



24 March 2020

*This announcement contains inside information
for the purposes of Article 7 of Regulation (EU) No 596/2014 (MAR)*

**EKF Diagnostics Holdings plc
("EKF", the "Company" or the "Group")**

Detailed trading review including COVID-19 update

***Net cash levels of £14.3m at 20 March 2020
Current trading and cash generation continue to be robust
Significant opportunity for growth with COVID-19 manufacturing contract***

EKF Diagnostics Holdings plc (AIM: EKF), the AIM quoted point-of-care business, provides shareholders with an update on current trading in light of the COVID-19 pandemic, including the strong cash position of the Group, and its continuing solid positive cash flow. The Company also provides shareholders with a detailed review of trading for the year ended 31 December 2019.

Due to the unprecedented practical challenges that corporate reporters and their auditors are facing during the ongoing Coronavirus crisis, the FCA has strongly requested that all listed companies observe a temporary moratorium on the publication of preliminary financial statements. As an AIM quoted company EKF is not formally covered by this request, however the Company will be observing this moratorium following advice from its auditors, PricewaterhouseCoopers LLP. Whilst the detailed trading review below provides a comprehensive review of the Company's trading position, the statements are unaudited. Full audited Financial Statements for the year ended 31 December 2019 will be provided as soon as reasonably practicable.

COVID-19 update – key points

- Contract manufacturing opportunity with Longhorn Vaccines and Diagnostics, USA, for specimen collection tubes for COVID-19 testing – initial orders c. \$1m and expected to grow significantly
- Robust plan in place to mitigate the effect of the disruption on the business
- Substantial net cash balances of £14.3m as at close of business on 20 March 2020 with continuing strong free cashflow
- Demand for diabetes and haemoglobin tests remains, with patients using these tests being in the higher risk category for COVID-19
- German state approval received to keep Barleben manufacturing facility open in event of a lockdown
- Current beneficial exchange rates as a US Dollar / Euro denominated business, with a natural currency hedge across operations in the UK, US and Europe

Financial Highlights for the year ended 31 December 2019 (unaudited data)

- Revenue up 6% to £44.9m (2018: £42.5m)
- Gross profit up 4% to £23.7m (2018: £22.7m)
- Adjusted EBITDA* up 12% to £12.0m (2018: £10.7m)
- Profit before tax £5.5m (2018: £12.2m; £5.8m excluding exceptional gain from Renalytix AI plc spin-out)
- Basic Earnings per share of 0.81p (2018: 2.21p), underlying Basic Earnings per share* of 1.20p (2018: 1.01p)
- Cash generated from operations of £6.1m (2018: £9.9m)
- Cash at 31 December 2019 of £12.1m (2018: £10.3m), net cash of £11.4m (2018: £9.4m)
- Maiden dividend preserved and payable to shareholders on 1 December 2020

** Excluding exceptional items and share based payments*

Operational Highlights for the year ended 31 December 2019

- McKesson OEM of DiaSpect Tm successfully launched with positive first six months of business
- Successful completion of early stage development batches of a bulk dietary ingredient for Ixcela, Inc.
- Mount Sinai agreement provides EKF with advanced access to innovative commercial opportunities

Christopher Mills, Non-Executive Chairman of EKF, commented:

“With good cash resources and a business which is growing strongly, EKF has moved into a phase where we are confident that we can provide an income for shareholders and the prospect of significant upside from our relationships with MSIP and others. Trading in 2020 to date has been satisfactory and in line with management expectations.

“Despite these difficult times, EKF is in a very strong position. We have a substantial net cash balance, continuing solid positive cash flow and the business remains robust. We see significant opportunities globally, particularly within the USA. Being a medical device company focussing on tests monitoring diabetes and haemoglobin, both conditions putting patients in higher risk categories should they contract COVID-19, EKF is well positioned to assist the medical and scientific community.”

EKF Diagnostics Holdings plc

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About EKF Diagnostics Holdings plc (www.ekfdiagnostics.com)

EKF is a leading point-of-care diagnostics and central laboratory assay manufacturer with an estimated 80,000 hemoglobin, hematocrit, HbA1c, glucose and lactate analyzers in regular use across more than 100 countries. EKF specializes 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 analyzers.

