

14 September 2021

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

Half-year Report
Further upgrade to current year trading

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care business, announces its unaudited interim results for the six months ended 30 June 2021, as well as a further upgrade to current year trading.

The strong trading from the beginning of the year continued into the second quarter of 2021. This continues to reflect improving trading in the core business and ongoing strong demand for EKF's contract manufacturing services for COVID-19 sample collection devices and associated kits. The Board is now very confident that trading for the full year will be comfortably ahead of already materially upgraded management expectations.

Financial Highlights

- Revenue up 46.5% to £38.56m (H1 2020: £26.33m)
- Adjusted EBITDA* up 42.9% to £12.76m (H1 2020: £8.93m)
- Net profit after tax up 122% to £9.19m (H1 2020: £4.14m)
- Net cash generated from operations of £1.13m (H1 2020: £6.94m)
- Net cash of £20.38m (30 June 2020: £16.28m) (31 December 2020: £21.41m)
- Dividend of 1.1p per ordinary share to be paid on 1 December 2021 (record date: 5 November 2021)

* Earnings before interest, tax, depreciation and amortisation adjusted for exceptional items and share-based payments

Operational Highlights

- Core business revenues up £1.21m (6%) in first six months of 2021
- Life Sciences revenues including contract manufacturing for PrimeStore MTM and PBS up 142% to £18.50m
- Signed multi-million dollar global supply contract for phosphate-buffered saline (PBS) with global private sector partner, whilst also broadening customer base and reducing reliance on this single customer
- Opened new PrimeStore MTM and PBS manufacturing facilities in Cardiff and Boerne to meet wider customer demand in UK and USA
- Trellus Health admitted to AIM on 28 May 2021

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

"The Board is very confident that trading for the year ending 31 December 2021 will be comfortably ahead of already upgraded management expectations.

"The Group remains confident that its growth strategy, as outlined to shareholders at the Annual General Meeting in May, and set out above, will create a business which, aside from any COVID-19 related revenues, is capable of generating significant double-digit growth in adjusted EBITDA over the next three to four years."

A copy of the investor presentation is available here: <https://www.ekfdiagnostics.com/documents-reports.html>

EKF Diagnostics will be hosting a live online presentation open to all investors on Wednesday 15 September 2021 at 5.15 pm (BST), via video conference call. If you would like to register, please contact Walbrook PR on 020 7933 8780 or email ekf@walbrookpr.com.

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BUSINESS REVIEW

The strong trading from 2020 and the beginning of the year continued into the second quarter of 2021. This continues to reflect improving trading in the core business and ongoing strong demand for our contract manufacturing services for COVID-19 sample collection devices and associated kits. The Board is now very confident that trading for the full year will be comfortably ahead of already materially upgraded management expectations.

Revenues for the six months ended 30 June 2021 were £38.56m (H1 2020: £26.33m), an increase of 46.5%. Adjusted EBITDA was up by 42.9% at £12.76m (H1 2020: £8.93m). Earnings per share have increased by 126%.

STRATEGY

Our aim over the next four years is to use our internally generated resources to:

1. invest in the existing core business to maximise the value of our distribution network and drive aggressive organic growth (including investment in the existing contract fermentation business);
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 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.

We have made good progress against these objectives, as set out below. Discussions are progressing as planned for a number of earnings enhancing acquisitions, and we have identified a number of potential products to expand our existing core business.

OPERATIONS

Diabetes

Sales in the diabetes segment have seen good growth in the period, reaching £10.18m, an increase of 8%, with improvements coming across the majority of the diabetes portfolio as our distribution partners saw growth returning. In particular, sales of β -HB (Beta-Hydroxybutyrate) were up 14% year-on-year, including a contribution from an OEM agreement with a leading distributor. Sales of Quo-Test and Quo-Lab are up 24% and 18% respectively, however sales of the STAT-Site product line have reduced following the discontinuation of STAT-Site β -HB due to obsolescence of components.

Hematology

Overall, revenues from our hematology portfolio have been flat. Within this we have seen 12% growth of our DiaSpect Tm product, primarily driven by our OEM agreements with Fresenius and McKesson. Meanwhile, global hematology screening programmes have continued to be affected by the COVID-19 pandemic, although we have seen signs of programmes beginning to come online again in the latter part of the year, and in particular our major customer in Peru has started to significantly increase their orders as the territory opens up and much needed screening programmes are coming back online.

