genedrive

genedrive plc
Interim Report 2021

Advancing molecular diagnostics to the point-of-care

Introduction and Highlights

Genedrive® is an innovative, easy-to-use platform that brings molecular diagnostics to decentralised laboratories

Results available in as little as 27 minutes

Overview

Genedrive® is a small patented molecular diagnostics platform which enables rapid nucleic acid amplification and detection from various sample types, including plasma, sputum and buccal swabs, with minimal hands-on time and single button operation it provides diagnostics results without the need for specialist knowledge or data interpretation. With no manual calibration required, Genedrive® is ideal for lower throughput decentralized laboratories.

How Genedrive® works

Genedrive® utilises proprietary technology to rapidly amplify and detect nucleic acid sequences without the requirement for nucleic acid isolation.

Following amplification, melt curve analysis is used to establish the presence of the target sequence in the sample and the results are automatically interpreted by Genedrive®.

Simple → Versatile → Low cost → Portable → Fast

** Depending on assay, results are available in as little as 27 minutes.*

Half Year Report

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces unaudited interim results for the six months to 31 December 2020.

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 Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB). The Company recently released a high throughput SARS-CoV-2 assay and has in development a Genedrive® Point of Care version of the assay, both based on Genedrive® chemistry.

Financial Highlights

- Total revenue and other income of £0.4m (2019: £0.6m) including pathogen detection orders from the US Department of Defense. COVID-19 headwinds continued to impact the Company's HCV and DoD commercial operations
- Operating loss of £2.9m (2019: £2.6m)
- All loan notes converted into ordinary shares in the period, leaving the Company debt free
- Finance income of £3.6m (2019: £0.8m costs) on conversion of loan notes, reverting the Company's position to net assets of £5.3m (30 June 2020: £3.3m net liabilities)
- R&D spend of £2.3m (2019: £2.3m)
- Cash of £3.8m at 31 December 2020 (30 June 2020: £8.2m)
- Cash of £2.8m as of 15 March 2021 with R&D tax credit of £1.0m still owing

Operational Highlights (including post period)

- Cooperation Agreement with Beckman Coulter Life Sciences ("Beckman") for Genedrive 96 SARS-Cov-2 Kit validation with Beckman extraction chemistry. Moved to commercial distribution agreement into Europe and USA post period end with first Beckman purchases (circa $400k) in February 2021
- Significant opportunity with European MoH remains active and ongoing and, if successful, could be low double digit millions of pounds in revenue
- COVID-19 headwinds continued to impact the Company's HCV and DoD commercial operations
- AIHL test, the Genedrive® MT-RNR1 ID kit completed implementation studies in Manchester and Liverpool Hospitals. Product on track for summer 2021 commercial launch with good Key Opinion Leader engagement.
- Regulatory approvals for the 96 SARS-CoV-2 kit still outstanding with WHO and FDA. Timings are uncertain
- New commercial partnership with Mountain Horse Solutions to provide better access to DoD
- Point of Care ("POC") COVID-19 test still under development and timelines extended to maintain important product differentiation characteristics including rapid test results, full biosafety to users, and extraction free chemistry

Acronyms used throughout this document

HCV	Hepatitis C Virus
mTB	Tuberculosis
DoD	US Department of Defense
AIHL	Antibiotic Induced Hearing Loss

Interim Management Report

> During 2020 the Company's development focus moved to the global COVID PCR testing opportunity. While commercial progress has been slowed by registration requirements, the Company made great strides in the development of our COVID test portfolio, POC test platform development, scalable manufacturing capability, and a commercial distribution arrangement with Beckman Coulter that has potential to be significant and long-term. Much of our focus has shifted away from low and middle income markets to more western markets with DoD, AIHL, and COVID, driven by the market dynamics and restrictions of travel. These markets however work under standard commercial terms and cycles, and offer more predictable, and often higher margin commercial opportunities, and we anticipate this focus will remain for the foreseeable future."

David Budd
Chief Executive Officer of genedrive plc

Interim management report

In April 2020 the Company made the strategic decision to refocus the resources of the business towards COVID-19 testing, a step driven both by our experience and capability in PCR test development, and the headwinds we started to see in our on-market assays as a result of the pandemic.
An equity raise in May 2020 generated £8.0m to help fund development of a rapid high throughput test and a longer-term point-of-care test based on the Genedrive® platform. Investments here have started to reap returns in the first half of 2020/21 and we have seen the emergence of our first revenues and commercial leads that have the potential to support the Company over the coming years.

COVID-19

High Throughput Genedrive® 96 SARS-COV 2 Kit

genedrive's expertise in lyophilised (freeze-dried and temperature stable) PCR chemistry provides a unique opportunity for the Company to service a global market cheaply and easily. Coupled with the expertise of Cytiva's bead manufacturing, genedrive has been able to bring a range of high volume, standardised, consistent quality 96-well plate tests to the market.