A presentation for investors is available to view here: <https://www.ekfdiagnostics.com/documents-reports.html>

COVID-19 update

As can be seen in the detailed trading review the business performed well in 2019. Trading in 2020 to date has been satisfactory and in line with management expectations. We believe the outlook for 2020 is positive for the following reasons:

1. EKF has substantial net cash balances (£14.3m as at 20 March 2020);
2. EKF has strong free cashflow;
3. The business remains robust due to the demand for diabetes and haemoglobin tests, which we expect to be in part driven by the fact that patients that need these tests are also in the at higher risk category for contracting COVID-19; and
4. EKF benefits from the exchange rate as we are a dollar and Euro denominated business. EKF is also able to manage currency across its operations in the UK, US and Europe.

Production scale up for COVID-19 test component demand

EKF Diagnostics is rapidly scaling up production for the US and globally to meet the demand of one of the core components in the COVID-19 molecular testing supply chain, PrimeStore MTM. Sample collection and transport is an essential part of COVID-19 testing as PrimeStore MTM is the first and only US FDA Cleared Microbial Nucleic Acid Storage and Transport Device and was designed for viral pandemics. PrimeStore MTM deactivates the pathogens in the sample, rendering them non-infectious, allowing for safe transport and laboratory handling. Samples collected using this device can also be maintained at ambient temperature for days, eliminating the need for cold chain procedures, and handled at laboratories with a lower biosafety containment rating than is otherwise required. This has the benefit of significantly increasing the number and spread of laboratories able to handle samples.

EKF Diagnostics is an existing contract manufacturing partner of Longhorn Vaccines and Diagnostics LLC (LHNVD), the inventor and owner of PrimeStore MTM. We have seen growing demand for the sample collection device manufactured at our Boerne Texas site. Initial purchase orders are nearing \$1m and we expect that to continue to grow significantly.

Operational mitigation

The recent COVID-19 pandemic has created uncertainty in the market in the short term. Many countries are either closed or on the verge of being shut down, and government action is having a significant effect on economies across world. The eventual severity and length of the economic disruption is impossible to forecast. We believe we have a robust plan in place to mitigate the effect of the disruption on the business including taking the following actions (amongst others):

- Organising for as many staff as possible to work from home
- Improving our computer networking to facilitate remote working
- Gaining designation as a company essential to basic medical care which allows our premises to remain open even in a lockdown – we have already gained approval from the German authorities to keep the Barleben factory open in such circumstances
- Improved social distancing by limiting physical meetings, expanding flexible working, and altering production practices
- Preparing requests for support from local authorities should we have to reduce working hours
- Banning international travel and limiting domestic travel
- Increasing supplier and customer contact so as to be able to anticipate issues and react quickly
- Increasing raw material stock holding
- Increasing cleaning and disinfection cycles

We have insurance cover in place in case there is a loss of business, although it cannot be guaranteed that cover will be sufficient to protect against all eventualities.

At the date of this announcement we have seen limited disruption to either our customer or supplier logistics (although we have noticed some increases in the cost of airfreight). Revenue generation from our core business has been very largely unaffected. Indeed, we are now providing a key component into the COVID-19 testing supply chain. Nonetheless we have modelled a number of scenarios covering different levels of significant reductions in revenue without taking into account the benefits from any mitigation strategies. As a result of our current strong cash balances and robust business, we are confident that the business can survive even catastrophic reductions in revenue for an extended period.

Conclusion

Despite these difficult times, EKF is in a very strong position. The Company has a substantial net cash balance, continuing solid positive cash flow, and the business remains robust. The Company has significant opportunities globally, particularly within the USA. Being a medical device company focussing on tests monitoring diabetes and haemoglobin (patients with these conditions are in a higher risk category regarding COVID-19), EKF is well positioned to assist the medical and scientific community.

DETAILED TRADING REVIEW FOR THE YEAR ENDED 31 DECEMBER 2019

Chairman's Statement

It gives me great pleasure to be able to report that EKF continues to perform strongly, with excellent growth in revenues and earnings. The core business has grown revenue at a steady rate and adjusted earnings before interest, depreciation and amortisation (AEBITDA) at a much faster rate.

