



13 March 2019

EKF Diagnostics Holdings plc
(“EKF”, the “Company” or the “Group”)

Final results

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care business, announces its final results for the year ended 31 December 2018.

Financial highlights

- Revenue up 2% to £42.5m (2017: £41.6m)
- Gross profit broadly flat at £22.7m (2017: £22.9m)
- Adjusted EBITDA* up 15% to £10.7m (2017: £9.3m)
- Profit before tax £12.2m (2017: £4.3m), over 2.8 times higher
- Basic Earnings per share of 2.21p (2017: 0.59p), underlying basic earnings (excluding exceptional items and share based payments) of 1.01p (2017: 0.58p)
- Cash generated from operations of £9.9m (2017: £10.1m)
- Cash at 31 December 2018 of £10.3m (31 Dec 2017: £8.2m), net cash of £9.4m (31 Dec 2017: £7.0m)

* Excluding exceptional items and share based payments

Operational Highlights

- Successful flotation of Renalytix AI plc creating significant shareholder value
- Achieved US FDA 510(k) clearance for point-of-care and CLIA waiver for the DiaSpect Tm
- Major private label distribution agreement with McKesson for the Tm
- US FDA 510(k) clearance for Quo-Test in clinical laboratory setting
- Upgrade to Elkhart (Indiana, USA) enzyme facility and contract to supply enzymes to US biopharma Orogenics for use in their pharmaceutical products

Christopher Mills, Non-executive Chairman of EKF, said:

“This has been a very successful year, which has allowed us to provide significant rewards for shareholders. We are confident that we will continue to make progress in 2019. Trading in the first quarter to date has been satisfactory, in line with management expectation.”

EKF Diagnostics Holdings plc

Christopher Mills, Non-executive Chairman
Julian Baines, CEO
Richard Evans, FD & COO

Tel: 029 2071 0570

N + 1 Singer

Aubrey Powell / Lauren Kettle / George Tzimas (Corporate Finance)
Tom Salvesen (Corporate Broking)

Tel: 020 7496 3000

Walbrook PR Limited

Paul McManus
Lianne Cawthorne

Tel: 020 7933 8780 or ekf@walbrookpr.com
Mob: 07980 541 893
Mob: 07584 391 303

CHAIRMAN'S STATEMENT

It is a pleasure to report to shareholders on another successful year for EKF, with record revenue, earnings, and profits.

Strategy

Since I joined the business in April 2016, the Group has followed a consistent strategy of concentrating on its point-of-care diagnostics and central laboratory reagents business. While the task of simplification of the business was largely completed in 2017, we continue to actively seek cost saving opportunities through improved efficiency and targeted action plans, while seeking to position the business for further growth.

Renalytix AI plc

In January 2018 we announced our intention to create value from our sTNFR biomarker technology. In short order this process led to the development, founding, and successful flotation on AIM of an exciting developer of artificial intelligence-enabled diagnostics for kidney disease, including the raising of £22.25m for working capital. Of this, £3.1m was provided by EKF. As at the date of this statement, Renalytix AI plc ("Renalytix") is valued at over £75m in its own right, and is making good progress towards its goals.

EKF's shareholding in Renalytix comprising 20,964,295 ordinary shares was distributed to relevant EKF shareholders in October 2018. The market value of those shares at the date of this statement, post admission to AIM, is circa £29.3m. As a requirement of Renalytix's flotation, these shares are being held in escrow and share certificates will be sent to the underlying shareholders once the lock-in ends on 22 April 2019.

This process has been extremely successful and has provided a very significant benefit to EKF shareholders. I would like to thank the EKF directors and staff who put an enormous amount of work into its achievement.

We remain very excited about the future prospects for Renalytix and are confident that it will deliver further significant value to shareholders over the longer term.

Share buy back

The Group has continued to acquire its own shares in the market. During the year the Group has acquired and cancelled 3,461,409 shares representing 0.76% of the Ordinary shares in issue as at 1 January 2018, at a total cost of £940,000. Subject to continuing shareholder approval, the Group intends to continue to acquire shares for cancellation when it is appropriate to do so.

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

The make-up of the Board has once again remained stable. The Non-executive Directors have again waived their salary but received an appropriate bonus to recognise the very significant contribution they make to the success of the Group over and above their duties as directors.

