RNS Number : 5006F
Genedrive PLC
17 November 2020

The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

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

Audited Final Results

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces its audited Final Results for the year ended 30 June 2020.

Financial Highlights

- Revenue for the year to 30 June 2020 in line with expectations at £1.1m (2019: £2.4m), with H2 revenues significantly impacted by COVID-19 disruption
- Year-end cash of £8.2m (Dec 2019: £3.5m) following a successful equity fundraise in May 2020
- Balance sheet further strengthened through conversion of the US$8.0m Global Health Investment Fund bond
- At year end over £1.0m of initial orders for Genedrive® 96 SARS-CoV-2 kit, pending regulatory approvals
- Post year end, no material sales for 96 SARS-CoV-2 test as we await further registrations, but further orders are anticipated through a widened network of partners. Pipeline includes an advanced opportunity for supply to a Ministry of Health of a European country, which if converted to a sale, could be for low double digit millions of pounds and delivered in the first quarter of 2021
- Unaudited cash of £5.1m at 31 October 2020 after securing long lead time supplies and building initial stocks

Operational Highlights

- HCV test obtained WHO pre-qualification status
- AIHL test CE-marked and distributor contracted for UK product launch
- Framework contract with the DoD increased by $2.0m
- Genedrive® 96 SARS-CoV-2 test CE marked and modest first commercial sales achieved
- Genedrive® SARS-CoV-2 Kit for Point of Care demonstrates positive results from saliva in approximately 15 minutes. Development remains on track with launch anticipated in March 2021
- Post CE mark for 96 SARS-CoV-2 Kit - expanded extraction claims achieved and migrated Kit across wider range of RT-PCR instrument platforms

- First overseas regulatory approval in September 2020 with South Africa Health Products Regulatory Authority validating the test
- Initial feedback from FDA EUA submission received in November 2020 but no visibility on EUA timescales
- Expecting additional regulatory approvals, but timing remains undefined
- Post year end significant progress made with collaboration agreement with Beckman Coulter to bring a fully automated testing solution to the market
- Recent vaccine news is very welcome but the Board remains confident that high throughput and point of care Covid-19 testing opportunities will be a critical part of controlling the pandemic for a considerable period of time

David Budd, Chief Executive Officer of Genedrive plc, said: *"With a growing pipeline and opportunities across a range of healthcare markets I believe genedrive is very well placed for the future. We remain confident in our SAR CoV-2 products and through our network of commercial and other partners we see significant commercial opportunities ahead although additional regulatory clearances are still awaited in certain key territories. We will enter 2021 with a stronger product portfolio and a stronger balance sheet and ready to enter a new growth phase for the Company and its assays."*

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The person responsible for the release of this announcement on behalf of genedrive plc is Matthew Fowler, Chief Financial Officer.

Notes to Editors

About genedrive plc

genedrive plc is a molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications. The Genedrive® HCV-ID kit has received CE-IVD Certification and has been launched in Africa and Asia Pacific. genedrive has distribution agreements with subsidiaries of Sysmex Corporation for the distribution of

the Genedrive® platform in the EMEA and SE Asia (ex-India), and with ARKRAY Healthcare pvt Ltd for the distribution of the Genedrive® HCV-ID Kit and Genedrive® platform in India. The Company has assays on market for the detection of certain biological targets and has tests in development for tuberculosis (mTB) and Antibiotic Induced Hearing Loss (AIHL).

Further details can be found at: www.genedriveplc.com and www.genedrive.com.

Chairman's Statement

"Our adaptability and people drive the Company's ability to bring innovation and rapid product development to customers."

The past 12 months have brought some immense challenges and indeed some significant opportunities as key industry players found their place to contribute to the global Covid-19 crisis. genedrive has adapted well and emerged in a stronger position with an expanded product portfolio, a stronger balance sheet and a growing pipeline of sales opportunities.

With the challenge of Covid-19 came the opportunity for genedrive to innovate and respond - which we did with the development and launch of the Genedrive® 96 SARS CoV-2 Kit. Combining our deep technical capabilities in PCR with our manufacturing partner's abilities in freeze drying, we developed a unique and innovative Covid-19 test that we launched in and began selling in June. In parallel with the high volume test we began to develop a point of care Covid-19 test to run directly on the Genedrive® platform - a product that will be launched in the coming months.

In order to develop and launch a range of Covid-19 products the Group raised £8.0m (gross) through an equity funding announced in May 2020. Part of these funds were used in June 2020 to pay the interest due to Global Health Investment Fund (GHIF) when they elected to convert their $8.0m convertible bond. Conversion of this bond significantly strengthened the Group's balance sheet, reducing cash debt to £2.7m, (2019: £8.5m).

The focus of healthcare systems around the world on Covid-19 clearly impacted our assay strategies in the second half of the year with little commercial traction owing to low activity in hospitals on non-Covid related products. Our AIHL hospital trial programme was slowed, but still continued throughout the period through the energy and commitment of our clinical partners in the NHS, and is now due to complete imminently. Our HCV product saw limited sales but with WHO pre-qualification status achieved during the initial lockdown period, we are hopeful to see a positive pick-up in sales as and when the world returns to the new normal. Our US DoD contract was not directly impacted with sales being approximately as expected, but availability of funding may affect the timing of the next phase of the customer's purchase plans.

Performance

Revenue for the first half of the year was £0.6m and was on plan with our targets for the full year. However when Covid-19 began to impact in early 2020 it impacted our ability to commercialise the HCV product and full year revenues were £1.1m (2019: £2.4m).

Operational performance in the first half of the year was centred around the development of our AIHL product that was CE marked in November 2019 and launched into NHS Hospital trials in January 2020. We remain enthusiastic about the product's opportunities and very pleased with the partnership entered into with Inspiration Healthcare plc, experts in neonatal care and able to exploit the potential of this neonatal test.

