18 August 2015

EKF Diagnostics Holdings plc
("EKF", the "Company")

Trading update

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care, central laboratory and molecular diagnostics business, provides the following trading update for the six months ending 30 June 2015.

Introduction & non-binding preliminary proposal to acquire PoC

The Directors remain confident that EKF offers value to shareholders. The Company has a strong Point-of-Care ("PoC") business with a large installed base and, coupled with new product launches anticipated for 2015 and beyond, we expect to deliver significant growth. To achieve this growth, the Directors recognise that EKF needs to invest significantly in these new products and platforms, namely sTNFR, PrecisionPath, PointMan™ and a PKU monitoring system.

We have now received a non-binding preliminary proposal to acquire, on a cash free debt free basis, EKF's Point-of-Care assets, which excludes the clinical chemistry and molecular businesses, for $110m.

We anticipate making an announcement on the conclusion of the strategic review shortly.

Trading for the six months ended 30 June 2015

EKF expects its results for the first half of 2015 to show unaudited revenues of £16.8m, around the same level as last year, despite not having materially benefited from any tender wins in the current period. Unaudited adjusted EBITDA for the period will be around £0.7m (H1 2014: £2.2m). This reduced level of earnings reflects the continuing impact of the investment in our Molecular division.

Tender wins
EKF relies heavily on tender wins for revenue generation, the timing of which can be very uncertain and outside of our control. In 2014, tender wins represented over 20% of our full year revenues, which was broadly split 40%/60% across H1 and H2 respectively. During H1 2015, tender wins only accounted for around £0.5m, mainly due to the delay of certain tenders into H2. EKF has developed the strongest tender pipeline it has ever had and a number of these tenders will be decided in H2. To that end we have secured a significant tender in the Middle East to deliver a number of our diabetes products in 2015 and 2016. Once exact quantities have been confirmed we will update the market accordingly.

Molecular division impact
The two core molecular platforms that EKF continues to concentrate its resources on are PrecisionPath and PointMan. At an adjusted EBITDA level, just over £1m has been invested into the Molecular division in H1 2015 (H1 2014: £0.1m).

Cash
The unaudited cash position at 30 June 2015 was £2.1m (31 Dec 2014: £8.3m), and the net debt position was £5.0m (31 Dec 2014: net cash of £2.4m). The net debt position is expected to improve in the second half of the year following tender wins and the continuing payments being made by our Mexican debtors. As announced previously, a one off £1.4m cash payment was made in January 2015 as a settlement for the total deferred cash consideration due in relation to the acquisition of DiaSpect Medical AB. No further deferred cash consideration payments are expected to be paid by EKF in H2 2015.

The Board remains confident that, given the high number of opportunities currently planned for H2, it will achieve management expectations for the full year.

Point-of-Care

The Point-of-Care business continues to perform well, with underlying growth being seen across most product lines. The integration of the Quotient products into our Barleben facility has been very successful and by the end of 2015 we expect that year-on-year revenue growth for our diabetes product range will be substantial. Particularly pleasing is the positive effect this has made at a gross margin level; whilst the overall gross margin (which incorporates the lower margin molecular business) is likely to be around 45% for the first half of the year (H1 2014: 47%), the Point-of-Care business is likely to show a gross margin of around 52% for H1 2015 (H1 2014: 49%); this is likely to improve slightly going forward as we continue to seek operational efficiencies throughout the Group.

sTNFR

During the period we have made significant progress in establishing sTNFR as the most efficacious biomarker for predicting the progression of diabetic patients to end stage kidney disease. We have been genuinely excited by not only our own data generated in conjunction with our partner, the Joslin Diabetes Center, but also by the quality of the engagement with several top-tier pharmaceutical companies who are promoting and/or developing novel therapies in this area, such as SGLT-2 inhibitors. Our aim is to position sTNFR as a routine test for risk stratification and as a complementary diagnostic for new therapies. The establishment and acceptance of such a biomarker takes time as further data will need to be independently generated to support clinical utility and completion of pivotal trials for these new therapies. We believe that we will ultimately be capable of generating long term value by aligning ourselves with those therapeutic companies who see the commercial benefit that our diagnostic can bring to their revenue line. Our discussions to date provide us with significant confidence and the challenge remains in terms of the time factor both with our putative partners and consequently in setting expectations externally with our shareholder base and other stakeholders.

PrecisionPath

Whilst we have encountered issues with Selah, we have continued to invest in PrecisionPath, a Next-Generation Sequencing ("NGS") test for patients with metastatic cancer. We have announced a partnership with Greenville Health System ("GHS") and the launch of our PrecisionPath Colon cancer test at a cost of $975 and a turnaround time of less than seven days per reportable test. This has, in turn, led to discussions with private insurers to establish a reimbursement level. The relationship with GHS, and consequent verification of the patient benefit from a quick turnaround at a very competitive price per test has resulted in the reimbursement review progressing well; we expect to hear some positive news in this regard in the not too distant future.