The London Stock Exchange now requires AIM listed companies such as EKF to adopt a recognised corporate governance code and we have chosen that issued by the Quoted Companies Alliance. Further details of compliance can be found in the Corporate Governance Statement in the Annual Report, once published, and on the Company's website in accordance with AIM Rule 26.

Outlook

This has been a very successful year, which has allowed us to provide significant rewards for shareholders. We are confident that we will continue to make progress in 2019. Trading in the first quarter to date has been satisfactory, in line with management expectations.

Christopher Mills
Non-executive Chairman
13 March 2019

CHIEF EXECUTIVE'S REVIEW

In 2018 we have been highly successful in achieving the operational goals we set ourselves at the beginning of the year. I am pleased to announce that we delivered 6.3% year on year organic growth excluding the effect of the completion of the Saudi Arabian Quo-Test contract which had contributed circa £1.6m more to revenues in 2017 than in 2018. The delivery of replacement revenues through new contract wins and additional organic sales growth has not only mitigated the impact of this source of revenue ending, but has allowed us to maintain overall revenue growth.

Operations

In 2018 we promised to deliver in five main areas to ensure we maintain sustainable organic growth for the foreseeable future, which were: -

1. DiaSpect Tm FDA 510(k) CLIA Waiver.
2. Delivery of a major contract alongside this clearance - the McKesson OEM contract in the US.
3. Upgrade of our Elkhart (Indiana, USA) enzyme facility.
4. Deliver a major contract alongside the upgrade - the Oragenics contract.
5. FDA 510(k) clearance of Quo-Test.

I am proud to say that we have delivered on all the above, although the Quo-Test 510(k) clearance crept into 2019. The OEM contract with McKesson in the US for the DiaSpect Tm gives us an opportunity to quickly expand our haemoglobin Point-of-Care franchise in the US where we already have a strong foothold.

The Oragenics contract in Elkhart has enabled us to broaden our offering in pharmaceutical enzymes. The additional investment has led to a significant upgrade of the facility and we are now in a position to attract other partners alongside Oragenics.

Point-of-Care

One of the two main strands of EKF's business involves the development, manufacture, and sale of instruments and related consumables for use in the diagnosis of conditions in situations which are near-patient. They have the advantage of giving rapid results which can be communicated and acted on immediately, yet offer equivalent accuracy to laboratory based analysers.

Hematology

In 2018, sales of haematology products have risen by 6% to £13.7m (2017: £12.9m).

For many years our Hemo Control analyser range (sold in the USA as the HemoPoint H2) has been our best seller in this area. Following FDA 510(k) clearance for the DiaSpect Tm in point-of-care and CLIA waiver settings, we anticipate that future growth will be maintained globally.

Once we had clearance, we signed a private label distribution agreement with McKesson Medical-Surgical Inc., an affiliate of McKesson Corporation, one of the largest companies in the US by revenue, and one of the largest distributors of medical supplies, who will sell the Tm as the McKesson Consult® Hb analyser. Whilst this partnership is in its infancy we have already opened over 25 new accounts in the US.

Diabetes

Sales of diabetes products are down by 5% this year from £11.5m to £11.0m, due to the end of the Quo-Test contract in Saudi Arabia. Sales of Quo-Lab are up by 20%, and sales of Quo-Test excluding Saudi Arabia are up by 6%.

We were pleased to announce that the Quo-Test analyser has received US Food and Drug Administration 510(k) clearance for professional use in a clinical laboratory setting. This will allow us to enter the US market with this product.

Lactate Scout

Our new Lactate Scout 4 hand-held lactate analyser for fast and accurate sports performance monitoring was launched at the Medica 2018 show. Lactate Scout 4 is designed for use in the field as a training companion for individuals or sports teams. We are working to adapt our existing lactate technology for use in clinical settings. Having taken professional guidance, and consultations with interest groups including potential end users, we are determined to

deliver the right solution for this market, which will involve adapting the base product to ensure good usability in this market, and subsequently carrying out some limited clinical trials.

Central Laboratory

The second main strand of EKF's business is the supply of reagents for use on central laboratory analysers. As an adjunct to this, we also sell our own range of laboratory standard analysers. In 2018, Central Laboratory sales were £13.3m, an increase of 5%.

During the year we signed a distribution agreement for Asahi Kasei's Glycated Albumin products. This has now been launched in the US and the first orders have been received.