Despite good progress on the AIHL test, the second half of the year was defined by our innovation and rapid development of two Covid-19 tests. We made a decision in March 2020 to develop a high throughput test, CE marked it at the end of May and began commercial sales in June. Our historical distribution partners do not cover Europe, so we have been working to establish new relationships in Europe while focusing on opportunities in India, Africa and the United States. The subsequent roll out and sales of the test have been impacted by delays in obtaining regulatory approvals from third party agencies as well as expanding claims to new platforms and both automated and manual extraction processes, to further improve product performance and positioning. Post year end we received South African approval for the test and also entered into a collaborative relationship with Beckman Coulter to deliver a high volume testing solution on their automated equipment. We have ongoing dialogue with the Indian regulators but progress has been slow. In November the FDA provided initial feedback of our EUA application, and requested additional information primarily related to new requirements and methodologies they introduced after our initial submission earlier in the year. We also provided additional data to the World Health Authority (WHO) in November. At this time we do not have visibility from the FDA, WHO or the Indian regulatory agency on approval timelines but we believe the opportunities in these countries remain very significant. The focus of our development on Covid-19 products will continue into early calendar year 2021. Once the development is complete the team will revert to our Tuberculosis product development activities. Tuberculosis is still a significant unmet need and an attractive opportunity for the Company and one which we are targeting to launch a new product in 2022.

Governance and People

The Board has continued to focus on a strong governance framework, ensuring that internal controls, values and culture align with our strategy. We aim to have a governance structure that meets the medium term requirements of the Company.

The Board remains focused on ensuring its own effectiveness and that of the governance processes throughout the Group. We believe we have a board that reflects our strategy and ambition and will continue to review its effectiveness.

Outlook

In the short term the Covid-19 global crisis significantly impacts our ability to be definitive in our outlook. With a focused portfolio of products and our reliance on healthcare markets, demand will be impacted by the priorities of countries Covid-19 responses. But conversely our Covid-19 products, the on-market high volume lab assay and the soon to be launched point of care saliva based test, provide great opportunities. Although initial

commercialisation of the high volume assay has experienced some delay we continue to focus on building sales through collaborations such as the one with Beckman Coulter and our other existing relationships. Our pipeline of sales opportunities for the 96 SARS-CoV-2 test is growing and includes a potential supply contract to a Ministry of Health of a European country. If converted to a sale this would be for low double digit millions of pounds of revenue and delivered in the first quarter of the new calendar year without the need for prolonged regulatory approvals. For our point of care test we are expecting to CE mark and launch the product in March 2021. We expect it will contribute significantly to the on-going management of Covid-19 and will also be an important contributor to sales for genedrive. Until such opportunities with our Covid-19 tests are crystalised we will continue to manage the cost base appropriately.

Despite these challenges our strategy is to position ourselves to react decisively and quickly to adapt to the changes and take advantage of opportunities that will emerge. In terms of AIHL and DoD Pathogen detection we expect to see a step up in demand through the coming year as these products enter new phases in their lifecycles. Whilst the past year presented many challenges it has also offered many opportunities which have the potential to deliver significant revenues and cash flows for the Group. The level of demand for Covid-19 testing remains high and even with vaccines on the horizon we believe this demand will continue for a considerable period of time and we will continue to maintain focus on our two product strategy with both lab based and point of care solutions. I remain confident of genedrive's ability to deliver and grow significantly over the coming years.

Dr Ian Gilham
Chairman
16 November 2020

Chief Executive's Review

"The previous year brought some immense challenges and fantastic opportunities."

Overview

During the first half of the year we continued to execute on our product and commercial strategy. However with the emergence of Covid-19 in the second half of the year we saw revenues on our core assays stall, just as many companies found as global markets went into quarantine. Despite the impact on revenues, Covid-19 brought real opportunity to genedrive as a commercial stage molecular diagnostics company. We were quick to develop solutions and brought a genuinely unique product to market in rapid time.

Reacting to the COVID-19 global crisis

As announced on 25 March 2020, following the rapid global shift of healthcare emphasis towards testing and treatment of Covid-19, the Company refocused a significant part of its

core resources towards development of two SARS-CoV-2 tests to detect active Covid-19 infections.

The first test is a high throughput laboratory test and the second test, expected to be launched in March 2021, is a point-of-care test that will run on the Genedrive® instrument. The high throughput test was CE marked in May 2020 and we commenced commercial sales in June 2020. Despite having CE marking, our historical distribution partners focus on Africa, Asia and India and so we have been working to establish new relationships in Europe. In the UK, we have not focused on opportunities in the NHS due to their existing supply contracts, and their migration to 384-well format platforms in the new 'Lighthouse' labs. We do however believe our point of care device should have considerable relevance to the NHS.

After CE marking and initial launch, we continued to extend the product's claims, including the introduction of automated extraction processes and with the development of the Genedrive® Exporter tool to simplify analysis for the user. The registration and regulatory approval processes of the test has had to take account of the various formats of our product - we effectively have three distinct product variants for different lab machines. As indicated in May we obtained the CE mark on the Roche Lightcycler and have extended the validation to include the ABI 7500 FAST and BioRad CFX96 systems to the range of instruments on which the assay is CE Marked.

We have focused in specific target markets and obtained South African approval in September 2020 which was a clear validation of the product. We are currently pending on regulatory approvals in the US (EUA approval), with WHO and in India but have limited information on timescales which we believe is owing to the huge burden of activity on their regulatory bodies.

While there has been excellent sales funnel progression since the summer, there have been no material deliverable contracts to date as further key registrations have not yet been achieved. We have also focused commercially on the larger, more strategic opportunities that by their nature take longer to come to fruition. These are higher risk, but higher reward. We remain optimistic about the full potential of the test, and our pipeline of sales opportunities for 96 SARS-CoV-2 test includes a supply opportunity to a Ministry of Health of European country which the company is engaged with directly. This opportunity is at an advanced stage but may of course not conclude successfully. If we are successful the total revenue expectation is for low double digit millions of pounds in the first quarter of the new calendar year and we do not expect additional approval processes. We expect that our high throughput test will make a significant contribution to revenue over the coming periods. Finally, new relationships in new markets, such as with Beckman Coulter are presenting new and unique revenue opportunities for the Company.

