28 October 2020

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

Trading update and notice of interim results

Omega (AIM: ODX), the medical diagnostics company focused on CD4, infectious diseases and food intolerance, announces the following trading update in advance of releasing its interim results for the six months ended 30 September 2020 on Monday 30 November 2020.

Financial update

Turnover is expected to be £3.16m, representing a 29% decrease over the prior period. There is a minimal currency effect between revenues for this half-year period compared to the prior period and EBITDA for the period is expected to be a loss of approximately £1.3 million. These results are in line with management's expectation at the half-year stage and reflect a predicted impact on the short-term performance of our food intolerance business due to the coronavirus pandemic as detailed in our results to 31 March 2020.

Segmental revenues are expected to be as follows:

	Six months ended 30 September 2020	Six months ended 30 September 2019	% increase
Food intolerance	£2.53m	£4.08m	- 38%
Global health	£0.59m	£0.12m	+ 392%
Allergy	£0.04m	£0.26m	- 85%
TOTAL	**£3.16m**	**£4.46m**	**- 29%**

Cash at 30 September 2020 was £6.95 million which was in line with expectation given the trading performance and capital investment in plant and machinery made in the period to support the COVID-19 opportunities outlined below.

The Board remains confident in the Company's prospects and has made substantial progress over recent months in positioning the business for a significantly improved performance in the second half of the financial year.

Operational update

VISITECT® CD4

VISITECT® CD4 Advanced Disease test
In April this year, the Company signed a supply agreement with Clinton Health Access Initiative, Inc. ("CHAI")[1] to accelerate access to the VISITECT® CD4 Advanced Disease test[2] in low-income countries, lower-middle income countries and upper-middle income countries (together "Eligible Countries"). The VISITECT® CD4 Advanced Disease test is currently the only available instrument-free lateral flow point-of-care test, anywhere in the world, for identifying patients with advanced HIV who are at risk of potentially life-threatening opportunistic infections. The Company believes that CHAI has made good progress in its objectives and is actively working with six Eligible Countries in Africa, with additional countries coming onboard in the coming months ahead. The Company has already received a number of purchase orders from certain countries under the CHAI programme which will be supplied in the second half of the current financial year.

On 21 August 2020, Omega announced it had received World Health Organisation ('WHO') Prequalification for its VISITECT® CD4 Advanced Disease test which expands market reach, with the product now eligible to participate in the procurement processes of UN agencies. The Company remains confident that the CHAI initiative is seeding future growing demand which can now be supported by longer-term donor programmes following WHO prequalification.

VISITECT® CD4 350 test
Implementation of the test by the Nigerian Ministry of Health has been delayed due to COVID-19. Our distribution partner has only recently been able to recommence dialogue with the authorities regarding the implementation plan and we will provide further updates once orders are placed with the distributor. We remain confident that this demand will materialise, and that Nigeria remains a large market opportunity.

COVID-19

Strategy outline
At the time of the fundraise in June, the Company's stated strategy was to pursue opportunities to meet the needs of global healthcare systems that require both antibody tests (denoting previous infection) and antigen tests (denoting current infection) and to develop multiple tests, typically in conjunction with UK industry partners and consortia, using both ELISA[3] platforms and lateral flow technology (as currently used for the VISITECT® CD4 tests). The Company intentionally deployed this strategy to allow flexibility in reacting to what was likely to be a fluid situation.

Capacity outline
To attain targeted capacity, particularly for lateral flow tests, the Company has undertaken significant refurbishment works in its Alva, Scotland facility. The building layout has been substantially re-engineered to allow for volume manufacturing as well as to enable socially distanced working for employees due to the pandemic. The Company remains on target to reach a production capacity of 300,000 lateral flow tests per week by the end of November, increasing to 0.5 million tests per week by the end of December, which is testimony to the hard work of many people to achieve such change within such a short timeframe. Due to the potential significant interest in an antigen rapid test, we are currently investigating further capacity expansion of the Alva site.

Mologic ELISA antibody test
In June, the Company announced it signed a supply agreement with Mologic Ltd ("Mologic") under which Mologic supplies raw materials to enable Omega to manufacture its CE marked ELISA antibody test. Following initial orders for this test, traction has not materialised as the Company was originally anticipating. The Company believes this is due, in part, to competition from ELISA antibody tests that are now available on larger automated instruments and an evolving market need that seems more geared towards lateral flow antibody tests. This dynamic exemplifies why the Company adopted the multiple products strategy as outlined above. We are reviewing the potential for using the test in our in-house laboratory testing service.