Contract Manufacturing

Infectious disease test kits

We have continued to see strong demand for our contract manufacturing product lines across our manufacturing sites in the US, Germany, and the UK. Due to our direct relationships with major end users, we have switched towards end user customers and away from sales direct to Longhorn to the mutual benefit of Longhorn and EKF. At the same time, we have seen a change in the mix of products we are being requested to manufacture, with emphasis moving from PrimeStore MTM filled tubes towards tubes filled with Phosphate Buffered Saline (PBS) which we have introduced as a low-cost alternative to MTM. However, we continue the production of PrimeStore MTM tubes for public health systems customers in the UK and Ireland, as well as the manufacture and collation of home testing kits that are distributed through the two largest high street pharmacy chains in the UK, and a new contract for supply of PrimeStore MTM to testing labs based at major UK airports.

In addition, we continue to manufacture kits for employee testing purposes as well as home testing kits including PBS and swab for distribution in US and Europe via our major industrial partner.

This business is servicing customers in the US, the UK, and Europe, including public health authorities in the UK and Ireland, universities, and private laboratories, as well as our major industrial partner. Whilst this major industrial partner represented less than half of our contract manufacturing revenues for PrimeStore MTM and PBS for the first half of the year, we have already seen a shift to a wider mix of revenues from a broader customer base. We expect to see the share of revenue contribution from other customers continue to rise as we move through the year.

In addition, with the expectation that sales of these products will continue for the foreseeable future, we are adding two further factory units to our existing site in Cardiff which was opened in January, and have added off-site manufacturing space in Boerne.

It is a measure of our success in creating and servicing this business, which we started from scratch last year, that we are now discussing the supply of products for non-COVID-19 indications, driven by demand from our customers. These products include areas such as in molecular diagnostics for which work has already started in the US. We see this as a significant growth opportunity for EKF.

Central Laboratory & Life Sciences

Our Central laboratory and Life Sciences sector combines revenues derived from Clinical Chemistry, lab analysers, contract fermentation and enzymes. Central Laboratory sales continue to be affected by the pandemic, mainly in the USA.

We continue to see a strong pipeline of opportunities to supply contract manufacturing services from our Elkhart and South Bend sites, and have committed resources to add capacity. The construction of new fermenters is in progress, work having commenced on a new fermentation facility with a total investment of \$9.3m, of which \$3.4m has already been paid on deposit, and the aim of delivering significant revenues by 2024. These opportunities are arising in the research and molecular enzyme areas as well as food grade fermentation digestive proteins.

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. With an end to the shutdown of professional sports in Europe we have seen an improvement in Lactate Scout sales which have grown by 40% year on year.

PARTNERSHIP WITH MOUNT SINAI

Our Preferred Partnership Agreement (PPA) with Mount Sinai Innovation Partners (MSIP) provides us with advanced access to innovative commercial opportunities arising from Mount Sinai Health System owned technologies, managed by MSIP, in the field of healthcare technologies. This relationship had already lead to the

successful spin-out of Renalytix plc (“Renalytix”) and their subsequent spin-out of Verici Dx plc (“Verici”). Our residual holding in Renalytix is valued at £10.8m (as at 30 June), and our holding in Verici, received as a dividend from Renalytix, is valued at 30 June at £1.8m.

In May 2021, Trellus Health plc, which was formed by MSIP, EKF, and its management in 2020, successfully floated on AIM. EKF’s investment in Trellus was transferred to relevant EKF shareholders in 2020.

Following the completion of his tenure as CEO of the Group, Julian Baines will take responsibility for the management of our relationship with MSIP. A pipeline of new opportunities has been identified.

Financial review

Revenue

Revenue for the period was £38.56m (H1 2020: £26.33m), an increase of 46.5%.

	Unaudited 6 months ended 30 June 2021 £’000	Unaudited 6 months ended 30 June 2020 £’000	+/- %
Hematology	5,856	5,853	0.1%
Diabetes (including βHB)	10,183	9,419	8.1%
Central Laboratory	2,372	2,639	(10.1%)
Contract Manufacturing	17,469	6,459	170.5%
Other	2,679	1,959	36.8%
Total revenue	38,559	26,329	46.5%

Gross profit

Gross profit is £18.54m (H1 2020: £14.91m). The gross profit margin is 48% (H1 2020: 57%). The gross margin percentage has reduced mainly as a result of the product mix.

Administrative expenses

In H1 2021, administrative expenses have reduced to £7.02m (H1 2020: £8.25m), representing 18.2% of revenue for the period (H1 2020: 31.3%). The reduction is largely caused by a credit for share-based payments following the ending of the cash-settled share-based payment incentive scheme for two Directors. The scheme for a senior employee remained in place at the period end. Administrative expenses include research and development (R & D) costs of £0.61m (H1 2020: £0.63m). In addition, further R & D costs of £0.32m (H1 2020: £0.31m) have been capitalised. Non-exceptional administrative costs have increased by 3.4% compared to H1 2020 mainly due to increased sales volumes, as well as further expenditure on quality assurance and regulatory costs as a result of the increased regulatory burden in Europe.