The second test, the point of care assay on the Genedrive® device is due for preliminary release (Research Use Only) around December 2020 with a full CE marked product targeted for March 2021. While first to market opportunities are significant, the underlying qualities and reliability of a test are also of significant importance. I therefore believe that customers are looking for accurate validated products and that the advantages of being deployable and rapid, mean we can address a global market flexibly with the Genedrive® device. Post

year end we announced that our test would be a saliva based assay with a design goal of achieving results within 15-20 minutes and with a limit of detection within the accepted product profile targets of the UK Government. While recent vaccine news is very welcome, we have a high degree of confidence that high throughput and point of care Covid-19 testing opportunities will be a critical part of controlling the pandemic for a considerable period of time. We remain fully focused on exploiting the commercial opportunities arising on testing for both assays.

Our performance

HCV

The CE marked Genedrive® HCV ID Kit was brought to market in March 2018. It is the first low cost, qualitative molecular decentralised testing product on the market. We achieved World Health Organisation pre-qualification status in May 2020. Prequalification means the Genedrive® HCV ID kit will be included in the WHO list of prequalified in vitro diagnostics (IVDs) and becomes eligible to participate in the procurement processes of UN agencies. WHO Member States are encouraged to use the WHO list of prequalified IVDs for their respective procurement decisions. To date, it has been a challenging opportunity due to low funding in market for HCV drugs and consequently diagnostics. The redirection of healthcare's focus to Covid-19 saw sales activity reduce significantly in the second half of the year.

Despite the Covid-19 market issues, the market opportunity remains, and as healthcare priorities move back away from Covid-19 with our WHO pre-qualification status and our experienced distribution partners we are positioned to quickly and efficiently exploit opportunities.

Pathogen detection tests for US DoD

Revenue in the year was £0.4m down £0.5m on the prior year, but this was expected as 2019/20 was a transition year for the DoD contract. The initial DoD development contract that had been worth approximately $10.0m over its life came to an end during 2019, and was extended by $2.0m in November 2019. This extension allows the DoD to continue ordering into their new financial year when it is expected they will enter a long-term supply contract. While final unit numbers and assays will be subject to confirmation and allocation of funding, the expectation is that the DoD will procure up to 500 Genedrive®'s and associated assays over a three year period and we now expect to begin contract discussions in early 2021.

The DoD development contract has been a success for genedrive over the years supporting development of the Genedrive® capabilities, providing funding to the Group, delivering a complex product to the customer specification, and providing ongoing revenue. We had significant headwinds in being able to supply the DoD for part of the year owing to supplier quality issues. The Company ultimately transferred production of DoD product to Cytiva. We have every belief that the product and the customer will form a significant part of the business in the coming years.

Antibiotic Induced Hearing Loss

In June 2018 the Group was part of an award from UK NHS National Health Research for the development and implementation of a point of care test for the prevention of hearing

loss in new-born children when exposed to certain antibiotics. The genedrive allocation of the award has been used to fund the product through development, and is now supporting our in-hospital validation processes during clinical trials at 2 NHS sites. The Genedrive® MT-RNR1 assay has been designed and manufactured to run a highly accurate test in 27 minutes - within the National Institute of Clinical Excellence "golden hour" needed for clinicians to assess and prescribe alternative antibiotics. I am thoroughly excited about the global commercial and clinical prospects as well as the healthcare benefits of this first use of a molecular test in a neonatal emergency setting.

The product is due to be launched on a targeted basis in UK and Ireland at the end of 2020 with full commercial roll out planned for June 2021. We signed a distribution agreement with Inspiration Healthcare plc in April 2020. With the neonatal sales knowledge of Inspiration Healthcare we expect commercial traction from early adopters at launch, then 12-18 months later waves of large demand following write-up and inclusion in paediatric guidelines; if successful there should be adoption in the NHS and further afield.

The market is potentially very attractive as being both large and at a higher margin compared to global health-related tests. This opportunity is well suited to the Genedrive®, needing multiple, low-cost units to deliver fast testing at a point of need.

mTB

Tuberculosis remains one of the largest molecular testing markets in the world and in terms of routes to market and process it is well defined. It is an important market for the Group and a vital component of our strategy. We have therefore not changed our stance on the importance of accessing this market, but owing to the focus on Covid-19 have pushed out our time horizon for product launch to 2022.

Outlook

At the end of a challenging year, we are now in a fundamentally stronger position, aided by the £8m (gross) fund raise in May 2020 and the conversion of loan notes in June 2020 and post year end in September 2020. We were nimble in reacting to Covid-19 and we now have four assays on market: HCV, DoD Biohazard, AIHL, and COVID 96 rapid test, and while there have been delays and there remain some uncertainties around regulatory approvals for the Covid tests, we remain confident in the product's potential and our pipeline. We also have two products in development: mTB and a COVID point-of-care test. These products are expected to produce meaningful revenues in the future.

It has been a challenging year, but genedrive was in the fortunate position to have invested in the capabilities and people needed to exploit its position in PCR, and emerge a better and stronger company. Our products and pipeline provide us with confidence that we will deliver strong growth and much increased shareholder value.

David Budd
Chief Executive Officer
16 November 2020

Financial Review

"The fundraise in May 2020 provided a net capital injection of £7.5m to help fund the development and launch of the Genedrive® COVID-19 products."

Revenue and other income for the year was £1.1m (2019: £2.4m). COVID-19 had an impact on sales in the second half of the year and the expected sales traction on our HCV and DoD assays did not take place as expected with customers prioritising their activities elsewhere.

