



14 July 2020

OMEGA DIAGNOSTICS GROUP PLC
("Omega" "Company" or the "Group")

FINAL RESULTS
FOR THE YEAR ENDED 31 MARCH 2020

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance testing, announces its audited results for the year ended 31 March 2020.

Omega provide high quality in-vitro diagnostics products for use in hospitals, clinics, laboratories and healthcare practitioners in over 75 countries and specialise in the areas of infectious disease, food intolerance and allergy.

Financial Highlights:

- Like for like revenue of continuing operations increased by 12% to £9.82m (2019: £8.75m)
- Reported revenues increased by 1% to £9.82m (2019: £9.76m)
- Exceptional charges of £7.73m (2018: Exceptional gains of £1.66m) as detailed in the Financial Review below
- Statutory loss for the year of £6.83m (2019: profit of £0.97m)
- Adjusted loss before tax* of £0.40m (2019: loss of £0.30m)
- EBITDA from continuing operations of £0.89m (2019: £0.20m)
- Adjusted EPS (0.2p) (2019: (0.2p))
- Positive cashflow generated from operating activities, with cash inflow of £0.55m (2019: £0.37m)

* Adjusted for exceptional items, amortisation of intangible assets and share based payment charges.

Operational & Post-Period End Highlights:

- VISITECT® CD4 Advanced Disease test added to Global Fund procurement list following opinion from the Expert Review Panel for Diagnostics
- VISITECT® CD4 Advanced Disease – Médecins Sans Frontières (MSF) completes successful multi-site trial in three countries (Democratic Republic of Congo, Malawi and Zimbabwe)
- Supply agreement signed with Clinton Health Access Initiative (CHAI) to accelerate access of VISITECT® CD4 Advanced Disease in low and middle income countries.
- VISITECT® CD4 receives approval from Nigerian Ministry of Health
- Food intolerance division returns to double-digit sales growth and makes significant progress with partners in China
- Chinese regulatory approval of China-specific Food Detective® test to run in laboratory settings
- Agreement signed with UK Rapid Test Consortium to produce COVID-19 antibody lateral flow self-test for UK government and design freeze achieved
- CE marking of ELISA COVID-19 antibody test in conjunction with Mologic Ltd and first commercial sale
- Material Transfer Agreement signed with Mologic Ltd to access its COVID-19 antibody lateral flow test and antigen ELISA and lateral flow tests
- Placing and open offer to raise £11 million
- Cessation of allergy development activities, resulting in net impairment of capitalised development costs of £7.73m

Commenting, William Rhodes, Interim Non-executive Chairman, said: *"We believe that our outlook for the coming fiscal year is excellent – while we have decided to stop development of the allergen product lines, and the Food intolerance revenues are slowed by COVID-19, we are rapidly developing new tests, together with our partners, for COVID-19 that will need to be made and sold, ultimately, in the hundreds of thousands of units, if not millions. We are meeting this challenge by deploying more of our Company's resources in this area, as well as looking to expand our manufacturing capabilities to handle the tremendous increases in volume that will be needed. We see our VISITECT® product lines once again growing significantly as the world balances COVID-19 with the need to test patients with other life threatening, and in some cases chronic, diseases such as HIV. China has already demonstrated a profound ability*

to return to normal in many of its activities and markets, and we, together with our partner, anticipate returning to growth in Food intolerance as the pandemic ebbs.

“Perhaps most importantly to us, and hopefully to you, our shareholders, Omega has been well positioned and highly proactive in playing a key role in developing and manufacturing much needed COVID-19 tests for use throughout the world and, more specifically, to also be able to serve the needs of the people of the UK and Scotland. It has been very gratifying to all Omega associates that we can contribute in this way, and do our part to enhance people’s lives, protect their health and ultimately help us all to return to a more normal way of life.”

The information communicated in this announcement is inside information for the purposes of Article 7 of EU Regulation 596/2014.

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Chairman's Statement

With the advent of COVID-19, we have undertaken a number of processes to ensure the safety and health of our associates in all of our facilities. Fortunately, we have not to date had any employees fall ill from COVID-19. We take this responsibility of ensuring we do all that we can to promote workplace safety very seriously.

Along with the pandemic has come the opportunity for Omega to “rise to the occasion”, and leverage our talent, resources, facilities and manufacturing capabilities to rapidly move forward in developing and producing test kits for both COVID-19 antibody testing as well as antigen-based direct tests that identify active infections. We are almost uniquely positioned to manufacture both handheld lateral flow test kits that can be used at point of care or even at home, as well as ELISA format assays that are used in clinical laboratories to meet higher throughput testing needs.

We are proud that we have been able to quickly focus on these products, along with our partners, to not only meet the testing needs of Scotland and the UK, but also make them available globally. This has led us to re-evaluate various parts of our business and where we have the best opportunities to not only make a difference in people's lives but also create the best financial return, and therefore we are planning to deploy our resources a bit differently in the upcoming fiscal year, 2021.

In terms of our core businesses, we have also been working hard to deliver value to our customers and our shareholders. Our Chief Executive, Colin King, highlights specific performance metrics in each of our focus areas in his CEO Report. I would like to touch on a few of the most significant strategic aspects of each:

Food intolerance

We continued to see growth in this business, primarily with our partner in China. Along with them, we made excellent progress in advancing through Chinese product registration and development, and this despite the impact of COVID-19 there. We believe we are well positioned for growth, with the full understanding that it may take a bit longer considering the global pandemic and, more particularly, China's own return to normalcy. That said, both our partner and we are expecting to grow this business and will continue to deploy resources to achieve significant growth as the opportunities to do so arise.

The US, on the other hand, continues to present challenges. While we see significant opportunity there for our food intolerance testing products, the regulatory environment and market access in the US has proved to be difficult for these tests, and having a US partner is important to access the market – although where the testing is performed may be less important than how we access our US customers. Our current distribution partner had experienced financial issues, and, as such, we decided to terminate that agreement. We are now actively re-evaluating our path forward in the US and expect to formalise our strategy, approach to the consumer and necessary relationships during the balance of 2020.