Strategy

The core strategy of the business remains unchanged. It is threefold:

- 1) to continue to build our installed base of point-of-care analysers which then generate an ongoing stream of revenue through the sale of proprietary consumables;
- 2) to supply a range of clinical chemistry reagents for use on our own and third party analysers; and
- 3) to grow our contract and partnership enzyme manufacturing business.

To this core, we have added our Preferred Partnership Agreement ("PPA") with Mount Sinai Innovation Partners ("MSIP") which allows us advanced access to innovative commercial opportunities arising from certain technologies managed by MSIP.

MSIP Preferred Partnership Agreement

MSIP is responsible for driving the real-world application and commercialisation of discoveries and inventions made within the Mount Sinai Health System ("MSHS"), New York's largest integrated healthcare delivery system.

EKF has established a longstanding and close working relationship with MSIP, through the highly successful spin-off of Renalytix AI plc, the developer of artificial intelligence-enabled diagnostics for kidney disease, made in close collaboration with the Icahn School of Medicine at Mount Sinai ("Mount Sinai"), the medical school of MSHS. This collaboration has already delivered considerable value to EKF shareholders. This new agreement with MSIP provides a framework to explore other commercial opportunities together and to select and support pioneering medical approaches that could make a major difference to people's lives around the world, as well as much-needed improvements in healthcare economics

The PPA, which is non-exclusive, provides EKF with access to opportunities which benefit from a clinician and demand-focused approach to developing commercially relevant healthcare products and services, and access to deep domain expertise in clinical disciplines and academia, commercial healthcare enterprises and other key stakeholders in the US healthcare market.

In connection with the PPA, the Company has signed a non-binding term sheet with MSIP, which will allow the Company to explore the opportunity to support the licensing of technology originating from Mount Sinai to establish a novel digital health platform for earlier intervention in and better management of the care pathway for patients with Inflammatory Bowel Disease ("IBD"). Better evaluation and personalised management of IBD patients, including the implementation of appropriate care delivery pathways in a more timely manner than current practice allows, is expected to deliver better healthcare outcomes (including quality of life) and on a more cost-effective basis than current approaches.

Work on bringing this opportunity to fruition is ongoing, and we will update shareholders with progress in the future. We anticipate that other opportunities will flow from the PPA in due course.

Renalytix AI plc ("RenalytixAI")

In November 2018 RenalytixAI, a spin-out from EKF, was separately floated on AIM, with 20,964,295 RenalytixAI shares having been distributed by EKF to shareholders just prior to the float. At 31 December 2019 the RenalytixAI share price was £3.64 per share or an equivalent market value of the dividend to EKF shareholders at that date of £76.3m, which represents approximately 16.8p of incremental value received per EKF share.

In April 2019 we purchased a further 100,074 RenalytixAI shares at a price of just under £1.236 pence per share, to add to the holding acquired in the initial public offering, bringing our total holding to 2,677,981 shares. At 31 December 2019 these were held at a fair value of £9.75m. The unrealised gain of £6.50m on these shares has been taken to Other Comprehensive income. While global events since year end have reduced the RenalytixAI share price, the company continues to make significant progress against its objectives, which have been and continue to be delivered at a far greater pace than that thought possible at the time of its IPO in November 2018. The Board considers there to be very substantial further value accretion to come from EKF's continuing investment in RenalytixAI.

Share capital

During the year to 31 December 2019 we have not utilised the permission we hold from shareholders to acquire shares for cancellation. It remains our intention to do so when appropriate.

We have continued the process of simplifying our share capital through the cancellation of 250,000 share options at the election of the holder, in return for a small payment.

Dividend

We are pleased to confirm that, given the progress in EKF's business and its strong cash generation, it remains our intention to make an inaugural dividend payment to shareholders of 1p per ordinary share, as previously indicated. If approved by shareholders at the Company's next annual general meeting, payment will be on 1 December 2020 to shareholders on the register on 17 November 2020.

Cash-settled share-based incentive

The Company operates a cash-settled, share based incentive for the Executive Directors, which is designed to pay out in the event that the Company is acquired by a third party (an "Exit"). Since the date of implementation of the Incentive in June 2016, the EKF share price had nearly trebled by late 2019 and the Company has moved from being loss making into EBITDA profitability and from being cash consumptive to strongly cash generative. In addition, EKF shareholders have benefitted from the additional material value deriving from the establishment and spin-out of RenalytixAI.