UK-RTC AbC-19™ Rapid test
Since becoming involved with the UK Rapid Test Consortium ("UK-RTC") in April this year, in order to jointly develop and manufacture a COVID-19 Rapid Test as part of the Government's five pillar national testing strategy for COVID-19, the Company has supported Abingdon Health Ltd ("Abingdon"), lead partner of the UK-RTC, in developing and CE marking its AbC-19™ Rapid test. The manufacturing processes have since been successfully transferred from Abingdon to Omega.

Following the announcement earlier this month that the Company has signed a supply contract with Abingdon to enable Abingdon to supply the Department of Health and Social Care ("DHSC"), the Company remains on track to increase capacity to produce up to 200,000 AbC-19™ Rapid tests per week by the end of November, with the capacity contributing to the overall target of 300,000 lateral flow tests per week mentioned above. This capacity will be used initially to manufacture tests to supply Abingdon so that it may meet the requirement to supply DHSC with its first purchase order of 1 million tests. In addition, Abingdon continues to progress self-test approval with the MHRA. The

Company is optimistic that it will see further orders materialise from DHSC and other sources, both domestic and overseas, in the second half of the current financial year.

Mologic lateral flow antibody test

As announced in September, Omega CE marked Mologic's lateral flow antibody test for COVID-19 for sale under Omega's VISITECT ® brand. The Mologic lateral flow antibody test is a Point-of-Care test that differentiates itself by testing for three antibodies - IgA, IgG and IgM - picking up positive patients at an earlier stage than most other antibody tests. This test will be used in primary care settings such as GP surgeries and for other professional use. Following a commercial launch by the Company of its VISITECT® COVID-19 IgM/IgA/IgG test earlier this month (http://www.omegadiagnostics.com/Products/COVID-19/VISITECT-COVID19MAG), we are seeing early sales traction with this product that provides confidence for performance in the second half of the financial year.

Antigen testing

As mentioned above, there is significant potential interest in producing a Point-of-Care antigen rapid test which has the benefit of speed, convenience and ease of use. Such a test would allow for the introduction of same-day, Point-of Care mass testing which has significant potential to help both the UK and other countries, in the absence of a universal vaccine, to successfully function in an environment where COVID-19 is now endemic.

The Company signed a material transfer agreement ("MTA") with Mologic in June of this year providing access to raw materials and know-how to manufacture their lateral flow antigen test. This test determines the concentration of COVID-19 (SARS-CoV-2) antigens in a saliva or swab extract sample to identify an individual with an infection. Mologic is currently evaluating a prototype in a number of healthcare settings and the results to date look promising. If this continues, then by the end of November, Omega would look to commence technical transfer of the test prior to commencing manufacturing.

Omega intends to CE-Mark the test under the MTA, after which both parties will work together to commercialise the test under an expanded Supply Agreement arrangement.

FOOD INTOLERANCE TESTING

During the first half of this financial year, sales of food intolerance products have remained at revenue levels approximately 35% to 40% lower than in the prior period which remains within the sensitivity modelling undertaken by the Company as a result of the pandemic. Sales in October 2020 are expected to be approximately 20% higher than in October 2019 which is an encouraging early sign of recovery.

Omega believes there are significant near-term opportunities for this business unit in China, where we still await confirmation regarding regulatory approval of a self-test version of Food Detective®. In addition, the Company is applying focus and, more importantly, additional resource to accessing the US market.

Colin King, CEO of Omega, commented: *"We are encouraged to see the early signs of recovery in our food intolerance business which we feel has performed well in the context of the wider pandemic impact. We are particularly pleased with the Company's progress on two fronts: VISITECT® CD4 Advanced Disease receiving the highest level of regulatory approval in achieving WHO prequalification; and we have made significant progress in developing products in our specialist areas to support the global, and in particular UK, response to the COVID-19 pandemic. These achievements position the Company for a significantly improved second half performance."*

[1] *The Clinton Health Access Initiative, Inc. (CHAI) is a global health organisation committed to saving lives. CHAI works with partners to strengthen the capabilities of governments and the private sector to create and sustain high-quality health systems.*

[2] VISITECT® CD4 Advanced Disease is a rapid, semi-quantitative lateral flow assay for the estimation of CD4 protein on the surface of CD4+ T cells in human whole blood that indicates whether the level is above or below 200 cells/µL. It can be used in decentralised settings at the point-of-care or primary healthcare level, identifying those at risk of Opportunistic Infections and supporting diagnostic decision-making, particularly for patients living with advanced HIV disease.

[3] ELISA (Enzyme Linked Immuno-Sorbent Assay) tests are one of the most tested and proven laboratory technologies used by the global diagnostic industry and remain the principle reference point from which rapid diagnostics are coordinated, especially serological tests, including tests for COVID-19.

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

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