Allergy and autoimmune

We continued to be disappointed with sales progress in this area, even though we were able to CE mark 69 allergens to be run on our partner's (IDS) instruments. However, given the costs to develop additional allergens, the slow pace of increasing sales, and the need for us to focus our resources on areas that promise to yield higher near-term returns, such as COVID-19 test kit development and production, we have taken the necessary steps to discontinue development of additional allergens. We will continue to produce the 69 allergens developed for IDS but will wind down all additional development efforts in this area.

Infectious disease

While the advent of the COVID-19 pandemic has slowed our sales of the VISITECT® product line, we see this as an inevitable delay due to our distributors and various country governments needing to refocus their resources and attention on COVID-19. Ultimately, though, this does not change demand for CD4 testing – HIV, unfortunately, will not simply go away.

We have successfully brought two VISITECT® products to market; the VISITECT® Advanced Disease test, meant to be used with individuals whose disease is more severe and who need to be more routinely monitored, and VISITECT® 350, which is used with those living with the disease but whose condition is better controlled.

While a strong market exists for the VISITECT® 350 test, with the largest demand in Nigeria, we expect that the VISITECT® Advanced Disease test, with a 200 cells/µl cut-off, will be the larger opportunity. For example, the US government, through PEPFAR, has indicated support for a lateral flow CD4 assay, and Unitaid, via the Clinton Health Access Initiative

(CHAI), is investing at least \$20 million through the end of 2021 to accelerate the deployment of Advance HIV disease care which will specifically include our CD4 lateral flow assay with a 200 cells/ μ l cut-off.

Unlike any other diagnostics companies producing CD4 tests of various formats, we believe that Omega has the only fully validated, commercially available lateral flow CD4 test kit that can meet the specifications called for by these multiple funding agencies.

Results

The Group's financial results for the year ended 31 March 2020 are set out in the consolidated financial statements and are discussed in detail in the Financial Review.

Board and management

I have been pleased to continue to serve in the role of Interim Non-Executive Chairman throughout the year and plan to continue until such time as a permanent successor is appointed. I would like to thank my colleagues on the board and all the employees of the Omega Group who, collectively, have achieved much in our core business and who have demonstrated flexibility in rising to the new challenges and opportunities presented by COVID-19.

Fundraising and going concern

Since the announcement on 9 April 2020, regarding the Company's involvement with the UK Rapid Test Consortium ("UK-RTC") to develop a lateral flow antibody test for COVID-19 on behalf of the UK Government, the Company's share price has risen considerably from 11p per share the day before the announcement. This has enabled some long-standing shareholders to finally realise some value from investments made many years ago, which is very pleasing. It has also presented an opportunity for the Company to attract a new institutional following and I am grateful for the support shown from both existing and new shareholders in supporting the Company's recent placing and open offer which has raised £10.5 million net of expenses and will be used by the Company to exploit the opportunities which were outlined in the circular posted to shareholders on 22 June 2020.

The directors have considered the principal risks and uncertainties the Group faces and other factors impacting the Group's future performance such as the coronavirus pandemic. While the impact of the pandemic in terms of length, severity and disruption to business is not possible to forecast, given the significant new investment into the Company from the placing and open offer, the Directors are comfortable that the Group can survive unprecedented reductions in revenue for at least the next twelve months and that the Group has adequate resources to continue to exist for the foreseeable future. The Directors therefore continue to adopt the going concern basis in preparing its consolidated financial statements.

Outlook

We believe that our outlook for the coming fiscal year is excellent – while we have decided to stop development of the allergen product lines, and the Food intolerance revenues are slowed by COVID-19, we are rapidly developing new tests, together with our partners, for COVID-19 that will need to be made and sold, ultimately, in the hundreds of thousands of units, if not millions. We are meeting this challenge by deploying more of our Company's resources in this area, as well as looking to expand our manufacturing capabilities to handle the tremendous increases in volume that will be needed. We see our VISITECT® product lines once again growing significantly as the world balances COVID-19 with the need to test patients with other life threatening, and in some cases chronic, diseases such as HIV. China has already demonstrated a profound ability to return to normal in many of its activities and markets, and we, together with our partner, anticipate returning to growth in Food intolerance as the pandemic ebbs.

Perhaps most importantly to us, and hopefully to you, our shareholders, Omega has been well positioned and highly proactive in playing a key role in developing and manufacturing much needed COVID-19 tests for use throughout the world and, more specifically, to also be able to serve the needs of the people of the UK and Scotland. It has been very gratifying to all Omega associates that we can contribute in this way, and do our part to enhance people's lives, protect their health and ultimately help us all to return to a more normal way of life.

William Rhodes
Interim Non-executive Chairman

Chief Executive's Review

Our revenue in the twelve months to 31 March 2020 was £9.8 million and, based on continuing operations, this showed a growth of 12% on the year prior. This growth was driven by our Food intolerance business which returned to double-digit growth of 14% over the prior year.

Our statutory loss for the year was £6.8 million compared to a profit of £0.97 million in the prior year. The main driver for the loss was as a result of the recent decision to stop development of the Allergy product range to run on the IDS system. This incurred a £7.73 million net write off.

Gross profit from continuing operations increased from £5.6 million to £6.3 million reflecting the higher sales with gross profit percentage being maintained at 64%. EBITDA increased on prior year from £0.2 million to £0.9 million.

Core business Food intolerance

The Food intolerance division sales continued to grow on last year's increase of 7%, with a further 13.9% growth. This resulted in sales in 2020 of £9.2 million (2019: £8.0 million). The main driver for the growth was our partner in China, which procured £1.2 million of Food Detective® product.

Sales of FoodPrint® increased by 4% to £5.66 million (2019: £5.46 million). The Group sold a further 23 instruments, taking the cumulative number of installations to 216 instruments in 42 countries. Revenue per instrument decreased by 9% to £26,189 (2019: £28,942).

Sales of Food Detective® increased by 57% in the year to £2.63 million (2019: £1.67 million).

Our development team and our strategic partner in China have made excellent progress with the development and registration of our Food intolerance product in China, despite the outbreak of COVID-19 in China. Our partner received regulatory approval for the Chinese version of the Food Detective® test for use in a laboratory at the beginning of April and it is now working with the authorities to gain approval to allow the test to be run directly by the public. In preparation for the expected launch, we shipped orders (over three deliveries) totalling 98,040 tests by March 2020.

Our strategy to address the US market has suffered a setback following one of our partners running into financial difficulties and we have now terminated its distribution agreement. As a result of this, we are now assessing different options to grow our revenues in this key market and expect to commence implementing this revised strategy towards the end of calendar year 2020.