Research and development costs were £4.7m (2019: £4.9m) and reflected an increased spend in the second half of the year related to the COVID-19 assay. Overall spend was slightly down on the year to June 2019 owing to reduced activity and tight cost control in the first half of the year.

Administration costs were £2.0m, up slightly from the prior year £1.9m. The majority of this cost increase was related to the second half of the financial year where certain share price linked costs increased as the share price increased.

The trading loss for the year was £5.6m (2019: £4.4m) and the increase was owing to the reduced revenue in the year. There were no exceptional costs in the year (2019: £0.4m gain), giving an operating loss of £5.6m (2019: £4.0m).

Financing costs

Financing costs were £14.7m (2019: £0.5m). The finance costs are associated with the convertible bonds outstanding during the year. The finance cost on the convertibles has several elements: an interest charge that unwinds the discount on these long term liabilities, a foreign exchange impact from the US dollar denominated GHIF bond and finally a derivative charge for the 'option' of the bond holders to convert the bond to shares in the Group. The interest on unwinding the discount and foreign exchange movements were £1.0m and were broadly in line with the prior year £1.1m. Owing to the increase in the Group share price from 20.5p at 30 June 2019 to 102p at 30 June 2020, the cost of the conversion rights on the two bonds increased by £13.8m and this is treated as an expense through the finance costs. In the prior year a falling share price since 30 June 2018 created a £0.3m gain. These movements are non-cash and merely reflect the changing value of the options to convert. As GHIF converted their bond on the 16 June 2020 and BGF partially converted their bond in September 2020, the only financing costs remaining will relate to the residue £1.5m BGF bond and as the share price rises or falls against the 30 June 2020 price of 102p a further charge or release to financing costs will be recognised.

Taxation

The tax credit for the year was £1.0m (2019: £0.9m). The Group investment in R&D falls under the UK Government's R&D tax relief scheme for small and medium companies where it meets the qualifying criteria. The tax credit was larger than originally forecasted owing to the increase in qualifying criteria as the Group invested and developed the COVID-19 assay

that was not expected at the start of the year. As the Group did not make a profit in the year it collects the tax credit in cash following submission of tax returns. The expected receivable on the balance sheet is £1.0m (2019: £1.0m).

The loss for the financial year after tax was £19.4m (2019: £3.6m), with £14.7m of this loss being non-cash financing costs relating to convertibles bonds.

Cash resources

Net cash outflow from operations was £4.8m (2019: £4.6m). The operating losses were £5.6m (2019: £4.4m) with working capital contributing £0.8m (2019: £0.2m consumption) mainly from an increase in trade and other payables.

The tax credit received was £1.0m (2019: £1.0m) and relates to cash received under the UK Government's R&D tax relief scheme. The current year tax debtor is £1.0m (2019: £1.0m) and we would expect receipt in the months following release of these statutory accounts.

The net proceeds from financing activities were £6.9m (2019: £5.3m). The net proceeds from equity were £7.5m. Cash paid to GHIF as part of the conversion of their loan note was £0.7m.

The increase in cash was £3.0m (2019: £1.7m) meaning a closing cash position of £8.2m (2019: £5.2m).

Balance sheet

Balance sheet net liabilities at 30 June 2019 totalled £2.5m and this increased slightly to £3.3m at 30 June 2020. The deficit is mainly owing to the non-cash accounting adjustment on the BGF derivative and without this item the balance sheet would be in net assets as a result of the equity raise in May 2020. As the balance sheet position has remained in net liabilities throughout the year, there was no requirement under section 656 of the Companies Act to call a meeting of shareholders and discuss the net liabilities position.

Current assets of £10.3m (2019: £6.9m) included cash of £8.2m (2019: £5.2m) following the successful May 2020 fund raise. The tax receivable was £1.0m (2019: £1.0m) for the current year Corporation Tax Research and Development tax claim and this should be paid by the end of the calendar year. The remaining working capital-related items make up £1.0m (2019: £0.8m) with the largest increase in inventory being high average balances of COVID-related materials which are being held to mitigate long lead time supply.

Current liabilities were £2.2m (2019: £1.2m) with the large increase related to the purchase commitment on COVID-19 materials as well as property rent that was deferred during lockdown but that was paid post year end.

Capital and reserves were affected by two notable items in the second half of the financial year. The fund raise in May 2020 provided a net capital injection of £7.5m to help fund the development and launch of the Genedrive® COVID-19 products. Secondly in June 2020, GHIF, the holders of an $8.0m convertible bond, exercised their right to convert their bond into shares in genedrive plc. As part of the settlement with GHIF, the Group paid GHIF £0.7m and issued 7.1m shares. The net equity impact of the GHIF conversion was a £10.9m credit to reserves. In addition to these two large movements, there were share-

based payment movements of £46k and a loss for the year of £19.4m, meaning an increase in net liabilities of £0.8m.

Going concern

We have experienced delays commercialising the Genedrive® 96 SARS CoV-2 test and the lack of revenue has impacted our cash position. However we continue to focus on obtaining product approvals and securing sales and we are managing the cost base until revenues are assured. We are confident in our sales forecasts but securing cash generative revenue in the forthcoming months is necessary otherwise the Group will have
to reduce costs and raise additional funds. We continue to adopt a going concern basis for the preparation of the accounts, but 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.

Risk management and the year ahead

Risk is managed closely and is spread across our businesses and managed to individual materiality. The Board has reviewed and considered the impact of the UK's departure from the EU and has considered the issues relating to a no-deal departure. The Board has considered all of the above factors in its review of going concern and has been able to conclude the review satisfactorily.

