexibility in transportation and delivery, reducing the time-to-market and improving sustainability. Bringing our supply chain closer together, improves the Group's agility and resiliency, with both economic and environmental advantages. This was highlighted no better than in our ability to bring the CYP2C19 assay to market so quickly.

Performance

Both genedrive and our UK distributor have made significant in-roads across both the Academic Health Science Networks and individual Trusts, we truly believe that the clinical argument has been won. The next step on our journey is to secure interim funding until the date that the specialist commissioning kicks in to support the adoption UK wide. In the meantime, we are not sitting still and continue to establish distributors outside of the UK. We are also funding several Key Opinion Leader presentation and discussions across Europe and beyond. Our commercial

team has made solid progress in thirteen countries internationally as we find wider interest in our products and our company worldwide.

Outlook

Using genetic and genomic testing for diagnosis and treatment optimisation has seen a considerable upsurge in recent years. This surge is propelled by rapid advancements in scientific knowledge and technological innovation. I take great pride in witnessing genedrive as a front runner in this field.

Our developments have facilitated remarkable advancements in personalised medicine, making it possible to customise treatment strategies for patients.

We are pioneers in what we do, so there is no well-trodden path between our technological advances and the commercial benefits. The NICE recommendation for our AIHL test demonstrates the beneficial impact of the test to both patients and wider society, whilst simultaneous providing potential and substantial cost savings to the NHS and we see that as instrumental to our UK roll out and expansion into international market.

Our focus remains on pharmacogenetic testing as we continue to invest in product development focusing on maximising the benefits of our continually advancing Genedrive® platform, characterised by its compactness, user-friendliness, rapid results, precision, and cost-effectiveness, qualities that makes it well-suited for extensive adoption. We believe our products are uniquely positioned for time-critical pre-emptive pharmacogenetic testing in emergency care and we will continue to explore opportunities outside of MT-RNR1 and CYP2C19.

James Cheek
Chief Executive Officer

Financial Review

Revenue for the year was £0.06m (2022: £0.05m) and continues to reflect the time required for our products to gain commercial traction. The MT-RNR1 test is in routine use in Greater Manchester, paving the way for other early adopters in the UK, whereas international revenues are dependent on product registration and language translation, which has been achieved post year end in six countries. Research and development costs were £3.9m (2022: £3.9m) as we prepared for the regulatory approval of our second molecular point of care assay effectively expanding our range of assays and developing a pipeline for future innovative products. Administration costs have been tightly managed reducing by £0.4m from the prior year to £1.4m (2022: £1.8m). The operating loss for the year was £5.2m (2022: £5.6m).

Financing costs and income

Financing costs were £0.8m (2022: £0.02m) including a non-cash fair value adjustment in respect of the derivative financial instrument of £0.7m (2022: £nil) and financing income was £0.03m (2022: £nil)

Taxation

The tax credit for the year was £0.8m (2022: £1.0m). 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 £0.8m 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 £4.8m (2022: £5.8m). The operating loss cashflows were £4.9m (2022: £5.3m) with a working capital inflow of £0.1m (2022: outflow £0.4m) mainly due to the reduction in inventory.

The tax credit received was £1.0m (2022: £1.2m) and relates to cash received under the UK Government's R&D tax relief scheme.

Capital expenditure in the period was £0.05m (2022: £0.06m) and the proceeds from investment funding, net of transaction costs were £2.0m (2022: £6.7m). The decrease in cash for the year was £2.0m (2022: £2.0m increase) meaning a closing cash position of £2.6m (2022: £4.6m).

Our unaudited cash balance as at the 23 November 2023 was £1.0m, reflecting a monthly burn rate of £0.4m since the year end. The further payment of £0.3m pursuant to the Investor Placing Agreement announced on 29 November 2023 is due to be received shortly.

Funding

Requiring additional funding to finance the development of the CYP2C19 project and commercialisation of AIHL, the Company entered into an Investor Placing Agreement of up to £5m on 31 March 2023, of which £2.3m was drawn down in the year to 30 June 2023 and a further £0.6m since then. Further details can be found in note 6.

The Company also continues to actively seek non-dilutive funding and participation in the DEVOTE programme will see 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 validation and verification of our CYP2C19 product.

