



Execution of strategy and simplification of structure to deliver accelerated mid-term growth plans

Clinigen Group plc (AIM: CLIN, 'Clinigen' or 'the Group'), the global pharmaceutical Products and Services group, has today published its half year results for the six months ended 31 December 2020.

FINANCIAL SUMMARY

Six months ended 31 December	2020 £m	2019 £m	Growth	
			Reported	Organic ⁴
<i>Adjusted measures¹</i>				
Net revenue ²	231.9	224.6	3%	4%
Gross profit	100.6	108.1	(7%)	(5%)
EBITDA ³	54.6	62.1	(12%)	(9%)
Basic earnings per share	26.2p	30.8p	(15%)	
Operating cash flow ⁵	60.7	10.1	>100%	
<i>Statutory measures</i>				
Revenue	258.1	243.7	6%	7%
Gross profit	100.6	108.1	(7%)	(5%)
Profit before tax	22.7	24.8	(8%)	
Basic earnings per share	13.5p	14.1p	(4%)	
Interim dividend per share	2.15p	2.15p		
Operating cash flow ⁵	27.5	10.1	>100%	
Net debt	351.5	322.3	9%	

FINANCIAL HIGHLIGHTS

- Total net revenue up 4% on an organic basis to £231.9m (2019: £224.6m) in spite of COVID-19 headwinds. Organic net revenue growth for FY21 is now expected to be in the upper half of the 5% to 10% range, up from the lower end as previously guided, driven by the Services division.
- As expected, adjusted EBITDA decreased by 9% on an organic basis to £54.6m (2019: £62.1m) reflecting the impact of COVID-19 (5%-10% headwind) and a change in gross profit mix partially offset by good cost control. Management expect a stronger H2 weighting to EBITDA in-line with prior guidance. Adjusted EPS down 15% to 26.2p (2019: 30.8p).
- Excellent adjusted operating cash flow of £60.7m, reflecting continued reversal of prior year working capital headwind and continued focus on cash conversion.
- Net debt as at 31 December 2020 of £351.5m, (£329.7m excl. IFRS 16 adjustment) representing leverage of 2.8x, well below temporary banking covenant of 3.5x. Group expected to de-lever significantly over the course of this year, with target leverage of below 2.0x still anticipated within calendar year.
- Interim dividend of 2.15p (2019: 2.15p). Clinigen has not participated in any government funding scheme related to the COVID-19 pandemic.

OPERATIONAL HIGHLIGHTS

- Diversified business model continues to help mitigate the disruption caused by COVID-19 pandemic. Impact estimated to have taken 5%-10% off Group EBITDA.
- **Post period end, the Clinigen structure has been simplified, moving from three divisions to two: Products and Services⁶.** As part of the reorganisation, Sam Herbert, who joined as COO in January, will also lead Products; Pete Belden, previously EVP Clinical, will head up Services.
- **Services:** Net revenue growth of 21% (+21% organic) to £102.6m (2019: £84.5m); EBITDA down 9% (-12% organic) to £13.6m (2019: £14.9m) due to COVID-19 reducing hospital demand for innovative medicines and clinical trial activity alongside investment in the platform.
 - High number of business wins across the division expected to drive H2. As pandemic alleviates Services is positioned well for future growth at improving margins.
- **Products:** As expected, net revenue declined 9% (-8% organic) to £131.0m (2019: £144.3m); EBITDA down 13% (-10% organic) to £44.3m (2019: £51.0m) primarily due to COVID-19 hampering underlying hospital activity and demand alongside timing of shipments.
 - H2 supported by new partnered products and shipments to key customers. Onboarding of new product opportunities and revitalisation of Proleukin with new indications set to deliver meaningful medium to long-term growth.

Shaun Chilton, Chief Executive Officer, said:

“Clinical trial and hospital demand have been severely impacted by the pandemic as the focus remains on treating COVID-19 patients and the roll out of the vaccines. Like many companies focused on hospital-based treatments, and oncology in particular, we have seen some effect on our operations during the period, but the diversity of our business model has helped us to mitigate much of the disruption and we have ended the first half ahead of market expectations.

“During H1, we remained focused on our core business, on generating cash and improving synergies within Clinigen to support our future growth. We reorganised our structure, simplifying it from three to two divisions, to align us closer with our end-customers. We have made good progress in business development and continue to develop our digital solutions to help healthcare professionals’ source hard-to-find essential medicines quickly and easily.

“Moving into H2, we see strong cash conversion and improving operational performance reducing our leverage below 2.0x EBITDA within the calendar year. We may not be immune to the impact of the pandemic, but our business model gives us a degree of resilience. We continue to guide shareholders to an acceleration of growth in FY22.”

Notes

1. Group results on an adjusted basis exclude amortisation of acquired intangibles and products, and other non-underlying items (see note 3 and 4 of the condensed financial statements). Adjusted measures are presented as they allow a more effective year-on-year comparison and identification of core business trends by removing the impact of items occurring either outside the normal course of operations or as a result of intermittent activities such as business combinations and restructuring. The principles to identify adjusting items have been applied to the current and prior year comparative numbers on a consistent basis.
2. Adjusted net revenue excludes Managed Access pass through revenue which varies each period dependent on the mix of programs.
3. Adjusted EBITDA includes the Group’s share of EBITDA from its joint venture.
4. Organic growth is a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions. There were no acquisitions within the last 12 months of the reporting date. Constant currency is derived by applying the prior period’s actual exchange rate to this period’s result.
5. Operating cash flow is net cash flow from operating activities before income taxes and interest. Adjusted operating cash flow excludes the element of CSM acquisition consideration recognised in operating cash flow.
6. The review of results within this half year announcement have been presented using the new segment approach as this is considered to be of most use for the reader and for consistency with the full year annual reporting for FY21.

A virtual analyst briefing will be held at 9:30am on Tuesday, 23 February 2021. To register interest, please contact Instinctif Partners at clinigen@instinctif.com.

An audio replay file will be made available shortly afterwards via the Group's website: www.clinigengroup.com.

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Notes to Editors

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical Products and Services group focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time. The Group operates from sites in North America, Europe, Africa and the Asia Pacific.

Clinigen has more than 1,250 employees across five continents in 16 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 34 of the top 50 pharmaceutical companies; interacting with over 22,000 registered users across more than 115 countries.

For more information on Clinigen, please visit www.clinigengroup.com

Cautionary statement

This announcement contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Clinigen Group plc. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Recipients are cautioned not to place undue reliance on any forward-looking statements contained herein. Except as required by law, Clinigen undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.

GROUP OVERVIEW

Clinigen is dedicated to providing healthcare professionals (HCPs) and their patients with greater access to medicines around the world, and in the process increasing the value of a pharmaceutical product by extending and expanding its lifecycle.

The Group has now reorganised its reporting structure from three divisions to two: Products and Services. This change is directly linked to Clinigen's strategy to create an integrated lifecycle platform for our pharmaceutical clients and healthcare professionals around the world to deliver the right medicine to the right patient at the right time.

Within Services, Clinigen provides a unique set of niche, high value services to Pharma and Biotech clients prior to product launch. This combined offering helps to accelerate drug development plans and enable compliant early access for patients with unmet needs.

Within Products, Clinigen enables access to critical medicines at a country, regional, and global level. The Group's focus is to build a portfolio of specialist medicines to service the needs of healthcare professionals and their patients in both licensed and unlicensed markets.