Matthew Fowler
Chief Financial Officer
16 November 2020

Consolidated Statement of Comprehensive Income
for the year ended 30 June 2020

	Note	**Year ended 30 June 2020 £'000**	Year ended 30 June 2019 £'000
Continuing operations			
Revenue	2	**1,059**	2,362

Research and development costs		**(4,673)**	(4,877)
Administrative costs		**(2,026)**	(1,934)
Trading loss		**(5,640)**	(4,449)
Exceptional items	3	**-**	439
Operating loss		**(5,640)**	(4,010)
Finance costs	4	**(14,744)**	(508)
Loss on ordinary activities before taxation		**(20,384)**	(4,518)
Taxation on ordinary activities	5	**965**	882
Loss for the financial year		**(19,419)**	(3,636)
Loss/total comprehensive expense for the financial year		**(19,419)**	(3,636)
Loss per share (pence)			
- Basic and diluted	6	**(55p)**	(14p)

Consolidated Balance Sheet

as at 30 June 2020

	Note	**30 June 2020 £'000**	30 June 2019 £'000
Assets			
Non-current assets			
Plant and equipment		**147**	164
Contingent consideration receivable	7	**47**	153
		194	317
Current assets			
Inventories		**413**	123
Trade and other receivables		**398**	556
Contingent consideration receivable		**212**	106
Current tax asset		**1,018**	971
Cash and cash equivalents		**8,218**	5,184
		10,259	6,940
Liabilities			
Current liabilities			
Deferred revenue		**(67)**	(88)
Trade and other payables		**(2,129)**	(1,129)
		(2,196)	(1,217)
Net current assets		**8,063**	5,723

Total assets less current liabilities		**8,257**	6,040
Convertible bonds	8	**(11,599)**	(8,518)
Net liability		**(3,342)**	(2,478)
Capital and reserves			
Share capital			
Called-up equity share capital	9	**780**	510
Other reserves		**42,620**	28,112
Accumulated losses		**(46,742)**	(31,100)
Total deficit		**(3,342)**	(2,478)

Consolidated Statement of Changes in Equity

for the year ended 30 June 2020

	Share capital £'000	Other reserves £'000	Accumulated losses £'000	Total equity £'000
Balance at 30 June 2018	282	24,745	(27,464)	(2,437)
Share issue	228	3,015	-	3,243
Deferred consideration equity component	-	315	-	315
Equity-settled share-based payments	-	49	-	49
FX on translation of overseas assets	-	(12)	-	(12)
Transactions settled directly in equity	228	3,367	-	3,595
Total comprehensive loss for the year	-	-	(3,636)	(3,636)
Balance at 30 June 2019	510	28,112	(31,100)	(2,478)
Share issue - deferred consideration	13	(13)	-	-
Share issue	150	7,383	-	7,533
Share issue - conversion of GHIF bond (note 9)	107	7,092	3,777	10,976
Equity-settled share-based payments	-	46	-	46
Transactions settled directly in equity	270	14,508	3,777	18,555
Total comprehensive loss for the year	-	-	(19,419)	(19,419)
Balance at 30 June 2020	**780**	**42,620**	**(46,742)**	**(3,342)**

Consolidated Cash Flow Statement

for the year ended 30 June 2020

	Note	**Year ended 30 June 2020 £'000**	Year ended 30 June 2019 £'000
Cash flows from operating activities			
Operating loss for the year		**(5,640)**	(4,010)
Depreciation, amortisation and impairment		**57**	98
Exceptional items (all non-cash)		**-**	(439)
ATL Research credits		**(53)**	(89)
Share-based payment		**32**	49
Operating loss before changes in working capital and provision		**(5,604)**	(4,391)
Increase in inventories		**(290)**	(12)
Decrease in trade and other receivables		**158**	60
Decrease in deferred revenue		**(21)**	88
Increase/(Decrease) in trade and other payables		**1,000**	(346)
Net cash outflow from operations		**(4,757)**	(4,601)
Tax received		**971**	980
Net cash outflow from operating activities		**(3,786)**	(3,621)
Cash flows from investing activities			
Finance income		**13**	18
Finance costs		**(15)**	-
Acquisition of plant and equipment and intangible assets, net of loss on disposals		**(40)**	(97)
Proceeds from disposal of discontinued operations		**-**	56
Net cash outflow from investing activities		**(42)**	(23)
Cash flows from financing activities			
Proceeds from share issue	9	**7,546**	3,243
Proceeds from bond issue		**-**	2,366
Cash paid to settle convertible bonds		**(685)**	-
Cash paid to settle deferred consideration		**-**	(300)
Net inflow from financing activities		**6,861**	5,309
Net increase in cash equivalents		**3,033**	1,665
Effects of exchange rate changes on cash and cash equivalents		**1**	(10)
Cash and cash equivalents at beginning of year		**5,184**	3,529
Cash and cash equivalents at end of year		**8,218**	5,184

Analysis of net funds		
Cash at bank and in hand	**8,218**	5,184
Net funds	**8,218**	5,184

Notes to the Consolidated Financial Statements

for the year ended 30 June 2020

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 2019 has been extracted from the Group's audited financial statements which were approved by the Board of Directors on 3 October 2019 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, but did include a matter to which the auditors drew attention by way of emphasis without qualifying their report.

The report of the auditor on the 30 June 2020 financial statements was unqualified, did not contain a statement under Section 498(2) or Section 498(3) of the Companies Act 2006 but did include a matter to which the auditors drew attention by way of emphasis without qualifying their report relating to the basis of preparation which is reproduced below:

Material uncertainty relating to going concern

We draw attention to note 1 on going concern in the financial statements concerning the group and parent company's ability to continue as a going concern. The going concern status of the group and parent company is dependent upon the achievement of 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 funding from shareholders. As stated in note 1 on going concern, these events or conditions, indicate that a material uncertainty exists which may cast significant doubt on

the group and parent company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

The information included in this preliminary announcement has been prepared on a going concern basis under the historical cost convention, and in accordance with International Financial Reporting Standards (IFRSs) as adopted by the EU and the International Financial Reporting Interpretations Committee (IFRIC) interpretations issued by the International Accounting Standards Board ("IASB") that are effective or issued and early adopted as at the date of these financial statements and in accordance with the provisions of the Companies Act 2006.