We have continued to see strong performance from sales of Beta-Hydroxybutyrate (β -HB) Liquicolor reagent, which are up 10% in GBP terms. As mentioned earlier, our project to increase capacity and significantly upgrade our main wet chemistry site in Elkhart, Indiana has continued, and is expected to complete in 2019. The work we have done there has enabled us to sign an exclusive, multi-million dollar agreement with Oragenics, Inc., a Florida-based biopharmaceutical company, for the manufacturing of Oragenics' lantibiotic bulk drug substances in the United States. Under the collaboration agreement, EKF Diagnostics will manufacture compounds intended for preclinical and early stage clinical trials.

Regulatory update

Our major successes in 2018 have been the achievement of FDA 510(k) clearances for the DiaSpect Tm and Quo-Test. In addition, we have received regulatory approval for β -HB in both Mexico and Colombia, as well as registration of DiaSpect Tm in India. In China, we have had some successes but continue to work on the complex process of getting registrations in place. We continue to work using our own resources and with our partners to extend the span of our registrations.

sTNFR Project – Renalytix AI plc

There has been a longstanding unmet need in the field of End Stage Renal Disease ("ESRD"). Kidney disease costs the US Healthcare system over \$40bn per annum in dialysis alone. In 2017 we started looking for ways to maximise the value of our sTNFR biomarker technology based around this unmet need. It soon became clear that there was a significant opportunity to use this as the springboard for a unique business with the ultimate aim being to develop and sell artificial intelligence enabled diagnostics for ESRD. It was also clear that it was best that this should be progressed entirely outside EKF. A team was put in place to take the new business forward, led by James McCullough. This team rapidly assembled a set of partners including the world - leading centre in the care of kidney disease, the Icahn School of Medicine at Mount Sinai ("ISMMS"). In early November 2018, £22.5m was raised with ISMMS becoming a major shareholder. The funds are primarily being used for the acquisition of licences from ISMMS, to develop the company's products and technology, for corporate purposes, and for general working capital. The Renalytix AI shares which EKF had received in return for its past investment and technology have been distributed to EKF shareholders, and the company has been floated separately on AIM. EKF retains an interest in the business having participated in the fundraising. A company as at the date of this statement valued at circa £75m, post admission to AIM, has been created, which the Directors believe has the potential to be a game changer in the diagnosis and treatment of ESRD.

Outlook

2018 has been a year in which we have achieved all our major milestones, including setting up a number of platforms for growth in 2019 and beyond. We are continuing to build a solid and reliable business with opportunities for significant growth, while ensuring excellent financial results.

Julian Baines
Chief Executive Officer
13 March 2019

FINANCE DIRECTOR'S REVIEW

Revenue

Revenue for 2018 was £42.5m (2017: £41.6m), which is an increase of 2%. At constant exchange rates, revenue for the year would have been 1% higher, so organic growth is over 3%, despite the ending of the large Saudi Arabia contract.

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

| | 2018 £'000 | 2017 £'000 | +/- % |
|--------------------|---------------|---------------|------------|
| Hematology | 13,728 | 12,911 | +6% |
| Diabetes Care | 10,964 | 11,547 | (5%) |
| Central Laboratory | 13,289 | 12,597 | +5% |
| Other | 4,562 | 4,529 | +1% |
| Total | 42,543 | 41,584 | +2% |

Gross profit

Gross profit is broadly flat at £22.7m (2017: £22.9m), while the gross margin percentage on sales is 53.3% (2017: 55.0%). In 2017 there were releases of inventory provisions set in previous years; this did not recur in 2018.

Administration costs and research and development

Administration costs have fallen substantially, to £10.6m (2017: £18.2m), reflecting the focus on operational improvements. The biggest factor was the effect of exceptional items, which are again strongly positive in the year. The most important exceptional item this year is the substantial gain made on the Group's shares in Renalytix AI plc as a result of its successful separate flotation. The gain recognised in EKF's books is discounted to take account of the restrictions on the shares which were distributed to EKF's shareholders prior to the flotation. In addition to Renalytix, there was an exceptional gain following the satisfactory conclusion to a loan agreement with a former employee, offset by business restructuring costs. Excluding the effect of exceptional items, administration costs reduced from £19.7m in 2017, to £17.0m in 2018.

Research and development costs included in administration expenses were £1.6m (2017: £2.2m). A further £0.6m was capitalised as an intangible asset, bringing gross R&D expenditure for the year to £2.2m, a reduction from the expenditure in 2017 of £2.9m, largely caused by the completion of expenditure last year on the DiaSpect Tm FDA clearance process.