An important area of focus continues to be the strengthening of links across the business by deepening the relationships with both pharmaceutical and biotech companies (clients) and HCPs (customers). Simplifying the operating model from three to two divisions will help join-the-dots to drive further revenue synergies whilst also making the business more transparent for business development and investment valuation purposes.

COVID-19

The ongoing impact of COVID-19 has been estimated to take c5%-10% off H1 EBITDA. This relates primarily to COVID-19 impacting hospital demand, particularly within oncology, and reducing clinical trial activity, both of which are expected to continue until the pandemic alleviates.

The pandemic continues to create uncertainty, but the Group sees a number of near-term opportunities across both divisions to accelerate growth. Adapting to the environment and adjusting to client and HCP needs has been demonstrated with COVID-19 related business wins across the Services division.

The Group's main priorities are to continue to protect the well-being of its staff, whilst ensuring the continued supply of products to HCPs for their patients. Both aims were achieved during the period thanks to measures put in place at the beginning of the pandemic which continue to work well.

CURRENT TRADING AND OUTLOOK

FY21 organic net revenue growth is now expected to be in the upper half of the 5% to 10% medium term range, up from the lower end that was previously guided. This growth is being driven primarily by the Services division and 'Partnered' products (defined below) of the Products division, which are at a lower overall margin. The second half of the financial year has started in line with this expectation.

Investment in the platform is set to continue to onboard Erwinase and a high number of new business wins, particularly within Services. The Board continues to expect accelerated long-term revenue and profit growth from FY22.

Applying average January 2021 exchange rates to the second half of the financial year, the currency headwind on H2 FY21 EBITDA is estimated to be between 3.5% to 4.5%. The adverse currency impact primarily reflects the strengthening of sterling against the US dollar with each 1% movement against H2 FY20 average rate (1.26) impacting EBITDA by £0.4m.

With continued strong cash generation, paying down debt is a focus and the Group remains committed to achieving net debt leverage within a range of 1.0x to 2.0x EBITDA on an ordinary basis within the calendar year.

SERVICES (Previously Clinical Services and Managed Access)

Within Services, Clinigen provides a unique set of niche, high value services to Pharma and Biotech clients prior to launch. This combined offering helps accelerate drug development plans and enable compliant early access for patients with unmet needs. The division comprises of two service lines:

- **Clinical:** Provision of innovative logistics, packaging, distribution and biorepository solutions alongside global sourcing and supply of comparator medicines, ancillaries, and devices for use in clinical studies to both industry and investigator led researchers.
- **Managed Access:** Design and implementation of global Managed Access Programs (MAPs – otherwise known as Compassionate Use, Named Patient, Early Access, or Expanded Access) to enable pre-approval access to innovative new medicines for the treatment of unmet medical needs.

COVID-19 has created some headwinds for the Services division with the impact of delayed or cancelled studies and lower uptake on Managed Access Programs being felt. However, the continued high number of business wins and delivery against key projects has led to a 21% increase in net revenues to £102.6m (2019: £84.5m). The second half is well supported by these business wins, albeit margins will remain subdued as investments continue to support these business wins and as the mix favours lower margin Sourcing activity. The value of the pipeline continues to grow strongly boding well for the outlook.

Six months ended 31 December	2020 £m	2019 £m	Growth	
			Reported	Organic
Clinical	89.9	71.8	25%	
Managed Access	12.7	12.7	0%	
Divisional Total	102.6	84.5	21%	21%
Divisional EBITDA	13.6	14.9	(9%)	(12%)

All numbers are presented to reflect the new organisational structure.

Net revenue excludes Managed Access pass through revenue which varies each period dependent on the mix of programs.

Clinical: Despite a number of trials being cancelled or delayed due to COVID-19, the Clinical business grew net revenue 25% to £89.9m (2019: £71.8m), driven by new business wins across the division, including the previously announced multi-year large pharma comparator sourcing contract that was signed in FY20. Whilst these new business wins are encouraging there is a higher weighting of comparator sourcing revenue which is at lower overall margins.

There continues to be a high number of business wins across both existing and new clients with a 13% increase in work orders signed for non-sourcing projects, versus H1 FY20, that will contribute to future growth and offer new opportunities for cross selling within both the Clinical and Managed Access businesses.

Whilst COVID-19 has affected the number of clinical trials and led to delays and/or cancellations resulting in reduced client activity and an uncertain market in the short to medium term the outlook remains positive given the continued increase in global pharma R&D. Driving improvement in service levels and overall competitiveness, as well as cross-selling opportunities that exist should help offset much of the near-term risk whilst Clinigen's 'Direct-to-patient' and 'On Demand' offerings could become crucial as clients potentially adapt to more decentralised trial models. Clinigen has also now signed more than 30 COVID-19 related clinical projects (14 in H1) that are expected to contribute in H2. One of which, for vaccine storage, is expected to be a key contributor to performance across Clinical during H2.

Managed Access: Net revenue flat at £12.7m (2019: £12.7m) with the impact of COVID-19 being offset by an increase in the number of MAP wins for H1 versus H1 2019 and the contribution from programs signed in FY20.

As at 31 December 2020, there were 149 individual product MAPs (Dec 2019: 118, June 2020: 131), including products in the COVID-19 space such as Synairgen's SNG001 program for the treatment of hospitalised patients with COVID-19. Collectively, the top 10 MAPs contributed 28% of the Managed Access gross profit (Dec 2019: 34%, June 2020: 38%).

On Cliiport, the Group's proprietary online platform for Managed Access, the number of registered users (HCPs) grew strongly to 22,179 (Dec 2019: 16,977, June 2020: 18,625). Further enhancements are expected in

H2 to automate this interactive ordering platform in order to drive operational efficiencies and enhance both the pharmaceutical client and HCP experience.

Although the impact of COVID-19 on hospital demand, particular for oncology, has been severe, when the pandemic abates and demand returns to more normal levels, the business will benefit from the increasing number of MAPs in place as well as the strong pipeline coming through in the medium to long term.

PRODUCTS (Previously Commercial Medicines and Global Access)

Within Products, Clinigen enables access to critical medicines at a country, regional, and global level. The Group's focus is to build a portfolio of specialist medicines to service the needs of healthcare professionals and patients in both licensed and unlicensed markets. The Products portfolio comprises three distinct strategies:

- **Owned:** Medicines that have been acquired or developed by Clinigen. Clinigen acquires products with the goal to maintain access to those that rely on them and growing access into new markets and disease areas through a targeted product revitalisation strategy. Products developed in-house were previously supplied on an 'on-demand' form, the Unlicensed to Licensed (UL2L) strategy.
- **Partnered:** Partner of choice for Pharma and Biotech to provide access to their medicines in both licensed and unlicensed markets at a country, regional or global level through an exclusive access or licensing arrangement.
- **On-Demand:** Sourcing and supply of unlicensed and short supply medicines in response to demand for access from healthcare professionals.

The impact of the pandemic has been more pronounced on the Products division due to the reduced demand for non-COVID-19 products, particularly in oncology. Net revenue for H1 decreased by 9% to £131.0m (2019: £144.3m). The performance of the Products division is expected to remain subdued until oncology treatments return to pre-pandemic levels, albeit the overall performance will continue to improve in H2 and beyond as new partnered products are onboarded and as the revitalisation of Proleukin in new indications takes shape.