The information in this preliminary announcement has been extracted from the audited financial statements for the year ended 30 June 2020 and as such, does not contain all the information required to be disclosed in the financial statements prepared in accordance with the International Financial Reporting Standards ('IFRS').

This announcement was approved by the board of directors and authorised for issue on 16 November 2020.

Going concern

The Directors have concluded that it is necessary to draw attention to the revenue and cost forecasts in the business plans. 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 funds from shareholders or debt providers. While the Board is confident that it will achieve the required revenue, and has a successful track record in both reducing costs and raising funds, there remains uncertainty as to the level of sales that will be achieved in the forthcoming months, especially in light of on-going regulatory delays on the Genedrive® 96 SARS CoV-2 test, in addition to uncertainty around the amount of cost reduction that may be required and the amount of funding that could be raised from shareholders or debt providers. This combination of factors represents a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern. However, based on the relative likelihood of achieving versus not achieving, the Board believe 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 Company was 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 profit 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 from 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	Administrative costs £'000	Total £'000
Year ended 30 June 2020			
Revenue	1,059	-	1,059
Segment EBITDA	(3,584)	(1,999)	(5,583)
Less depreciation and amortisation	(30)	(27)	(57)
Operating loss	**(3,614)**	**(2,026)**	**(5,640)**
Net finance costs			(14,744)
Loss on ordinary activities before tax			**(20,384)**
Taxation			965
Loss for the financial year			**(19,419)**
Total comprehensive expense for the year			**(19,419)**

Business segments	Diagnostics segment £'000	Administrative costs £'000	Total £'000
Year ended 30 June 2019			
Revenue	2,362	-	2,362
Segment EBITDA	(2,483)	(1,868)	(4,351)
Less depreciation and amortisation	(32)	(66)	(98)
Exceptional items	-	439	439
Operating loss	**(2,515)**	**(1,495)**	**(4,010)**
Net Finance costs			(508)
Loss on ordinary activities before tax			**(4,518)**
Taxation			882
Loss for the financial year			**(3,636)**
Total comprehensive expense for the year			**(3,636)**

	Diagnostics segment £'000	Administrative costs £'000	Total £'000
Year ended 30 June 2020			
Segment assets	800	9,653	10,453
Segment liabilities	(1,323)	(12,472)	(13,795)

Year ended 30 June 2019			
Segment assets	720	6,532	7,252
Segment liabilities	(598)	(9,132)	(9,730)

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 2020 £'000**	Year ended 30 June 2019 £'000
United Kingdom	**597**	1,439
Europe	**35**	16
United States of America	**420**	907
Rest of world	**7**	-
	1,059	2,362

Revenues from customers accounting for more than 10% of total revenue in the current or prior years are detailed below:

£420k of revenue was derived from the US Department of Defense (2019: £907k);
£280k of revenue was derived from Innovate UK (2019: £1,107k); and
£210k of revenue was derived from the UK National Institute for Health Research (2019: £300k).

3. Exceptional items

	Year ended 30 June 2020 £'000	Year ended 30 June 2019 £'000
Exceptional gain on settlement of deferred consideration payable	**-**	635
Impairment of deferred consideration receivable	**-**	(196)
	-	439

During the year to June 2019 the Company entered into a fifth Deed of Amendment in relation to the Visible Genomics Sale and Purchase Agreement. The fifth Deed of Amendment became effective on 10 December 2018 and varied the remaining £1,250,000 consideration payable. The difference between the total fair value of amended consideration payable and the £1,250,000 created a gain of £635,000 which was treated as exceptional.

4. Finance income/(costs)

Group	**Year ended 30 June 2020 £'000**	Year ended 30 June 2019 £'000
Interest income on bank deposits	**13**	18
Gain on amendment to convertible bonds	**-**	325
Movement in fair value of derivative embedded in convertible bonds	**(13,807)**	318
Finance cost on liabilities measured at amortised cost	**(808)**	(889)
Foreign exchange movement in convertible bonds	**(142)**	(280)
	(14,744)	(508)

5. Taxation on ordinary activities

(a) Recognised in the income statement

	Total	
Current tax:	**Year ended 30 June 2020 £'000**	Year ended 30 June 2019 £'000
Research and development tax credits	**(1,018)**	(971)
Less: recognised as ATL Research credits	**53**	89
Total tax credit for the year	**(965)**	(882)

(b) Reconciliation of the total tax charge

The tax assessed on the loss on ordinary activities for the year is lower (2019: lower) that the weighted average applicable tax rate for the year ended 30 June 2020 of 19.0% (2019: 19.0%). The differences are explained below:

	Year ended 30 June 2020 £'000	Year ended 30 June 2019 £'000
Loss before taxation on continuing operations	**(20,384)**	(4,518)
Tax using UK corporation tax rate of 19.0% (2019:19.0%)	**(3,873)**	(858)
Adjustment in respect of R&D tax credit recognised as Above The Line ('ATL')	**13**	4
Adjustment in respect of R&D tax credit claimed	**(415)**	(379)
Items not deductible for tax purposes - permanent	**2,807**	11

Items not deductible for tax purposes - temporary	**(6)**	-
Deferred tax not recognised	**777**	304
Rate differences	**(268)**	36
Total tax credit for the year	**(965)**	(882)

(b) Reconciliation of the total tax charge continued

No deferred tax assets are recognised at 30 June 2020 (2019: £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 £16,151k (2019: £10,989k) available to carry forward to future periods; this excludes management expenses.

The Finance Bill 2020, which was subsequently enacted on 19 March 2020, includes provisions to keep the corporation tax rate at 19.0% and not reduce the rate to 17.0%.

