

Regulatory Story

[Go to market news section](#)



Omega Diagnostics Group PLC - ODX Strategic Review of operations and Trading Update
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Omega Diagnostics Group PLC ("Omega" or "the Company" or the "Group")

Strategic Review of operations and Trading Update

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces the following strategic review and trading update for the year ended 31 March 2018.

Strategic review

Following his appointment as Group CEO in December 2017, Colin King undertook a strategic review on behalf of the Board, reflecting the input received from shareholders during the interim results roadshow in December and January.

The key outcomes of this review are as follows;

- A focus on delivery for VISITECT® CD4, Allersys and Food Intolerance.
- The need to demonstrate and crystallise value for shareholders over the short to medium term. There is a recognition of the challenges associated with this given the Board's belief that the sum of the individual parts at present may be substantially greater than the perceived value of the whole.
- To reduce our cost base significantly with the proposed closure of both the German Allergy Business and our manufacturing site in Pune, India. The estimated financial impact of the above closures is as follows;
 - An elimination of EBITDA losses which, for the year ended 31 March 2018, amounted to approximately £0.8m for both sites.
 - Non-cash asset write-downs of approximately £5m for the German business (inclusive of approximately £0.8m for Allergodip) and £0.7m for the Indian site.

- A simplification of our UK businesses whereby the operations of four separate legal entities have been amalgamated into one entity, effective from 31 March 2018. This has enabled us to streamline certain functions with expected future annualised savings of c. £0.2m.

These decisions have not been taken lightly but the headwinds experienced and commented upon in our interim report on 14 December 2017 have continued and the Board will now focus its efforts and resources where it believes it can generate the greatest return. This is consistent with the messages received from shareholders that we have been trying to do too much with too little resources and that there is a need for focus. We will start by, at minimum, meeting external expectations.

The Board is exploring whether the two loss making operations can be sold. Discussions to date do not indicate that a material sum can be realised, but the Board will continue to consider any potential offers for the German Allergy Business and the manufacturing site in India.

The cash cost of closing these two operations is not expected to be greater than £0.6m. Cash balances at 31 March 2018 are expected to be approximately £0.1m and the Company has an overdraft facility of £2m.

The Board is committed to delivering value for its shareholders and will seek to do this in a manner consistent with realising the value of VISITECT® CD4, working with our partner IDS to deliver on Allersys and exploring all avenues for realising value for our Food Intolerance business particularly in the USA. Following the closure of these two loss making operations, it is expected that the Group will return to profitability on a lower revenue base.

Trading update

Turnover is now expected to be £13.6m, a reduction of 6% in constant currency terms and 5% behind last year's result (2017: £14.2m) on an actual basis. This is reflective of pressures on gross margin and continuing headwinds in our core business, as outlined in our interim statement. Profit before tax (before share-based payments, IFRS-related discount unwinds and amortisation of intangible assets) is expected to be negative by c. £0.7m before the effect of asset write-downs referred to above. This includes an exceptional charge of £0.2m relating to the change in CEO announced on 14 December 2017.

Segmental revenues are expected to be as follows;

	Revenue to 31 March 2018	Revenue to 31 March 2017	% increase	% increase CER*
Food Intolerance	£7.56m	£8.00m	-6%	-7%
Allergy/Autoimmune	£3.31m	£3.59m	-8%	-12%
Infectious Disease/Other	£2.73m	£2.66m	3%	3%
TOTAL	£13.60m	£14.25m	-5%	-6%

* Constant exchange rate ("CER") numbers have been restated to remove the impact of foreign exchange movements in the year by restating the performance for the six months ended 30 September 2017 using the exchange rates during the prior period.

Core business update

Increase FoodPrint® traction in the USA

The number of new partner companies in North America reduced to two in the second half of the year with the withdrawal of one company for their internal financial reasons. Of the remaining two, one company is still awaiting regulatory approval for testing samples collected in the US, resulting in lower than expected sales volumes, with samples currently imported only from outside the US. As part of the strategic review noted above, we are actively pursuing opportunities to target and add additional sales channels which we firmly believe have the potential to create significant value in the world's largest market for food sensitivity testing.

Allersys® product range

Since the last update on 21 December 2017, we have added two additional allergens with a further two expected by the end of this month which will extend the Allersys® menu to 53 allergens. Whilst the length of time taken over discussions with IDS has been frustrating for shareholders, the aim is to conclude a long-term supply agreement that creates value over a sustained period. We anticipate providing a further update shortly.

Visitect® CD4

As announced on 29 November 2017, we achieved a major milestone in CE-Marking our VISITECT® CD4 test for monitoring the immune status of people living with HIV (monitoring around a cut-off of 350 CD4+ T cells per microlitre of blood). We have recently appointed our first dedicated distributor for CD4 in Nigeria, a country with an estimated 3.2 million people living with HIV. We have also commenced the product registration process with the National Agency for Food and Drug Administration and Control in Nigeria which, once complete, will allow business to business sales to commence through our distributor.

We have also made progress with a second version of the VISITECT® CD4 test, to be used for identifying advanced HIV disease. This is defined as those patients with lower than 200 CD4+ T cells per microlitre of blood. Two pilot batches of devices have been evaluated at a major hospital facility in South Africa and both successfully met our performance design goals. A third batch is currently under evaluation and if acceptable performance is demonstrated we will commence some final robustness and optimisation and then proceed to validation.

Outlook

Beyond the immediate restructuring challenges outlined above, we remain confident in our key value drivers.

The outlook for CD4 is encouraging with the first of what we believe will be many individual country distributorships being signed recently. The major sales hurdle we still need to overcome is the individual country by country registration process, the timing for which we cannot control. We have however started this process with six key countries and plan to commence a further six registrations over the coming months ahead.

We are looking forward to working with and supporting IDS with the launch of Allersys once contract discussions are concluded which we believe is now imminent.

We see the opportunity for securing the growth in Food intolerance in the USA and in China with the latter being dependent upon securing a regulatory approval pathway which will extend beyond the current year.

With a renewed focus and following the closure of two loss making operations, it is expected that the Group will return to profitability on a lower revenue base. We have the resources to drive Allersys and the Food Intolerance business as we commercialise VISITECT® CD4 and look forward to announcing progress later in the year.

David Evans, Chairman of Omega commented: *"We have a considerable amount of work to do on delivering on our strategic plan and our operational objectives for 2018/19. As the*

decisions we are making will straddle the year-end the financial impact of those decisions will impact both 2017/18 and 2018/19 by way of asset write downs and restructuring costs which are exceptional by nature. I look forward to updating you further on the announcement of our Annual Results before the end of June."

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

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