Six months ended 31 December	2020	2019	Growth	
Net revenue	£m	£m	Reported	Organic
Owned	54.4	56.0	(3%)	
Partnered	35.0	35.9	(3%)	
On-Demand	41.6	52.4	(21%)	
Divisional Total	131.0	144.3	(9%)	(8%)
Divisional EBITDA	44.3	51.0	(13%)	(10%)

All numbers have been presented to reflect the new organisational structure.

Owned Products: Clinigen has a portfolio of 19 owned products (7 acquired and 12 developed). Net revenue for H1 decreased by 3% to £54.4m (2019: £56.0m) reflecting the continued impact of COVID-19 on hospital procedures, the timing of shipments to key customers and the loss of Ethylol sales due to manufacturing disruption offset by good growth from the developed products.

Key asset Proleukin has continued to recover in H1, but demand still remains below prior year levels due to the overall COVID-19 impact on oncology treatments in the US and increased by the fact ICU beds are being ring fenced for treatment of COVID-19 patients. H2 is expected to bring a continued recovery in the US alongside increased shipments to customers evaluating the product in new oncology settings.

Foscavir H1 net revenues remained resilient due to the delay of an expected generic competitor in the US and EU, albeit approval and launch of generics in both markets has now occurred. This is expected to have a negative impact on H2 growth rates.

Further progress was made on internationalising Glycopyrronium Bromide Oral Solution with partners in new territories. New dosage forms of Melatonin were launched to help deliver further growth in H2.

The balance of the acquired portfolio saw some decline on the previous year which was largely due to the impact of COVID-19 on hospital demand.

Further diversification of the portfolio through both acquisition and development is expected over time. Alongside the opportunity for acquisitions there are 13 assets in the development pipeline that could deliver a total of £90m in lifetime net revenues.

Partnered: Net revenue for H1 decreased 3% to £35.0m (2019: £35.9m). There has been positive progression with the total number of partnered products (both for licensed and unlicensed markets) rising to 178 (June 2020: 156). Growth across the AAA region remains strong and is positioned well for further growth in H2 and beyond post the approval of Hunterase (Idursulfase-beta) ICV in Japan alongside new partnered products being onboarded.

Onboarding of Erwinase remains on track and is expected to be a meaningful contributor to growth from FY22.

On-Demand: Net revenue fell by 21% to £41.6m (2019: £52.4m) primarily due to the impact of COVID-19 in the EU and continued decline of UK Specials.

The AAA region saw good growth in spite of the market backdrop by continuing to meet in-market demand for shortages. The On-Demand performance is likely to remain subdued until the pandemic subsides; but to lessen the impact and drive growth, the product mix is being adapted to meet market needs.

A key medium to long term growth driver for the On-Demand business and for the wider Products division will be driving engagement of the HCP community through the Group's upgraded digital online services platform, Clinigen Direct which now has visitors from 188 countries.

GROUP INFRASTRUCTURE

The Group's ERP system is working effectively post implementation in October 2019 and further progress has been made to delivering long lasting value to the Group from this investment.

The ERP system is by far the Group's most extensive capital expenditure project and it is a critical feature for leveraging the operational benefit of the enlarged Group for the future. The operational efficiency obtained from its implementation will allow the Group to better compete on a global scale and further investments in automation are expected.

In the period, the Group's Online Services platform was launched to provide, at first, its UK hospital customers a one-stop automated portal for ordering medicines from the Products division (Clinigen Direct) and will be further developed in H2 to include the Managed Access products from the Services division (Cliniport). Over the following months the platform's geographic reach is to be extended in a targeted manner to provide greater healthcare access to patients around the globe.

Increased investment in the Clinical business of the Services division to expand footprint in the US, Germany and Belgium is underway with significant expansion of cold chain storage, fuelled by COVID-19 projects and an increasing pipeline of cold chain products. Some of this new capacity is expected to come online within the current financial year. In South Africa, the Group entered into an agreement to acquire its purpose-built facility in the region, which will deliver an overall saving within a five-year period. The change to working practices caused by COVID-19 is likely to realise further opportunities to optimise the Group's infrastructure over time.

Lastly, over the period end, the Group successfully implemented its 'Brexit' solution and continues to offer an uninterrupted supply of products and services to healthcare professionals, patients and pharma clients across both the UK and EU. The Brexit solution represented the culmination of many months of internal planning and preparation alongside an extensive I.T. and back office solution implementation.

BOARD AND MANAGEMENT

At the AGM, John Hartup, formerly the Senior Independent Non-Executive Director, stepped down as a Director of the Company. Anne Hyland was appointed Senior Independent Director in his place and Alan Boyd was appointed to engage with the workforce on behalf of the Board as the designated Non-Executive Director. The Nomination Committee has started the search process for a new independent Non-Executive Director.

At the senior management level, the Directors appointed Sam Herbert as Chief Operating Officer (COO). Sam is an experienced healthcare and logistics leader on an international basis. He has strong digital and technological knowledge which will support Clinigen's growing organisational and distribution requirements. His immediate roles and responsibilities as COO will also include leading the Products division.

Shaun Chilton

Chief Executive Officer

FINANCIAL REVIEW

Despite significant headwinds from the pandemic, Clinigen has maintained its strong performance and is trading ahead of previous guidance, with the Group well positioned to grow in the second half. Organic net revenue growth for FY21 is now expected to be in the upper half of the 5% to 10% range, up from the lower end as previously guided. This growth is being driven by the Services division and 'Partnered' products which are at a lower overall margin. Investment in the platform is set to continue in order to onboard Erwinase and to support the high number of business wins, particularly within Services.

Excellent cash conversion in the period of 111% follows on from a strong H2 in FY20, demonstrating the Group's strong cash generation abilities after a period of working capital investment in the previous year. Net debt increased as expected to £351.5m following the payment of contingent consideration for CSM and represents a net debt to EBITDA leverage ratio of 2.8x. The Board remains committed to achieving a leverage ratio –below 2.0x within the calendar year.

Summary adjusted income statement

Six months ended 31 December			Growth	
	2020 £m	2019 £m	Reported	Organic ³
<i>Adjusted results¹</i>				
Reported revenue	258.1	243.7	6%	7%
Net revenue ²	231.9	224.6	3%	4%
Gross profit	100.6	108.1	(7%)	(5%)
Administrative expenses	(46.1)	(46.3)	0%	4%
EBITDA from joint venture	0.1	0.3	(53%)	(15%)
EBITDA	54.6	62.1	(12%)	(9%)
Depreciation and amortisation	(7.4)	(4.3)	69%	
EBIT	47.2	57.8	(18%)	
Finance expense	(2.7)	(6.0)	(55%)	
Profit before tax	44.5	51.8	(14%)	
Basic earnings per share	26.2p	30.8p	(15%)	
Dividend per share	2.15p	2.15p		

1. The summary adjusted income statement presents Group results on an adjusted basis excluding amortisation of acquired intangibles and products, and other non-underlying items relating to acquisitions (see note 3 and 4 of the condensed financial statements).
2. Adjusted net revenue excludes Managed Access pass through revenue which varies each period dependent on the mix of programs.
3. Organic growth is a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions. There were no acquisitions within the last 12 months of the reporting date. Constant currency is derived by applying the prior period's actual exchange rate to this period's result.

The Group has previously reported its results split into three divisions: Commercial Medicines, Unlicensed Medicines and Clinical Services. From 1 January 2021, the Group structure has been simplified, moving from three divisions to two: Services and Products. This change better reflects the alignment of the Group's activities to its end customers: pharmaceutical clients and healthcare professionals.