In accordance with the provisions of the Finance Act 2000 in respect of research and development allowances, the Group is entitled to claim tax credits for certain research and development expenditure. These credits are disclosed partly as Above The Line research and development credits ('ATL Research credits') within research and development costs and partly as research and development tax credits within taxation on ordinary activities. The total amount included in the financial statements in respect of the year ended 30 June 2020 was £1,018k which included £53k disclosed as ATL Research credits deducted from research and development costs with the balance of £965k disclosed within taxation on ordinary activities as detailed above.

6. Earnings per share

Group	**2020 £'000**	2019 £'000
Loss for the year after taxation	**(19,419)**	(3,636)

Group	**2020 Number**	2019 Number
Weighted average number of ordinary shares in issue	**35,556,905**	26,037,433
Potentially dilutive ordinary shares	**-**	-
Adjusted weighted average number of ordinary shares in issue	**35,556,905**	26,037,433
Loss per share on continuing operations		
- Basic	**(55)p**	(14)p
- Diluted	**(55)p**	(14)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	Number
Potentially dilutive shares on the convertible bond, net of interest charge*	11,025,134
Potentially dilutive shares on deferred consideration	500,000
Potentially dilutive shares from share options	4,125,562
Potentially dilutive shares within the SIP	198,050
Potentially dilutive ordinary shares	15,848,746

* 4,478,681 of these shares were issued on 30 September 2020, see note 9.

7. Contingent consideration receivable

	Greater than 12 months £'000	Less than 12 months £'000	Total £'000
Balance at 30 June 2018	340	172	512
Received in the period	-	(57)	(57)
Impairment of	(187)	(9)	(196)
Balance at 30 June 2019	**153**	**106**	**259**
Balance at 30 June 2020	**47**	**212**	**259**

Under the terms of sale and purchase agreement for the disposal of the Services business, a total of £512k of future contingent consideration was held on the balance sheet at June 2018. In June 2019 £57k was received for the first six months of trading of the new entity. The amount received in 2019 was lower than the amount expected and so an impairment charge of £196k was posted to value the deferred consideration at the new fair value.

The amount provided on the balance sheet of £259k represents 30 months' trading. The amount owing for the period to June 2020 was overdue at the balance sheet date and so there is effectively 24 months of consideration within the balance of £212k. A payment of £137k was received in August 2020.

8. Convertible bonds

	GHIF host £'000	GHIF derivative £'000	BGF host £'000	BGF derivative £'000	Total host £'000	Total derivative £'000	Total £'000
Balance at 30 June 2018	5,621	4	-	-	5,621	4	5,625
Fair value impact of Deed	(563)	238			(563)	238	(325)

of Amendment							
Issue of loan note (BGF)	-	-	2,104	396	2,104	396	2,500
Prepaid arrangement fees (BGF)	-	-	(122)	-	(122)	-	(122)
Movement in fair value of embedded derivative	-	(99)	-	(219)	-	(318)	(318)
Finance cost of convertible bonds	710	-	168	-	878	-	878
Foreign exchange movement (GHIF)	280	-	-	-	280	-	280
Balance at 30 June 2019	6,048	143	2,150	177	8,198	320	8,518
Amortised arrangement fees (BGF)	-	-	36	-	36	-	36
Arrangement costs	-	-	(15)	-	(15)	-	(15)
Movement in fair value of embedded derivative	-	4,841	-	8,966	-	13,807	13,807
Finance cost of convertible bonds	487	-	285	-	772	-	772
Foreign exchange movement (GHIF)	142	-	-	-	142	-	142
Balance prior to settlement	6,677	4,984	2,456	9,143	9,133	14,127	23,260
Payment of cash at settlement date	(685)	-	-	-	(685)	-	(685)
Conversion to shares at settlement date	(5,992)	(4,984)	-	-	(5,992)	(4,984)	(10,976)
Balance at 30 June 2020	**-**	**-**	**2,456**	**9,143**	**2,456**	**9,143**	**11,599**

None of the fair value movements relate to changes in the entity credit risk.

Global Health Investment Fund 1 LLC ('GHIF')

On 21 July 2014, the Company entered into a Collaboration and Convertible Bond Purchase Agreement ('Agreement') with the Global Health Investment Fund 1 LLC ('GHIF'). The purpose of the Agreement was to fund the Company's development, production and commercialisation of Genedrive® to address Global Health Challenges and achieve Global Health Objectives. Further, as part of the Agreement, GHIF and the Company entered into a Global Access Commitment. Under the Global Access Commitment, the Company will undertake appropriate regulatory strategic steps and registrations to secure access for Genedrive® in developing countries in tuberculosis, malaria or other infectious diseases as agreed between the parties.

On 23 June 2016, the Company and GHIF entered into a Deed of Amendment and Restatement of the Agreement, which came into effect on 11 July 2016. The principal effects of the Deed of Amendment were to extend the maturity of the GHIF bond by two years to 21 July 2021, and to split the GHIF bond into two tranches: the first tranche of US$2.0m has a conversion price of £1.50 per ordinary share and the second tranche of US$6.0m has a conversion price remaining at £4.89 per ordinary share.

During the year to 30 June 2019, the Company entered into a second Deed of Amendment with the Global Health Investment Fund 1 LLC ('GHIF') that became effective on 10 December 2018. The principal effects of the Deed of Amendment were to alter the June 2016 Deed of Amendment and Restatement of the five-year US$8.0m and 5% coupon convertible bond with GHIF as follows:

- The maturity date of the GHIF bond was extended from December 2021 to December 2023
- The deferment of interest period was extended from January 2019 to January 2022
- The strike price of the first US$2.0m tranche was reduced from 150p to 28.75p
- The strike price of the second US$6.0m tranche was reduced from 489p to 150p

On 6 June 2020, GHIF exercised its rights to convert tranches 1 and 2 simultaneously. Under the terms of the conversion, GHIF was allotted and issued 7,100,000 new ordinary shares, which was the capped number of shares which can be issued under the convertible bond, and was also be paid approximately £685k in cash reflecting the balance of accrued interest owed, in full satisfaction of the obligations of the Company under the convertible bond. As part of the conversion, GHIF has entered into a lock-in and orderly marketing agreement with Peel Hunt LLP, the Company's Nominated Adviser and Joint Broker. Under this arrangement 5,100,000 of the GHIF shares are subject to an orderly marketing agreement until 30 June 2021 and the remaining 2,000,000 GHIF shares will not be sold prior to 30 June 2021 (subject to various carve outs).