The initial Genedrive® 96 SARS-COV 2 Kit was launched in the summer of 2020 on Roche Lightcycler formats and post launch we expanded the range of platforms to include the ABI 7500 FAST and BioRad CFX96. We also made a number of refinements to the product to incorporate extraction requirements of key customers and to improve on our data analysis tool, Genedrive® Exporter.

During the period we acquired some smaller customers via distributors, but the focus of the Company has been on securing larger more strategic opportunities. In January 2021 we announced that Beckman Coulter Life Sciences ("Beckman") had contracted to be a distributor across the USA and Europe. This relationship began as a collaboration to validate the Genedrive® PCR kit on the Beckman Biomek automated workstation using Beckman RNA extraction chemistry. We completed validation of our kit, and this distribution agreement gives the Company reason to be optimistic of the potential Beckman brings in terms of expertise, reach and a new sales channel into the USA, which we did not have previously.

The first sales to Beckman were completed in February 2021 ($0.4m) to support an aggressive marketing campaign by Beckman, and we expect material orders as the Beckman sales activities progress and customers are acquired for the Genedrive® test. In addition we are still actively engaged in an opportunity with a European Ministry of Health as we communicated in December 2020. This remains an active opportunity for genedrive and, if successful, the total revenue could be low double digit millions (pounds) over a short period of time with the opportunity for future additional business as well. We expect to make a significant impact with our high-throughput test. The opportunities with Beckman or the European Ministry of Health could be transformational for the Company.

The strongest headwind on our ability to acquire customers is the speed of regulatory approvals. We continue to experience delays in gaining the key regulatory approvals from the FDA, WHO and in India. In May 2020, approvals were occurring rapidly, but the urgency of regulatory bodies in granting new approvals has subsided. There are no confirmed timelines for these processes and despite lodging our file claims over Summer 2020 we are unable to affect the speed with which our submissions might get reviewed. In India our application has been repeatedly frustrated by test requirements that are neither documented nor communicated to applicants. Although our application remains on-going we are reducing our attention on the market as there appears no certainty of a positive outcome against unknown requirements. We are currently importing into the USA while our FDA EUA has been applied for, which is permitted under FDA regulations. Lack of EUA reduces the potential customer base, but we have proceeded on this basis with the full support of Beckman. We have obtained regulatory approval in Europe, in South Africa and Thailand. Performance in external trials (covering over 200 samples across four sites) has been very good, and we remain confident in the performance of the product. The Company has implemented a regular review process of emerging viral variants, and to date the reported strains have not adversely affected our assay design.

Point of Care

As the market for COVID-19 testing develop further, we see many opportunities for deployable and accurate molecular tests at the point of care ("POC"). Lateral flow tests are being widely deployed specifically in the UK and we believe the current laboratory based testing infrastructure will have to be supplemented with on-site PCR confirmations for many settings. We remain committed to the future contribution the Genedrive® unit can make in POC testing and to the Company.

In October the Company announced that Genedrive® chemistry had been adapted to detect the SARS-CoV-2 virus direct from saliva, within 15 minutes for positive samples, and a full negative cycle taking approximately 20 minutes. Our intention is to develop this test to full manufacture on the Genedrive®.

Variable behaviour of external commercial synthetic COVID-19 controls in the POC test development has resulted in some delay in our release timing. Despite this technical issue, we have identified complementary approaches and are focussed on releasing a product in calendar Q2 2021 with differentiated, core performance features based on either saliva or swabs that we believe will provide competitive advantage. We continue to plan a two phase release, with the second phase migrating to bead based chemistry to reduce costs and increase scalability.

While the high throughput COVID testing market size has matured, decentralised opportunities are evolving rapidly. We believe that the market need for focussed, accurate rapid testing solutions are increasing, and that in many cases only molecular POC solutions can provide the sensitivity needed. Our target product profile remains extremely attractive and suited to the potential of the Genedrive® platform in occupational, healthcare, or potentially even school settings.

Pathogen Detection (DoD)

Orders in the period to the DoD generated revenues of £0.3m (2019: £0.3m). This includes orders for Genedrive® units from a new customer within the DoD for evaluation and review. We understand there is a high level of interest from the potential new customer (previously indicated a potential of 500 units over three years) and we had expected to be entering into contract negotiations and volume discussions in Autumn 2020. Owing to COVID-19 distraction in the US, we have not seen the timeline progress as we had expected.

