27 February 2019

Good H1 performance with adjusted EPS up 9% and strong cash flow

Clinigen Group plc (AIM: CLIN, 'Clinigen' or 'the Group'), the global pharmaceuticals and services group, has today published its half year results for the six months ended 31 December 2018.

FINANCIAL SUMMARY

Six months ended 31 December	2018	2017	Growth	
	£m	£m	Reported	Constant currency
Revenue	208.9	167.8	24%	25%
Adjusted gross profit	80.0	63.9	25%	27%
Adjusted EBITDA	41.8	34.4	22%	24%
Reported profit before tax	12.9	15.8	(18)%	
Reported earnings per share	7.7p	10.2p	(25)%	
Adjusted earnings per share	23.0p	21.2p	9%	
Interim dividend per share	1.95p	1.76p	11%	
Operating cash flow	36.9	32.7	13%	
Net debt	192.4	141.8		

FINANCIAL HIGHLIGHTS

- Adjusted gross profit up 25% (2% on an organic basis*)
- Adjusted EBITDA up 22% (8% on an organic basis*) to £41.8m (2017: £34.4m)
- Adjusted EPS up 9% to 23.0p (2017: 21.2p)
- Strong cash flow performance with operating cash flow of £36.9m (2017: £32.7m)

OPERATIONAL HIGHLIGHTS

- Increasing balance across divisions, reflecting portfolio strategy
- EU and US infrastructure strengthened by CSM and iQone acquisitions – CSM YoY EBITDA up approximately 20%
- Commercial Medicines enhanced by rights acquisitions: Proleukin® and Imukin® ROW and intention to acquire Proleukin® US
- Unlicensed Medicines delivering strong organic performance and continued good growth in Africa and Asia Pacific

Shaun Chilton, Group Chief Executive Officer, said:

"The business has transformed over the last 12 months through a combination of substantial corporate and product acquisitions, investment in infrastructure and underlying growth. This has resulted in an improved balance across our complementary businesses - reflecting our portfolio strategy.

"Operationally, we saw good growth in Africa and Asia Pacific and the Unlicensed Medicines business, with adjusted EPS up 9% and operating cash flow up 13%. Notably, CSM, which we acquired in October 2018, saw approximately 20% year on year growth in EBITDA.

"We have started the second half of the year well and in-line with the Board's expectations. We remain well placed to deliver on our vision to be the trusted global leader in the global supply and distribution of critically important hospital medicines."

Note: Group results on an adjusted basis exclude amortisation of acquired intangibles and products, and other non-underlying items relating to acquisitions (see note 3 and 4 of the condensed financial statements). Adjusted EBITDA includes the Group's share of EBITDA from its joint venture. Constant currency growth is derived by applying the prior period's actual exchange rate to this period's result.

*Year on year comparisons referred to as 'organic' are a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions. Business and product acquisitions in the current period are excluded from organic EBITDA, and for the acquisitions completing in the prior year, they are included on a pro-forma basis as if they occurred on the first day of the prior year. Organic growth is presented to aid the reader's understanding of the underlying performance of the business.

Operating cash flow is net cash flow from operating activities before income taxes, interest and working capital movements.

- Ends -

An analyst briefing will be held at 9:30am on Wednesday, 27 February 2019 at the offices of Instinctif Partners, 65 Gresham Street, London EC2V 7NQ.

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 and services company with a unique combination of businesses focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines. The Group has sites in North America, Europe, Africa and Asia Pacific. In October 2018, the Group acquired CSM, a specialist provider of packaging, labelling, warehousing and distribution services, with sites in the US and Europe, and iQone, a specialist pharmaceutical company in Switzerland.

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.

OVERVIEW

Clinigen's vision is to be the trusted global leader in the supply and distribution of critically important hospital medicines.

To achieve this vision, Clinigen has spent the last eight years building and developing an international platform and now has a unique combination of businesses that synergistically facilitate access to medicines at key points in a medicine's lifecycle: in clinical trials, unlicensed and licensed markets.

Clinigen's specialty products and niche services are delivered through a combination of a global reach and local regulatory and operational expertise, to meet its mission of 'Right Medicine, Right Patient, Right Time'. The Group has created a compelling combination of capabilities which means it is the most logical partner for a pharmaceutical or biotech company to realise fully the long-term commercial value of its asset(s) while being the 'go to' company for healthcare professionals (HCPs) to access difficult to find medicines.