To aid understanding, administrative expenses in each period are made up as follows:

	Unaudited 6 months ended 30 June 2021	Unaudited 6 months ended 30 June 2020	Audited Year ended 31 December 2020
Non-exceptional administration expenditure before R & D capitalisation	8,960	8,668	17,234
Effect of share-based payments	(1,392)	300	5,292
Less capitalised R & D	(317)	(308)	(586)

Effect of exceptional items	(234)	(408)	(1,282)
Total administrative expenses	7,017	8,252	20,658

The charge for depreciation of fixed assets and for the amortisation of intangibles is £2.83m (H1 2020: £2.32m).

Operating profit and adjusted earnings before interest tax and depreciation

The Group generated an operating profit of £11.56m (H1 2020: £6.72m). We consider a more meaningful measure of underlying performance is obtained by examining adjusted EBITDA, which for H1 2021 was £12.76m (H1 2020: £8.92m). This excludes the effects of a credit for share-based payments of £1.39m (H1 2020: charge of £0.30m) and exceptional profits of £0.23m (H1 2020: £0.41m). The increase in operating profit and adjusted EBITDA is caused by the substantial increase in volumes associated with sales of contract manufacturing products.

Finance costs

Finance costs are £0.16m (H1 2020: £0.47m). The main charge results from an increase in the fair value of deferred consideration, the size of which is determined by the increase in EKF's share price.

Tax

There is a tax charge of £2.24m (H1 2020: £2.11m). The increase partly reflects the increase in profit, but also that expenses relating to the cash-settled share-based payment incentive scheme, accrued in previous years, are now deductible for tax purposes as a result of payments having been made.

Earnings per share

Basic earnings per share has increased to 1.99p (H1 2020: 0.88p), an increase of 126%. Diluted earnings per share are 1.98p (H1 2020: 0.87p)

Balance sheet

Fixed assets

We have capitalised £1.47m (H1 2020: £1.19m) of property plant and equipment. The expenditure includes continuing work on improvements to the facilities in South Bend and Elkhart in the US, further automation in Germany, and the cost of fitting out the first stage of the new manufacturing facility in Cardiff. Further expenditure in South Bend and Elkhart, in Germany, and for the second stage of the Cardiff facility is planned for the second half of the year.

Intangible assets

The value of intangible fixed assets is £35.13m (31 December 2020: £37.05m). The decrease is mainly the result of amortisation plus exchange rate movements. An amount of £0.62m has been capitalised.

Investments

Investments includes our holdings in Renalytix plc and Verici Dx plc. The investments are held at fair value which has been calculated based on the market value of the shares which at 30 June 2021 was £10.80 (31 December 2020: £4.875) per share for Renalytix and £0.685 (31 December 2020: £0.585) per share for Verici. The resulting unrealised gain during H1 2021 of £6.21m is shown as a movement in Other comprehensive income.

Deferred consideration

The remaining deferred consideration relates to the share-based payment to the former owner of EKF-Diagnostic

GmbH. Finalisation of the position is expected to conclude shortly.

Cash and working capital

The gross cash position at 30 June 2021 was £20.78m (31 Dec 2020: £16.90m), and the Group had cash net of bank borrowings of £20.38m (31 Dec 2020: £16.28m).

Cash generated from operations in H1 2020 is £1.13m (H1 2020: £6.94m). Inventory levels have increased as a result of the increase in order volume but also to ensure security of component supply. Trade debtors have increased as a result of increased trading activity and because of extended terms granted to certain commercial partners. We have continued to see very little evidence to date of collection difficulties as a result of COVID-19. Payables have reduced because of payments made in relation to the cash-settled share-based payment incentive scheme.

Capital structure

We have not made any share buy backs during the period. Our authorisation to make further share buy backs remains in place and we will make further purchases if considered appropriate.

Dividend

At the Annual General Meeting in May 2021 shareholders approved the payment of a dividend of 1.1p per ordinary share, to be paid on 1 December 2021 to shareholders on the register at close of business on 5 November 2021. As this declaration is irrevocable, the value of £5.005m is shown as a liability with the debit shown in the statement of changes in equity.

Outlook

The Board is very confident that trading for the year ending 31 December 2021 will be comfortably ahead of already materially upgraded management expectations.

The Group remains confident that its growth strategy, as outlined to shareholders at the Annual General Meeting in May, and set out above, will create a business which, aside from any COVID-19 related revenues, is capable of generating significant double-digit growth in adjusted EBITDA over the next three to four years.

