



17 October 2016

**Omega Diagnostics Group PLC**  
**(“Omega” or “the Company”)**

**Trading Update and Notice of Interim Results**

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces the following trading update for the six months to 30 September 2016, in advance of releasing its interim results on Monday, 21 November 2016.

**Financial update**

Turnover is expected to be £6.83m, 3% ahead of last year’s first half in constant currency terms and 11% ahead of last year’s result (30 September 2015: £6.15m) on an actual basis, reflecting the weakening of sterling against the US dollar and euro throughout the period. Profit before tax (before share based payments, IFRS-related discount unwinds and amortisation of intangible assets) is in line with management’s expectation at the half-year stage.

Segmental revenues are expected to be as follows:

	Revenue to 30 September 2016	Revenue to 30 September 2015	% increase
Food Intolerance	£3.84m	£3.34m	+ 15%
Allergy/Autoimmune	£1.76m	£1.59m	+ 11%
Infectious Disease/Other	£1.23m	£1.22m	+ 1%
<b>TOTAL</b>	<b>£6.83m</b>	<b>£6.15m</b>	<b>+ 11%</b>

**Core business update**

*Food Intolerance*

We continue to see real growth in revenue on a constant currency basis, supplemented by currency related gains. We have seen particularly strong growth in North America with our microarray-based Foodprint® test which includes significant organic growth with one key customer and another new customer win which offers large potential.

*Allergy/Autoimmune*

Revenue in the first half of the current financial year was stable on a constant currency basis in our German domestic business, compared to the previous period. After recent years of decline in revenue due to reimbursement pressures, it is encouraging that this trend has been arrested in the current period. The weakening of sterling against the euro has led to an increase in revenue reported above.

*Infectious Disease*

This segment continues to be the most price-competitive in which we operate with gains in some regions being offset by regional reductions elsewhere. A small percentage reduction in revenue in actual terms has been positively impacted by the weaker position of sterling, as noted above.

## **Allergy development - IDS-iSYS automation update**

At the end of last week, we held the pre-launch design meeting to review the technical files, labelling, external evaluation results and all the product claims for the launch panel of 41 allergens. It is particularly pleasing to report that the outcome from this meeting is that we have now CE-Marked all 41 allergens and a full inventory of these allergen tests are now available for sale. We have received a first purchase order for product from one end-user customer and we aim to fulfil this once we conclude a long-term supply contract with them in the very near future. We are also continuing to advance discussions with IDS over the longer term supply of allergy tests on a wider basis.

As previously reported in August, we secured a Scottish Enterprise research and development grant of £1.8 million and this has enabled us to accelerate recruitment of skilled project managers and leaders into the scientific team that is responsible for delivering menu expansion, beyond the initial launch panel. This will ensure that we enhance our product offering on a continuous basis.

## **Infectious Disease**

### *CD4 update*

At the time of the last update on 27 June 2016, we had selected a test design which showed no ambient temperature effect ("ATE"), over the range 20-35°C, when tested on in-house samples. Since then, we have tested the design at varying temperatures on over 100 HIV-positive samples at a UK hospital and we have confirmed no evidence of ATE over several weeks of testing, which mirrors our in-house testing reported previously.

In addition, over 400 HIV-positive samples have been tested by non-Omega staff at two further UK sites and the data from all three sites is within expectation and has demonstrated a similar relationship between the Visitect® test result and the recognised gold standard test of flow cytometry. The test results from these 500+ patients also indicate that our design goal parameters for sensitivity and specificity can be met on a visual interpretation of the Visitect® test result.

Accordingly, the product has reached a key milestone whereby we have now entered formal design control. To support this process, we have recently recruited an experienced project manager who is now leading this selected test design through optimisation to ensure we can achieve manufacturing robustness and scalability. Thereafter, we plan to manufacture batches of devices for external field trials and to complete the claim support work required for CE-Marking.

### *Rapid test manufacturing*

In September 2016, the manufacturing facility in Pune, India underwent a final factory inspection, the outcome of which was a recommendation that we be issued with a final factory licence from the Maharashtra State Government which allows the facility to operate as a commercial production unit. We have also undergone a Stage-1 BSI Quality Management System review of all our manufacturing documentation for ISO 9001:2008 and ISO 13485:2012. This will be followed by an implementation review Stage-2 assessment, followed by a final external audit assessment by BSI over the next few weeks. We remain on course to bring this facility on line with CE-Marked malaria and pregnancy tests available for sale in the final quarter of the current financial year.

As a result of this encouraging progress we will pre-launch the malaria product range at the forthcoming meeting of the American Society of Tropical Medicine and Hygiene in Atlanta in November, which is the largest international scientific organisation of experts dedicated to reducing the worldwide burden of tropical infectious diseases and improving global health.

We believe our increased investment in infrastructure to support our core business and development opportunities provides a stronger foundation for the future.

## Outlook

First half trading performance is in line with management's expectation, with revenue ahead of last year on a like-for-like basis, supplemented by a gain of £0.5m in the period due a weaker sterling exchange rate compared to the prior period.

We have made significant progress with our chosen Visitect® CD4 test design and we now have a stronger team with a clearer roadmap to complete the technical work needed to achieve launch and we remain confident of delivering a product that meets a large unmet need in the global health community.

We continue to see opportunities for our Food Intolerance division in the North American market and are actively pursuing a number of exciting prospects in what is an attractive consumer-driven market.

We have CE-Marked our launch panel of Allersys® reagents and we are now completing our first commercial contract and pursuing a growth strategy for longer term competitiveness in this field.

Finally, we have made significant progress in bringing our Pune facility to a state of readiness so that it may begin to generate a commercial return by the end of the current financial year.

**Andrew Shepherd, Chief Executive Officer of the Company commented:** *"We are pleased with the positive progress that has been made in our key business areas and are looking to the future with increased confidence regarding commercialisation of CD4, the Allersys programme and the Malaria product range."*

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

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