Clinigen now has approximately 1,200 employees across five continents in 14 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 29 of the top 50 pharmaceutical companies; interacting with approximately 14,000 registered users across 98 countries, shipping over 2 million units in the first half.

The ability to partner with pharmaceutical and biotech companies on a long-term basis by using the three Clinigen operations sequentially to provide continued specialist lifecycle and commercialisation support, is now becoming a reality.

Three of the top 25 pharmaceutical companies are working across the Group using its clinical and Investigator Initiated Trials (IITs) support services; unlicensed medicine management; and licensing and/or divestment of medicines. The intention is for more companies to work with multiple parts of the business. This creates long-term revenue and gross profit flow as medicines move through the continuum of the three Clinigen businesses.

Having made a number of substantial acquisitions, of both companies and products, in the last 18 months, integration and commercial opportunities remain a priority. Good progress was made in bringing Clinical Trials Services (CTS) and the recently acquired CSM under one leadership structure and focusing the iQone capabilities in Europe to support Clinigen's owned speciality medicines portfolio. CTS and CSM are now one unit called Clinical Services (CS).

The acquisition of the US rights to Proleukin, announced in February 2019 and expected to close in April 2019, is another major development for the business, as Clinigen already owns the rights to Proleukin outside the US.

The acquisition will be highly earnings enhancing and is an interesting and important medicine with long-term potential. It will also transform the Group's US position, combining well with CSM's existing US capabilities and giving the Group a platform from which to develop its presence in the world's biggest pharmaceutical market.

In the first half of the current financial year, Group revenues increased by 24% (25% on a constant currency basis) to £208.9m (2017: £167.8m). Adjusted gross profit increased by 25% (27% on a constant currency basis, 2% on an organic basis*), driven by a full period's contribution from Quantum, three months contribution by CSM and a strong performance from Unlicensed Medicines.

Adjusted EBITDA increased by 22% (24% on a constant currency basis and 8% on an organic basis*) to £41.8m (2017: £34.4m). Adjusted EPS increased by 9% to 23.0p (2017: 21.2p).

Operating cash flow was again strong at £36.9m (2017: £32.7m) reflecting the highly cash generative nature of the Group.

Current trading and outlook

Strategically, the focus continues on building the Group's platform and on the integration of the recently acquired products and businesses. The Group is capitalising on its market-leading positions and geographical footprint in order to drive organic growth.

The second half of the year has started in line with the Board's expectations, with the Group well positioned to deliver another good year of progress.

Acquisitions and integration

CSM

On 2 October 2018, the Group acquired CSM, a specialist provider of packaging, labelling, warehousing and distribution services with infrastructure in the US, Belgium and Germany. The acquisition expands Clinigen's capabilities, diversifies CS' global client and customer base, adds important continental EU infrastructure, and reinforces the links between the Group's three business operations.

The CSM business has continued to trade well and in the year to 31 December 2018, saw EBITDA growth of approximately 20%. Following actions already taken at CSM and those planned in the remainder of the year, the Group is on track to deliver cost synergies of at least £1m and revenue synergies of around £3m by the end of its first financial year of ownership.

iQone

On 9 October 2018, the Group acquired iQone, a Swiss-based specialty pharmaceutical business. This acquisition is helping support growth of Clinigen's Commercial Medicines portfolio in key EU markets, differentiating the early access business within Unlicensed Medicines from its competitors by providing EU medical scientific liaison (MSL) capability. This secures long-term unlicensed agreements and enhances the Group's proposition as a commercial partner for pharmaceutical companies.

Proleukin (US rights)

On 13 February 2019, the Group signed an agreement with Novartis to acquire the US rights to Proleukin. Clinigen already owns the rights to Proleukin outside the US, acquired in July 2018. The acquisition will be modestly EPS accretive in the current financial year as the product transitions to Clinigen, and at least 25% accretive in the first full financial year.

As part of Commercial Medicines, Proleukin is an excellent fit within the Group's existing oncology and infectious disease medicines. The product has significant potential for revitalisation, which will provide further breadth and diversity to the portfolio and material increases in revenues.

For the Group as a whole, it creates an ideal platform to expand the existing footprint in the higher value US market, enabling Clinigen to exploit other opportunities across the business.