Balance sheet

Balance sheet net assets at 30 June 2023 were £2.0m (2022: £5.6m). Fixed assets were £0.4m (2022: £0.2m) and include right to use lease assets of £0.2m (2022: £0.02m).

Current assets of £4.1m (2022: £6.4m) included cash of £2.6m (2022: £4.6m). Inventories of £0.5m (2022: £0.7m), consisted mainly of raw materials used in manufacturing and R&D. The remainder of current asset values were in receivables of £0.2m (2022: £0.1m) and tax. The tax receivable was £0.8m (2022: £1.0m) for the current year Corporation Tax Research and Development tax claim.

Current liabilities were £2.4m (2022: £1.0m) and include a derivative financial instrument £1.3m (2022: £nil) resulting from the Investor Placing Agreement, as set out in note 6.

The shares to be issued reserve of £0.5m (2022: £nil) relates to the warrants issued as part of the Investor Placing Agreement.

Net assets closed at £2.0m (2022: £5.6m). The comprehensive loss for the year was £5.2m (2022: £4.7m).

Going concern

As outlined in the Chairman's statement, the Group and Company needs to bridge the funding gap before revenue generation allows us to be self-sufficient. The Board is actively considering financing options. This short-term funding requirement is partly as a result of the uncertainty of further drawdowns from the Investor Placing Agreement which are conditional on certain factors including the Company's share price. The Company remains in close dialogue with the investors, further drawdowns would extend the cash runway and therefore the timeline for our planned financing activities. The Group does also expect to receive an R&D tax credit of c£0.8m in Q1 of 2024 which, if received, would extend the cash runway (absent any further funding received) towards the end of Q1 2024 and provide a longer window for our planned financing activities. As well as equity or debt financing we are also actively seeking non-dilutive funding such as grants, funding partners for the FDA approval and charitable organisations willing to support the adoption of our quality-of-life enhancing innovations.

We are beginning to gain commercial traction, RNR1 is in routine use at a small number of hospitals and with the appointment of international distributors, language packs and registrations complete, we are confident that significant revenues will follow. NHS specialist commissioning would expediate this, but as we are not in control of the process, there is uncertainty as to the timing.

The NICE EVA (Early Value Assessment) recommendation supports our belief that our RNR1 test quickly and accurately identifies babies, who may be at risk of hearing loss if given aminoglycoside antibiotics, allowing equally effective alternative antibiotics to be used instead and that the long-term savings to the NHS associated with hearing loss and fitting cochlear implants could be substantial.

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 2023

	Note	**Year ended 30 June 2023 £'000**	Year ended 30 June 2022 £'000
Continuing operations			
Revenue	2	**55**	49
Research and development costs		**(3,924)**	(3,871)
Administrative costs		**(1,355)**	(1,793)
Operating loss		**(5,224)**	(5,615)

Finance costs	3	**(757)**	(16)
Loss on ordinary activities before taxation		**(5,981)**	(5,631)
Taxation	4	**831**	956
Loss for the financial year		**(5,150)**	(4,675)
Loss/total comprehensive expense for the financial year		**(5,150)**	(4,675)
Loss per share (pence)			
- Basic and diluted	5	**(5.5p)**	(5.5p)

Consolidated Balance Sheet

as at 30 June 2023

	Note	**30 June 2023 £'000**	30 June 2022 £'000
Assets			
Non-current assets			
Property, plant and equipment		**392**	206
		392	206
Current assets			
Inventories		**525**	748
Trade and other receivables		**158**	107
Contingent consideration receivable		**-**	15
Current tax asset		**831**	956
Cash and cash equivalents		**2,601**	4,589
		4,115	6,415
Total assets		**4,507**	6,621
Liabilities			
Current liabilities			
Trade and other payables		**(935)**	(994)
Lease liabilities		**(222)**	(16)
Derivative financial instruments	6	**(1,290)**	-
		(2,447)	(1,010)
Non-current liabilities			
Lease liabilities		**(19)**	-
Total liabilities		**(2,466)**	(1,010)
Net assets		**2,041**	5,611
Equity			
Called-up equity share capital	7	**1,485**	1,388
Other reserves	8	**52,777**	51,294
Accumulated losses		**(52,221)**	(47,071)
Total equity		**2,041**	5,611