Christopher Mills
Non-Executive Chairman

14 September 2021

**CONSOLIDATED INCOME STATEMENT
FOR THE 6 MONTHS ENDED 30 JUNE 2021**

	Notes	Unaudited 6 months ended 30 June 2021 £'000	Unaudited 6 months ended 30 June 2020 £'000	Audited Year ended 31 December 2020 £'000
Continuing operations				
Revenue	3	38,559	26,329	65,260
Cost of sales		(20,019)	(11,417)	(27,840)
Gross profit		18,540	14,912	37,450
Administrative expenses		(7,017)	(8,252)	(20,658)
Other income		34	57	133
Operating profit		11,557	6,717	16,895
Depreciation and amortisation		(2,830)	(2,316)	(4,611)
Share-based payments		1,392	(300)	(5,292)
Exceptional items	4	234	408	1,282
EBITDA before exceptional items and share-based payments		12,761	8,925	25,516
Finance income		22	29	53
Finance costs		(155)	(497)	(1,592)
Profit before income tax		11,424	6,249	15,356
Income tax charge	5	(2,237)	(2,108)	(3,971)
Profit for the period		9,187	4,141	11,385
Profit attributable to:				
Owners of the parent		9,069	4,011	11,114
Non-controlling interest		118	130	271
		9,187	4,141	11,385
Earnings per ordinary share attributable to the owners of the parent during the period				
	6	Pence	Pence	Pence
Basic		1.99	0.88	2.45
Diluted		1.98	0.87	2.42

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
FOR THE 6 MONTHS ENDED 30 JUNE 2021**

	Unaudited 6 months ended 30 June 2021 £'000	Unaudited 6 months ended 30 June 2020 £'000	Audited Year ended 31 December 2020 £'000
Profit for the period	9,187	4,141	11,385
Other comprehensive income/(expense):			
Changes in fair value of equity instruments at fair value through other comprehensive income (net of tax)	4,040	4,445	3,276
Currency translation differences	(1,334)	3,951	734
Other comprehensive income (net of tax)	2,706	8,396	4,010
Total comprehensive income for the period	11,893	12,537	15,395
Attributable to:			
Owners of the parent	11,779	12,456	15,235
Non-controlling interests	114	81	160
Total comprehensive income for the period	11,893	12,537	15,395

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2021**

	Notes	Unaudited as at 30 June 2021 £'000	Unaudited as at 30 June 2020 £'000	Audited as at 31 December 2020 £'000
Assets				
Non-current assets				
Property, plant and equipment		12,957	13,331	12,620
Right-of-use assets		890	941	1,019
Intangible assets	7	35,134	39,347	37,051
Investments		12,818	14,345	6,608
Deferred tax assets		14	21	14
Total non-current assets		61,813	67,985	57,312
Current Assets				
Inventories		9,766	8,144	8,487
Trade and other receivables		16,107	10,545	13,182
Corporation tax receivable		-	-	371
Cash and cash equivalents		20,784	16,895	21,913
Total current assets		46,657	35,584	43,953
Total assets		108,470	103,569	101,265
Equity attributable to owners of the parent				
Share capital		4,550	4,546	4,550
Share premium		200	95	200
Other reserve		9,394	11,093	5,354
Foreign currency reserves		2,698	7,210	4,028
Retained earnings		67,580	55,637	63,516
		84,422	78,581	77,648
Non-controlling interest		435	472	552
Total equity		84,857	79,053	78,200
Liabilities				
Non-current liabilities				
Borrowings		310	422	323
Lease liabilities		475	721	690
Deferred tax liability		4,586	2,940	2,636
Total non-current liabilities		5,371	4,083	3,649
Current liabilities				
Trade and other payables		13,152	14,211	14,435
Lease liabilities		456	248	380
Deferred consideration		3,033	1,840	2,901
Current income tax liabilities		1,512	3,946	1,515
Borrowings		89	188	185
Total current liabilities		18,242	20,433	19,416
Total liabilities		23,613	24,516	23,065
Total equity and liabilities		108,470	103,569	101,265

**CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE 6 MONTHS ENDED 30 JUNE 2021**

	Unaudited 6 months ended 30 June 2021 £'000	Unaudited 6 months ended 30 June 2020 £'000	Audited Year to 31 December 2020 £'000
Cash flow from operating activities			
Profit before income tax	11,424	6,249	15,356
Adjustments for			
- Warranty claim	(251)	(455)	(1,414)
- Depreciation	919	872	1,844
- Amortisation and impairment charges	1,911	1,444	2,767
- Deferred consideration (FV adjust)	132	455	1,516
- Foreign Exchange	(40)	-	26
- Bad debt written down	-	-	45
- Profit/(loss) on disposal of assets	(9)	14	(22)
- Loss on disposal of intangible assets	-	-	8
- Share-based payments	(1,392)	300	4,775
- Dividend received	-	-	(31)
- Net finance costs	1	13	23
Changes in working capital			
- Inventories	(1,450)	(2,056)	(2,557)
- Trade and other receivables	(2,960)	(1,974)	(3,426)
- Trade and other payables	(5,126)	2,075	1,888
Cash generated by operations	3,159	6,937	20,798
Interest paid	(11)	(29)	(47)
Income tax paid	(2,019)	(849)	(6,942)
Net cash generated by operating activities	1,129	6,059	13,809
Cash flow from investing activities			
Purchase of investments	-	-	(3,810)
Purchase of property, plant and equipment (PPE)	(1,342)	(1,187)	(1,631)
Purchase of intangibles	(623)	(393)	(1,014)
Proceeds from sale of PPE	14	27	68
Proceeds from sale of investments	-	-	7,670
Interest received	22	29	53
Net cash used in investing activities	(1,929)	(1,524)	1,336
Cash flow from financing activities			
Proceeds from issue of ordinary shares	-	100	209
Dividend	-	-	(4,550)
Share option buy back	-	-	(7)
Repayment of borrowings	(89)	(126)	(183)
Principal lease payments	(257)	(166)	(469)
Dividends paid to non-controlling interests	(231)	(210)	(209)
Net cash used in financing activities	(577)	(402)	(5,209)
Net increase in cash and cash equivalents	(1,377)	4,133	9,936
Cash and cash equivalents at beginning of period	21,913	12,074	12,074
Exchange gains on cash and cash equivalents	248	688	(97)
Cash and cash equivalents at end of period	20,784	16,895	21,913

Changes in fair value of equity instruments at fair value through other comprehensive income	-	-	4,040	-	-	4,040	-	4,040
Currency translation differences	-	-	-	(1,330)	-	(1,330)	(4)	(1,334)
Total comprehensive income	-	-	4,040	(1,330)	9,069	11,779	114	11,893
Transactions with owners								
Dividends to owners	-	-	-	-	(5,005)	(5,005)	-	(5,005)
Dividends to non-controlling interest	-	-	-	-	-	-	(231)	(231)
Total contributions by and distributions to owners	-	-	-	-	(5,005)	(5,005)	(231)	(5,236)
At 30 June 2021	4,550	200	9,394	2,698	67,580	84,422	435	84,857

NOTES FORMING PART OF THE INTERIM FINANCIAL STATEMENTS

1. General information and basis of presentation

EKF Diagnostics Holdings plc is a public limited company incorporated in the United Kingdom (Registration Number 04347937). The address of the registered office is Avon House, 19 Stanwell Road, Penarth, CF64 2EZ.

The Group's principal activity is the development, manufacture, and supply of products into the in-vitro diagnostics (IVD) market place. Within this area, the Group has a growing business in contract manufacturing.

The financial information in these interim results is that of the holding company and all of its subsidiaries. It has been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 ("IFRS"). The accounting policies applied by the Group in this financial information are the same as those applied by the Group in its financial statements for the year ended 31 December 2020 and which will form the basis of the 2021 financial statements except for a number of new and amended standards which have become effective since the beginning of the previous financial year. These new and amended standards are not expected to materially affect the Group.

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.

The financial information presented herein does not constitute full statutory accounts under Section 434 of the Companies Act 2006 and was not subject to a formal review by the auditors. The financial information in respect of the year ended 31 December 2020 has been extracted from the statutory accounts which have been delivered to the Registrar of Companies. The Group's Independent Auditor's report on those accounts was unqualified, did not include references to any matters to which the auditor drew attention by way of emphasis without qualifying their report and did not contain a statement under section 498(2) or 498(3) of the Companies Act 2006. The financial information for the half years ended 30 June 2021 and 30 June 2020 is unaudited and the twelve months to 31 December 2020 is audited.

These interim accounts have not been prepared in accordance with the UK-adopted International Accounting Standard 34, "Interim Financial Reporting".

2. Significant accounting policies

Going concern

The Group meets its day-to-day working capital requirements through the use of cash reserves and existing bank facilities.

The Directors have considered the applicability of the going concern basis in the preparation of these financial statements. This included the review of internal budgets and financial results which show, taking into account reasonably probable changes in financial performance, that the Group should be able to operate within the level of its current funding arrangements. While we have seen some disruption to our core business as a result of the COVID-19 pandemic, current trading suggests that our base case forecasts are still applicable. In addition, our range of COVID related products has been highly successful, bringing significant benefits to the Group, including higher revenue, profits, and cash balances. We believe the Group is in a strong position, however it is difficult to assess

reliably whether there will be any material disruption in the future, and for how long our COVID range will remain relevant. We have modelled a number of scenarios covering reductions in revenue of 10% and 50%, without taking into account the potential benefits of any mitigation strategies such as potential cost savings or insurance claims. While the eventual severity and length of the economic disruption stemming from the pandemic is impossible to forecast these models give the Directors reasonable confidence that the business can survive our worst case scenarios for reductions in revenue for at least the next 12 months.

