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**EKF Diagnostics Holdings PLC** 

19 May 2021

## **EKF Diagnostics Holdings plc**

("EKF", the "Company" or the "Group")

#### **AGM Statement**

Strong trading continues into Q2, upgrading full year expectations Growth Plans & Managed Succession

EKF Diagnostics Holdings plc (AIM: EKF), the AIM-listed point-of-care business, provides an update to shareholders ahead of its Annual General Meeting ('AGM') today at Harwood Capital, 6 Stratton Street, Mayfair, W1J 8LD at 10.30 a.m., including an upgrade to current year trading.

As previously announced, the Company is providing a facility for shareholders to join the AGM, either online or telephonically and investor questions will be addressed afterwards. For dial-in details please contact Walbrook PR via email at <a href="mailto:ekf@walbrookpr.com">ekf@walbrookpr.com</a> or call +44 (0)20 7933 8780.

## The Chairman's AGM statement is produced below:

#### Introduction

As fellow shareholders know, 2020 was by far our most successful year to date, with record turnover and profits. This strong performance continues into the new financial year, driven by a very meaningful recovery in trading from both our core business which, despite the ongoing effects of the pandemic, has performed more strongly than expected with growth in the first quarter, and continued strong demand for our contract manufacturing services for COVID-19 sample collection devices and associated kits.

After multiple upgrades last year and a step change in year-on-year performance, the announcement in March of a multi-million dollar contract expansion for the supply of sample collection devices to a large multinational customer drove a further material upgrade to revenue expectations and a significant one for profit for 2021. The March upgrades were based just on visible orders under the supply agreement and a continuing conservative approach to forecasting on the core business. Strong trading continues into the second quarter 2021 and the Board is now confident that trading for the full year will be comfortably ahead of already upgraded management expectations.

There is clear scope to evolve our contract manufacturing activities beyond the current pandemic catalyst and to capture the significant additional potential for the core business. Recognising this, the Board has been evaluating EKF's growth strategy with a view to ensuring and driving sustainable growth into the future.

While our approach to forecasting and guidance to analysts may be conservative, our aspirations are ambitious. Your Board is very clear that there are excellent opportunities to support accelerated growth within our core business, and to utilize our strong cash generation effectively to generate further considerable value for shareholders. In this vein, I wanted to take the opportunity today to outline the next stage in our strategy to deliver additional substantial growth.

This does not in any way imply that our COVID-19 business will not continue for many years to come. Our largest contract is for a minimum of two years. In addition, we continue to win new clients who may add to our current production. In fact, we are investing in our COVID-19 related activities as we strive to increase capacity in our manufacturing facilities to meet the increasing demands of our clients. Our manufacturing capabilities are applicable to other forms of diagnostic tests and we are already making third party products for other healthcare applications.

#### Strategy to 2024

In 2020, the core business (excluding contract manufacturing and associated revenues for COVID-19 sample collection tests and kits) delivered revenues of circa £38.5m. We believe that our evolving strategy outlined below will allow us to create a business which, aside from any COVID-19 related revenues, is capable of generating significant double-digit growth in adjusted EBITDA¹ over the next 3 to 4 years. This can be achieved through investment in aggressive organic growth in areas of our business where we already have expertise and proprietary technology, as well as by funding other means of delivering additional shareholder value such as targeted acquisitions. We believe that the investment of between £10-15m in funding the strategy below will generate a material contribution to the planned growth in adjusted EBITDA.

As at 31 December 2020, we had net cash of £21.4m, having generated £13.8m of cash from operations compared to £5.1m the year before. Our strategy for growth to 2024 and beyond will see us use these funds to:

- 1. invest in the existing core business to maximise the value of our distribution network and drive aggressive organic growth;
- 2. continue to maximise value for EKF shareholders from our agreement with Mount Sinai Innovation Partners ("MSIP"), which allows us advanced access to innovative commercial opportunities and where we can build on the ongoing successes of Renalytix AI plc, Verici Dx plc and the further success that we are confident Trellus Health plc will see;
- 3. seek out complementary and targeted earnings-enhancing acquisitions with key strategic value to the core business;
- 4. deliver against these aims and allow us to continue to follow a progressive dividend policy and to generate enhanced shareholder returns; and
- 5. continue to maximise the opportunity to assist clients to control the impact of COVID-19, and to evolve our new contract manufacturing capabilities in this area to a broader range of diagnostic and other healthcare settings

# 1. Investing in the existing core business to drive aggressive organic growth

We believe we have a number of excellent growth opportunities to exploit in our Point-of-Care and Central Laboratory & Life Sciences businesses, where we can invest now to maximise the future value of our existing and expanding distribution network for our core products.

In particular, we have identified a demand-driven opportunity within our existing contract fermentation business to expand our facilities in South Bend, Indiana. To meet the requirements from several customers for increased production, without any disruption to the continuity or security of supply, we plan to invest in our fermentation capacity increasing our annual manufacturing capacity eight-fold at least. Specifically, we intend to invest in new installations of 1,500L, 3,000L and 14,000L fermenters, to be delivered as validated operations by third party turnkey experts in this space. This capacity expansion will result in significantly increased EBITDA contributions from these operations as we fulfil demand from both well established and newer customer relationships across a diverse range of end products.