Consolidated Statement of Changes in Equity

for the year ended 30 June 2023

	Share capital £'000	Other reserves £'000	Accumulated losses £'000	Total equity £'000
Balance at 30 June 2021	**950**	**45,000**	**(42,358)**	**3,592**
Transactions with owners in their capacity as owners:				
Share issue	426	6,186	-	6,612
Share issue - deferred consideration	8	(8)	-	-
Equity-settled share-based payments	4	116	(38)	82
Transactions settled directly in equity	438	6,294	(38)	6,694
Total comprehensive loss for the year	-	-	(4,675)	(4,675)
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**

Consolidated Cash Flow Statement

for the year ended 30 June 2023

	Note	**Year ended 30 June 2023 £'000**	Year ended 30 June 2022 £'000
Cash flows from operating activities			
Operating loss for the year		**(5,224)**	(5,615)
Depreciation, amortisation and impairment		**61**	63
Depreciation, right-of-use assets		**193**	187
Share-based payment		**96**	38
Operating loss before changes in working capital		**(4,874)**	(5,327)
Decrease / (increase) in inventories		**223**	(192)
(Increase) / decrease in trade and other receivables		**(51)**	51
Decrease in trade and other payables		**(59)**	(292)
Net cash outflow from operating activities before taxation		**(4,761)**	(5,760)

Tax received		**956**	1,166
Net cash outflow from operating activities		**(3,805)**	(4,594)
Cash flows from investing activities			
Finance income		**29**	-
Finance costs		**-**	(16)
Acquisition of plant and equipment		**(52)**	(62)
Proceeds from disposal of discontinued operations		**15**	107
Net cash (outflow) / inflow from investing activities		**(8)**	29
Cash flows from financing activities			
Proceeds from the investment placing agreement	6	**2,300**	-
Transaction costs relating to investment placing agreement		**(283)**	-
Proceeds from share issue		**-**	7,200
Transaction costs relating to share issue		**-**	(506)
Repayment of lease liabilities		**(193)**	(119)
Net inflow from financing activities		**1,824**	6,575
Net (decrease) / increase in cash equivalents		**(1,989)**	2,010
Effects of exchange rate changes on cash and cash equivalents		**1**	5
Cash and cash equivalents at beginning of year		**4,589**	2,574
Cash and cash equivalents at end of year		**2,601**	4,589
Analysis of net funds			
Cash at bank and in hand		**2,601**	4,589
Net cash		**2,601**	4,589

Notes to the Financial Information

for the year ended 30 June 2023

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 2022 has been extracted from the Group's audited statutory financial statements which were approved by the Board of Directors on 18 November 2022 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 2023 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 2023 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 with UK-adopted International Accounting Standards.

This announcement was approved by the board of directors on 29 November 2023 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 and drawdowns from the Investor Placing Agreement, which are subject to certain conditions as described in note 6. 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 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 early 2024 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 in early 2024 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 now 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.

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 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)

Business segments	Diagnostics segment £'000	Corporate costs £'000	Total £'000
Year ended 30 June 2022			
Revenue	49	-	49
Operating loss	**(3,822)**	**(1,793)**	**(5,615)**
Net finance costs			(16)
Loss on ordinary activities before taxation			**(5,631)**
Taxation			956

Loss for the financial year	(4,675)
Total comprehensive expense for the year	**(4,675)**

	Diagnostics segment £'000	Corporate costs £'000	Total £'000
Year ended 30 June 2023			
Segment assets	960	3,547	4,507
Segment liabilities	(877)	(1,589)	(2,466)
Year ended 30 June 2022			
Segment assets	1,003	5,618	6,621
Segment liabilities	(905)	(105)	(1,010)

Additions to non-current assets: Diagnostics segment £353k (2022: £124k) and Corporate costs £88k (2022: £31k).

Geographical segments

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

All on continuing operations	**Year ended 30 June 2023 £'000**	Year ended 30 June 2022 £'000
United Kingdom	**35**	37
Europe	**16**	10
United States of America	**4**	2
Rest of the world	**-**	-
	55	49

Revenues from three customers accounted for more than 10% of total revenue in the current year (2022: two).