Reflecting this delivery of value to shareholders by the Executive Directors, EKF's Remuneration Committee determined that, in the absence of any other performance-related pay mechanism, it was appropriate to distribute, as performance-related pay, a portion of the amount that would otherwise be payable under the Incentive on an Exit. The determination followed consultation with a majority of shareholders representing over 60% of the total voting rights in the Company, who were in support of the proposed action.

The Executive Directors each received an equal payment of approximately £1.345 million in November 2019, comprising a baseline payment for value creation up to a 20 pence share price, plus a variable amount calculated as to 5% of the excess value over 20 pence per share, calculated using a reference share price of 27 pence.

Any future amounts payable to the Executive Directors under the Incentive in the event of an Exit shall be reduced by all previously paid amounts, including the payment of £200,000 to each of the Executive Directors in 2017. Accordingly, the aggregate amount payable to them under the Incentive is unchanged by the payments described above and the total value available to Shareholders on an Exit will be unaffected. The Remuneration Committee considers that the remaining unpaid amounts under the incentive continue to provide strong motivation to the Executive Directors, who will receive a further potential variable reward in the event of an Exit, equal to 5% of the excess value obtained over 27 pence per share.

Results overview

The Chief Executive's and Finance Director's statements contain a review of the year and an overview of the financial performance of the Group.

Board and Corporate Governance

All Board members have served throughout the year. The Board continues to believe that the current make-up of the Board is appropriate.

We have adopted the corporate governance code issued by the Quoted Company Alliance. Further details of compliance are found in the Corporate Governance Statement and on the Company's website.

Outlook

With good cash resources and a business which is growing strongly, EKF has moved into a phase where we are confident that we can provide an income for shareholders and the prospect of significant upside from our relationships with MSIP and others. Trading in 2020 to date has been satisfactory and in line with management expectations.

I would also like to remind everyone that despite these difficult times EKF is in a very strong position. We have a substantial net cash balance, continuing solid positive cash flow, and the business remains robust. We see significant opportunities globally, particularly within the USA. Being a medical device company focussing on tests monitoring diabetes and haemoglobin, both conditions putting patients in higher risk categories for contracting COVID-19, EKF is well positioned to assist the medical and scientific community.

We have taken stringent steps to protect our supply chain, build inventory, and most importantly we have received German state approval to keep our Barleben manufacturing facility open in event of a lockdown.

Christopher Mills
Non-executive Chairman

24 March 2020

Chief Executive's Review

Review of 2019

2019 has seen the Company continue its momentum by delivering on its strategic goals and, as mentioned above, the Board is confident that this progress will continue in 2020 and beyond. Further upside is expected from the OEM contract with McKesson-Surgical Inc. for the distribution of DiaSpect Tm in the US, the enzyme manufacturing business with Oragenics, Inc. and increased manufacture of the Longhorn PrimeStore MTM sample collection device.

We are excited by the possibilities being opened to us through our non-exclusive Preferred Partnership Agreement with Mount Sinai Innovation Partners, details of which are described in the Chairman's Statement.

Operations

Point-of-care

i. Haematology

Haematology sales have risen very slightly over 2018. Hemo Control sales fell due to the completion of Pakistan, Saudi and Tanzanian anaemia screening tenders in 2018.

This was offset however by growth through EKF's private label distribution agreement with McKesson for DiaSpect Tm. It is sold in the US by McKesson under its own branded line, as the *McKesson Consult® Hb analyser*. The agreement follows US Food and Drug Administration 510(k) clearance and CLIA waiver for the DiaSpect Tm in April 2018. The full launch of the *McKesson Consult® Hb analyser* took place in April 2019. Initial sales have been encouraging. We have also seen significant haematology sales in Peru and Egypt.

ii. Diabetes

From 2019 we are reporting sales of β -HB products under diabetes rather than Central Laboratory as we consider β -HB to be part of our diabetes portfolio.

Sales of our Diabetes products increased by 9%. Sales of β -HB products improved by 18%, with the majority of sales coming from the USA. Diabetes sales have also been driven by increased sales of Quo-Test where we are gaining traction in the UK and seeing continued growth in APAC. Quo-Lab sales were impacted by a technical issue with reagents which has now been solved.