The move into our new purpose-built facility in Ely, for our Food intolerance business unit, has been significantly delayed due to the main contractor going into administration in 2019 and then further delayed due to the COVID-19 outbreak. We are now expecting the building to be completed by October this year.

Allergy and autoimmune

The Allergy and autoimmune division sales, which include discontinued operations, decreased by 59% on the prior year to £0.4 million (2019: £0.98 million). The main reason for the decline was caused by the 2019 revenues including a contribution from the German Allergy business in the first quarter.

We increased the Allergy menu running on the IDS instrument to 69 CE marked allergens and these are now in routine production. Post year end, we have, however, made the decision to stop ongoing development of this product range. We will continue to manufacture the 69 allergens to meet any orders placed on us by IDS. As a result of changes to underlying assumptions of future revenues, under IAS 36, there is an impairment to the carrying value of the intangible asset and licence fee (combined £8.75 million), partially offset by a release of grant income from the balance sheet (£1.02 million) leading to an exceptional P&L charge of £7.73 million. This has no cash impact on the business and the cessation of future allergy development activities will reduce ongoing cash outflows.

Autoimmune sales were flat at £0.37 million (2019: £0.35 million) and this product range has now been discontinued as no longer being core to our business.

Infectious disease

The Infectious disease division sales including discontinued operations decreased by 66% on the prior year to £0.25 million (2019: £0.73 million). The main reason for this decline was that the prior year included a first quarter revenue contribution from the legacy Infectious disease business which was sold in June 2018. In addition, expected growth in revenues from VISITECT® CD4 did not materialise as planned due to delays in gaining regulatory approvals, particularly in Nigeria.

VISITECT® CD4 – key achievements in the last financial year:

VISITECT® CD4 Advanced Disease test was included in the Global Fund procurement list in September 2019, following successful conclusion of a quality risk assessment review by the Expert Review Panel for Diagnostics (ERPD).

VISITECT® CD4 350 received Nigerian MOH approval in January 2020.

Commercialisation for our VISITECT® CD4 350 will be primarily focused on Nigeria, following approval by MOH, noted above. As a result of the approval, the test has been included in the Nigerian National HIV Control Programme. The health authorities are currently determining the overall demand across all regions within Nigeria prior to placing orders on our distributor. This process is currently on hold due to the current outbreak of COVID-19. We remain confident that this demand will materialise, and that Nigeria remains a large market opportunity.

We believe that VISITECT® CD4 Advanced Disease is the larger opportunity out of the two test formats. The US government, through the US President's Emergency Plan for AIDS Relief (PEPFAR), has included support for a "lateral flow CD4 assay" in its current operational guidance and the Global Fund has indicated it will financially support the initiative.

Our plans to commercialise VISITECT® CD4 Advanced Disease products comprise three sales channels:

1. Advanced HIV Disease Initiative co-ordinated by Unitaïd via Clinton Health Access Initiative (CHAI)
2. Médecins Sans Frontières (MSF)
3. United Nations NGO networks

1. Advanced HIV Disease Initiative – Unitaïd is investing \$20 million to run through to the end of 2021 in a package of care which includes a CD4 lateral flow assay with a cut-off at 200 CD4 cells/ μ L. This initiative is being driven by Unitaïd and will be implemented by CHAI. The aim of the initiative is to accelerate the deployment of advance disease care across low and middle income countries (LMIC). The programme will act as the catalyst to establish a deployment in those countries and allow other aid agencies such as the Global Fund and PEPFAR to continue after that initial set-up. The programme is open to all LMIC countries but will initially target five or six countries as early adopters prior to a wider roll-out. A supply agreement was signed between Omega and CHAI in April 2020 to provide the framework for this programme to commence with a minimum of 100,000 tests and up to 500,000 tests to be ordered by CHAI between April 2020 and December 2021.

2. MSF – MSF has recently successfully concluded a multi-site study across three countries (Zimbabwe, Malawi and the Democratic Republic of Congo). The key conclusion is that the test is ideally suited for use in remote settings. Despite the positive results, procurement of our VISITECT® CD4 Advanced Disease test has been delayed as a result of COVID-19 with resources being re-deployed to deal with this crisis.

3. United Nations NGO networks – these are all prospective and significant buyers, however procurement requires WHO prequalification approval to be completed. This approval incorporates three stages:

- (1) Review of technical documents which is currently underway.
- (2) WHO product evaluation, which will take place in Kenya. This has been delayed due to COVID-19 and we are currently awaiting ethics approval prior to commencement of the study. We remain hopeful that we will complete the evaluation before the end of the calendar year.
- (3) Site audit was performed in late January and we have recently submitted our corrective action plan for approval, which will hopefully close out this stage.

Fundraising

I am very pleased with the level of support we received from new and existing shareholders in supporting our vision on how best to make a success of the opportunities that have presented around COVID-19 testing. The significant levels of investments made, both through the placing and open offer totalling £11 million will enable the company to execute on this vision whilst at the same time, bring products to market that are priced at socially responsible levels.

I look forward to providing updates on significant developments throughout the year on our CD4, COVID-19 and Food Intolerance business units.

Outlook

The outbreak of COVID-19 has impacted our core business in quarter one but the full extent of the impact is still unknown at this stage. However, there are several reasons to be optimistic as we look forward.

Food intolerance in China, with the expected self-test approval later this year, offers significant growth opportunities.

For CD4, the CHAI programme to accelerate the deployment of our VISITECT® CD4 Advanced Disease test, and the expected WHO prequalification approval later this year, will see the adoption of this unique and important test in several key countries.

The COVID-19 outbreak itself has provided significant short-term opportunities as we work with partners to leverage our skills to develop and manufacture both ELISA and lateral flow rapid tests to cover both antibody and antigen testing. We are in the process of significantly increasing capacity in both our manufacturing sites (Alva and Littleport) as part of our contribution to the UK Rapid Test Consortium to manufacture rapid antibody self-tests for the UK government. Additionally, we have signed an agreement with Mologic to CE mark, manufacture and sell both antibody and antigen tests in two formats namely ELISA and lateral flow.

We are, therefore, confident as we look forward that we are well positioned to deliver growth to the business.