3. Finance income/(costs)- net

	Year ended 30 June 2023 £'000	Year ended 30 June 2022 £'000
Interest income on bank deposits	**30**	-
Transaction costs relating to investment placing agreement (note 6)	**(81)**	-
Movement in fair value of derivative financial instrument (note 6)	**(675)**	-
Finance lease costs	**(31)**	(16)
	(757)	(16)

4. Taxation

(a) Recognised in the income statement

Current tax:	**Year ended 30 June 2023 £'000**	Year ended 30 June 2022 £'000
Research and development tax credits	**(831)**	(956)
Total tax credit for the year	**(831)**	(956)

(b) Reconciliation of the total tax credit

The tax credit assessed on the loss for the year is lower (2022: lower) than the weighted average applicable tax rate for the year ended 30 June 2023 of 20.5% (2022: 19.0%). The differences are explained below:

	Year ended 30 June 2023 £'000	Year ended 30 June 2022 £'000
Loss before taxation on continuing operations	**(5,981)**	(5,631)
Tax using UK corporation tax rate of 20.5% (2022: 19.0%)	**(1,226)**	(1,070)
Adjustment in respect of R&D tax credit claimed	**(295)**	(412)
Items (taxable) for tax purposes - permanent	**140**	(7)
Items not deductible for tax purposes - temporary	**(2)**	(3)
Deferred tax not recognised	**686**	703
Rate differences	**(134)**	(167)
Total tax credit for the year	**(831)**	(956)

No deferred tax assets are recognised at 30 June 2023 (2022: £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 £21,676k (2022: £19,032k) available to carry forward to future periods; this excludes management expenses.

5. Earnings per share

	2023 £'000	2022 £'000
Loss for the year after taxation	**(5,150)**	(4,675)

Group	**2023 Number**	2022 Number
Weighted average number of ordinary shares in issue	**94,165,295**	84,860,240
Potentially dilutive ordinary shares	**-**	-
Adjusted weighted average number of ordinary shares in issue	**94,165,295**	84,860,240

Loss per share on continuing operations		
- Basic	**(5.5)p**	(5.5)p
- Diluted	**(5.5)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	**2023 Number**	2022 Number
Potentially dilutive shares from share options and warrants	**1,163,817**	971,238
Potentially dilutive shares within the SIP	**339,967**	208,703
Potentially dilutive ordinary shares	**1,503,784**	1,179,941

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. A further drawdown was made in June 2023 of £0.3m and the remaining balance as at the balance sheet date of £2.7m 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.

Pursuant to the facility, the Noteholders were granted warrants exercisable at 41.6p to subscribe for 2,500,000 ordinary shares and were granted warrants exercisable at 24.607p to subscribe for 682,731 ordinary shares. All warrants remain outstanding at 30 June 2023 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 £2.3m during the financial year 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**				

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).

7. Share capital

Allotted, issued and fully paid:

	Number	£'000
Balance at 30 June 2021	63,320,048	950
Share issue - equity-settled share-based payments	271,546	4
Share issue - deferred consideration	500,000	8
Share issue	28,450,852	426
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**

On 1 October 2021 the Company issued 28,450,852 shares as part of a placing and open offer to shareholders for net proceeds of £6.6m.

On 10 December 2021 the Company issued 500,000 shares in genedrive plc to the former owner of Visible Genomics as part of a Deed of Amendment agreed in December 2018 to the Visible Genomics Sale and Purchase Agreement.

On 3 April 2023 the Company issued 6,500,000 shares with a nominal value of £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 2021	46,055	115	(196)	1,522	(2,496)	45,000
Share issue - deferred consideration	107	(115)	-	-	-	(8)
Share issue	6,264	-	-	-	-	6,264
Equity-settled share-based payments	-	-	-	38	-	38
Transactions settled directly in equity	6,371	(115)	-	38	-	6,294
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**

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.

9. Post balance sheet events

The Company made two £0.3m drawdowns under the Investor Placing Agreement (note 6) and issued 724,997 and 1,614,669 warrants to the Noteholders in July 2023 and November 2023 respectively.
The Company signed the DEVOTE funding grant post year end.

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