The Company has found liaising commercially with the US DoD without specialist US representation challenging and so in March 2021 the Company contracted with Mountain Horse Solutions as its distributor of the Pathogen detection assays in the USA. This relationship will be an important next step to drive product uptake with both our existing customer base and with new departments and branches of the US military. Mountain Horse have existing framework agreements with the DoD which provide for more rapid order placement and replenishment without the need for new contracts to be negotiated, as well has having a breadth of experience and contacts in the specialised field of CBRNE. We are confident this new arrangement will help to grow the DoD business and that Pathogen Detection can make a significant contribution to the Company in the future.

Antibiotic Induced Hearing Loss (AIHL)

The AIHL assay is the first use of a Point of Care diagnostics test in neonatal emergency setting. The assay screens for a genetic mutation that can cause profound hearing loss following administration of certain antibiotics.

The AIHL assay gives an accurate result in 27 minutes, allowing clinicians time to prescribe alternatives antibiotics and avoid the lifelong impacts to hearing in the estimated 1 in 500 affected by the genetic defect.

The AHIL assays was CE marked in December 2019 and performance trials commenced at Manchester University NHS Trusts and Liverpool's Women's hospital in January 2020.

These trials successfully completed in November 2020 with in excess of 750 babies tested and all valid test results confirmed as 100% accurate through genetic sequencing. We expect the results of the trial to be published in clinical papers shortly, but the overall output is very positive proving the utility of a genetic test in an emergency setting.

Following launch we expect a number of early adopters, including those involved in the trials, to acquire the test to facilitate neonate testing and publications such as the recent Government guidance on the management of specific genetic mutation and their impact on hearing loss will help build awareness and users. Our next steps will be to work with key opinion leaders and paediatric bodies to get the use of the AIHL assays written into best practise guidance, at which point its adoption should become more standard across the NHS. In the longer term we will work to build a European and US market for a product that has equal applicability across the globe. The product remains on track for commercial launch in Summer 2021 and we expect this assay to be a significant pillar to the future of the Company.

Hepatitis C (HCV)

Despite attaining WHO pre-qualified status in May 2020, the HCV assay has continued to be affected by headwinds associated with COVID-19. We have seen a continuous stream of activity across our markets for HCV product, but as healthcare systems and funds are focused extremely heavily on COVID-19 the activity has not generated sales and revenues from HCV have been low. Long term we still see the HCV market as attractive for genedrive and there is still interest from WHO tenders and in various pockets across the globe – however meaningful revenues are likely 12 months away from when COVID-19 is more controlled and health systems able to return to more normal activities.

[1]Chemcial Biological Radiological Nuclear and Explosive

Financial Results

Revenue for the period was £0.4m (2019: £0.6m). Of total revenues, the vast majority was related to our pathogen detection assay sold to the DoD with small additional amounts on HCV, grant income and some early plate sales of our 96-SARS-COV 2 kit. Research and development costs were £2.3m (2019: £2.3m), as we continued our efforts on development activities for our COVID-19 assays. Administration costs were £954k (2019: £901k). The trading loss for the period was £2.9m (2019: £2.6m).

Financing income of £3,552k (2019: £765k costs) is the reduced value of the convertible loan notes issued to Business Growth Fund of £3.9m (2019: £246k debit) offset by normal interest accruals on the long-term liability of £310k (2019: £772k). These movements are non-cash and the final issue of shares to BGF on 16 December 2020 terminated the loan and all remaining commitments thereunder.

After financing costs, the profit before taxation was £0.6m compared to the prior period loss of £3.3m. The profit increases to £1.0m (2019: £3.0m loss) after estimating the six-month taxation credit as £370k (2019: £290k). The basic income per share was 1.9p (2019: 8.9p loss per share).

Cash Resources

The operating loss for the period was £2.9m (2019: £2.6m) and working capital consumption was £1.2m, a contrast to the prior year (£0.1m) as we built stocks and purchased raw materials related to our 96 SARS-COV 2 Kit. Net cash out-flows from operations were significantly up at £4.1m (2019: £1.7m) and as the R&D tax credit was not received in the period (2019: £971k) the net cash flow from operating activities was also £4.1m.

There were some small investments in capital equipment as we brought in additional diagnostics analysers to support development of our 96 SARS-COV 2 Kit. Contingent consideration from discontinued operations were £137k (2019: nil) and we have £122k remaining on the balance sheet.

£359k was paid to settle cash interest on the convertible loan note to BGF (2019: £nil), leaving total cash outflows for the period of £4.4m (2019: £1.7m). Closing cash was £3.8m (2019: £3.5m) but with £1.0m owing for the R&D tax credit (2019: £nil owing). The cash balances at 15 March 2021 were £2.8m with approximately £1.4m owing on the R&D tax credit and receivables; the current burn rate without further material revenues is around £0.4m per month.