The Services division comprises the old Clinical Services division and the Managed Access element of the old Unlicensed Medicines division. The Products division comprises the old Commercial Medicines division and the Global Access (including Specials) element of the old Unlicensed Medicines division.

A number of adjusted measures are used by the Board in reporting, planning and decision making. Adjusted results reflect the Group's trading performance and exclude amortisation of acquired intangibles and products, and non-underlying costs relating to acquisitions which are explained in note 4 of the condensed financial statements.

Overall, net revenue increased by 3% (4% on an organic basis) to £231.9m (2019: £224.6m) whilst gross profit fell by 7% (-5% on an organic basis) to £100.6m (2019: £108.1m).

Profitability

Six months ended 31 December	2020	2019	Growth	
Adjusted EBITDA by business	£m	£m	Reported	Organic
Products	44.3	51.0	(13%)	(10%)
Services	13.6	14.9	(9%)	(12%)
Central unallocated costs	(3.3)	(3.8)	(13%)	(43%)
	54.6	62.1	(12%)	(9%)

Reconciliation of adjusted profit before tax to reported profit before tax

The table below shows the reconciling items between the adjusted profit before tax of £44.5m (2019: £51.8m) and the reported profit before tax of £22.7m (2019: £24.8m).

Six months ended 31 December	2020	2019
	£m	£m
Adjusted profit before tax	44.5	51.8
Amortisation of acquired intangibles and products	(20.3)	(22.6)
Acquisition costs	(0.1)	(0.3)
Restructuring costs	(1.9)	(1.4)
Foreign exchange on revaluation on contingent consideration	1.3	2.5
Unwind of discount on contingent consideration	(0.7)	(5.1)
Tax on joint venture in South Africa	(0.1)	(0.1)
Total adjustments	(21.8)	(27.0)
Reported profit before tax	22.7	24.8

The adjustments to profit before tax comprise costs relating to amortisation, acquisitions and the Group's share of the tax charge on the joint venture earnings of £0.1m (2019: £0.1m).

Total amortisation was £24.3m (2019: £23.9m), of which £13.2m (2019: £15.2m) related to acquired intangibles, £7.1m (2019: £7.4m) related to acquired product licences, £3.7m (2019: £1.1m) related to software and £0.3m (2019: £0.1m) related to internally developed product licences.

Restructuring costs were £1.9m (2019: £1.4m), in respect of redundancies as well as preparations for Brexit.

There was a £1.3m foreign exchange credit (2019: £2.5m) arising from revaluation of the contingent consideration on CSM and iQone which is denominated in foreign currency.

Reported profit before tax fell by 8%, in line with gross profit.

Finance cost

The adjusted net finance expense was £2.7m (2019: £6.0m) with the decrease due to a significant credit on the revaluation of the Group's borrowings. The average interest charge on gross debt was 2.2% (2019: 2.8%) with the decrease due to the reduction in base rates in both the UK and US. The reported net finance cost was £3.5m (2019: £11.2m), after taking account of the non-cash £0.7m unwind of discount on the contingent consideration relating to the acquisitions (2019: £5.1m).

Taxation

Taxation was £4.7m (2019: £6.0m), based primarily on the prevailing UK and overseas tax rates. This charge is calculated as £9.6m based on the adjusted profit of £44.5m, offset by a credit of £4.9m in respect of the adjusted items.

The Group's adjusted effective tax rate (ETR) increased to 21.6% (2019: 21.0%) due to a higher proportion of earnings in Europe and the US.

Earnings per share

Adjusted basic EPS, calculated excluding amortisation of acquired intangibles and products, and other non-underlying items, decreased by 15% to 26.2p (2019: 30.8p). The decrease reflects the Group's lower profit from operations and increased depreciation and amortisation offset by lower finance costs due to foreign exchange and lower base rates.

Reported basic EPS was 13.5p (2019: 14.1p). The decrease is less than the decrease in adjusted basic EPS due to the lower unwind of discount now that the CSM and Proleukin deferred consideration has been settled.

Dividend

The Board is committed to a sustainable and progressive dividend policy and expects interim and final dividend payments to be split approximately one-third to two-thirds respectively.

The Board has maintained the interim dividend at 2.15p per share (2019: 2.15p). The interim dividend will be paid on 13 April 2021 to shareholders on the register on 19 March 2021.

Cash flow and net debt

Adjusted operating cash flow for the period was £60.7m (2019: £10.1m), representing a return to the strong cash generation of the Group following a period of investment in working capital.

Capital expenditure was £12.3m (2019: £9.4m), which includes £3.8m related to warehouse, IT and other infrastructure investments, £3.5m related to ongoing investment in the Group ERP system following its launch, and £5.0m on product development. Capital expenditure for H2 of FY21 is expected to be higher than the first half due to the increase in spend on development of Proleukin and setup costs for Erwinase.

The Group paid £67.9m (US\$89.5m) as a final settlement of the CSM earn out in September 2020.

The other main cash outflows were tax paid of £8.7m (2019: £15.3m), interest paid of £5.1m (2019: £5.3m) and dividends paid of £7.2m (2019: £6.3m).

As a result of the payment of the CSM earn out but offset by strong operating cash flow, net debt increased by £39.6m to £351.5m. Net debt is expected to decrease by the end of the current financial year as operational cash flow offset by capital expenditure is used to repay debt. Pro forma leverage is expected to decrease in the current financial year, from 2.8x at the end of the period, before reducing more substantially thereafter and a target leverage below 2x within H1 of FY22.

Treasury management

The Group's operations are financed by retained earnings and bank borrowings, and on occasion, the issue of shares to finance acquisitions.

At the period end, there were two covenants that applied to the bank facility: interest cover of not less than 4.0x and net debt/adjusted EBITDA cover of not more than 3.0x, which was extended to 3.5x for the December 2020 covenant testing date as a precautionary measure. As at 31 December 2020, interest cover was 12.7x and the net debt/adjusted EBITDA leverage was 2.8x. The leverage ratio in H2 is expected to reduce to a similar level to the end of the previous financial year (2.3x).

Borrowings are denominated in a mixture of sterling, euros and US dollars, and are managed by the Group's UK-based treasury function, which manages the Group's treasury risk in accordance with policies set by the Board.

Clinigen reduces its exposure to currency fluctuations on translation by typically managing currencies at Group level using bank accounts denominated in foreign currencies. Where there is sufficient visibility of currency requirements, forward contracts are used to hedge exposure to foreign currency fluctuations.

A £20.5m (2019: £11.4m) charge was recognised during the period in respect of currency translation differences within other comprehensive income arising from the impact of the strengthening of sterling on the translation of the Group's net investment in overseas entities.

The Group's treasury function does not engage in speculative transactions and does not operate as a profit centre. The Group has applied hedge accounting where permissible to match hedges to the transactions to which they relate thereby reducing volatility in the results which may arise from gains and losses on hedging instruments.

Mid-term guidance

The fundamentals of the business remain strong and the Group is well positioned to for long term growth across both divisions. Future organic net revenues are targeted to grow by at least 5% to 10% on a medium term view with the FY21 now expected to be in the upper half of this range.

Further investments in the platform, particularly in the US and EU infrastructure, digital capabilities, the ERP platform and product development will continue in order to help drive longer-term organic growth. As such, operational leverage is expected to soften in FY21, as previously guided, before improving in FY22 and beyond.