Business Growth Fund ('BGF')

The Company entered into an agreement with the Business Growth Fund ('BGF') that became effective on 10 December 2018. Under the terms of the agreement BGF and the Company entered into a convertible loan arrangement. The main terms of the convertible loan note are:

- £2.5m loan that matures on 30 June 2025
- Interest accrues on the loan at a rate of 7%, payable quarterly
- Interest can be deferred into the principal up until 31 December 2021 and then needs to be paid in full
- The loan converts at 28.75p which was 125% of the share price on 10 December
- Certain warranties have been granted by the Company and the Executive Directors to BGF and BGF consent is required on certain matters
- The loan came conditional with a £1m subscription to the December 2018 fundraising process
- The maximum number of shares to be issued to BGF on conversion of the Loan Notes, when aggregated with the ordinary shares held by BGF and persons acting in concert with BGF, is capped at 29.9% of the issued share capital of the Company

Accounting for the convertible bonds

GHIF

Whilst the bond holder has the option to convert into a fixed number of shares, due to the GHIF convertible bond being denominated in a different currency to the Company's functional currency, IFRS requires the convertible bond to be accounted for as a compound

instrument, comprising a debt host (liability component) and a derivative (equity component). The debt host was required to be recorded initially at fair value and subsequently measured at amortised cost.

The derivative was measured at the settlement date using a Quanto Option Valuation model which takes account of the multicurrency aspects of the convertible bond. Changes in fair value are recorded in profit and loss. The variables used in running the model were volatility of the Company's share price of 40%, expected life of the derivative of 0.008 years, risk free interest rate of 0.098% and no dividend yield.

On conversion, the compound instrument has been derecognised. The consideration received for the issue of shares was measured by reference to the face value of the debt of £7,199,000, being the outstanding principal and accrued interest. The difference of £3,177,000 between the carrying amount of the instrument and the consideration received has been recognised directly in equity. No gain or loss has been recorded in the profit and loss account as a result of the conversion.

BGF

The convertible nature of the loan grants BGF an option to convert to equity but the instrument includes adjustments to the conversion price if additional equity is issued by the Company meaning that the number of shares that would be issued is not fixed. The bond also includes options relating to early redemption by the Company subject to it making an early redemption payment. These features represent embedded derivatives which are recognised separately from the debt host.

The debt host was initially recorded at fair value and is subsequently measured at amortised cost.

The derivative is measured at fair value and movements recorded in profit and loss. At 30 June 2020, the derivative has been valued using a Black-Scholes pricing model using the following inputs: volatility of the Company's share price of 40%, expected life of the derivative of 1.5 years, risk free interest rate of 0.098% and no dividend yield.

On 30 September 2020, BGF Investments LP exercised its right to convert £1,000,000 of its £2,500,000 Loan Note instrument into new ordinary shares of 1.5p each in the Company. Under the conversion BGF was allotted and issued 4,478,681 new ordinary shares and was paid approximately £134,000 in accrued interest owed on this tranche of the loan.

9. Share capital

Allotted, issued and fully paid:

	Number	£'000
Balance at 30 June 2018	18,783,115	282
Shares issued	15,217,391	228
Balance at 30 June 2019	**34,000,506**	**510**
Share issue - deferred consideration	**869,565**	**13**

Share issue	**10,000,000**	**150**
Share issue - equity-settled share-based payments	**16,000**	**-**
Share issue - conversion of GHIF bond	**7,100,000**	**107**
Balance at 30 June 2020	**51,986,071**	**780**

At the balance sheet date there are three convertible and potentially convertible arrangements that could result in the issue of additional shares:

Note 8 details the option to convert the Loan Note held by BGF, being £2.5m at the balance sheet date and £1.5m following partial conversion on 30 September 2020 at 28.75p.

On 10 December 2021 the Company will issue 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.

Note 20 of the full report and accounts details share options that could also be exercised and result in the issue of additional shares.

10. 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 2018	25,988	-	(196)	1,437	(2,484)	24,745
Share issue	3,015	-	-	-	-	3,015
Deferred consideration - equity component	-	315	-	-	-	315
Transfer of shares to SIP members	-	-	-	-	-	-
Equity-settled share-based payments	-	-	-	49	-	49
FX on translation of overseas assets	-	-	-	-	(12)	(12)
Transactions settled directly in equity	3,015	315	-	49	(12)	3,367
Balance at 30 June 2019	29,003	315	(196)	1,486	(2,496)	28,112
Share issue - deferred consideration	187	(200)	-	-	-	(13)
Share issue	7,383	-	-	-	-	7,383
Share issue - conversion of GHIF bond	7,092	-	-	-	-	7,092
Equity-settled share-based payments	14	-	-	32	-	46
Transactions settled directly in	14,676	(200)	-	32	-	14,508

equity						
Balance at 30 June 2020	**43,679**	**115**	**(196)**	**1,518**	**(2,496)**	**42,620**

Shares to be issued relate to the equity component of deferred consideration, full details are contained in note 9.

The employee Share Incentive Plan reserve represents 17,882 shares in genedrive plc (2019: 18,864 shares) all of which are held by Epistem SIP Trustee Ltd. These shares are listed on the Alternative Investment Market and their market value at 30 June 2020 was £1.02 per share or £18,240 (2019: £3,867). The nominal value held at 30 June 2020 was £268 (2019: £283).

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.

END

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