The charge for depreciation of fixed assets and amortisation of intangible assets reduced to £4.0m (2017: £4.6m). 2017 included an impairment charge relating to the closure of our Polish operations in that year.

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

The Group made an operating profit of £12.2m (2017: £4.7m). This again reflects the significant exceptional gain on Renalytix and other items, without which operating profit would have been £5.8m, still an increase of 23.4%. 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 because the Board believes it gives clearer comparability of operating performance between periods. In 2018 we achieved adjusted EBITDA of £10.7m (2017: £9.3m), an increase of 14.7%. 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 £0.9m (2017: £1.5m), and exceptional profits of £6.5m (2017: £1.6m). The increase in adjusted EBITDA of £1.4m would be higher by £0.2m without the effect of exchange rates, with £1.6m therefore being attributable to improved underlying performance.

Finance costs

Net finance costs have reduced to £0.03m (2017: £0.42m). While interest costs on borrowings have continued to reduce, the main effect is a result of a lower charge associated with the change in fair value of deferred consideration.

Tax

There is an income tax charge of £1.9m, an increase from the 2017 charge of £1.4m. The charge is lower than would have been expected because of the utilisation of past tax losses.

Balance sheet

Property plant and equipment

Additions to fixed assets were £1.2m (2017: £1.4m). 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.

Intangible assets

The carrying value of intangible assets has continued to fall, from £43.6m in 2017 to £41.8m as at 31 December 2018. This is largely the result of the annual amortisation charge. There was a £0.6m disposal of capitalised development costs which were sold to Renalytix AI plc.

Investments

As part of the fund raising for the Renalytix project, EKF agreed to invest the sum of £3.1m for 4.79% of Renalytix's enlarged (post IPO) share capital.

Deferred consideration

The remaining deferred consideration 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 this year.

Cash and working capital

Despite the £3.1m investment in Renalytix and share buy-backs totalling £0.9m, net cash has increased from £7.0m to £9.4m. Gross cash has increased to £10.3m (2017: £8.2m). Borrowings, which were mainly used to fund a new building at our plant in Barleben, Germany, are reducing over the loan period to 2023, while the remaining balance of a loan from a former employee of EKF Molecular was written back.

Inventory has increased slightly from £5.6m to £6.1m due to a number of strategic decisions to increase raw material holdings to ensure continuity of supply. Trade and other receivables have dipped slightly, largely for non-trading reasons. Trade payables have increased, chiefly because of the effect of the increased liability relating to the cash settled share-based payments.

Richard Evans
Finance Director and Chief Operating Officer
13 March 2019

CONSOLIDATED INCOME STATEMENT

FOR THE YEAR ENDED 31 DECEMBER 2018

| | 2018 £'000 | 2017 £'000 |
|---|---------------|---------------|
| Revenue | 42,543 | 41,584 |
| Cost of sales | (19,847) | (18,721) |
| Gross profit | 22,696 | 22,863 |
| Administrative expenses | (10,586) | (18,186) |
| Other income | 89 | 52 |
| Operating profit | 12,199 | 4,729 |
| Depreciation and amortisation | (3,991) | (4,623) |
| Share-based payments | (939) | (1,514) |
| Exceptional items | 6,454 | 1,562 |
| EBITDA before exceptional items and share-based payments | 10,675 | 9,304 |
| Finance income | 43 | 53 |
| Finance costs | (77) | (475) |
| Profit before income tax | 12,165 | 4,307 |
| Income tax charge | (1,866) | (1,367) |
| Profit for the year | 10,299 | 2,940 |
| Profit attributable to: | | |
| Owners of the parent | 10,110 | 2,715 |
| Non-controlling interest | 189 | 225 |
| | 10,299 | 2,940 |
| | Pence | Pence |
| Earnings per Ordinary Share attributable to the owners of the parent during the year | | |
| From continuing operations | | |
| Basic | 2.21 | 0.59 |
| Diluted | 2.19 | 0.58 |

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
FOR THE YEAR ENDED 31 DECEMBER 2018

| | 2018 | 2017 |
|--|---------------|-------|
| | £'000 | £'000 |
| Profit for the year | 10,299 | 2,940 |
| Other comprehensive income: | | |
| <i>Items that may be subsequently reclassified to profit or loss</i> | | |
| Currency translation differences | 1,383 | (622) |
| Other comprehensive gain for the year | 1,383 | (622) |
| Total comprehensive gain for the year | 11,682 | 2,318 |
| Attributable to: | | |
| Owners of the parent | 11,526 | 2,096 |
| Non-controlling interests | 156 | 222 |
| Total comprehensive gain for the year | 11,682 | 2,318 |