Balance Sheet

Balance sheet net assets at 31 December 2020 totalled £5.3m (30 June 2020: £3.3m net liabilities). The large change on the net position of the balance sheet in the period is owing to the consolidated profit of the period of £1.0m (2019: £3.0m loss) as well a large positive movement on the conversion of the loan note. When converted to shares, the liabilities attached to the loan note were reversed through reserves and this created a credit of £7.6m that was split across the Share Premium and Accumulated losses.

Principal risks and uncertainties

There are a number of potential risks and uncertainties which could have a material impact on the Company's performance over the remaining six months of the financial year and could cause actual results to differ materially from expected and historical results. The Directors do not consider that these principal risks and uncertainties have changed materially since publication of the annual report for the year ended 30 June 2020; a more detailed explanation of the risks for the Company can be found on page 21 of the annual report.

Going Concern

As detailed in Note 1 to these financial statements, the Directors have concluded that it is necessary to draw attention to the revenue and cost forecasts in the business plans and the uncertainty that surrounds revenues especially in relation to the Company's Covid assays. 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 and the delays on the POC product, 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. The directors have reviewed cashflows models of expected revenues and have sensitized these models for various downsides and based on the relative likelihood of achieving versus not achieving these forecasted revenues 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. 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.

Outlook

Whilst the speed of commercialisation of the 96 SARS-COV 2 Kit has been slower than anticipated owing to delays in regulatory approvals, the post period end contract with Beckman and the on-going opportunity with a European Ministry of Health provide us with optimism for the remainder of our financial year.

Looking further ahead the POC potential for Genedrive® remains and while we have focused on refining our solution we are confident that despite the delays there will be a place in the market for a fast accurate and deployable solution for PCR testing. Further, we have taken steps to accelerate the potential of AIHL and the DoD and also expect near term revenue contribution from these areas.

While cognisant of the need for cash generative revenues the Board is confident in the strategy to focus on larger commercial opportunities in the COVID-19 space and expect progression from this strategy in the coming months, alongside progress with the commercialization of AIHL, DoD and HCV products.

David Budd
Chief Executive Officer

Dr I Gilham
Chairman

25 March 2021

Unaudited Consolidated Statement of Comprehensive Income

For the six months ended 31 December 2020

	Note	Six months ended 31 December 2020 Unaudited £000	Six months ended 31 December 2019 Unaudited £000	Year ended 30 June 2020 Audited £000
Revenue & other income	(4)	**355**	627	1,059
Research and development costs		**(2,332)**	(2,293)	(4,673)
Administrative costs		**(954)**	(901)	(2,026)
Operating loss	(4)	**(2,931)**	(2,567)	(5,640)
Finance costs	(5)	**3,552**	(765)	(14,744)
Profit/(Loss) on ordinary activities before taxation		**621**	(3,332)	(20,384)
Taxation on ordinary activities		**370**	290	965
Profit/(Loss) for the financial year from continuing operations		**991**	(3,042)	(19,419)
Total Comprehensive Income/(Expense) for the period		**991**	(3,042)	(19,419)
Earnings/(Loss) per share (pence) from continuing operations				
– Basic		**1.9p**	(8.9p)	(55.0p)
– Diluted		**1.8p**	(8.9p)	(55.0p)

Unaudited Consolidated Statement of Change in Equity

For the six months ended 31 December 2020

	Share Capital £000	Other Reserves £000	Accumulated Losses £000	Total £000
At 30 June 2019	510	28,112	(31,100)	(2,478)
Share issue – deferred consideration	13	(13)	–	–
Equity –settled share based payments	–	16	–	16
Transactions settled directly in equity	13	3	–	16
Total comprehensive expense for the financial period	–	–	(3,042)	(3,042)
At 31 December 2019	523	28,115	(34,142)	(5,504)
Share issue	150	7,383	–	7,533
Share issue – conversion of GHIF bond	107	7,092	3,777	10,976
Equity –settled share based payments	–	30	–	30
Transactions settled directly in equity	257	14,505	3,777	18,555
Total comprehensive loss for the financial period	–	–	(16,377)	(16,377)
At 30 June 2020	780	42,620	(46,742)	(3,342)
Share issue – conversion of BGF bond	**167**	**2,332**	**5,167**	**7,666**
Equity –settled share based payments	**–**	**14**	**–**	**14**
Transactions settled directly in equity	**167**	**2,346**	**5,167**	**7,680**
Total comprehensive income for the financial period	**–**	**–**	**991**	**991**
At 31 December 2020	**947**	**44,966**	**(40,584)**	**5,329**