Finally, I would like to thank all the Group's employees for their continued support and commitment. The COVID-19 outbreak has shown not only their great desire to ensure we manage the business through these difficult times but also their amazing flexibility which has allowed us to progress the various COVID-19 opportunities at a faster than normal rate. They have also ensured that the sites remain secure and that they and their colleagues are protected.

Colin King
Chief Executive

Financial review

The financial results for the year have been impacted by the decision for our Allergy business unit to stop developing further allergens beyond the 69 we have CE marked to date, giving rise to an exceptional loss. There have been no discontinued operations in the year, as there were in the prior year, which I will detail later. I will therefore deal first with a summary of financial performance from continuing operations.

Continuing operations financial summary

	2020 £	2019 £	+/- %
Food intolerance revenue	9,170,864	8,050,142	+13.9%
Allergy and autoimmune revenue	398,678	401,251	- 0.6%
Infectious disease revenue	249,120	305,363	-18.4%
Total revenue	9,818,622	8,756,756	+12.1%
Gross profit	6,293,973	5,632,329	+11.7%
Gross profit percentage	64.1%	64.3%	
Exceptional items	(7,732,532)	—	
EBITDA	893,007	199,668	+347%
Adjusted loss before taxation	(395,673)	(218,060)	-81.5%

Group revenue from continuing operations increased by 12.1% to £9.82 million, due mainly to the performance in our Food intolerance division which benefited from sales of a newly developed version of the Food Detective® kit for the Chinese market. Sales of this kit in China generated revenues of £1.24 million (2019: £Nil) and are included within total Food Detective® sales of £2.63 million (2019: £1.67 million). China is expected to be a strong growth driver over the coming years. Sales of our laboratory test, FoodPrint®, achieved sales of £5.66 million (2019: £5.46 million) with the “top ten” markets by revenue achieving growth of 5.3% over the prior year, outstripping the overall growth rate of 3.7%. Revenues for autoimmune and infectious disease products continue to be principally derived of sales through our Indian subsidiary and amounted to £0.65 million (2019: £0.71 million).

The gross profit margin percentage has been maintained for continuing operations at 64.1% (2019: 64.3%) in line with our target range, with rising raw material costs having been mitigated by the slightly higher product mix towards our Food intolerance products.

Administrative overheads from continuing operations increased by £0.67 million to £5.37 million (2019: £4.70 million). The majority of this increase relates to the commencement of intangible asset amortisation charges of £0.56 million (£0.43 million relating to Allergy and £0.13 million relating to VISITECT® CD4).

Selling and marketing costs reduced marginally to £1.49 million (2019: £1.53 million) with increased headcount costs of £0.1 million being offset by reduced marketing spend of £0.14 million

As noted above, there is an exceptional cost in the year comprising an impairment charge of intangible assets. This follows the decision to stop all future expenditure on the Allergy development programme. Due to significant adverse changes in underlying assumptions, we reassessed our impairment models and concluded that the recoverable amount of the Allergy assets, comprising a licence fee of £1.48 million and capitalised development costs of £7.27 million, was less than its current carrying value. Accordingly, an impairment charge in accordance with IAS 36 has been recognised to record these assets at their current estimated recoverable amount.

Following confirmation from Scottish Enterprise that the R&D grant awarded in 2016 has been successful in supporting the development of the 69 allergens we have developed to date, and having confirmed that Scottish Enterprise will not seek repayment of £1.4 million drawn down to date, we have recognised a proportionate amount of deferred income, previously on the balance sheet, as exceptional income in the year.

Exceptional items summary (pre-taxation)

	2020		2019	
	Continuing operations £	Discontinued operations £	Continuing operations £	Discontinued operations £
Impairment of intangible asset	(8,747,683)	—	—	—
Credit from government grant deferred income	1,105,151	—	—	—
Gain on sale of Infectious disease business	—	—	—	901,808
Omega Diagnostics GmbH closure	—	—	—	758,875
Total	(7,732,532)	—	—	1,660,683

Discontinued operations financial summary

	2020 £	2019 £
Food intolerance revenue	—	—
Allergy and autoimmune revenue	—	578,907
Infectious disease revenue	—	423,656
Total revenue	—	1,002,563
Gross profit	—	531,095
Gross profit percentage	—	53%
Exceptional items	—	1,660,683
EBITDA	—	(73,370)
Adjusted (loss)/profit before taxation	—	(85,177)

The discontinued operations comprise the Allergy business that was closed down and operated by our German subsidiary, Omega Diagnostics GmbH, the manufacturing operations in Pune, India, that were closed down and operated by our Indian subsidiary, Omega Dx (Asia) Pvt Limited, and the legacy Infectious disease business that was sold by Omega Diagnostics Limited to Lab 21 Healthcare Ltd in June 2018.

The remainder of the Financial Review addresses the results for total operations.

Loss before tax and EBITDA

The Group has recorded a statutory loss before tax of £8.30 million, which includes the net exceptional charges of £7.73 million noted above.

The Group also monitors its EBITDA level as being a measure of profit that is more aligned with the cash-generating activities of the business. The Group generated an EBITDA in the year of £0.89 million (operating loss before exceptional items of £0.32 million with add-backs of £0.47 million for depreciation, £0.68 million for amortisation and £0.06 million for share-based payments). In the prior year, the Group generated an EBITDA of £0.12 million (operating loss before exceptional items of £0.38 million with add-backs of £0.33 million for depreciation, £0.14 million for amortisation and £0.03 million for share-based payments).

Segmental performance as presented in the notes to the financial statements shows that the Food intolerance division and the Allergy and autoimmune segment were EBITDA positive after an allocation for Group overheads. The Infectious disease segment shows an EBITDA loss due to the decision to retain manufacturing staff in the business, following the divestment of the legacy Infectious disease business to Lab 21 Healthcare Ltd, ahead of ramping up production for VISITECT® CD4 and the more recent opportunities which have presented for COVID-19 testing.

Taxation

The current year tax credit of £1.47 million includes a current year credit movement in deferred tax of £1.52 million predominantly relating to the intangible asset impairment noted above, a prior year debit movement in deferred tax of £0.22 million and a current year credit of £0.17 million relating to a receipt from HMRC for surrendering SME R&D tax credits.

