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EKF Diagnostics Holdings PLC
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EKF Diagnostics Holdings plc
("EKF" or the "Company" or the "Group")

Pre-Close Trading Update

EKF Diagnostics Holdings plc (AIM: EKF), a worldwide manufacturer of point of care in-vitro diagnostic devices, provides the following pre-close trading update for the financial year ended 31 December 2011.

Current Trading

Trading has been strong in the second half of 2011 with unaudited revenues for the year ended 31 December 2011 of approximately £21.6m. As a result, adjusted EBITDA will be significantly ahead of market expectations. Cash at 31 December 2011 was £5.3m, with a net cash position of around £2.8m.

The strong second half was due to a large order for the Hemo_Control hemoglobin testing device received from the Mexican Institute of Social Security, the start of shipments of cuvettes to Peru for the infant malnutrition programme there and continued strong shipments of the Quo-Test HbA1c testing device, which saw the 1,000th Quo-Test unit shipped in the fourth quarter.

There continues to be a positive market reaction to Quo-Test which, in part, has been attributable to the growth in China but also due to the SKUP study. At the request of our distribution network, we had an evaluation undertaken by the Scandinavian Evaluation of Laboratory Equipment for Primary Health Care (SKUP). The evaluation was for the Quo-Test under optimal conditions in a hospital laboratory and in primary health care in Denmark. The results of this report, which were published at the end of 2011, are very favourable.

The acquisition of Stanbio in June 2011 has provided additional revenue impetus and Stanbio demonstrated strong organic growth in the second half, as well as allowing us to develop synergies across the Group, one effect of which was the success in Mexico.

To maximize these synergies we now have a fully integrated sales infrastructure and we have focused on becoming more operationally flexible and driving efficiencies within the Group to manage the continued growth we are expecting in 2012.

Product Development

We are planning commercial launch of Quo-Lab, our low cost HbA1c analyser for developing markets, and our BIOSEN HbA1c instrument in the first half of 2012. We are already in advanced negotiations with a number of customers for the Quo-Lab instrument. In addition, we have seen considerable interest from, and remain in active discussion with, a number of larger companies. Any such agreements are predicated on the addition of other analytes to the instrument and this work is currently being undertaken. We also expect to launch our point of care test for acute kidney injury in the second half of the year.

Slightly longer term, we are currently evaluating the opportunity in separate development projects to develop a point of care coagulation test and a point of care test for Vitamin D. We are also looking to have our kidney markers available on an automated laboratory instrument.

In addition to our development of new products, we have a number of programmes in place to drive the costs down on our existing products, thereby increasing margins and allowing us to make them more accessible to a wider range of new customers.

Channel Development

In addition to product-driven growth, we note that point of care diagnostics is beginning to establish itself in both Eastern Europe, where EKF has a very strong presence, and in Asia where we have established a number of partners who will help us to participate in the growth there based on increasing per capita GDP and a greater incidence of western diseases.

We expect to ship HemoPoint H2 instruments and cuvettes to Alere in the United States in Q1 2012 under the terms of our 2011 agreement. The Board believes that access to one of the largest direct sales forces in the North American point of care market will grow our market share in the U.S. hemoglobin testing market significantly.

Regulatory

In respect to Quo-Test, we are in the process of engaging with the US FDA via a Pre-IDE submission in order that the application process is more rigorous than when previously submitted by Quotient prior to its acquisition by EKF. It is anticipated that the submission under 510k regulations will be made in the first half of 2012.

Outlook

We are very pleased to announce such strong trading results for 2011 and ahead of market expectations. We now move into 2012 from a very strong position and, whilst we continue to evaluate acquisition opportunities in a pro-active manner, we are confident in our ability to deliver continued organic growth. In addition, we expect 2012 trading will benefit from the first sales of our HemoPoint H2 instruments through one of the largest direct sales forces in

North America. We believe that this will be strong driver of increased shareholder value.

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About EKF Diagnostics Holdings plc

EKF Diagnostics Holdings plc was formed in July 2010 following the acquisition of EKF-diagnostic GmbH for €14.32m and refocused its strategy to one of building a substantial point of care diagnostics business. As part of this strategy, the Group has integrated three further acquisitions, Quotient Diagnostics Limited (acquired in October 2010 for a maximum of £5.41m), Argutus Medical Limited (acquired in December 2010 for £2.18m) and Stanbio Laboratory L.P. (acquired in June 2011 for a maximum of US$25.5m).

The Company, with its head office in Cardiff and operations in London, Germany, Poland, Russia, Ireland and the US, is a leading diagnostics business, focused on the development, production and distribution of chemical reagents and analysers for the testing of Glucose, Lactate, Haemoglobin, Haematocrit and HbA1c.

In May 2011 EKF entered into a distribution agreement with Alere Inc ("Alere"), a global diagnostics company, under which Alere was appointed the exclusive distributor of EKF's CLIA waived Hemo_Control device and cuvettes in the US, Canada and United Kingdom. The device is distributed in the US under the name HemoPoint H2.

For more information please visit the website: www.ekfdiagnostics.co.uk

This information is provided by RNS
The company news service from the London Stock Exchange

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