Unaudited Consolidated Balance Sheet

As at 31 December 2020

	Note	31 December 2020 (unaudited) £000	31 December 2019 (unaudited) £000	30 June 2020 (audited) £000
Non-current assets				
Intangible assets		**–**	–	–
Plant and equipment		**432**	130	147
Contingent consideration receivable		**47**	153	47
		479	283	194
Current assets				
Inventories		**707**	125	413
Trade and other receivables		**373**	605	398
Contingent consideration receivable		**75**	106	212
Current tax asset		**1,398**	300	1,018
Cash and cash equivalents		**3,793**	3,499	8,218
		6,346	4,635	10,259
Liabilities				
Current liabilities				
Deferred income		**–**	(77)	(67)
Trade and other payables		**(1,245)**	(1,052)	(2,129)
Lease liabilities		**37**	–	–
		(1,282)	(1,129)	(1,217)
Net current assets		**5,064**	3,506	8,063
Total assets less current liabilities		**5,543**	3,789	8,257
Non-current liabilities				
Lease liabilities		**(214)**	–	–
Convertible bonds	(7)	**–**	(9,293)	(11,599)
Net assets/(liabilities)		**5,329**	(5,504)	(3,342)
Capital and reserves				
Called-up equity share capital	(8)	**947**	523	780
Other reserves	(9)	**44,966**	28,127	42,620
Retained earnings		**(40,584)**	(34,154)	(46,742)
Total shareholder equity/(deficit)		**5,329**	(5,504)	(3,342)

Unaudited Consolidated Staminate of Cash Flow

For the six months ended 31 December 2020

	31 December 2020 (unaudited) £'000	31 December 2019 (unaudited) £'000	30 June 2020 (audited) £'000
Cash flows from operating activities			
Operating loss for the year	**(2,931)**	(2,567)	(5,640)
Depreciation and amortisation on non-leased assets	**29**	33	57
Loss on disposal of fixed assets	**–**	2	–
ATL Research credits	**(10)**	(10)	(53)
Share – based payment	**15**	16	32
Operating loss before changes in working capital and provisions	**(2,897)**	(2,526)	(5,604)
Increase in inventories	**(294)**	(2)	(290)
Decrease/(increase) in trade and other receivables	**25**	(49)	158
Decrease in deferred revenue	**(67)**	(11)	(21)
(Decrease)/increase in trade and other payables	**(884)**	(77)	1,000
Net cash outflow from operations	**(4,117)**	(2,665)	(4,757)
Tax received	**–**	971	971
Net cash outflow from operating activities	**(4,117)**	(1,694)	(3,786)
Cash flows from investing activities		–	
Finance income	**4**	10	13
Finance costs	**(15)**	–	(15)
Receipt of contingent consideration	**137**	–	–
Acquisition of plant and equipment and intangible assets	**(61)**	(1)	(40)
Net cash inflow/(outflow) from investing activities	**65**	9	(42)
Cash flows from financing activities			
Proceeds from share issue	**–**	–	7,546
Cash paid to settle convertible bonds	**(359)**	–	(685)
Net (outflow)/inflow from financing activities	**(359)**	–	6,861
Net (decrease)/Increase in cash equivalents	**(4,411)**	(1,685)	3,033
Effects of exchange rate changes on cash and cash equivalents	**(14)**	–	1
Cash and cash equivalents at beginning of period/year	**8,218**	5,184	5,814
Cash and cash equivalents at end of period/year	**3,793**	3,499	8,218
Analysis of net funds			
Cash at bank and in hand	**3,793**	3,499	8,218

Notes to the Unaudited interim financial statements

1. General information

genedrive plc ('the Company') 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 diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications. The Company is a limited liability company incorporated and domiciled in the UK. The address of its registered office is 48 Grafton Street, Manchester, M13 9XX. The Company has its listing on AIM.

The financial information for the period ended 31 December 2020 and similarly the period ended 31 December 2019 has been neither audited nor reviewed by the auditor. The financial information for the year ended 30 June 2020 has been based on information in the audited financial statements for that period. The interim financial statements for the period ended 31 December 2020 do not constitute statutory accounts as defined in section 434 of the Companies Act 2006. A copy of the statutory accounts for the year ended 30 June 2020 has been delivered to the Registrar of Companies, the accounts had an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006 but did include a reference to a material uncertainty that might cast significant doubt over the Group's ability to continue as a going concern, to which the auditor drew attention by way of emphasis.

These interim financial statements were approved by the Board of Directors on 25 March 2021.

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

2. Significant accounting policies

Basis of accounting

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

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

Going concern: The financial statements have been prepared on a going concern basis. The Group's business activities, together with the factors likely to affect its future development, performance and position are set out in the strategic report and Chairman's statement in the Annual Report and financial statements for the period ended 30 June 2020. The Financial Reporting Council issued "Going Concern and Liquidity Risk: Guidance for Directors of UK Companies" in 2009, and "Guidance on the Going Concern Basis of Accounting and Reporting on Solvency and Liquidity Risks" in 2016. The Directors have considered these when preparing the interim financial statements.