We retain cumulative tax losses of approximately £7.6 million that are carried forward and available for offset against future profits. Our UK companies continue to benefit from government policies on tax that encourage investment in research and development activities. In the year a research and development expenditure credit of £0.15 million (2019:

£0.17 million) was accrued in the income statement and is included as a credit within administration costs and carried as a debtor at 31 March 2020. In addition, we received a SME R&D tax credit of £0.17 million relating to the year ending 31 March 2019.

Earnings per share

Adjusted earnings per share were (0.2) pence versus (0.2) pence in the prior year. The adjusted loss after tax of £0.40 million (2019: £0.27 million) is calculated on 140.3 million fully diluted (2019: 127.1 million) shares in issue. The calculation of adjusted loss after tax is contained in notes to the financial statements and on the adjusted loss before taxation reconciliation statement. Statutory earnings per share were (4.9) pence (2019: 0.8 pence) on statutory loss after tax of £6.83 million (2019: profit of £0.97 million).

Research and development

During the year, we invested a total of £2.10 million in all development activities, a reduction of £0.5 million from the prior year (2019: £2.60 million), representing 21.4% (2019: 26.6%) of Group turnover. Expenditure on our Allergy project reduced to £0.88 million (2019: £0.98 million) before Allergy-related contributions of £0.28 million from the Scottish Enterprise R&D grant. The menu at the end of the financial year extended to 69 allergens before the decision to cease future development as noted above. Expenditure on VISITECT® CD4 reduced to £0.76 million (2019: £0.96 million) and was incurred in support of product evaluations in three African countries with Médecins Sans Frontières, the Ministry of Health approval in Nigeria and the ongoing application in relation to the WHO prequalification process.

We also reduced expenditure on enhancements to our Food intolerance products, investing £0.42 million in the year (2019: £0.51 million). This expenditure continued the yield improvements in manufacturing of FoodPrint® slides and progress with the Chinese version of our Food Detective® test.

Of the total expenditure, £2.06 million (2019: £2.45 million) has been capitalised on the balance sheet in accordance with IAS 38 – Development Costs whilst earlier stage R&D expenditure of £0.04 million (2019: £0.15 million) has been expensed through the income statement.

A summary of the carrying value of capitalised development costs, after impairment of the Allergy asset, is shown in the table below:

	2019		Incurred in year		Amortised in year		Impaired in year*		2020
	£	£	£	£	£	£	£	£	
Allergy	6,800,239	879,455	(432,743)	(7,246,951)					—
VISITECT® CD4	3,815,177	761,903	(130,925)	(16,068)					4,430,087
Food/other	1,020,800	421,331	—	—					1,442,131
Total	11,636,216	2,062,689	(563,668)	(7,263,019)					5,872,218

*allergy impairment figure of £7,246,951 excludes an impairment charge of £1,484,663 of the IDS licence fee which is included in the intangible assets note under licences/software. The immaterial CD4 impairment charge of £16,068 relates to a historical project which has since ceased.

Property, plant and equipment

Expenditure on fixed assets in the year was £0.20 million, lower than in the prior year (2019: £0.34 million). Expenditure was incurred principally at the Littleport site in England and included expenditure on manufacturing equipment, of which £0.15 million was offset through new asset finance leasing.

Impact of IFRS 16 – Leases

Following the adoption of IFRS 16, the Group has also recognised right of use assets of £1.98 million from the start of the financial year. This sum has been depreciated by £0.25 million in the year leaving a carrying value on the balance sheet of £1.73 million.

As at 31 March 2020, the outstanding liabilities in connection with leases recognised under IFRS 16 included short-term liabilities of £0.09 million and long-term liabilities of £1.70 million.

Financing

The Group generated a positive cash flow from its operating activities, principally from its Food intolerance testing segment, and this has been supplemented by its funding initiatives from other sources since the financial year end. The Group continues to have a strong relationship with the Bank of Scotland as principal bankers to the Group and, in

September 2019, we agreed a further renewal of the overdraft facility of £2.0 million (2019: £2.0 million) until 30 September 2020.

The directors then approached the Company's bank to seek additional short-term funding to mitigate the effects of the pandemic. On 14 May 2020, the bank agreed to increase the Group's overdraft facility from £2 million to £3 million for a period of six months, thereby due to expire on 14 November 2020. The directors intend to agree with the bank that after 14 November, the facility will revert to £2 million but remain in place.

The Group also raised additional equity funds from shareholders on two occasions during the year. In May 2019, the Group raised £0.63 million of new equity capital through a direct subscription from certain shareholders, resulting in the issue of 6,347,950 new ordinary shares at 10 pence per share. In September 2019, the Group issued a further 17,000,000 new ordinary shares at 10 pence per share via a placing and direct subscription and this raised £1.58 million after expenses. Since the financial year end, there have been further developments which are noted in the section below relating to COVID-19 and events since the balance sheet date.

Operating cash flow

The Group monitors its cash requirement carefully and it is a key priority to manage working capital efficiently and to be effective in converting operating income into cash.

Cash inflow from operating activities during the year was £0.55 million (2019: £0.37 million). The Group has achieved a conversion rate of adjusted operating loss (operating loss plus amortisation of intangible assets plus share-based payments) to operating cash of 123% (2019: 379%). At 31 March 2020, the Group's net overdraft utilisation was £0.57 million (2019: £0.74 million). Our ability to continue to generate sufficient future operating cash flow is dependent on the prospects for our VISITECT® CD4 products and the recent opportunities to have emerged with COVID-19 testing (see below).

COVID-19 and events since the balance sheet date

The global coronavirus pandemic has caused much uncertainty throughout the world, with many countries going into lockdown causing a negative effect on economies. Our initial response to the pandemic was to identify key activities to be undertaken from the end of March, for the next few months, and to then take advantage of the government's Coronavirus Job Retention Scheme for staff who could be placed on furlough leave. This support mechanism is delivering what it was designed to do and has helped to preserve cash in the short term. We have also received additional support from our bank, which has increased our overdraft facility from £2 million to £3 million with effect from 14 May 2020 for six months. We have seen an impact from COVID-19 through reduced level of sales in Q1 of the new financial year, compared to the same Q1 for the year just ended, but the impact is within sensitivity models we have run and for which the increased overdraft was sought from the bank.