Currency sensitivity

The Group's activities expose it to currency risk primarily in relation to the US dollar and euro. The Group uses forward contracts which will reduce the impact of this risk for the current financial year. If the current exchange rates are assumed to apply throughout H2 of FY21, the Group estimates it would have a 3.5% - 4.5% negative impact on adjusted EBITDA for H2. Current spot exchange rates to pound sterling as at 19 February 2021 were USD: 1.39; EUR: 1.15; ZAR: 20.3; and AUD: 1.79. A 1% strengthening in sterling versus the US dollar H2 FY20 average rate (1.26) and euro H2 FY20 average rate (1.14) reduces FY21 EBITDA by approximately £0.4m and £0.1m respectively.

Capital allocation

The Group's capital allocation framework exists in order to prioritise the use of cash and maximise shareholder value whilst retaining the flexibility to make value enhancing acquisitions. The four principles within the framework are as follows:

- Reinvest for organic growth
- Maintain a progressive dividend policy
- Aim to paydown and maintain net debt within a range of 1.0x to 2.0x EBITDA on an ordinary basis
- Make acquisitions in line with the Group's strategy with a disciplined approach to valuation

Principal risks facing the business

Clinigen operates an embedded risk management framework, which is monitored and reviewed by the Board. There are a number of potential risks and uncertainties that could have a material impact on the Group's financial performance and position. These include risks relating to the political environment, competitive threat, counterfeit products penetrating the supply chain, compliance, reliance on technology, cyber risk, foreign exchange, people, COVID-19 and the identification, strategic rationale and integration of acquisitions. These risks and the Group's mitigating actions are set out on pages 45 to 47 of the Annual Report 2020.

Nick Keher

Chief Financial Officer

Condensed consolidated income statement

		Six months ended 31 December 2020			Six months ended 31 December 2019		
(In £m)	Note	Underlying	Non-underlying (note 4)	Total	Underlying	Non-underlying (note 4)	Total
Revenue	3	258.1	–	258.1	243.7	–	243.7
Cost of sales		(157.5)	–	(157.5)	(135.6)	–	(135.6)
Gross profit	3	100.6	–	100.6	108.1	–	108.1
Administrative expenses		(53.5)	(20.9)	(74.4)	(50.6)	(21.7)	(72.3)
Profit from operations		47.1	(20.9)	26.2	57.5	(21.7)	35.8
Finance expense	5	(2.7)	(0.8)	(3.5)	(6.0)	(5.2)	(11.2)
Share of profit of joint venture		–	–	–	0.2	–	0.2
Profit before income tax		44.4	(21.7)	22.7	51.7	(26.9)	24.8
Income tax (expense)/credit	6	(9.5)	4.8	(4.7)	(10.8)	4.8	(6.0)
Profit attributable to owners of the Company		34.9	(16.9)	18.0	40.9	(22.1)	18.8
Earnings per share (pence)							
Basic	7			13.5p			14.1p
Diluted	7			13.3p			13.8p

Condensed consolidated statement of comprehensive income

		Six months ended 31 December 2020			Six months ended 31 December 2019		
(In £m)		Underlying	Non-underlying (note 4)	Total	Underlying	Non-underlying (note 4)	Total
Profit for the period attributable to owners of the Company		34.9	(16.9)	18.0	40.9	(22.1)	18.8
Other comprehensive income items that may be reclassified to profit or loss							
Cash flow hedges		0.6	–	0.6	1.0	–	1.0
Currency translation differences		(20.5)	–	(20.5)	(11.4)	–	(11.4)
Total other comprehensive expense for the period		(19.9)	–	(19.9)	(10.4)	–	(10.4)
Total comprehensive income/(expense) attributable to owners of the Company		15.0	(16.9)	(1.9)	30.5	(22.1)	8.4

All amounts relate to continuing operations.

Condensed consolidated statement of financial position

(In £m)		31 December		30 June
	Note	2020	2019	2020
Assets				
Non-current assets				
Intangible assets	9	750.9	781.6	788.3
Property, plant and equipment		13.7	12.7	13.4
Right-of-use assets		18.5	14.9	20.4
Investment in joint ventures and associates		–	6.6	–
Deferred tax assets		3.0	2.8	7.2
Total non-current assets		786.1	818.6	829.3
Current assets				
Inventories		55.0	52.0	43.5
Trade and other receivables		116.0	134.8	125.9
Derivative financial instruments		0.8	1.2	0.2
Corporation tax receivables		0.9	–	–
Cash and cash equivalents		62.9	39.8	143.1
Total current assets		235.6	227.8	312.7
Total assets		1,021.7	1,046.4	1,142.0
Liabilities				
Non-current liabilities				
Trade and other payables		(7.4)	(7.4)	(8.9)
Borrowings and lease liabilities	10	(410.0)	(358.2)	(450.7)
Deferred tax liabilities		(30.2)	(36.7)	(33.6)
Total non-current liabilities		(447.6)	(402.3)	(493.2)
Current liabilities				
Trade and other payables		(131.8)	(198.1)	(194.9)
Corporation tax liabilities		–	(1.3)	(3.7)
Borrowings and lease liabilities	10	(4.4)	(3.9)	(4.3)
Derivative financial instruments		–	–	(0.3)
Total current liabilities		(136.2)	(203.3)	(203.2)
Total liabilities		(583.8)	(605.6)	(696.4)
Net assets		437.9	440.8	445.6
Equity attributable to owners of the Company				
Share capital	12	0.1	0.1	0.1
Share premium account		240.2	240.2	240.2
Merger reserve		88.2	88.2	88.2
Hedging reserve		0.5	0.7	(0.1)
Foreign exchange reserve		(2.8)	3.6	17.7
Retained earnings		111.7	108.0	99.5
Total equity		437.9	440.8	445.6

The notes below form an integral part of these condensed consolidated financial statements.

Condensed consolidated statement of cash flows

		Six months to 31 December		Year to
(In £m)	Note	2020	2019	30 June 2020
Operating activities				
Profit before income tax		22.7	24.8	22.6
Share of profit of joint venture		–	(0.2)	(0.3)
Finance expense	5	3.5	11.2	19.7
Profit from operations		26.2	35.8	42.0
<i>Adjustments for:</i>				
Amortisation of intangible fixed assets		24.3	23.9	50.1
Impairment of intangible fixed assets		–	–	4.2
Depreciation of property, plant and equipment		3.4	3.0	6.4
Impairment of investment in joint venture		–	–	5.9
Movement in fair value of derivative financial instruments		(0.3)	1.7	0.1
(Payment)/increase in fair value of contingent consideration	13	(33.2)	–	11.8
Currency revaluation on contingent consideration	4	(1.3)	(2.5)	2.0
Equity-settled share-based payment expense		1.6	2.0	3.5
Operating cash flows before movements in working capital		20.7	63.9	126.0
Increase in inventories		(11.3)	(17.4)	(8.6)
Decrease/(increase) in trade and other receivables		8.2	(26.3)	(15.6)
Increase/(decrease) in trade and other payables		9.9	(10.1)	(7.0)
Cash generated from operations		27.5	10.1	94.8
Income taxes paid		(8.7)	(15.3)	(23.9)
Interest paid		(5.1)	(5.3)	(10.3)
Net cash flows from/(used in) operating activities		13.7	(10.5)	60.6
Investing activities				
Purchase of intangible fixed assets (excluding products)	9	(10.1)	(8.5)	(20.1)
Purchase of property, plant and equipment		(2.2)	(0.9)	(2.9)
Purchase of subsidiaries, net of cash acquired	13	(34.7)	–	–
Purchase of specialty pharmaceutical products		–	(29.7)	(58.4)
Net cash flows used in investing activities		(47.0)	(39.1)	(81.4)
Financing activities				
Proceeds from increase in loan		–	25.0	107.6
Loan repayments	10	(30.8)	(10.4)	(17.1)
Principal element of lease repayments		(1.7)	(1.9)	(3.4)
Step acquisition of Clinigen Ireland	13	(1.8)	–	–
Dividends paid	8	(7.2)	(6.3)	(9.2)
Net cash flows (used in)/from financing activities		(41.5)	6.4	77.9
Net (decrease)/increase in cash and cash equivalents		(74.8)	(43.2)	57.1
Cash and cash equivalents at beginning of the period		143.1	83.5	83.5
Exchange (losses)/gains		(5.4)	(0.5)	2.5
Cash and cash equivalents at end of the period		62.9	39.8	143.1