One of the great strengths of our business has been the establishment of an enviable distribution network in Point-of-care and we believe we are well positioned to maximise the value of this network, both for existing and new EKF product deployments as well as after providing development services for white labelled third-party products, leveraging already strong customer relationships. We already expect to see growth from a number of areas including the roll-out of McKesson's Consult OEM version of DiaSpect Tm, the launch of DiaSpect Tm into blood banks in the US, positive signs of a recovery in  $\beta$ -HB Liquicolor reagent sales across a number of customers. We also expect to significantly grow the market penetration of our new Lactate Scout product, Lactate Response, to be used within ambulances to test patients at risk of Sepsis. We believe this to be a substantial market opportunity and look forward to updating shareholders on the pathway through regulatory approvals and commercial launch in initially targeted geographies in 2022. Overall, we are promoting opportunities for our distributors by delivering differentiated products and broadening their range of products through further innovation.

In summary, we are very optimistic about the opportunities we have to deliver significant, robust organic growth from our existing core business between now and 2024, as well as the emerging opportunities in diagnostic testing and contract development and manufacture which are described below.

# 2. Maximise value from our agreement with Mount Sinai Innovations Partners (MSIP)

As we highlighted in our recent full year results announcement, one of the key aspects of our growth strategy is focussed around our Preferred Partnership Agreement ("PPA") with MSIP. This relationship allows us access to innovative commercial opportunities arising from certain technologies managed by MSIP. We have already delivered considerable value to EKF shareholders through our relationship with Renalytix AI plc ("RENX"), which combined biomarkers originally licensed by EKF, data, expertise and access to biobank samples at Mount Sinai and a strong management team to create a breakthrough approach to measuring and managing risk of chronic kidney disease. EKF shareholders received nearly 21m shares in RENX which floated at a share price of £1.21 and the shares yesterday

closed at £10.35, representing a value delivery of 47.7p per share to our shareholders to date. In addition, last year we sold part of our holding in RENX realising a profit of £5.7m (equivalent to 1.25p per EKF share)<sup>2</sup>, and our remaining holding, based on yesterday's closing share price, represents a gain of £9.17m (equivalent to 2.01p per EKF share).

Assuming all EKF shareholders retained the 21m RENX shares issued to them in 2018, they will have benefitted from a further distribution of shares in the RENX spinout, Verici Dx plc ("VRCI"). Those VRCI shares distributed in 2020 are now worth, based on yesterday's VRCI closing price of £0.595, approximately £12.5m (equivalent to 2.74p per EKF share). EKF itself as a RENX shareholder received 2,677,981 VRCI shares today worth c. £1.6m based on the £0.595 VRCI price (equivalent to 0.35p per EKF share).

The most immediate opportunity from the MSIP collaboration relates to our \$5m investment in Trellus Health plc ("TRLS"), a company working to transform the way chronic conditions are treated, with an initial focus on Inflammatory Bowel Disease (IBD), including Crohn's disease and ulcerative colitis. EKF's original 31.1% holding (c. 28m shares) was distributed to shareholders in December 2020 and we anticipate a successful debut on AIM on or around 28 May 2021. At EKF's July 2020 investment price, these shares were worth £3.2m (equivalent to 0.70p per EKF share).

In total these ventures have generated potentially up to 54.85p for EKF shareholders (excluding any uplift at IPO or beyond on the valuation of Trellus Health), and we believe the MSIP relationship will generate further exciting opportunities to deliver value to shareholders.

## 3. Targeted, earnings enhancing acquisitions

We also believe there are exciting opportunities available to acquire strategically relevant, earnings enhancing acquisitions to support the core business and increase our capabilities of our Life Sciences business, moving us up the value chain from just component and kit manufacture on the testing side of the business. The key criteria when seeking acquisitions will be how we can integrate these businesses into our current model to deliver enhanced earnings contribution.

## 4. Progressive dividend policy

EKF is strongly cash generative and as such the investment required in organic growth is expected to be met from existing available resources. Whilst we believe that investment in all three of our strategic goals above will provide significantly greater value returns for our investors, we also acknowledge those shareholders that are seeking income from cash dividend payments. At the end of last year we paid our inaugural cash dividend of 1p per share (in respect of 2019) and recently confirmed that, given our strong cash generation in 2020, we intend to make a further dividend payment to shareholders of 1.1p per ordinary share, which we propose to on pay on 1 December 2021 to shareholders on the register on 5 November 2021. It is our intention to maintain a modest but progressive dividend policy.