After making enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. For this reason the Group continues to adopt the going concern basis in the preparation of the financial statements.

3. Segmental reporting

Management has determined the Group's operating segments based on the monthly management reports presented to the Chief Operating Decision Maker ('CODM'). The CODM is the Executive Directors and the monthly management reports are used by the Group to make strategic decisions and allocate resources.

The principal activity of the Group is the design, development, manufacture and selling of diagnostic instruments, reagents and certain ancillary items. This activity takes place across various countries, such as the USA, Germany, Russia, and the United Kingdom, and as such the Board considers the business primarily from a geographic perspective. Although not all the segments meet the quantitative thresholds required by IFRS 8, management has concluded that all segments should be maintained and reported.

The reportable segments derive their revenue primarily from the manufacture and sale of medical diagnostic equipment. Other services include the servicing and distribution of third party company products under separate distribution agreements.

Currently the key operating performance measures used by the CODM are Revenue and adjusted EBITDA (earnings before interest, tax, depreciation and amortisation, adjusted for exceptional items and share-based payments).

The segment information provided to the Board for the reportable geographic segments is as follows:

Period ended 30 June 2021 unaudited

	Germany £'000	USA £'000	Russia £'000	Other £'000	Total £'000
Income statement					
Revenue	17,288	19,772	1,384	4,481	42,925
Inter-segment	(2,746)	(1,616)	-	(4)	(4,366)
External revenue	14,542	18,156	1,384	4,477	38,559
Adjusted EBITDA*	5,326	7,521	364	(450)	12,761
Share-based payment	-	-	-	1,392	1,392
Exceptional items	251	-	-	(17)	234
EBITDA	5,577	7,521	364	925	14,387
Depreciation	(342)	(246)	(11)	(320)	(919)
Amortisation	(438)	(61)	-	(1,412)	(1,911)
Operating profit/(loss)	4,797	7,214	353	(807)	11,557
Net finance costs	(8)	5	16	(146)	(133)
Income tax	(692)	(1,464)	(75)	(6)	(2,237)
Profit/(loss) for the period	4,097	5,755	294	(959)	9,187
Segment assets					
Operating assets	41,595	67,395	432	(618)	108,804
Inter-segment assets	(143)	(16,480)	-	(4,495)	(21,118)
External operating assets	41,452	50,915	432	(5,113)	87,686
Cash and cash equivalents	4,382	6,177	966	9,259	20,784
Total assets	45,834	57,092	1,398	4,146	108,470
Segment liabilities					
Operating liabilities	5,714	21,240	230	17,148	44,332
Inter-segment liabilities	(446)	(17,794)	-	(2,878)	(21,118)
External operating liabilities	5,268	3,446	230	14,270	23,214
Borrowings	399	-	-	-	399
Total liabilities	5,667	3,446	230	14,270	23,613
Other segmental information					
Non-current assets – PPE	5,796	5,014	82	2,065	12,957
Non-current assets – Right-of-use assets	78	585	2	225	890
Non-current assets – Intangibles	24,376	10,416	77	265	35,134
Intangible assets -additions	366	120	-	137	623
PPE - additions	456	679	-	206	1,341
Right-of-use assets - additions	44	(35)	15	103	127

Year ended December 2020 audited

	Germany	USA	Russia	Other	Total
	£'000	£'000	£'000	£'000	£'000
Income statement					
Revenue	25,637	39,459	2,904	4,432	72,432
Inter-segment	(5,351)	(1,767)	-	(54)	(7,172)
External revenue	20,286	37,692	2,904	4,378	65,260
Adjusted EBITDA*	7,343	20,094	883	(2,754)	25,516
Share-based payment	-	-	-	(5,292)	(5,292)
Exceptional items	877	-	-	405	1,282
EBITDA	8,220	20,094	833	(7,641)	21,506
Depreciation	(787)	(511)	(24)	(522)	(1,844)
Amortisation	(1,646)	(1,120)	(1)	-	(2,767)
Operating profit/(loss)	5,787	18,463	808	(8,163)	16,895
Net finance costs	(24)	13	39	(1,567)	(1,539)
Income tax	(820)	(3,497)	(171)	517	(3,971)
Profit/(loss) for the year	4,943	14,979	676	(9,213)	11,385
Segment assets					
Operating assets	39,961	36,899	355	30,529	107,744
Inter-segment assets	(112)	(11,427)	-	(16,853)	(28,392)
External operating assets	39,849	25,472	355	13,676	79,352
Cash and cash equivalents	3,130	7,459	1,257	10,067	21,913
Total assets	42,979	32,931	1,612	23,743	101,265
Segment liabilities					
Operating liabilities	7,135	17,836	158	25,820	50,949
Inter-segment liabilities	(1,332)	(14,915)	-	(12,145)	(28,392)
External operating liabilities	5,803	2,921	158	13,675	22,557
Borrowings	508	-	-	-	508
Total liabilities	6,311	2,921	158	13,675	23,065
Other segmental information					
Non-current assets – PPE	5,912	4,632	93	1,983	12,620
Non-current assets – ROU assets	-	-	-	1,019	1,019
Non-current assets – Intangibles	24,039	10,979	77	1,956	37,051
Intangible assets -additions	679	335	-	-	1,014
ROU assets – additions	-	-	-	518	518
PPE – additions	779	575	54	223	1,631