The Directors have concluded that it is necessary to draw attention to the revenue and costs forecasts in the business plans and the uncertainty that surrounds revenues especially in relation to the Company's Covid assays. In order for the Company to continue as a going concern, there is a requirement to achieve a certain level of sales and there is a level of uncertainty surrounding these sales especially in relation to the Covid assays. If an adequate sales level cannot be achieved to support the Group and Company, the Directors have the options to reduce ongoing spend or seek additional funding from shareholders. While the Board is confident that it will achieve the required revenue, and has a successful track record in both cutting costs and raising funds, there remains uncertainty as to the level of sales that will be achieved, the amount of cost reduction that may be required and the amount of funding that could be raised from shareholders. This combination of factors represents material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern.

Notes to the Unaudited interim financial statements continued

In arriving at these conclusions the Directors have:

- Reviewed cash flow forecasts extending to 30 April 2022. These cashflows included a number of various outcomes as part of scenario modelling.
- Considered a base scenario using the Directors best estimates of costs and revenues in the current financial year to 30 June 2021 and beyond.
- Sensitized the revenue in the base case scenario down by 55% and assumed that the Directors take some cost reduction steps in terms of projects and investment programmes, but without affecting headcount.
- Reviewed an extreme downside scenario in which there were no new revenues in the forecast period and that included both headcount and non-headcount cost reductions that are within the Company's control.

The base and sensitized cash flow forecasts do not include any mitigating factors available to management in terms of reducing the headcount of the business - which is a significant cost driver. In all scenarios there remains the option for the Company to raise additional funds from shareholders or debt providers, a path where the Group has a successful recent track record.

The majority of the cashflow models indicate that the Company can trade throughout the period to 30 April 2022. However the headroom under the extreme downside scenario is not significant and indicates that the Company would have to raise additional funds to continue as a going concern to April 2022.

There are not believed to be any contingent liabilities which could result in a significant impact on these cashflows if they were to crystallise.

Based on the relative likelihood of achieving versus not achieving the cashflow models, the Board believe it is appropriate to continue to adopt the going concern basis of accounting in preparing these interim financial statements. These interim financial statements do not include the adjustments that would result if the Company was unable to continue as a going concern.

New accounting standards adopted in the period

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

Estimates

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

In preparing these interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation were the same as those that applied to the consolidated financial statements for the year ended 30 June 2020, with the exception of changes in estimates that are required in:

- determining the provision for taxation; and
- valuing the conversion of the GHIF and BGF convertible loans.

Revenue recognition

a. Product sales

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

Notes to the Unaudited interim financial statements continued

2. Significant accounting policies continued

b. Collaboration and licensing revenue

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

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

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

c. Other income – development grant funding

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

Research and development

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

Intangible assets

Intangible assets are stated at cost less accumulated amortisation and any accumulated impairment losses. Amortisation is calculated so as to write off the cost of an intangible asset, less its estimated residual value, over the useful economic life of that asset. All intangible assets are subject to impairment review and amortisation in each financial reporting period. In assessing value in use, the estimated future cash flows are discounted to their net present values using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to that asset.

Right of use asset

A right-of-use asset is recognised at the commencement date of a lease. The right-of-use asset is measured at cost, which comprises the initial amount of the lease liability, adjusted for, as applicable, any lease payments made at or before the commencement date net of any lease incentives received and any initial direct costs incurred.

Right-of-use assets are depreciated on a straight-line basis over the unexpired period of the lease or the estimated useful life of the asset, whichever is the shorter. Where the Group expects to obtain ownership of the leased asset at the end of the lease term, the depreciation is over its estimated useful life. Right-of use assets are subject to impairment or adjusted for any remeasurement of lease liabilities.

The Group has elected not to recognise a right-of-use asset and corresponding lease liability for short-term leases with terms of 12 months or less and leases of low-value assets. Lease payments on these assets are expensed to profit or loss as incurred.

Foreign currencies

Transactions in foreign currencies are translated at the exchange rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the balance sheet date. Non-monetary items

Notes to the Unaudited interim financial statements continued

carried at fair value and denominated in foreign currencies are retranslated at the rates prevailing on the date when fair value is determined.

Exchange differences arising on the settlement of monetary items and on the retranslation of monetary items are taken to the Consolidated Statement of Comprehensive Income. Exchange differences arising on non-monetary items, carried at fair value, are included in the income statement, except for such non-monetary items in respect of which gains and losses are recorded in equity.