Condensed consolidated statement of changes in equity

(In £m)	Share capital (note 12)	Share premium account	Merger reserve	Hedging reserve	Foreign exchange reserve	Retained earnings	Total equity
At 1 July 2020	0.1	240.2	88.2	(0.1)	17.7	99.5	445.6
Profit for the period	–	–	–	–	–	18.0	18.0
Currency translation differences	–	–	–	–	(20.5)	–	(20.5)
Cash flow hedges							
– Effective portion of fair value movements	–	–	–	0.4	–	–	0.4
– Transfers to income statement (revenue)	–	–	–	0.2	–	–	0.2
Total comprehensive income/(expense)	–	–	–	0.6	(20.5)	18.0	(1.9)
Share-based payment scheme	–	–	–	–	–	1.6	1.6
Step acquisition of Clinigen Ireland	–	–	–	–	–	(0.2)	(0.2)
Dividend paid (note 8)	–	–	–	–	–	(7.2)	(7.2)
Total transactions with owners of the Company, recognised directly in equity	–	–	–	–	–	(5.8)	(5.8)
At 31 December 2020	0.1	240.2	88.2	0.5	(2.8)	111.7	437.9

(In £m)	Share capital (note 12)	Share premium account	Merger reserve	Hedging reserve	Foreign exchange reserve	Retained earnings	Total equity
At 30 June 2019	0.1	240.2	88.2	(0.3)	15.0	95.2	438.4
Impact of adopting IFRS 16	–	–	–	–	–	(1.7)	(1.7)
At 1 July 2019	0.1	240.2	88.2	(0.3)	15.0	93.5	436.7
Profit for the period	–	–	–	–	–	18.8	18.8
Currency translation differences	–	–	–	–	(11.4)	–	(11.4)
Cash flow hedges							
– Effective portion of fair value movements	–	–	–	0.9	–	–	0.9
– Transfers to income statement (revenue)	–	–	–	0.1	–	–	0.1
Total comprehensive income/(expense)	–	–	–	1.0	(11.4)	18.8	8.4
Share-based payment scheme	–	–	–	–	–	2.0	2.0
Deferred taxation on share-based payment scheme	–	–	–	–	–	(0.2)	(0.2)
Tax credit in respect of tax losses arising on exercise of share options	–	–	–	–	–	0.2	0.2
Dividend paid (note 8)	–	–	–	–	–	(6.3)	(6.3)
Total transactions with owners of the Company, recognised directly in equity	–	–	–	–	–	(4.3)	(4.3)
At 31 December 2019	0.1	240.2	88.2	0.7	3.6	108.0	440.8

Notes forming part of the condensed consolidated financial statements

1. General information

Clinigen Group plc ('the Company') and its subsidiaries (together, 'the Group') is a global pharmaceutical products and services group headquartered in the UK, with offices in the US, South Africa, Australia, New Zealand, Japan, Hong Kong, Singapore, Greece, Belgium, Switzerland, France and Germany.

The company is a public limited company, which is listed on the AIM market of the London Stock Exchange and incorporated and domiciled in the UK. The address of its registered office is Pitcairn House, Crown Square, First Avenue, Burton-on-Trent, DE14 2WW, United Kingdom.

These condensed interim financial statements do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. Statutory accounts for the year ended 30 June 2020 were approved by the board of directors on 16 September 2020 and delivered to the Registrar of Companies. The report of the auditors on those accounts was unqualified, did not contain an emphasis of matter paragraph and did not contain any statement under section 498 of the Companies Act 2006. These condensed interim financial statements have been reviewed, not audited.

2. Basis of preparation

These condensed interim financial statements for the six months ended 31 December 2020 have been prepared in accordance with International Accounting Standard 34 'Interim financial reporting' ('IAS 34'). The condensed interim financial statements should be read in conjunction with the annual financial statements for the year ended 30 June 2020, which have been prepared in accordance with International Financial Reporting Standards ('IFRS' or 'IFRSs') as adopted by the EU. The financial statements for the year ending 30 June 2021 will be prepared in accordance with IFRS in conformity with the Companies Act 2006. This is not expected to have any impact on recognition, measurement or disclosure.

The Group meets its day-to-day working capital requirements through its bank facilities. The Group's forecasts and projections, taking account of reasonably possible changes in trading performance, show that the Group should be able to operate within the level of its current facilities. After making enquiries and having reassessed the principal risks, the Directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. The Group therefore continues to adopt the going concern basis of accounting in preparing the condensed interim financial statements.

The accounting policies applied in preparation of the condensed consolidated financial statements is on a consistent basis with those applied in the annual financial statements for the year ended 30 June 2020.

The preparation of interim consolidated financial statements in compliance with IAS 34 requires the use of certain critical accounting estimates. It also requires Group management to exercise judgment in applying the Group's accounting policies. The areas where significant judgements and estimates have been made in preparing the financial statements and their effect are disclosed in the notes to the Group's statutory consolidated financial statements for the year ended 30 June 2020 in note 2 on page 90 and in the notes to these interim condensed consolidated financial statements.

There have been no accounting standards, amendments and interpretations that are effective for the first time in respect of the Group condensed interim financial statements for the six months ended 31 December 2020 and which have had a material impact on these financial statements.

3. Segment information

The Group's reportable segments are strategic operating business units that provide different products and service offerings into different market environments. They are managed separately because each operational business requires different expertise to deliver the different product or service offering they provide.

Operating segments are reported in a manner consistent with the internal reporting provided to the Chief Operating Decision Maker during the reporting period. The Chief Operating Decision Maker has been identified as the Executive Directors. Subsequent to the period end, the organisation structure of the business has changed to the two reported businesses of Products and Services and with effect from 1 January 2021 the internal reporting to the Chief Operating Decision Maker has changed to this basis. The new two segment approach has been used in this half year announcement in order to provide the user with the most useful information and for consistency with the full year annual reporting for FY21.

3. Segment information (continued)

The results have been presented below on the previous three segment and the revised two segment basis below in order to provide clarity of the change. This change has been made to simplify the Group structure and better align the Group's activities to its end customers, pharmaceutical clients and healthcare professionals.