## 5. Driving value from our COVID-19 business and evolve our contract

## manufacturing capabilities

As I've mentioned above we do not believe our COVID-19 business will end suddenly. Our largest contract is for a minimum of two years and as we continue to win new clients we are investing further in our manufacturing capacity to meet the increasing demands of our clients. However, we know that we also have the opportunity to leverage this capability in test-kit contract manufacturing created across our sites in the US, UK and Europe to provide other services. We are already in discussions with our private sector partner, with whom we have a recently signed, multi-million dollar global supply contract, regarding the expansion of our support beyond their world-wide COVID-19 testing programme for their staff, to supporting a much broader commercial testing capacity to cover other areas of infectious disease, chronic disease and general health and wellness.

Our manufacturing capabilities are applicable in other areas of diagnostic testing, and for molecular disease and forensic test manufacture. We are also evaluating the potential to offer contract development services, whereby we would use our existing skills to support customers earlier in the process of product development and specification.

## Executive changes to deliver against this strategy most effectively

To optimise delivery against this strategy, we are also announcing a number of planned changes today to the responsibilities within the Senior Management team and Executive Directors to best align the skills and expertise of the excellent team we have to attaining the objectives for continuing success.

Mike Salter, who currently leads our US operations and has been instrumental in delivering much of the growth we've seen in this region, will become Chief Executive Officer. Julian Baines, currently CEO, will become Non-Executive Deputy Chairman and will take on a new role specifically focussed on delivering value from our relationship with MSIP. These changes will come into effect from 1 October 2021, with Mike and Julian continuing to work closely in the interim as the CEO responsibilities are transitioned to Mike. Richard Evans remains as Financial Director and Chief Operating Officer, although Richard has signalled that he will look to stand down from his position at the end of June 2022. The timing and sequencing of these changes allow for the orderly transition of key roles and responsibilities, and we are currently undertaking the necessary succession planning.

Mike Salter, an organic Chemist by training, is based in San Antonio Texas and has been head of our Americas business since joining EKF in October 2017. Mike was responsible for overseeing the growth of our Diabetes and Haematology business in the US and, by leveraging his business network he fixed licensing agreements, built production capacity and secured orders for our COVID-19 sample collection kit business. Mike has been a passionate leader of our US team and has been instrumental in securing many of our largest US contracts and growth opportunities and is the ideal candidate to deliver the accelerated organic growth described above.

Mike has over 35 years of experience in the Life Science and Diagnostics Industry. He joined Amersham plc, the UK's largest Life Science company, in 1984 and spent 20 years in various Operational, Product Management and Business Development

roles. When Amersham was acquired by GE in 2003 to become GE Healthcare Mike moved into senior commercial and business development roles leading new strategic Diagnostic initiatives. In 2016 Mike became General Manager of the Global Custom Genomics Business in 2016. Throughout his time at GE Healthcare Mike managed a successful multi-million dollar business providing Biotech and Lifesciences companies with products and services to support the development and launch of their new products. At EKF Mike has been responsible for delivering over \$20m of new contract manufacturing revenues from the US operations.

An additional board change is being made at the non-executive level and this and additional disclosures required under the AIM Rules are being made in a separate announcement. This also covers details of a final bonus payment being made to the executive directors in recognition of their very significant contribution to creating shareholder value over the past several years. A new remuneration scheme is being devised for Mike Salter and others, details of which will be disclosed in due course.

As a Board we are confident that the strategy outlined above can deliver compelling earnings growth across the business and represents the best way to utilise our strong cash generative qualities to maximise shareholder returns. The next phase for the business is one of accelerated growth and we look forward to updating shareholders on our progress. Mike and Julian will provide a short overview of the strategy to shareholders at today's AGM and we look forward to providing further details of our growth strategy to shareholders over the next few weeks.

I thank shareholders for their continued support and our dedicated staff and suppliers for their concerted efforts in challenging times. I look forward to sharing together in our future success as we deliver further value to our customers and partners through innovation and endeavour.

#### **Notes**

<sup>1</sup> Earnings before interest, tax, depreciation and amortisation, share-based payments and exceptional items

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<sup>2</sup> Calculation based on current number of shares in issue: 454,993,227

#### **EKF Diagnostics Holdings plc**

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## **About EKF Diagnostics Holdings plc** (<u>www.ekfdiagnostics.com</u>)

EKF is a leading point-of-care diagnostics and central laboratory assay manufacturer with an estimated 80,000 hemoglobin, hematocrit, HbA1c, glucose and lactate analysers in regular use across more than 100 countries. EKF specialises in developing tests for use in anemia and diabetes diagnosis and management, as well as providing a portfolio of reagents for use in clinical chemistry analysers.

EKF specialises in the development, production and worldwide distribution of point-of-care analyzers and clinical chemistry reagents for use in hospital and research laboratories, doctor's offices, blood banks and for in-field anaemia screening programmes. EKF is also a bulk manufacturer of enzymes and has custom manufacturing facilities in the across sites in the US, UK and Europe for a variety of life science products. Demand for contract manufacturing of COVID-19 sample collection tests and kits has grown dramatically during the pandemic, however the capabilities can be applied to other areas of diagnostic testing, molecular disease and forensic test manufacture.

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