The initial Selah purchase agreement was drafted to accommodate a reduction in deferred consideration payments if certain performance targets were not met; the lower than anticipated sales from Selah are now expected to result in the year two earn-out payment of $17.5m not being payable, and this benefit will be reflected in the H1 figures.

PointMan

Following some technical issues earlier in the year, we are now finalising the verification and validation process for the PointMan amplification technology with the intention of completing the CE Marking process in H2. In addition the partnerships with Angle, Gilupi and MGH continue to progress. The exquisite sensitivity of the PointMan technology enables us to detect three copies of a mutant gene in a standard blood draw, which will lead to a reduction in repeat tissue biopsies for cancer patients globally.

PKU

We are on course to launch our point-of-care Phenylalanine monitoring system for Phenylketonuria (PKU) in Q1 2016. PKU is an inherited genetic condition which requires treatment and monitoring from birth with either a special food diet or pharmaceutical drugs. EKF has developed a monitoring system which will enable patients to easily test their Phe levels which will lead to increased compliance, thereby helping them to manage their condition more effectively. We are in late stage discussions with a major food manufacturer with a view to licence the PKU system for use by patients alongside their dietary therapies. We believe this to be a more effective way of creating value than aligning ourselves with a pharmaceutical company as our diagnostic may result in less therapeutic intervention and we perceive that it is unlikely that any regulatory authority will make our test mandatory despite the patient benefits.

The estimated size of the global PKU market is in excess of €400 million, and we believe that monitoring alone would account for around €5m of this annually. Easy and accessible monitoring of the condition will enhance the management of PKU and is thus viewed as a real benefit to healthcare professionals, dieticians and patients alike.

Outlook

We are focussed operationally on the following:

- Growing the core underlying Point-of-Care business. The Company expects to see the benefits of revenues from tender orders in H2, including those which were delayed from H1. We will look to update the market with details of our Middle East tender win once we are able to do so. Mexico remains a key market for us and we are confident that if we can resolve the payment issues then we will secure substantially more business significantly beyond our 2014 revenues. The Kenyan tender remains there to be executed but we need to secure satisfactory payment visibility.
- Progressing sTNFR in a manner which will deliver further evidence of clinical utility, executing our strategy for regulatory submission and progressing further our discussions and collaborations with major pharmaceutical partners.
- Promoting PrecisionPath and the relationship we have with GHS to demonstrate clinical utility and value. Our biggest single goal remains reimbursement and one in which we continue to strive to achieve and one we remain confident of achieving.
- The delivery of a CE Marked PointMan product(s) and to secure key strategic partnerships beyond our existing relationships.
- Deliver real value in the management of PKU with a partnership with a major food manufacturer.

We will be announcing the conclusions of our strategic review shortly and we will consult with Shareholders following that review. We recognise that there will be a heterogeneity of views and we will endeavour to ensure that we as custodians of shareholder value discharge our responsibilities appropriately in the best interests of Shareholders.

David Evans, Chairman of EKF, commented:

"The first six months of this year have been particularly challenging given the visceral reaction of certain Shareholders in March leading to the initiation of the strategic review in April. Without doubt this has been at best a distraction, particularly given the one clear message from Shareholders of the desire for change. Despite the backcloth of increased uncertainty we have remained focused on both delivering value in the short-term and being able to evidence to our Shareholder base the foundations of the long-term strategic value we have built thus far. We fully recognise that to achieve those goals we need time and investment, neither of which we control. I will update the Shareholders separately on the strategic review shortly but the one gratifying aspect of the review is being on the receiving end of acknowledgements of what we have built so far, particularly in Point-of-Care."

"I believe the second six months, in operational terms, will be significantly better than the first as we will be able to evidence new tender wins and demonstrate further progress with our key strategic development projects in sTNFR, PrecisionPath, PointMan and PKU."

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About EKF Diagnostics Holdings plc - www.ekfdiagnostics.com

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 September 2010), Argutus Medical Limited (acquired in December 2010) and Stanbio Laboratory L.P. (acquired in June 2011). In 2013 EKF established a new subsidiary, EKF Molecular Diagnostics Ltd, to focus on molecular and companion diagnostics and acquired 360 Genomics Ltd, a business that owns diagnostics technologies for cancer gene detection.

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

In March 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.

In March 2014, EKF acquired Separation Technology, Inc., a Florida based manufacturer of in vitro diagnostics devices for the haematology testing market. In April 2014, EKF completed the acquisitions of Selah Genomics Inc., a US based developer of molecular diagnostics for personalised medicine and DiaSpect Medical AB., a Swedish based manufacturer of point-of-care haemoglobin analysers.