We are continuing development of the new Biosen R-Line range, a research use only version of our successful analyser for use in non-medical applications.

iii. Central Laboratory and Life Sciences

Sales in this market (which now exclude β -HB) have increased by 15%.

Sales to Oragenics, Inc. (for the outsourced manufacture of the enzyme for its Lantibiotic product) have been the main contributor of growth in the year, with Life Sciences revenues up 20% as a result. With our enzyme facility in Elkhart, USA, now operating at full capacity we have commenced the work necessary to bring our new South Bend facility into operation. We have also successfully completed early stage development batches of a bulk dietary ingredient for Ixcela, Inc.

Since the period end, we have released a new addition to our Diabetes Care portfolio in the US. The STAT-Site WB is a handheld dual-use whole blood β -ketone and glucose meter for professional use in the management of diabetes. The new analyzer is FDA CLIA-waived and can be used in point-of-care and Certificate of Waiver settings, such as physicians' offices, clinics and other non-traditional laboratory locations.

We have also launched our new Glycated Albumin liquid reagent product in the USA. In addition, we have successfully supplied the Jordanian Army with 26 Altair Clinical Chemistry analysers.

iv. Other

This category includes sales of a number of products including our Lactate Scout sports medicine product and other diagnostic tests, the most important of which is for pregnancy. Sales have reduced because of higher shipping charges.

Regulatory Update

Regulatory pressures in diagnostics continue to grow and we are therefore adding additional resources to our regulatory team to address this. In particular, the new requirements of the In Vitro Diagnostic Regulation (IVDR) in Europe place a significant additional burden on all IVD manufacturers and must be in place by May 2022.

Summary

We have not yet seen any material disruption to our business as a result of the COVID-19 pandemic. At this stage, it is difficult to assess reliably whether there will be any material disruption in the future, however we continue to monitor the situation closely. As mentioned in the Chairman's statement, we have comprehensive plans in place and we are fortunate that EKF has significant cash resources available. In addition, there will be an increased reliance on diabetes and haemoglobin testing throughout this year, as well as the PrimeStore MTM manufacturing opportunity which together have the potential to ameliorate or even counteract the possible effects of COVID-19 on other parts of our business.

Absent such matters which are outside our control, we have a growing business built on a good quality product portfolio which meets a broad range of medical needs in a significant number of countries worldwide. We remain very confident in the Group's future and its prospects for continued growth this year and beyond.

Julian Baines
Chief Executive Officer

24 March 2020

Finance Director's Review

Full Financial Statements for the year ended 31 December 2019 will be provided as soon as reasonably practicable, however the information below provides further details of the financial performance of the business over this period. Whilst the Board has approved the statements below, investors should note that these do not constitute statutory financial statements within the meaning of section 434 of the Companies Act 2006.

Revenue

Revenue for 2019 was £44.9m (2018: £42.5m), which is an increase of 6%. At constant exchange rates, revenue for the year would have been 1% lower, so organic growth is over 5%.

Revenue by disease state, which is presented for illustrative purposes only, is as follows:

	2019 £'000	2018 £'000	+/- %
Hematology	13,808	13,728	+1%
Diabetes Care	20,607	18,899	+9%
Central Laboratory	6,135	5,353	+15%
Other	4,367	4,563	(4%)
Total	44,917	42,543	+6%

In this presentation, sales of β -HB of £9.4m (2018: £7.4m) have been reclassified from Central Laboratory to Diabetes.

Gross profit

Gross profit is £23.7m (2018: £22.7m), which represents a gross margin percentage of 52.8% (2018: 53.3%). The reduced gross margin was largely due to higher than usual releases of inventory provisions during 2018.

Administration costs and research and development

Administration costs have increased to £18.3m (2018: £10.6m). The biggest factor was the effect of exceptional items, which were strongly positive in 2018. The most significant exceptional item in 2018 was the substantial gain made on the Group's investment in Renalytix AI plc as a result of its successful separate flotation. The revaluation of Renalytix shares to their fair value in 2019 is recognised through other comprehensive income. An additional factor was the revaluation of the share-based payment liability in 2019 as a result of the higher share price of EKF. Excluding the effect of exceptional items and share based payments, administration costs increased from £16.1m in 2018, to £16.5m in 2019.