Finally, as announced on 19 June 2020, we have recently taken the opportunity to raise additional equity funds of £11 million through a placing and open offer to strengthen the balance sheet during what remain uncertain times due to the COVID-19 pandemic. On 25 June 2020, the Company allotted 7,515,350 ordinary shares to new and existing shareholders at 40 pence per share under the authority granted at the AGM on 22 October 2019. Following the general meeting on 10 July 2020 the Company has allotted a further 20,015,750 new ordinary shares at 40 pence per share, comprised of 12,434,650 ordinary shares allotted to new and existing shareholders through the placing, 50,000 ordinary shares allotted to two directors who participated in the fundraising via direct subscription and 7,531,100 ordinary shares to existing shareholders to satisfy the demand through the open offer.

Section 172 (1) Companies Act 2006

The Board has considered the reporting requirements under section 172 of the Companies Act and there is a statement in the Director's Report.

Kieron Harbinson
Group Finance Director

Consolidated Statement of Comprehensive Income

for the year ended 31 March 2020

	2020		2019		
	Continuing operations		Continuing operations	Discontinued operations	Total
	£		£	£	£
Continuing operations					
Revenue	9,818,662		8,756,756	1,002,563	9,759,319
Cost of sales	(3,524,689)		(3,124,427)	(471,468)	(3,595,895)
Gross profit	6,293,973		5,632,329	531,095	6,163,424
Administration costs	(5,374,849)		(4,695,486)	(445,550)	(5,141,036)
Selling and marketing costs	(1,490,283)		(1,532,980)	(195,295)	(1,728,275)
Other income	257,930		324,794	—	324,794
Operating loss before exceptional items	(313,229)		(271,343)	(109,750)	(381,093)
Exceptional items	(7,732,532)		—	1,660,683	1,660,683
Operating (loss)/profit after exceptional items	(8,045,761)		(271,343)	1,550,933	1,279,590
Finance costs	(251,807)		(97,085)	—	(97,085)
Finance income – interest receivable	—		11	—	11
(Loss)/profit before taxation	(8,297,568)		(368,417)	1,550,933	1,182,516
Tax credit/(charge)	75		28,891	(237,154)	(208,263)
Tax credit – exceptional item	1,469,181		—	—	—
(Loss)/profit for the year	(6,828,312)		(339,526)	1,313,779	974,253
Other comprehensive income to be reclassified to profit and loss in subsequent periods					
Exchange differences on translation of foreign operations	(29,862)		20,568	(2,331)	18,237
Recycling of translation revenue on foreign operations	(78,493)		—	41,886	41,886
Tax credit/(charge)	8,724		(91)	—	(91)
Other comprehensive income for the year	(99,631)		20,477	39,555	60,032
Total comprehensive income for the year	(6,927,943)		(319,049)	1,353,334	1,034,285
Earnings per share (EPS)					
Basic and diluted EPS on profit for the year	(4.9p)		(0.3p)	1.0p	0.8p

	2020		2019		
	Continuing operations		Continuing operations	Discontinued operations	Total
	£		£	£	£
(Loss)/profit before taxation	(8,297,568)		(368,417)	1,550,933	1,182,516
Exceptional items	7,732,532		—	(1,660,683)	(1,660,683)
Amortisation of intangible assets	115,271		116,156	24,573	140,729
Share-based payment charges	54,092		34,201	—	34,201
Adjusted loss before taxation	(395,673)		(218,060)	(85,177)	(303,237)
Earnings per share (EPS)					
Adjusted EPS on loss for the year	(0.2p)		(0.1p)	(0.1p)	(0.2p)

Adjusted profit before taxation is derived by taking statutory profit before taxation and adding back exceptional items, amortisation of intangible assets and share-based payment charges. This is not a primary statement and the reported numbers are non-GAAP measures.

Consolidated Balance Sheet

as at 31 March 2020

	2020 £	2019 £
ASSETS		
Non-current assets		
Intangibles	9,676,669	17,044,293
Property, plant and equipment	1,432,042	1,569,581
Right of Use assets	1,731,827	—
Deferred taxation	1,538,443	1,371,260
Total non-current assets	14,378,981	19,985,134
Current assets		
Inventories	1,169,115	1,000,700
Trade and other receivables	3,287,702	2,489,389
Cash and cash equivalents	—	—
Total current assets	4,456,817	3,490,089
Total assets	18,835,798	23,475,223
EQUITY AND LIABILITIES		
Equity		
Issued capital	22,010,384	19,797,343
Retained earnings	(8,364,109)	(1,677,106)
Other reserves	(37,950)	70,405
Total equity	13,608,325	18,190,642
Liabilities		
Non-current liabilities		
Long-term borrowings	131,487	78,478
Lease liabilities	1,703,570	—
Deferred taxation	898,734	2,036,593
Deferred income	155,495	864,255
Total non-current liabilities	2,889,286	2,979,326
Current liabilities		
Short-term borrowings	85,678	98,574
Lease liabilities	87,018	—
Bank overdraft	565,166	744,708
Trade and other payables	1,600,325	1,461,973
Total current liabilities	2,338,187	2,305,255
Total liabilities	5,227,473	5,284,581
Total equity and liabilities	18,835,798	23,475,223

Consolidated Statement of Changes in Equity

for the year ended 31 March 2020

	Issued capital £	Retained earnings £	Translation Reserve £	Total £
Balance at 31 March 2018	19,797,343	(2,685,469)	10,282	17,122,156
Profit for the year ended 31 March 2019	—	974,253	—	974,253
Other comprehensive income – net exchange adjustments	—	—	18,237	18,237
Other comprehensive income – net exchange adjustments recycled	—	—	41,886	41,886
Other comprehensive income – tax charge	—	(91)	—	(91)
Total comprehensive income for the year	—	974,162	60,123	1,034,285
Share-based payments	—	34,201	—	34,201
Balance at 31 March 2019	19,797,343	(1,677,106)	70,405	18,190,642
Issue of share capital for cash consideration	2,343,395	—	—	2,343,395
Expenses in connection with share issue	(130,354)	—	—	(130,354)
Loss for year ended 31 March 2020	—	(6,828,312)	—	(6,828,312)
Other comprehensive income – net exchange adjustments	—	—	(29,862)	(29,862)
Other comprehensive income – net exchange adjustments recycled	—	78,493	(78,493)	—
Other comprehensive income – tax charge	—	8,724	—	8,724
Total comprehensive income for the year	—	(6,741,095)	(108,355)	(6,849,450)
Share-based payments	—	54,092	—	54,092
Balance at 31 March 2020	22,010,384	(8,364,109)	(37,950)	13,608,325