(In £m)	Six months ended 31 December 2020			Six months ended 31 December 2019		
	Reported revenue	Net revenue	Adjusted EBITDA	Reported revenue	Net revenue	Adjusted EBITDA
Commercial Medicines	79.6	79.6	36.5	75.5	75.5	39.3
Unlicensed Medicines	90.3	64.1	11.7	100.6	81.5	17.1
Clinical Services	89.9	89.9	9.7	71.8	71.8	9.5
Central unallocated costs & eliminations	(1.7)	(1.7)	(3.3)	(4.2)	(4.2)	(3.8)
Segmental result	258.1	231.9	54.6	243.7	224.6	62.1

(In £m)	Six months ended 31 December 2020			Six months ended 31 December 2019		
	Reported revenue	Net revenue	Adjusted EBITDA	Reported revenue	Net revenue	Adjusted EBITDA
Products	131.0	131.0	44.3	144.3	144.3	51.0
Services	128.8	102.6	13.6	103.6	84.5	14.9
Central unallocated costs & eliminations	(1.7)	(1.7)	(3.3)	(4.2)	(4.2)	(3.8)
Segmental result	258.1	231.9	54.6	243.7	224.6	62.1

Net revenue is presented after excluding pass through revenue of £26.2m (2020 £19.1m) from the Managed Access business within Services.

(In £m)	Six months ended 31 December 2020			Six months ended 31 December 2019		
	Underlying	Non- underlying	Total	Underlying	Non- underlying	Total
Revenue	258.1	–	258.1	243.7	–	243.7
Cost of sales	(157.5)	–	(157.5)	(135.6)	–	(135.6)
Gross profit	100.6	–	100.6	108.1	–	108.1
Administrative expenses excluding amortisation and depreciation	(46.1)	(0.6)	(46.7)	(46.3)	0.9	(45.4)
EBITDA	54.5	(0.6)	53.9	61.8	0.9	62.7
Analysed as:						
Adjusted EBITDA including share of joint venture	54.6	(0.6)	54.0	62.1	0.9	63.0
Joint venture EBITDA	(0.1)	–	(0.1)	(0.3)	–	(0.3)
EBITDA excluding share of joint venture	54.5	(0.6)	53.9	61.8	0.9	62.7
Amortisation of intangible assets	(4.0)	(20.3)	(24.3)	(1.3)	(22.6)	(23.9)
Depreciation of property, plant and equipment	(3.4)	–	(3.4)	(3.0)	–	(3.0)
Profit from operations	47.1	(20.9)	26.2	57.5	(21.7)	35.8
Finance expense	(2.7)	(0.8)	(3.5)	(6.0)	(5.2)	(11.2)
Share of joint venture profit	–	–	–	0.2	–	0.2
Profit before income tax	44.4	(21.7)	22.7	51.7	(26.9)	24.8
Analysed as:						
Adjusted profit before tax excluding share of joint venture tax	44.5	(21.8)	22.7	51.8	(27.0)	24.8
Joint venture tax	(0.1)	0.1	–	(0.1)	0.1	–
Profit before tax including share of joint venture tax	44.4	(21.7)	22.7	51.7	(26.9)	24.8
Income tax expense	(9.5)	4.8	(4.7)	(10.8)	4.8	(6.0)
Profit after tax	34.9	(16.9)	18.0	40.9	(22.1)	18.8

3. Segment information (continued)

Disaggregation of revenue

(In £m)	Six months ended 31 December 2020		Six months ended 31 December 2019	
	Reported revenue	Net revenue	Reported revenue	Net revenue
Products				
Owned	54.4	54.4	56.0	56.0
Partnered	35.0	35.0	35.9	35.9
On-Demand	41.6	41.6	52.4	52.4
	131.0	131.0	144.3	144.3
Services				
Clinical	89.9	89.9	71.8	71.8
Managed Access	38.9	12.7	31.8	12.7
	128.8	102.6	103.6	84.5
Inter-segment eliminations	(1.7)	(1.7)	(4.2)	(4.2)
Total revenue from external customers	258.1	231.9	243.7	224.6

4. Non-underlying items

Non-underlying items have been reported separately in order to provide the reader of the financial statements with a better understanding of the operating performance of the Group. These items include amortisation of intangible assets acquired through business combinations and acquired products, and one-off costs principally relating to the acquisitions. The associated tax impact is also reported as non-underlying.

(In £m)	Six months to 31 December	
	2020	2019
Administrative expenses		
a) Acquisition costs	–	0.2
b) Restructuring costs (relating principally to acquisitions)	1.9	1.4
c) Foreign exchange revaluation on contingent consideration	(1.3)	(2.5)
d) Amortisation of intangible fixed assets acquired through business combinations and acquired products	20.3	22.6
	20.9	21.7
Finance costs		
e) Unwind of discount on non-underlying liabilities	0.7	5.1
a) Acquisition costs	0.1	0.1
	0.8	5.2
Taxation		
f) Credit in respect of tax on non-underlying costs	(4.8)	(4.8)
	16.9	22.1

a) The acquisition costs in the prior year relate to legal fees and financing costs for the Group's recent product and business acquisitions.

b) Restructuring costs have been incurred during the period in respect of the integration of acquired businesses as well as preparations for Brexit.

c) Contingent consideration on iQone and CSM is denominated in foreign currency. The revaluation of these liabilities is treated as non-underlying as they relate to one-off items and do not reflect the underlying trading of the Group.

d) The amortisation of intangible assets acquired as part business combinations (namely brand, trademarks and licences, customer relationships, and contracts) and acquired products, is included in non-underlying due to its significance and to provide the reader with a consistent view of the underlying costs of the operating Group.

e) The non-cash unwind of the discount applied to the deferred and contingent consideration on the acquisitions of iQone and CSM (and Proleukin in the prior period).

f) The tax credit in respect of non-underlying items reflects the tax benefit on the costs incurred.

5. Finance expense

(In £m)	Six months to 31 December	
	2020	2019
Bank interest expense	4.6	4.8
Borrowing costs	—	0.1
Amortisation of facility issue costs	0.4	0.5
Foreign exchange on borrowings	(2.7)	0.3
Unwind of discount on lease liabilities	0.4	0.3
Underlying finance expense	2.7	6.0
Unwind of discount on non-underlying liabilities	0.7	5.1
Acquisitions finance costs	0.1	0.1
Total finance expense	3.5	11.2

6. Income tax

The Group has recognised a tax charge in the income statement based on the current projected full year effective tax rate of 20.7% (2019: 24.2%).

7. Earnings per share

(In £m)	Six months to 31 December	
	2020	2019
Profit after tax used in calculating reported EPS	18.0	18.8
Underlying profit after tax used in calculating adjusted EPS	34.9	40.9
Number of shares (million)		
Weighted average number of shares	133.0	132.6
Dilution effect of share options	1.9	2.4
Weighted average number of shares used for diluted EPS	134.9	135.0
Reported EPS (pence)		
Basic	13.5p	14.1p
Diluted	13.3p	13.8p
Adjusted EPS (pence)		
Basic	26.2p	30.8p
Diluted	25.9p	30.3p

8. Dividends

The final dividend in relation to the year ended 30 June 2020 of 5.46p (2019: 4.75p) per ordinary share was paid on 2 December 2020. This amounted to £7.2m (2019: £6.3m).

An interim dividend of 2.15p (2019: 2.15p) per ordinary share has been approved by the Board. This amounts to £2.9m (2019: £2.9m) and will be paid on 13 April 2021 to all shareholders on the register as at 19 March 2021.