Research and development costs included in administration expenses were £2.3m (2018: £1.6m). A further £0.5m was capitalised as an intangible asset, resulting from our development work to broaden and improve our product portfolio, bringing gross R&D expenditure for the year to £2.8m, an increase from the expenditure in 2018 which was £2.2m.

The charge for depreciation of fixed assets and amortisation of intangible assets increased to £4.4m (2018: £4.0m).

Operating profit and adjusted earnings before interest, tax, depreciation and amortisation

The Group generated an operating profit of £5.8m (2018: £12.2m). This again reflects the significant exceptional gain on Renalytix and other items in 2018. We continue to consider that adjusted earnings before interest, tax, depreciation and amortisation, share-based payments and exceptional items (adjusted EBITDA) is a better measure of the Group's progress as the Board believes it gives a clearer comparison of the operating performance between periods. In 2019 we achieved adjusted EBITDA of £12.0m (2018: £10.7m), an increase of 12.5%. The calculation of this non-GAAP measure is shown on the face of the income statement. It excludes the effect of non-cash share-based payment charges of £2.1m (2018: £0.9m), and exceptional profits of £0.3m (2018: £6.5m). IFRS 16 "Leases", which has been introduced in the Group this year has the effect of moving £0.3m into adjusted EBITDA while having no effect on unadjusted earnings. The increase in adjusted EBITDA of £1.3m would be higher by £0.1m without the effect of exchange rates, with £1.1m therefore being attributable to improved underlying performance, excluding the effect of the introduction of IFRS 16. This new accounting standard has no effect on the reporting of cashflow.

Finance costs

Net finance costs have increased to £0.27m (2018: £0.03m). While interest costs on borrowings have continued to reduce, the main charge results from an increase in the fair value of deferred consideration.

Tax

There is an income tax charge of £1.6m, a small decrease from the prior year charge (2018: £1.9m). The charge is lower than would have been expected largely because of tax savings in the USA offset by losses in the UK for which a deferred tax asset has not been recognised as the likely timing of recovery is considered too remote.

Balance sheet

Property plant and equipment

Additions to fixed assets were £1.5m (2018: £1.2m). The major programme has been the continuing work on the upgrading and refurbishment of the Group's facility in Elkhart, USA, where many of the Group's central laboratory products are manufactured, including those being supplied to Oragenics.

Right-of-use assets

As a result of the implementation of IFRS 16 "Leases" we recognised £0.7m of right-of-use assets.

Intangible assets

The carrying value of intangible assets has continued to fall, from £41.8m in 2018 to £37.8m as at 31 December 2019. This is largely the result of the annual amortisation charge.

Investments

Although EKF's pre spin-out shareholding in Renalytix AI plc was distributed to EKF shareholders in October 2018, EKF participated in the Renalytix AI initial public offering fund raising acquiring 2,577,907 ordinary shares at a cost of £1.21 each. Subsequently in April 2019, EKF acquired a further 100,074 ordinary shares in the market at a cost of approximately £1.236 per share. The resulting shareholding in Renalytix of 2,677,981 shares represents 4.51% of their share capital. As Renalytix is an AIM quoted business, our shares are held at "fair value" being the quoted middle market price, with any gain or loss being taken through Other Comprehensive Income in accordance with IFRS 13. In the event of an outright sale of this investment, a discount will apply.

Deferred consideration

The remaining deferred consideration of £1.4m (2018: £1.1m) relates to a share-based payment to the former owner of EKF-Diagnostic GmbH, payment of which is subject to an offsetting warranty related claim, the value of which is held in receivables. Conclusion of the position has taken longer than anticipated but is expected during 2020.

Cash and working capital

Despite the performance related bonuses paid to the directors of the company of approximately £2.7m, net cash has increased from £9.4m to £11.4m. Gross cash has increased to £12.1m (2018: £10.3m). Borrowings, which were mainly used to fund a new building at our plant in Barleben, Germany, are reducing over the loan period to 2023. Inventory has remained largely static at £6.1m in spite of higher revenue.

Richard Evans

Finance Director and Chief Operating Officer

24 March 2020