Share-based payments

The Group issues equity settled and cash-settled share-based payments to certain employees (including directors). Equity settled share-based payments are measured at fair value at the date of grant. The fair value determined at the grant date of the equity settled share-based payments is expensed on a straight-line basis over the vesting period, together with a corresponding increase in equity, based upon the Group's estimate of the shares that will eventually vest.

Fair value is measured using the Black-Scholes pricing model. The expected life used in the model has been adjusted, based on management's best estimate, for the effects of non-transferability, exercise restrictions and behavioural considerations.

Where the terms of an equity settled transaction are modified, as a minimum an expense is recognised as if the terms had not been modified. In addition, an expense is recognised for any increase in the value of the transaction as a result of the modification, as measured at the date of modification.

Where an equity settled transaction is cancelled, it is treated as if it had vested on the date of the cancellation, and any expense not yet recognised for the transaction is recognised immediately. However, if a new transaction is substituted for the cancelled transaction, and designated as a replacement transaction on the date that it is granted, the cancelled and new transactions are treated as if they were a modification of the original transaction, as described in the previous paragraph.

Cash settled share based payments are fair valued at the date services are delivered. A liability is created on the balance sheet for the value received. Until the liability is settled, the fair value is adjusted at each accounting period with changes reported in the profit and loss for that period.

Financial instruments (including convertible bond)

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

As disclosed in note 19, the Company has in issue a convertible bond which is a compound instrument comprising a liability component, or debt host, and an equity derivative component.

On initial recognition, convertible bonds are recorded at fair value net of issue costs. The initial fair value of the debt host is determined using the market interest rate applied by a market participant for an equivalent non-convertible debt instrument. Subsequent to initial recognition, the debt host is recorded using the effective interest method until extinguished on conversion or maturity of the bonds. The amortisation of the debt host and the interest payable in each accounting period is expensed as a finance cost.

Equity derivatives embedded in the convertible instruments which are required to be recorded as financial liabilities are initially recognised at fair value. At each reporting date, the fair values of the derivative are reassessed by management. Where there is no market for such derivatives, the Company uses option pricing models to measure the fair value.

The amortisation of the debt host, interest payable in the period and gains or losses on the fair value of the derivative are disclosed with finance income and costs detailed in note 5.

Notes to the Unaudited interim financial statements continued

3. Revenue

Income receivable in the form of Government grants to fund product development is recognised as development grant funding when the related eligible costs are incurred and recognised, £nil (2019: £0.3m).

4. Operating segments

	Diagnostic Segment £'000	Administrative Costs £'000	Total £'000
Six months ended 31 December 2020			
Revenue and other income	**355**	**–**	**355**
Segment EBITDA	**(1,818)**	**(911)**	**(2,729)**
Less depreciation and amortisation	**(159)**	**(43)**	**(202)**
Operating loss	**(1,977)**	**(954)**	**(2,931)**
Net Finance income			**3,552**
Profit on ordinary activities before taxation			**621**
Taxation			**370**
Profit for the financial period			**991**

	Diagnostic Segment £'000	Administrative Costs £'000	Total £'000
Six months ended 31 December 2019			
Revenue and other income	627	–	627
Segment EBITDA	(1,650)	(884)	(2,534)
Less depreciation and amortisation	(16)	(17)	(33)
Operating loss	(1,666)	(901)	(2,567)
Net Finance costs			(765)
Loss on ordinary activities before taxation			(3,332)
Taxation			290
Loss for the financial period			(3,042)

	Diagnostic Segment £'000	Administrative Costs £'000	Total £'000
Twelve months ended 30 June 2020			
Revenue and other income	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 taxation			(20,384)
Taxation			965
Loss for the financial period			(19,419)

Notes to the Unaudited interim financial statements continued

5. Net finance income/(costs)

	31 December 2020 £000	31 December 2019 £000	30 June 2020 £000
Net interest income on bank deposits	**4**	10	13
Movement in fair value of derivative embedded in convertible bond	**3,864**	(246)	(13,807)
Finance cost of convertible bond measured at amortised cost	**(290)**	(810)	(808)
Finance lease costs	**(26)**	–	–
Foreign exchange movement in convertible bond	**–**	281	(142)
	3,552	(765)	(14,744)

6. Earnings per share

The basic earnings per share is calculated by dividing the earnings attributable to ordinary shareholders for the year by the weighted average number of ordinary shares in issue during the year. The weighted average number of shares in issue during the period was 53,348,586 (2019: 34,100,566). Potentially dilutive options, after proceeds from conversion, add 1,289,692 shares to basic weighted average number of shares in issue (2019: nil).