OPERATIONAL REVIEW

Commercial Medicines *(encompassing medicines acquired, licensed and developed)*

Clinigen's Commercial Medicines operation has a threefold strategy:

- Continued revitalisation/growth of current portfolio of specialty medicines, coupled with selective acquisition of additional hospital assets
- Increasing the number of regional licensing agreements, individual medicines and portfolios
- Develop a long-term pipeline of medicines through the unlicensed to licensed (UL2L) model

Commercial Medicines represents 41% of adjusted Group gross profit. Although gross profit on an adjusted basis increased 6%, on an organic basis* it decreased 6% due to lower sales of Foscavir® and the dexrazoxane portfolio.

Gross margin was 71.3% (2017: 73.8%) with the decrease due to the change in mix from the higher margin specialty pharmaceutical products towards the lower margin products licensed in the Africa and Asia Pacific region.

Owned products

Anti-infective portfolio

Clinigen acquired the global rights (excluding US, Canada and Japan) to Imukin (recombinant human interferon gamma-1b) on 25 July 2018. Imukin is licensed in 19 countries globally to reduce the frequency of serious infections in patients with Chronic Granulomatous Disease (CGD) and for the treatment of Severe Malignant Osteopetrosis (SMO), both considered rare conditions.

The revitalisation strategy centres around improved understanding of the benefits of the product and also broadening the product's availability via the Group's international distribution network for both licensed and unlicensed supply. Imukin is one of two biologics in the portfolio, which provide greater inherent protection against generic threat because of a more difficult manufacturing process.

Foscavir's performance declined modestly due to reduced volumes in two of its main markets, the US and Japan. In both markets, as expected, volumes have come under some pressure from alternative therapies. Without immediate visibility of the long term impact, the business continues with its strategy to mitigate against the competitive landscape by extending the Foscavir franchise by seeking new presentations of the product and new indications.

Progress has been made on both counts – the Group continues to seek approval for the HHV6 encephalitis indication from the Japanese Ministry of Health, Labour and Welfare and the Foscavir bag line extension is expected to be launched in 2019.

Oncology portfolio

The main development in the oncology portfolio was the acquisition of the rest of world rights to Proleukin in July 2018, and the subsequent intention to acquire the global rights, announced in February 2019.

Proleukin is indicated for the treatment of metastatic melanoma and metastatic renal cell carcinoma. Following the most recent announcement, the Group will own the worldwide rights. Based on its current sales revenues,

Proleukin will become the largest product in the Commercial Medicines portfolio and will also be highly earnings enhancing.

Proleukin further diversifies the product portfolio and has significant potential for revitalisation. This applies not only to its current indication, but across multiple disease areas, as evidenced by the fact that it is being used in around 80 active studies within the US.

For the Group, the product creates opportunities for other divisions such as CS around the provision of Proleukin for comparator studies and IITs. It also creates an ideal platform to expand the existing footprint in the higher value US market, building on the infrastructure benefits obtained through the acquisition of CSM.

The focus for the dexrazoxane products has been on extending the market opportunity, by expanding the clinical understanding within the paediatric physician population.

Collectively these seven acquired products, along with iQone, contributed 62% of Commercial Medicines' adjusted gross profit (2017: 73%), demonstrating a further move away from reliance on any single asset towards a much more balanced portfolio.

Licensed products
Good progress continues to be made in the Africa and Asia Pacific region, with growth across all geographies. The Group has 215 (2017: 192) specialist pharmaceutical and medical-technology actively marketed licensed products in this region and continues to make progress in extending the commercial strategy in converting medicines from UL2L.

The partnership agreement with Bristol-Myers Squibb (BMS), signed in May 2018 and which will lead to the transfer of marketing authorisations (product registration certificates) in South Africa to Clinigen, is expected to begin generating revenues midway through 2019.

Developed products
The Commercial Medicines business also develops, licenses and commercialises medicines with a particular focus on those currently prescribed as unlicensed medicines in the UK (the UL2L pathway). At the end of the period, the business had 12 products in its portfolio.

The lead product in the developed product portfolio, Glycopyrronium Bromide Oral Solution 1mg/5ml (Glyco), continues to perform strongly. As announced in February 2019, Clinigen was granted an additional indication for Glyco to treat paediatric and adolescent hypersalivation. This new indication extends the Glyco franchise and creates an opportunity to further internationalise the product.