Consolidated Cash Flow Statement

for the year ended 31 March 2020

	2020 £	2019 £
Cash flows generated from operations		
(Loss)/profit for the year	(6,828,312)	974,253
Adjustments for:		
Exceptional item – impairment	7,732,532	—
Taxation	(75)	208,263
Taxation – exceptional item	(1,469,181)	—
Finance costs	251,807	97,085
Finance income	—	(11)
Operating (loss)/profit before working capital movement	(313,229)	1,279,590
(Increase)/decrease in trade and other receivables	(798,313)	620,454
(Increase)/decrease in inventories	(168,415)	196,438
Increase/(decrease) in trade and other payables	138,351	(1,078,437)
Gain on sale of property, plant and equipment	3,672	—
(Net liabilities written off)/asset provisions	—	(758,875)
Gain on sale of Infectious disease division	—	(901,808)
Depreciation	473,185	332,461
Amortisation of intangible assets	678,939	140,729
Movement in grants	306,391	382,234
Share-based payments	54,092	34,201
Taxation received	172,934	121,832
Cash flow from operating activities	547,607	368,819
Investing activities		
Finance income	—	11
Proceeds from the sale of the Infectious disease division	—	1,800,000
Purchase of property, plant and equipment	(201,584)	(339,817)
Purchase of intangible assets	(1,952,259)	(2,354,659)
Net cash used in investing activities	(2,153,843)	(894,465)
Financing activities		
Finance costs	(251,807)	(97,085)
Proceeds from issue of share capital	2,343,395	—
Expenses in connection with share issue	(130,353)	—
New sale and finance leasebacks	—	40,500
New finance leases	150,000	—
(Repayment)/drawdown of overdraft facility	(179,542)	744,708
Lease repayments	(295,643)	(153,153)
Net cash from financing activities	1,636,050	534,970
Net increase in cash and cash equivalents	29,814	9,324
Effects of exchange rate movements	(29,814)	(125,043)
Cash and cash equivalents at beginning of year	—	115,719
Cash and cash equivalents at end of year	—	—

Notes to the Preliminary Announcement

for the year ended 31 March 2020

1. Basis of preparation

The financial information set out in this preliminary announcement does not constitute statutory accounts as defined in Section 434(3) of the Companies Act 2006.

The consolidated balance sheet at 31 March 2020 and the consolidated statement of comprehensive income, consolidated cash flow statement, consolidated statement of changes in equity and associated notes for the year then ended have been extracted from the Group's financial statements which were approved by the Board of Directors on 13 July 2020 and are audited. The comparative consolidated financial information for the year ended 31 March 2019 is based on an abridged version of the Group's published financial statements for that year, which contained an unqualified audit report which included an emphasis of matter in relation to going concern. A copy of the 2019 financial statements has been filed with the Registrar of Companies.

The statutory accounts for 2020 will be finalised on the basis of the financial information presented in this preliminary announcement and will be delivered to the registrar of companies.

The consolidated financial statements have been prepared in accordance with IFRS as adopted by the European Union as they apply to the financial statements of the Group for the year ended 31 March 2020.

Basis of consolidation

The Group financial statements consolidate the financial statements of Omega Diagnostics Group PLC and the entities it controls (its subsidiaries). Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Subsidiaries are consolidated from the date of acquisition, being the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases. The financial statements of the subsidiaries used in the preparation of the consolidated financial statements are based on consistent accounting policies. All intercompany balances and transactions, including unrealised profits arising from them, are eliminated

Going concern

These financial statements have been prepared on a going concern basis, which contemplates the realisation of assets and the payment of liabilities in the ordinary course of business. The Group realised a loss of £6.83 million for the year ended 31 March 2020 (2019: profit of £0.97 million). As at 31 March 2020, the Group had net current assets of £2.1 million and an overdraft facility of £2.0 million, of which, £1.4 million was undrawn.

On 19 June 2020, the Group announced it was raising additional equity funds through a placing and open offer from existing and new institutional and retail shareholders to raise up to £10.5 million net of expenses. Following the general meeting on 10 July 2020, the Group confirms that the net proceeds raised from this exercise amounted to £10.5 million. The directors have also prepared updated forecasts to 30 September 2021 and have undertaken additional sensitivity analysis. This includes a scenario of:

- reducing the Company's revenues from its food intolerance business to approximately 50% of the anticipated level of revenue for the year ended 31 March 2021 before the COVID-19 pandemic.
- reducing the Company's revenues from its VISITECT® CD4 business to levels supported by contractual arrangements.
- reducing expected levels of revenue from the new COVID-19 tests to zero.

In preparing these forecasts, the Directors included certain cost mitigation measures that could be taken but did not include the proceeds from any insurance claims that could be applicable under its business interruption policy. As a result of the equity fundraise, the existing overdraft facility, which is set to expire in November 2020, is not envisaged to be required and has not been relied upon in the Group's base case or sensitised forecasts.

The directors have considered the principal risks and uncertainties the Group faces and other factors impacting the Group's future performance such as the coronavirus pandemic. While the impact of the pandemic in terms of length, severity and disruption to business is not possible to forecast, given the significant new investment into the Company from the placing and open offer, the Directors are comfortable that the Group has sufficient cash runway and can survive unprecedented reductions in revenue for at least the next twelve months.

After making enquiries, the Directors have a reasonable expectation that the Group has adequate resources to continue to exist for the foreseeable future. The Directors therefore continue to adopt the going concern basis in preparing its consolidated financial statements.