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 31 DECEMBER 2018

| | Group 2018 £'000 | Group 2017 £'000 |
|--|---------------------------------|---------------------------------|
| Assets | | |
| Non-current assets | | |
| Property, plant and equipment | 12,469 | 12,121 |
| Intangible assets | 41,773 | 43,600 |
| Investments | 3,271 | 152 |
| Deferred tax assets | 36 | 47 |
| Total non-current assets | 57,549 | 55,920 |
| Current assets | | |
| Inventories | 6,115 | 5,638 |
| Trade and other receivables | 7,434 | 7,396 |
| Cash and cash equivalents | 10,282 | 8,203 |
| Total current assets | 23,831 | 21,237 |
| Total assets | 81,380 | 77,157 |
| Equity attributable to owners of the parent | | |
| Share capital | 4,541 | 4,576 |
| Other reserves | 143 | 108 |
| Foreign currency reserves | 6,309 | 4,892 |
| Retained earnings | 52,536 | 50,394 |
| | 63,529 | 59,970 |
| Non-controlling interest | 375 | 528 |
| Total equity | 63,904 | 60,498 |
| Liabilities | | |
| Non-current liabilities | | |
| Borrowings | 695 | 872 |
| Deferred tax liabilities | 3,179 | 3,490 |
| Total non-current liabilities | 3,874 | 4,362 |
| Current liabilities | | |
| Trade and other payables | 10,094 | 9,429 |
| Deferred consideration | 1,104 | 1,062 |
| Current income tax liabilities | 2,219 | 1,473 |
| Borrowings | 185 | 333 |
| Total current liabilities | 13,602 | 12,297 |
| Total liabilities | 17,476 | 16,659 |
| Total equity and liabilities | 81,380 | 77,157 |

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 DECEMBER 2018

| | Group 2018 £'000 | Group 2017 £'000 |
|--|---------------------------------|------------------------|
| Cash flow from operating activities | | |
| Cash generated by operations | 9,861 | 10,118 |
| Interest paid | (35) | (106) |
| Income tax paid | (1,503) | (959) |
| Net cash generated by operating activities | 8,323 | 9,053 |
| Cash flow from investing activities | | |
| Purchase of investments | (3,119) | - |
| Purchase of property, plant and equipment (PPE) | (1,220) | (1,361) |
| Purchase of intangibles | (632) | (852) |
| Proceeds from sale of PPE | - | 128 |
| Interest received | 43 | 53 |
| Net cash used in investing activities | (4,928) | (2,032) |
| Cash flow from financing activities | | |
| Share based payments | - | (1,505) |
| Share buy back | (940) | (241) |
| Repayments on borrowings | (242) | (4,458) |
| Dividend payment to non-controlling interest | (309) | (215) |
| Net cash used in financing activities | (1,491) | (6,419) |
| Net increase in cash and cash equivalents | 1,904 | 602 |
| Cash and cash equivalents at beginning of year | 8,203 | 7,874 |
| Exchange gains/(losses) on cash and cash equivalents | 175 | (273) |
| Cash and cash equivalents at end of year | 10,282 | 8,203 |