7. 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 2019	6,048	143	2,150	177	8,198	320	8,518
Finance cost	620	–	180	–	800	–	800
Amortisation of arrangement fees	–	–	10	–	10	–	10
Movement in fair value of embedded derivative	–	88	–	158	–	246	246
Foreign exchange movement (GHIF)	(281)	–	–	–	(281)	–	(281)
Balance at 31 December 2019	6,387	231	2,340	335	8,727	566	9,293
Finance cost	(133)	–	105	–	(28)	–	(28)
Amortisation of arrangement fees	–	–	26	–	26	–	26
Arrangement costs	–	–	(15)	–	(15)	–	(15)
Movement in fair value of embedded derivative	–	4,753	–	8,808	–	13,561	13,561
Foreign exchange movement (GHIF)	423	–	–	–	423	–	423
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 June 2020	**–**	**–**	**2,456**	**9,143**	**2,456**	**9,143**	**11,599**
Finance cost	**–**	**–**	**189**	**–**	**189**	**–**	**189**
Amortisation of arrangement fees	**–**	**–**	**101**	**–**	**101**	**–**	**101**
Movement in fair value of embedded derivative	**–**	**–**	**–**	**(3,864)**	**–**	**(3,864)**	**(3,864)**
Balance prior to settlement	**–**	**–**	**2,746**	**5,279**	**2,746**	**5,279**	**8,025**
Payment of cash at settlement date	**–**	**–**	**(359)**	**–**	**(359)**	**–**	**(359)**
Conversion to shares at settlement date	**–**	**–**	**(2,387)**	**(5,279)**	**(2,387)**	**(5,279)**	**(7,666)**
Balance at 31 December 2020	**–**	**–**	**–**	**–**	**–**	**–**	**–**

Notes to the Unaudited interim financial statements continued

7. Convertible Bonds continued

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.

On 23 June 2016, the Company and GHIF entered into a Deed of Amendment & 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. To split the GHIF Bond into two tranches: the first tranche of US$2m has a Conversion Price of £1.50 per Ordinary Share and the second tranche of US$6m 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 that became effective on the 10 December 2018. The principal effects of the Deed of Amendment were extend the maturity date from December 2021 to December 2023 and change the Conversion Prices on the two tranches from 150p to 28.75p and from 480p 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).

The derivative was measured at fair value at 31 December 2019 and 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 were recorded in profit and loss.

Business Growth Fund (BGF)

The Company entered into an agreement with the BGF that became effective on the 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 were a conversion price of 28.75p, interest on the loan of 7% payable quarterly and a maturity date of June 2025. The loan note came with a conditional £1m subscription to the Company's December 2018 fund raise.

On 30 September 2020, BGF 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.

On 16 December 2020, BGF exercised its right to convert the remaining £1,500,000 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 6,718,022 new ordinary shares and was paid approximately £226,000 in accrued interest owed on this tranche of the loan.

The derivative was measured at fair value at 31 December 2019, 30 June 2020 and at the settlement dates using a Black-Scholes pricing model and changes in fair value were recorded in profit and loss.

Notes to the Unaudited interim financial statements continued

8. Share capital

Allotted, issued and fully paid:	No	£'000
Balance at 30 June 2019	34,000,506	510
Shares issued	869,565	13
Balance at 31 December 2019	34,870,071	523
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 2019	51,986,071	780
Share issue-equity settled share based payments	9,711	–
Share issue-conversion of BGF loan note	4,478,681	67
Share issue-conversion of BGF loan note	6,718,022	100
Balance at 31 December 2020	**63,192,485**	**947**

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.

9. Other Reserves

	Share Premium Account £000	Shares to be issued £000	Employee Share Incentive Plan Reserve £000	Share Options Reserve £000	Reverse Acquisitions Reserve £000	Total £000
At 30 June 2019	29,003	315	(196)	1,486	(2,496)	28,112
Issue of shares	187	(200)	–	–	–	(13)
Equity-settled share based payments	–	–	–	16	–	16
Transactions settled directly in equity	–	–	–	16	–	16
At 31 December 2019	29,190	115	(196)	1,502	(2,496)	28,115
Share issue	7,383	–	–	–	–	7,383
Share issue-conversion of GHIF bond	7,092	–	–	–	–	7,092
Equity settled share-based payments	14	–	–	16	–	30
At 30 June 2020	**43,679**	**115**	**(196)**	**1,518**	**(2,496)**	**42,620**
Share issue-conversion of BGF loan note	**2,332**	**–**	**–**	**–**	**–**	**2,332**
Equity settled share-based payments	**7**	**–**	**(7)**	**14**	**–**	**14**
At 31 December 2020	**46,018**	**115**	**(203)**	**1,532**	**(2,496)**	**44,966**

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