Pipeline
The Group continues to seek selective product acquisitions that fit within the acquired product portfolio, and in the Africa and Asia Pacific region looks to continue to increase the number of regional licensed products. In addition, the business continues to develop its pipeline of UL2L products, as well as complementary larger niche generic products.

Unlicensed Medicines *(encompassing early access/Managed Access and 'on-demand'/Global Access)*

Clinigen is the international leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet medical need. The Group manages early access programs to innovative new medicines and provides 'on-demand' access globally to medicines which remain unlicensed at the point of care.

The Group's strategy for Unlicensed Medicines remains unchanged: to capitalise on the considerable long-term international opportunity by increasing the number of exclusive supply agreements for high demand or niche products and to increase Clinigen's profile amongst HCPs through targeted marketing activity.

Cliniport, the Group's customisable, scalable web portal continues to be an invaluable part of Clinigen's service offering for its clients and strengthens its interaction with the customer. Currently, Cliniport holds a library of over 400 products and has a community of approximately 14,000 registered users. Over 40,000 orders have been placed on Cliniport over the last 12 months which has been responsible for 43% (June 2018: 47%) of activity in Unlicensed Medicines.

The Unlicensed Medicines operation represents 45% of adjusted Group gross profit. This operation increased gross profit by 36% to £35.7m (2017: £26.3m) due to a strong performance in early access and 'on-demand' access across the regions, and a full period's contribution from Quantum. Adjusted gross profit on an organic basis* increased by 10%.

At the end of the period, there were 119 Managed Access Programs (MAPs) (2017: 109), of which 88% of products shipped on behalf of the client were provided free of charge to patients. When the product is 'charged for', the revenue is passed through the Group's accounts. A shift in mix towards 'free of charge' products can have a material impact on the revenue generated without affecting gross profit which is why the Group views gross profit as the best measure of top-line growth.

Following the 15 programs that began in the second half of the last financial year, there were a further 11 programs signed in the first half of this financial year. The largest of these programs is anticipated to be an important driver of profit in the coming years.

In 'on-demand' access, the Group ethically supplies unlicensed or short supply medicines to patients via their physicians.

This business has made further progress against the key objective of increasing the number of 'on-demand' exclusive supply agreements for high demand or niche medicines. Seven new exclusive agreements were signed in the half taking the number of products under management to 56 (2017: 43).

On a regional basis, the Africa and Asia Pacific region delivered good growth across all geographies. Growth in Asia was excellent, driven by strong performances in both early access and 'on-demand' access and from expanding supply from the hub in Singapore into surrounding territories.

Clinical Services *(encompassing CTS and CSM)*

The strategy for CS is to continue to expand the original, core service of comparator sourcing into a more diverse, complementary set of services that target long-term adjacent growth segments in clinical trials, notably IITs.

Following the acquisition of CSM in October 2018, one immediate benefit to CS is to significantly expand the client base to 440 clients (2017: 63)† and create a much expanded, diversified set of value added clinical services: comparator and ancillary sourcing, on demand specialist packaging, labelling, supply and distribution, and biological sample management.

CS represents 14% of adjusted Group gross profit. Following two years of double digit growth (2017: 18%; 2016: 21%), CTS had a difficult year last financial year. In the half, adjusted gross profit on an organic basis* decreased by 3%. The foundations for the recovery are in place and an improved performance is expected in the second half.

CSM achieved a strong growth performance for its 12 months ended 31 December 2018, growing all major financial metrics, including EBITDA, approximately 20% year on year. The acquisition of CSM immediately benefited CS by diversifying its service offering, global client and customer base.

In the three months since the CSM acquisition, CSM has been fully integrated into the CS business, with the business development and strategic sourcing teams working under one leadership and management structure.

CS continues to be a trusted partner capable of delivering high quality services across the world with an extensive understanding of the complex regulatory environment. These strengths, combined with overlaying the services offered by CSM, position the CS operation well to take advantage of the rapidly developing market opportunity.

† Total clients includes CSM clients for 12 months ended 31 December 2018.