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| Consolidated | Share Share premium capital account £'000 | Share account £'000 | Other reserves £'000 | Foreign currency reserve £'000 | Retained earnings £'000 | Total £'000 | Non- controlling interest £'000 | Total equity £'000 |
|---|--|---------------------------|----------------------------|---|-------------------------------|----------------|--|--------------------------|
| At 1 January 2017 | 4,643 | 95,393 | 41 | 5,609 | (45,236) | 60,450 | 521 | 60,971 |
| Comprehensive income | | | | | | | | |
| Profit for the year | - | - | - | - | 2,715 | 2,715 | 225 | 2,940 |
| Other comprehensive income | | | | | | | | |
| Currency translation differences | - | - | - | (717) | 98 | (619) | (3) | (622) |
| Total comprehensive (expense)/income | - | - | - | (717) | 2,813 | 2,096 | 222 | 2,318 |
| Transactions with owners | | | | | | | | |
| Proceeds from shares issued | (67) | - | 67 | - | (3,121) | (3,121) | - | (3,121) |
| Capital reconstruction | - | (95,393) | - | - | 95,393 | - | - | - |
| Dividends to non-controlling interest | - | - | - | - | - | - | (215) | (215) |
| Share-based payments | - | - | - | - | 545 | 545 | - | 545 |
| Total distributions to owners | (67) | (95,393) | 67 | - | 92,817 | (2,576) | (215) | (2,791) |
| At 31 December 2017 and 1 January 2018 | 4,576 | - | 108 | 4,892 | 50,394 | 59,970 | 528 | 60,498 |
| Comprehensive income | | | | | | | | |
| Profit for the year | - | - | - | - | 10,110 | 10,110 | 189 | 10,299 |
| Other comprehensive income | | | | | | | | |
| Currency translation differences | - | - | - | 1,417 | (1) | 1,416 | (33) | 1,383 |
| Total comprehensive income | - | - | - | 1,417 | 10,109 | 11,526 | 156 | 11,682 |
| Transactions with owners | | | | | | | | |
| Share cancellation | (35) | - | 35 | - | (940) | (940) | - | (940) |
| Dividends to non-controlling interest | - | - | - | - | - | - | (309) | (309) |
| Distribution in specie | - | - | - | - | (7,027) | (7,027) | - | (7,027) |
| Total distributions to owners | (35) | - | 35 | - | (7,967) | (7,967) | (309) | (8,276) |
| At 31 December 2018 | 4,541 | - | 143 | 6,309 | 52,536 | 63,529 | 375 | 63,904 |

NOTES TO THE FINANCIAL STATEMENTS for the year ended 31 December 2018

1. Basis of presentation

EKF Diagnostics Holdings Plc is a company incorporated in the United Kingdom. The Company is a public limited company, which is listed on the AIM market of the London Stock Exchange.

The audited preliminary announcement has been prepared in accordance with the Group's accounting policies as disclosed in the financial statements for the year ended 31 December 2018 and International Financial Reporting Standards ("IFRSs") and International Financial Reporting Standards Interpretations Committee (IFRS IC) interpretations as adopted by the European Union and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS. This preliminary announcement was approved by the Board of Directors on 13 March 2019. The preliminary announcement does not constitute statutory financial statements within the meaning of section 434 of the Companies Act 2006. Statutory accounts for the year to 31 December 2017 have been delivered to the Registrar of Companies. The audit report for those accounts was unqualified and did not contain statements under 498 (2) or (3) of the Companies Act 2006 and did not contain any emphasis of matter.

Certain statements in this announcement constitute forward-looking statements. Any statement in this announcement that is not a statement of historical fact including, without limitation, those regarding the Company's future expectations, operations, financial performance, financial condition and business is a forward-looking statement. Such forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, amongst other factors, changing economic, financial, business or other market conditions. These and other factors could adversely affect the outcome and financial effects of the plans and events described in this announcement and the Company undertakes no obligation to update its view of such risks and uncertainties or to update the forward-looking statements contained herein. Nothing in this announcement should be construed as a profit forecast.

While the financial information included in this preliminary announcement has been prepared in accordance with the recognition and measurement criteria of International Financial Reporting Standards (IFRSs), this announcement does not itself contain sufficient information to comply with IFRSs. The Company will publish its full financial statements for the year ended 31 December 2018 by 9 April 2019, which will be available on the Company's website at www.ekfdiagnostics.com and at the Company's registered office at Avon House, 19 Stanwell Road Penarth CF64 2EZ. The Annual General Meeting will be held on Thursday 2 May 2019.

2. Geographic sales

Disclosure of Group revenues by geographic location of customer is as follows:

| | 2018 £'000 | 2017 £'000 |
|--|---------------|---------------|
| Americas | | |
| United States of America | 18,253 | 17,174 |
| Rest of Americas | 3,925 | 3,195 |
| Europe, Middle East and Africa (EMEA) | | |
| Germany | 6,208 | 6,016 |
| United Kingdom | 324 | 300 |
| Rest of Europe | 3,583 | 3,423 |
| Russia | 2,687 | 2,743 |
| Middle East | 1,467 | 2,912 |
| Africa | 1,229 | 1,611 |
| Asia and Rest of World | | |
| China | 994 | 915 |
| Rest of Asia | 3,751 | 3,168 |
| New Zealand/Australia | 122 | 127 |
| Total revenue | 42,543 | 41,584 |

No single external customer represented more than 10% of revenues in either 2018 or 2017.