9. Intangible assets

(In £m)	Brand	Contracts	Customer relationships	Trademarks & licenses	Computer software	Goodwill	Total
At 1 July 2020	50.3	5.9	74.4	244.1	29.2	384.4	788.3
Additions	—	—	—	5.0	5.1	—	10.1
Amortisation charge	(2.2)	(0.5)	(8.6)	(9.3)	(3.7)	—	(24.3)
Exchange differences	(0.1)	0.1	(1.4)	(13.2)	(0.2)	(8.4)	(23.2)
At 31 December 2020	48.0	5.5	64.4	226.6	30.4	376.0	750.9

10. Net debt

	31 December		30 June
(In £m)	2020	2019	2020
Revolving credit facility	215.8	199.5	250.8
Term loan	178.7	148.0	183.0
Lease liabilities	22.0	17.1	23.7
Unamortised issue costs	(2.1)	(2.5)	(2.5)
Total borrowings	414.4	362.1	455.0
Cash	(62.9)	(39.8)	(143.1)
Net debt	351.5	322.3	311.9

During the year the Group repaid £30.8m of its RCF using free cash flow generated from operations.

At the period end, there were two covenants that applied to the bank facility (calculated on a frozen GAAP basis, therefore excluding the impact of IFRS 16): interest cover of not less than 4.0x and net debt/adjusted EBITDA cover of not more than 3.5x with the leverage covenant limit raised from 3.0x as a matter of prudence given the near term uncertainty caused by COVID-19. As at 31 December 2020, interest cover was 12.7x and the net debt/adjusted EBITDA leverage was 2.8x. There were no instances of default, including covenant terms, in either the current or the preceding period.

11. Financial risk management and financial instruments

Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (including currency risk, interest rate risk and price risk), credit risk and liquidity risk. The condensed interim financial statements do not include all financial risk management information and disclosures required in the annual financial statements; they should be read in conjunction with the Group's annual financial statements as at 30 June 2020. There have been no changes in the risk management processes or in any risk management policies since the year end.

Financial instruments

	Designated at fair value	Amortised cost	Total carrying value	Fair value
At 31 December 2020 (In £m)				
Cash and cash equivalents	–	62.9	62.9	62.9
Trade and other receivables	–	94.0	94.0	94.0
Derivative financial instruments	0.8	–	0.8	0.8
Total financial assets	0.8	156.9	157.7	157.7
Trade and other payables	–	(126.3)	(126.3)	(126.3)
Contingent consideration	(7.4)	–	(7.4)	(7.4)
Borrowings	–	(416.5)	(416.5)	(416.5)
Total financial liabilities	(7.4)	(542.8)	(550.2)	(550.2)

	Designated at fair value	Amortised cost	Total carrying value	Fair value
At 31 December 2019 (In £m)				
Cash and cash equivalents	–	39.8	39.8	39.8
Trade and other receivables	–	113.6	113.6	113.6
Derivative financial instruments	1.2	–	1.2	1.2
Total financial assets	1.2	153.4	154.6	154.6
Trade and other payables	–	(136.9)	(136.9)	(136.9)
Contingent consideration	(61.5)	–	(61.5)	(61.5)
Borrowings	–	(362.1)	(362.1)	(362.1)
Total financial liabilities	(61.5)	(499.0)	(560.5)	(560.5)

11. Financial risk management and financial instruments (continued)

Fair value estimation

Financial instruments are classified as follows: Level 1 instruments are those valued using unadjusted quoted prices in active markets for identical instruments; Level 2 instruments are those valued using techniques based significantly on observable market data; and Level 3 instruments are those valued using information other than observable market data.

Derivative financial instruments at 31 December 2020 and 31 December 2019 comprise forward foreign exchange contracts. These derivatives have been fair valued using forward exchange rates that are quoted in an active market and fall within Level 2 of the fair value hierarchy.

Contingent consideration on acquisitions has been valued using management's latest forecast of the profit of the businesses during the earn out period and falls within Level 3 of the fair value hierarchy.

There are no Level 1 financial instruments at 31 December 2020, and there have been no transfers between valuation levels nor changes in valuation techniques during the period.

12. Share capital

	Number ('000s)	Cost (£m)
Issued and fully paid (Ordinary shares of 0.1p each)		
At 1 July 2019	132,479	0.1
Issue of new shares	420	–
At 30 June 2020	132,899	0.1
Issue of new shares	130	–
At 31 December 2020	133,029	0.1

13. Business combinations

There were no business combinations in the 6 months ended 31 December 2020 (2019: none).

The Group paid £67.9m (US\$89.5m) as a final settlement of the CSM earn out in September 2020. £33.2m (US\$43.8m) of this payment relates to the increase in consideration from outperformance of the earn out over the original amount estimated which is recognised within cash flow from operations. The remaining £34.7m (US\$45.7m) of this payment is the original estimate of the earn out at the time of acquisition and is recognised within cash used in investing activities.

The Group paid £1.8m in respect of the acquisition of the remaining 50% stake in Clinigen Ireland Ltd (previously QM Specials Ltd) following the exercise of its call option in June 2020. As this payment related to a change in ownership but not a change in control it is recognised within cash flows used in financing activities.

There is a remaining contingent consideration liability relating to the iQone acquisition which is payable in the years ending 30 June 2023 and 2024 based on the adjusted EBITDA generated by the iQone business in the 12 months to 31 December 2022 and 2023.

The undiscounted fair value of the contingent consideration has been estimated at €12.3m and could be in the range of €nil to €50m. There were no changes to the estimate of the liability during the period. The liability has been discounted at a rate of 16%. A 100bps change in the discount rate would increase/decrease the fair value by £0.2m, and a 10% change in the expected value of the EBITDA in both earn out periods would increase/decrease the fair value by £0.9m.

The contingent consideration liability outstanding at 31 December 2020 was £7.4m (2019: £6.9m) and is classified within non-current liabilities. The movement in the year of £0.5m comprised of a £0.6m unwind of discount recognised through non-underlying finance costs offset by a £0.1m exchange difference recognised through non-underlying administrative expenses.



Independent review report of Clinigen Group Plc

Report on the consolidated interim financial statements

Our conclusion

We have reviewed Clinigen Group Plc's consolidated interim financial statements (the "interim financial statements") in the half-yearly report of Clinigen Group Plc for the 6 month period ended 31 December 2020 (the "period").

Based on our review, nothing has come to our attention that causes us to believe that the interim financial statements are not prepared, in all material respects, in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the AIM Rules for Companies.

What we have reviewed

The interim financial statements comprise:

- the Condensed consolidated statement of financial position as at 31 December 2020;
- the Condensed consolidated income statement and Condensed consolidated statement of comprehensive income for the period then ended;
- the Condensed consolidated statement of cash flows for the period then ended;
- the Condensed consolidated statement of changes in equity for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the half-yearly report of Clinigen Group Plc have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as adopted by the European Union and the AIM Rules for Companies.

As disclosed in note 2 to the interim financial statements, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the group is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the directors

The half-yearly report, including the interim financial statements, is the responsibility of, and has been approved by the directors. The directors are responsible for preparing the half-yearly report in accordance with the AIM Rules for Companies which require that the financial information must be presented and prepared in a form consistent with that which will be adopted in the company's annual financial statements.

Our responsibility is to express a conclusion on the interim financial statements in the half-yearly report based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the AIM Rules for Companies and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

What a review of interim financial statements involves

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the half-yearly report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.