2. Segment information – Continuing operations

2020	Allergy and autoimmune £	Food intolerance £	Infectious disease and Other £	Corporate £	Total £
Statutory presentation					
Revenue	462,169	9,406,977	249,128	—	10,118,274
Inter-segment revenue	(63,491)	(236,113)	(8)	—	(299,612)
Total revenue	398,678	9,170,864	249,120	—	9,818,662
Cost of sales	(92,065)	(2,921,257)	(511,367)	—	(3,524,689)
Gross profit	306,613	6,249,607	(262,247)	—	6,293,973
Operating costs	(675,404)	(2,690,571)	(2,124,568)	(1,116,659)	(6,607,202)
Operating profit/(loss) before exceptional items	(368,791)	3,559,036	(2386,815)	(1,116,659)	(313,229)
Share-based payment charges	—	—	—	54,092	54,092
Depreciation	8,571	249,657	214,957	—	473,185
Amortisation	433,293	100,802	144,864	—	678,959
EBITDA	73,073	3,909,495	(2,026,994)	(1,062,567)	893,007
Share-based payment charges	—	—	—	(54,092)	(54,092)
Exceptional items	(7,732,532)	—	—	—	(7,732,532)
Depreciation	(8,571)	(249,657)	(214,957)	—	(473,185)
Amortisation	(433,293)	(100,802)	(144,864)	—	(678,959)
Net finance costs	(72,025)	(15,602)	(73,391)	(90,789)	(251,807)
Profit/(loss) before tax	(8,173,348)	3,543,434	(2,460,206)	(1,207,448)	(8,297,568)
Exceptional items	7,732,532	—	—	—	7,732,532
Share-based payment charges	—	—	—	54,092	54,092
Amortisation	551	100,782	13,938	—	115,271
Adjusted profit/(loss) before tax	(440,265)	3,644,216	(2,446,268)	(1,153,356)	(395,673)

2019	Allergy and autoimmune £	Food intolerance £	Infectious disease and Other £	Corporate £	Total £
Statutory presentation					
Revenue	401,251	8,226,864	351,227	—	8,979,342
Inter-segment revenue	—	(176,722)	(45,864)	—	(222,586)
Total revenue	401,251	8,050,142	305,363	—	8,756,756
Cost of sales	(139,400)	(2,468,212)	(516,815)	—	(3,124,427)
Gross profit	261,851	5,581,930	(211,452)	—	5,632,329
Operating costs	(114,508)	(2,820,935)	(1,578,500)	(1,389,730)	(5,903,672)
Operating profit/(loss) before exceptional items	147,343	2,760,995	(1,789,952)	(1,389,730)	(271,344)
Share-based payment charges	—	—	—	34,201	34,201
Depreciation	7,474	230,163	83,018	—	320,655
Amortisation	441	99,862	15,853	—	116,156
EBITDA	155,258	3,091,020	(1,691,081)	(1,355,529)	199,668
Share-based payment charges	—	—	—	(34,201)	(34,201)
Depreciation	(7,474)	(230,163)	(83,018)	—	(320,655)
Amortisation	(441)	(99,862)	(15,853)	—	(116,156)
Net finance costs	(102)	(3,311)	(11,706)	(81,955)	(97,074)
Profit/(loss) before tax	147,241	2,757,684	(1,801,658)	(1,471,685)	(368,418)
Share-based payment charges	—	—	—	34,201	34,201
Amortisation	441	99,862	15,853	—	116,156
Adjusted profit/(loss) before tax	147,682	2,857,546	(1,785,805)	(1,437,484)	(218,061)

3. Revenues – Continuing operations

	2020 £	2019 £
UK	558,431	608,106
Germany	—	—
Rest of Europe	2,764,400	2,785,310
North America	1,766,301	1,912,781
South/Central America	406,707	488,891
India	722,287	699,624
Asia and the Far East	2,629,771	1,482,321
Africa and the Middle East	970,765	779,723
	9,818,662	8,756,756

4. Finance costs

	2020 £	2019 £
Interest payable on bank overdraft	93,271	86,849
Interest payable on Right of Use Asset lease liabilities	148,819	—
Operating and other finance lease interest	9,717	10,236
	251,807	97,085

5. Taxation

	2020 £	2019 £
Tax credited/(charged) in the income statement		
Current tax – prior year adjustment	172,934	121,832
Deferred tax – current year	1,512,852	(92,833)
Deferred tax – prior year adjustment	(216,528)	(237,262)
	1,469,256	(208,263)
Tax relating to items charged or credited to other comprehensive income		
Deferred tax on net exchange adjustments – continuing operations	8,724	(91)
Total tax (charge)/credit	8,724	(91)

	2020 £	2019 £
Reconciliation of total tax charge/(credit)		
Factors affecting the tax charge/(credit) for the year:		
Profit/(loss) before tax	(8,297,567)	1,182,516
Effective rate of taxation	19%	19%
Profit/(loss) before tax multiplied by the effective rate of tax	(1,576,538)	224,678
Effects of:		
Expenses not deductible for tax purposes and permanent differences	19,765	45,632
Research and development and deferred tax credits	(110,574)	(126,571)
Losses in year not recognised (relating to closed German and India operations)	—	127,048
Provision released relating to India operation	(3,107)	—
Tax underprovided	5,527	115,430
Exceptional items (relating to closed German and India operations)	38,691	(172,820)
Adjustment due to different overseas tax rate	16,244	7,124
Impact of UK rate change on deferred tax	140,736	(12,258)
Tax (credit)/charge for the year	(1,469,256)	208,263

6. Earnings per share

Basic earnings per share are calculated by dividing net profit for the year attributable to ordinary equity holders of the Group by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share are calculated by dividing the net profit attributable to ordinary equity holders of the Group by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on the conversion of all the dilutive potential ordinary shares into ordinary shares. Diluting events are excluded from the calculation when the average market price of ordinary shares is lower than the exercise price.

	2020 £	2019 £
Profit/(loss) attributable to equity holders of the Group	(6,828,312)	974,253

	2020 Number	2019 Number
Basic average number of shares	140,296,603	126,959,060
Share options	45,023	163,517
Diluted weighted average number of shares	140,341,626	127,122,577

Adjusted earnings per share on profit for the year

The Group presents adjusted earnings per share, which are calculated by taking adjusted (loss)/profit before taxation and adding the tax credit or deducting the tax charge in order to allow shareholders to understand better the elements of financial performance in the year, so as to facilitate comparison with prior periods and to better assess trends in financial performance.

	2020 £	2019 £
Adjusted loss before taxation	(395,673)	(303,237)
Tax credit	75	28,891
Adjusted loss attributable to equity holders of the Group	(395,598)	(274,346)

The 2019 tax credit of £28,891 is derived from the total tax charge in the year of (£208,263) and deducting the tax charge of (£237,154) in relation to exceptional items relating to discontinued operations, giving the tax credit of £28,891.