3. Exceptional items

Included within administrative expenses are exceptional items as shown below:

| | Note | 2018 £'000 | 2017 £'000 |
|---------------------------------|------|---------------|---------------|
| – Warranty claim | a | 31 | 339 |
| – Business reorganisation costs | b | (120) | (183) |
| – Cancellation of shares | c | - | 1,406 |
| – A Webb loan | d | 90 | - |
| – Net receipt from legal action | e | 97 | - |
| – Renalytix | f | 6,356 | - |
| Exceptional items | | 6,454 | 1,562 |

- Estimated warranty claim in relation to the acquisition of EKF-diagnostic GmbH increased because of higher share price.
- Restructuring costs, mainly redundancy and notice costs, associated in 2018 with the closure of EKF's Polish facility and other restructuring activities.
- Fair value of shares released to EKF by former shareholders of Selah Genomics Inc. which had been issued as part of the consideration for the acquisition of Selah, but held in escrow. These shares were subsequently cancelled.
- Following settlement with Mr A Webb, the balance of the loan made by him in relation to the molecular diagnostic business has been written back.
- Receipt from legal action against a customer net of legal costs.
- The net profit made by the Group in relation to the Renalytix transaction. Full details are given in note 9.

4. Finance income and costs

| | 2018 £'000 | 2017 £'000 |
|--|---------------|---------------|
| Finance costs: | | |
| – Bank borrowings | 25 | 83 |
| – Other interest | 10 | 23 |
| – Financial liabilities at fair value through profit or loss | 42 | 369 |
| Finance costs | 77 | 475 |
| Finance income | | |
| – Interest income on cash and short-term deposits | 9 | 14 |
| – Other interest | 34 | 39 |
| Finance income | 43 | 53 |
| Net finance costs | 34 | 422 |

5. Income tax

| Group | 2018 | 2017 |
|---|--------------|-------|
| | £'000 | £'000 |
| Current tax: | | |
| Current tax on profit for the year | 2,248 | 2,045 |
| Adjustments for prior periods | 5 | (100) |
| Total current tax | 2,253 | 1,945 |
| Deferred tax: | | |
| Origination and reversal of temporary differences | (387) | (578) |
| Total deferred tax | (387) | (578) |
| Income tax charge | 1,866 | 1,367 |

The Finance Act 2015, which was substantively enacted in 2015, included legislation to reduce the main rate of UK corporation tax to 19% from 1 April 2017 and the Finance Act 2016, which was substantively enacted in 2016, included legislation to reduce the main rate of UK corporation tax to 17% from 1 April 2020.

The tax on the Group's profit before tax differs from the theoretical amount that would arise using the standard tax rate applicable to the profits of the consolidated entities as follows:

| | 2018 | 2017 |
|--|----------------|-------|
| | £'000 | £'000 |
| Profit before tax | 12,165 | 4,307 |
| Tax calculated at domestic tax rates applicable to UK standard rate of tax of 19% (2017: 19.25%) | 2,311 | 829 |
| Tax effects of: | | |
| – Expenses not deductible for tax purposes | 297 | 31 |
| – Remeasurement of deferred tax – change in future tax rate | (19) | (360) |
| – Income not subject to tax | (238) | 267 |
| – Utilisation of losses | (1,069) | (178) |
| – Adjustment in respect of prior years | 106 | (100) |
| – Impact of different tax rates in other jurisdictions | 277 | 634 |
| – Other movements | 201 | 244 |
| Tax charge | 1,866 | 1,367 |

There are no tax effects on the items in the statement of other comprehensive income.

6. Earnings per share

(a) Basic

Basic earnings per share is calculated by dividing the profit attributable to owners of the parent by the weighted average number of Ordinary Shares in issue during the year.

| | 2018 | 2017 |
|---|--------------------|-------------|
| | £'000 | £'000 |
| Profit attributable to owners of the parent | 10,110 | 2,715 |
| Weighted average number of Ordinary Shares in issue | 457,207,272 | 463,098,526 |
| Basic profit per share | 2.21 pence | 0.59 pence |

(b) Diluted

Diluted earnings per share is calculated by adjusting the weighted average number of Ordinary Shares outstanding assuming conversion of all dilutive potential Ordinary Shares. The Company has one category of dilutive potential ordinary shares being share options.