Period ended 30 June 2020 unaudited

	Germany £'000	USA £'000	Russia £'000	Other £'000	Total £'000
Income statement					
Revenue	10,713	17,160	1,360	100	29,333
Inter-segment	(2,981)	(23)	-	-	(3,004)
External revenue	7,732	17,137	1,360	100	26,329
Adjusted EBITDA	2,827	7,575	395	(1,872)	8,925
Share-based payment	-	-	-	(300)	(300)
Exceptional items	451	-	-	(43)	408
EBITDA	3,278	7,575	395	(2,215)	9,033
Depreciation	(452)	(201)	(10)	(209)	(872)
Amortisation	(403)	(52)	-	(989)	(1,444)
Operating profit/(loss)	2,423	7,322	385	(3,413)	6,717
Net finance costs	(7)	7	21	(488)	(467)
Income tax	(376)	(1,563)	(80)	(90)	(2,109)
Profit/(loss) for the period	2,040	5,766	326	(3,991)	4,141
Segment assets					
Operating assets	40,718	28,894	608	26,138	96,358
Inter-segment assets	(288)	-	-	(9,396)	(9,684)
External operating assets	40,430	28,894	608	16,742	86,674
Cash and cash equivalents	3,375	5,337	798	7,385	16,895
Total assets	43,805	34,231	1,406	24,127	103,569
Segment liabilities					
Operating liabilities	8,062	14,026	137	11,366	33,591
Inter-segment liabilities	(2,222)	(7,463)	-	-	(9,685)
External operating liabilities	5,840	6,563	137	11,366	23,906
Borrowings	610	-	-	-	610
Total liabilities	6,450	6,563	137	11,366	24,516
Other segmental information					
Non-current assets – PPE	6,370	5,425	111	1,425	13,331
Non-current assets – Right-of-use assets	93	634	-	214	941
Non-current assets – Intangibles	26,700	12,431	88	128	39,347
Intangible assets -additions	343	50	-	-	393
PPE - additions	333	609	51	115	1,108
Right-of-use assets - additions	58	4	-	17	79

* Adjusted EBITDA represents earnings before interest, tax, depreciation and amortisation adjusted for exceptional items and share-based payments

'Other' primarily relates to the holding company and head office costs.

Disclosure of Group revenues by geographic location

	Unaudited 6 months ended 30 June 2021 £000	Unaudited 6 months ended 30 June 2020 £000	Audited Year ended 31 December 2020 £000
Americas			
United States of America	16,016	14,702	33,474
Rest of Americas	1,026	1,390	568
Europe, Middles East and Africa (EMEA)			
Germany	4,286	2,984	5,873
United Kingdom	4,621	242	4,522
Ireland	4,384	2	5,408
Rest of Europe	2,920	1,621	3,127
Russia	1,384	1,360	2,904
Middle East	661	572	1,261
Africa	939	1,623	2,553
Rest of World			
China	424	338	767
Rest of Asia	1,861	1,448	2,883
New Zealand/Australia	37	46	97
Total Revenue	38,559	26,328	65,260

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

	Unaudited 6 months ended 30 June 2021 £'000	Unaudited 6 months ended 30 June 2020 £'000	+/- %
Hematology	5,856	5,853	0.1%
Diabetes (including βHB)	10,183	9,419	8.1%
Central Laboratory	2,372	2,639	(10.1%)
Contract Manufacturing	17,469	6,459	170.5%
Other	2,679	1,959	36.8%
Total revenue	38,559	26,329	46.5%

4. Exceptional items

Included within administration expenses and cost of sales are exceptional items as shown below:

		Unaudited 6 months ended 30 June 2021	Unaudited 6 months ended 30 June 2020	Audited year ended 31 December 2020
	Note	£000	£000	£000
Exceptional items include:				
- Business reorganisation costs	a	(17)	(15)	(58)
- Warranty claim	b	251	455	1,414
- Trellus	c	-	(32)	(74)
Exceptional items		<u>234</u>	<u>408</u>	<u>1,282</u>

- (a) Costs associated with the restructuring of the business
(b) Increase in the value of an estimated warranty claim in relation to the acquisition of EKF-diagnostic GmbH. The increase is a result of a higher share price.
(c) Start-up costs associated with the set-up of Trellus Healthcare Limited