FINANCIAL REVIEW

Summary adjusted income statement

Six months ended 31 December	2018	2017	Growth		
			Reported	Constant currency	Organic*
Adjusted results	£m	£m			
Revenue	208.9	167.8	24%	25%	1%
Gross profit	80.0	63.9	25%	27%	2%
Administrative expenses	(38.8)	(30.1)	29%		
EBITDA from joint venture	0.6	0.6	(5)%		
EBITDA	41.8	34.4	22%	24%	8%
Depreciation and amortisation	(1.4)	(0.6)			
EBITA	40.4	33.8	20%		
Finance cost	(3.7)	(2.1)			
Profit before tax	36.7	31.7	16%		
Basic earnings per share	23.0p	21.2p	9%		
Dividend per share	1.95p	1.76p	11%		

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). Adjusted EBITDA includes the Group's share of EBITDA from its joint venture. Constant currency growth is derived by applying the prior period's actual exchange rate to this period's result.

*Year on year comparisons referred to as 'organic' are a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions. Business and product acquisitions in the current period are excluded from organic EBITDA, and for the acquisitions completing in the prior year, they are included on a pro-forma basis as if they occurred on the first day of the prior year. Organic growth is presented to aid the reader's understanding of the underlying performance of the business.

When presenting the financial results, a number of adjusted measures are used which are considered by the Board and management 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, the Group achieved a good financial performance with its three key financial metrics; adjusted gross profit up 27% on a constant currency basis, adjusted EBITDA up 24% on a constant currency basis and adjusted EPS up 9%.

Gross profit by division	2018	2017	Growth		
Adjusted results	£m	£m	Reported	Constant currency	Organic*
Commercial Medicines	32.8	31.0	6%	7%	(6)%
Unlicensed Medicines	35.7	26.3	36%	38%	10%
Clinical Services	11.5	6.6	74%	73%	(3)%
	80.0	63.9	25%	27%	2%

The growth in adjusted gross profit was driven by a strong performance by the Unlicensed Medicines division and the acquisitions.

The growth in adjusted EBITDA was lower than the growth in adjusted gross profit due to the change in business mix following the acquisitions. Adjusted EBITDA on an organic basis* increased by 8% benefitting from a reduction in underlying overheads excluding the acquisitions, reflecting the continued focus on driving efficiencies across the Group.

See note 3 of the condensed financial statements for a reconciliation of adjusted EBITDA to the IFRS equivalent comparative.

Finance cost

The adjusted net finance cost was £3.7m (2017: £2.1m). The increase is due to the Group's higher net debt position following the recent acquisitions. The average interest charge on gross debt, which increases as leverage increases, was 2.9% (2017: 1.7%) during the period.

The reported finance cost was £4.7m (2017: £3.2m), after taking account of the non-cash £1.0m unwind of discount on the contingent consideration relating to the acquisitions (2017: £1.1m).

The table below shows the reconciling items between the adjusted profit before tax of £36.7m (2017: £31.7m) and the reported profit before tax of £12.9m (2017: £15.8m).

Reconciliation of adjusted profit before tax to reported profit before tax

Six months ended 31 December	2018 £m	2017 £m
Adjusted profit before tax	36.7	31.7
Amortisation of acquired intangibles and products	(16.2)	(9.5)
Acquisition costs	(5.0)	(3.7)
Restructuring costs	(1.1)	(1.3)
FX revaluation on deferred consideration	(0.3)	–
Unwind of discount on contingent consideration	(1.0)	(1.1)
Tax on joint venture in South Africa	(0.2)	(0.2)
Adjustment for fair value of acquired stock sold in the period	–	(1.1)
NuPharm legal settlement	–	1.0
Total adjustments	(23.8)	(15.9)
Reported profit before tax	12.9	15.8

The adjustments to profit before tax comprise costs relating to amortisation, acquisitions and the Group's share of the tax charge on the JV earnings of £0.2m (2017: £0.2m).

Total amortisation was £16.6m (2017: £9.7m), of which £13.7m (2017: £7.3m) related to acquired intangibles, £2.5m (2017: £2.2m) related to acquired product licences and £0.4m (2017: £0.2m) related to software.

Acquisition costs amounted to £5.0m (2017: £3.7m) relating predominantly to the CSM acquisition. The main acquisition costs were professional advisory and due diligence fees of £2.2m and £2.4m for securing 'certain funds' for the CSM acquisition.

Restructuring costs relating to the acquisitions are £1.1m (2017: £1.3m), most of which are redundancy costs resulting from streamlining the senior management teams and removing duplicate functions following the acquisitions.