| | 2018 | 2017 |
|--|--------------------|-------------|
| | £'000 | £'000 |
| Profit attributable to owners of the parent | 10,110 | 2,715 |
| Weighted average diluted number of Ordinary Shares | 461,489,617 | 469,343,547 |
| Diluted profit per share | 2.19 pence | 0.58 pence |

| | 2018 | 2017 |
|--|--------------------|-------------|
| Weighted average number of Ordinary Shares in issue | 457,207,272 | 463,098,526 |
| Adjustment for: | | |
| – Assumed conversion of share awards | 238,405 | 2,201,081 |
| – Assumed payment of equity deferred consideration | 4,043,940 | 4,043,940 |
| Weighted average number of Ordinary Shares including potentially dilutive shares | 461,489,617 | 469,343,547 |

7. Dividends

On 24th October 2018 the Company made a distribution in specie whereby the Company's shareholding in Renalytix AI plc, a developer of artificial intelligence enabled diagnostics for kidney disease, which has been floated separately from the Group, was distributed to ordinary shareholders of the Company. The rate was one Renalytix AI plc share for each 21.825 shares held in the company at a total value of £7,027,000 (2017: nil). The fair value per EKF share was 1.5357p, which has been calculated based on the market value of the Renalytix shares prior to the completion of the fundraising and their flotation on the AIM market, less a discount to account for the restrictions placed on the shares.

8. Cash generated by operations

| | Group | |
|--|---------------|---------------|
| | 2018 £'000 | 2017 £'000 |
| Profit before tax | 12,165 | 4,307 |
| Adjustments for: | | |
| – Depreciation | 1,158 | 1,160 |
| – Amortisation | 2,833 | 3,463 |
| – Warranty claim | (31) | (339) |
| – Loss/ (profit) on disposal of fixed assets | 13 | (33) |
| – Share-based payments | 939 | 1,510 |
| – Escrow cancellation | - | (1,371) |
| – Profit on sale of Renalytix | (6,356) | - |
| – Fair value adjustment | 42 | 369 |
| – Foreign exchange | (83) | 233 |
| – Net finance (income)/ costs | (8) | 53 |
| – Loan write back | (90) | - |
| Changes in working capital | | |
| – Inventories | (461) | 306 |
| – Trade and other receivables | 11 | 1,535 |
| – Trade and other payables | (271) | (1,075) |
| Net cash generated by operations | 9,861 | 10,118 |

In the statement of cash flows, proceeds from the sale of property, plant and equipment comprise:

| Group | 2018 £'000 | 2017 £'000 |
|--|---------------|---------------|
| Net book value | 13 | 95 |
| (Loss)/ profit on disposal of property, plant and equipment | (13) | 33 |
| Proceeds from disposal of property, plant and equipment | - | 128 |

Non-cash transactions

The principal non-cash transactions are: the creation of Renalytix AI plc and the subsequent distribution in specie, movements on deferred consideration provisions; the fair value adjustment relating to the deferred equity consideration in respect of EKF Germany, the warranty claim, and release of accruals no longer required.

9. Renalytix AI plc

During 2018, the Group founded Renalytix AI plc which, along with its subsidiary company Renalytix AI Inc., were floated separately from the Group in November 2018. The investment in Renalytix was previously held as an asset available for sale. Renalytix is a developer of artificial intelligence-enabled diagnostics for kidney disease.

As part of the creation of a separate business, intangible assets with a net value of £646,000 were sold to Renalytix by the Group, and the Group's wholly owned subsidiary Renalytix AI Inc. was sold to Renalytix AI plc, in return for shares in Renalytix AI plc. Following these transactions, EKF's shareholding in Renalytix comprised 20,964,295 ordinary shares.

The EKF holding was then distributed in specie to Relevant EKF shareholders, being those on the EKF register as at the date of record for the distribution in October 2018 at a rate of one Renalytix AI plc ordinary share (a "RENX share") for each 21.825 EKF ordinary shares held. The fair value of the shares distributed to Relevant EKF shareholders was calculated based on the proposed flotation price, less a discount to account for the restrictions placed on the shares. The discount was calculated taking into account, amongst other factors, the 180 day lock up period, sector volatility, and that the shares were issued pre-admission. The total fair value of the distributed shares was calculated as £7,027,000 with the profit on disposal, which has been shown as an exceptional profit, being calculated net of expenses of £25,000 and the value of the intangible asset transferred of £6,356,000. Subsequent to the distribution, EKF invested £3.1m in the shares of Renalytix at the same price as other new investors and, as at the date of this announcement, holds 2,577,907 RENX shares.