5. Income tax

	Unaudited 6 months ended 30 June 2021 £000	Unaudited 6 months ended 30 June 2020 £000	Audited Year ended 31 December 2020 £000
Current tax			
Current tax on profit for the period	(2,387)	(1,885)	(3,913)
Adjustments for prior periods	(4)	(87)	(89)
Total current tax	<u>(2,391)</u>	<u>(1,972)</u>	<u>(4,002)</u>
Deferred tax			
Origination and reversal of temporary differences	154	(136)	31
Total deferred tax	<u>154</u>	<u>(136)</u>	<u>31</u>
Income tax charge	<u>(2,237)</u>	<u>(2,108)</u>	<u>(3,971)</u>

6. Earnings per share

Basic earnings per share is calculated by dividing the profit attributable to equity holders of the parent by the weighted average number of ordinary shares in issue during the period.

Diluted profit 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 share, being share options.

	Unaudited 6 months ended 30 June 2021 £'000	Unaudited 6 months ended 30 June 2020 £'000	Audited year ended 31 December 2020 £'000
Profit attributable to owners of the parent	9,069	4,011	11,114
Weighted average number of ordinary shares in issue	454,993,227	454,247,073	454,524,101
Effect of dilutive potential ordinary shares	4,056,090	<u>4,290,848</u>	<u>4,278,975</u>
Weighted average number of ordinary shares – diluted	<u>459,049,317</u>	<u>458,537,921</u>	<u>458,803,076</u>
	Pence	Pence	Pence
From continuing operations			
Basic	1.99	0.88	2.45
Diluted	1.98	0.87	2.42

7. Intangible Fixed Assets

Group

	Goodwill £'000	Trademarks trade names & licences £'000	Customer relationships £'000	Trade secrets £'000	Develop- ment costs £'000	Software £'000	Total £'000
Cost							
At 1 January 2020	26,371	2,799	15,580	18,436	9,060	299	72,545
Disposal	-	(19)	-	-	(1,419)	-	(1,438)
Additions	-	62	-	-	308	23	393
Exchange differences	1,570	654	1,081	894	505	(10)	4,694
At 30 June 2020	27,941	3,496	16,661	19,330	8,454	312	76,194
Additions	-	84	-	-	278	259	621
Disposals	-	19	-	-	(4,063)	-	(4,044)
Exchange differences	(938)	(282)	(1,120)	(274)	(216)	22	(2,808)
At 31 December 2020	27,003	3,317	15,541	19,056	4,453	593	69,963
Additions	-	238	-	-	317	68	623
Disposal	-	(2)	-	-	-	-	(2)
Exchange differences	(718)	275	(338)	(498)	(116)	(14)	(1,409)
At 30 June 2021	26,285	3,828	15,203	18,558	4,654	647	69,175
Amortisation							
At 1 January 2020	2,550	2,389	10,358	13,141	6,340	-	34,778
Exchange differences	87	373	700	592	311	-	2,063
Disposal	-	(19)	-	-	(1,419)	-	(1,438)
Reclassification/transf er	-	-	-	-	-	-	-
Charge for the period	-	144	681	469	129	21	1,444
At 30 June 2020	2,637	2,887	11,739	14,202	5,361	21	36,847
Exchange differences	(32)	(172)	(747)	(191)	(80)	-	(1,222)
Disposal	-	19	-	-	(4,055)	-	(4,036)
Charge for the period	-	213	564	450	117	(21)	1,323
At 31 December 2020	2,605	2,947	11,556	14,461	1,343	-	32,912
Exchange differences	(54)	(84)	(251)	(362)	(30)	-	(781)
Disposal	-	(1)	-	-	-	-	(1)
Impairment	-	-	-	-	(8)	-	(8)
Charge for the period	-	(52)	588	1,234	107	42	1,919
At 30 June 2021	2,551	2,810	11,893	15,333	1,412	42	34,041
Net book value							
30 June 2021	23,734	1,018	3,310	3,225	3,242	605	35,134
31 December 2020	24,398	370	3,985	4,595	3,110	593	37,051
30 June 2020	25,304	611	4,922	5,127	3,093	290	39,347

8. Dividends

A dividend to shareholders of the holding company of 1.1p per ordinary share has been provided during the period following shareholder approval at the Annual General Meeting of the Company in May 2021 (six months to 30 June 2020 and year to 31 December 2020: both 1p). It will be paid on 1 December 2021 to shareholders on the register of members at the close of business on 5 November 2021.

9. Availability of this announcement

This announcement is available from the Company's website, www.ekfdiagnostics.com. If you would like to receive a hard copy of the interim report, please contact the EKF Diagnostics Holdings plc offices on +44 (0) 29 2071 0570 to request a copy.