Taxation

Taxation was £3.0m (2017: £3.8m), based primarily on the prevailing UK and overseas tax rates. This charge is calculated as £7.4m based on the adjusted profit of £36.7m, offset by a credit of £4.4m in respect of the adjusted items.

The Group's adjusted effective tax rate (ETR) decreased to 20.6% (2017: 21.5%) due to the higher proportion of earnings in the UK and the reduction in the UK corporation tax rate. The adjusted ETR also takes account of the reduction in the corporation tax rate going forward in the US.

Earnings per share

Adjusted basic EPS, calculated excluding amortisation of acquired intangibles and products, and other non-underlying items, increased by 9% to 23.0p (2017: 21.2p). The increase reflects the Group's higher adjusted profit from operations, offset by dilution and higher finance costs following the acquisitions and the related placing and debt refinancing.

Reported basic EPS was 7.7p (2017: 10.2p). The decrease is due to the additional amortisation and exceptional costs arising from the acquisitions.

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.

In view of the good first half results, the Board has increased the interim dividend by 11% to 1.95p per share (2017: 1.76p).

The interim dividend will be paid on 12 April 2019 to shareholders on the register on 22 March 2019.

Cash flow and net debt

Cash flow performance continues to be strong, with operating cash flow of £36.9m (2017: £32.7m). Net working capital increased by £2.3m in the period (excluding the effect of acquisitions, non-underlying items, and exchange adjustments) due to the growth in the business. The low levels of working capital in the business reflect a strong focus on credit control and general working capital management.

Capital expenditure (excluding product acquisitions) was £9.5m (2017: £5.1m), which includes £2.8m on new product development, £2.4m related to the Group ERP system, £2.3m related to warehouse, IT and other infrastructure investments, including preparation for the introduction of serialisation in February 2019 and £2.1m related to the development of owned products. Capital expenditure is expected to remain at an elevated level this year due to the ERP implementation and then it is expected to decrease in the following financial year.

During the period, the Group made two corporate acquisitions; CSM, acquired on 2 October 2018, and iQone on 9 October 2018. To fund these acquisitions, the Group's bank facility was refinanced (as detailed in the treasury management section) and £80m of equity finance was raised through a placing.

For CSM, the Group paid initial consideration of £115.5m (US$151.9m) in cash with additional contingent consideration which had a fair value of £31.5m (US$40.2m). For iQone, the Group paid initial consideration of £6.9m (€7.7m) cash and £2.2m (€2.5m) shares in Clinigen Group plc, with additional contingent consideration payable in five years which had a fair value of £5.2m (€5.8m).

The Group also spent £23.2m on two product acquisitions, Proleukin (ex US rights) and Imukin, and Foscavir bags.

The other main cash flows were tax paid of £6.1m (2017: £7.0m), interest paid of £3.4m (2017: £1.3m) and dividends paid of £5.1m (2017: £4.2m).

As a result of the acquisitions, net debt increased during the period by £55.9m to £192.4m and will increase further in the second half due to the planned acquisition of the US rights to Proleukin, as announced on 13 February 2019.

Treasury management

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

During the period, the debt facilities have been refinanced as part of the financing arrangements for the acquisition of CSM. The new financing increased the debt facility from £220m to £300m, extending the facility to October 2023. The facility includes an unsecured £150m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £150m.

During the period, 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 3.25x. As at 31 December 2018, interest cover was 14.1x and the net debt/adjusted EBITDA leverage was 2.2x.

Following the period end, the debt facilities have subsequently been increased to finance the acquisition of the US rights to Proleukin. The facility was increased by £75m to £375m which is composed of an unsecured £150m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £225m.

The Group's bank covenant leverage** on completion of the acquisition of Proleukin in April 2019 is expected to be around 2.4x net debt / EBITDA. Leverage is expected to reduce towards 2.0x by 31 December 2019.

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.

The Group 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. 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.

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 competitive threat, the regulatory environment, political environment, counterfeit products penetrating the supply chain, reliance on technology, reputational risk, and foreign exchange. These risks and the Group's mitigating actions are set out on pages 42 to 45 of the Annual Report 2018.

**Bank covenant leverage is calculated by dividing adjusted EBITDA of the Group for the last 12 months by net debt at the period end. Adjusted EBITDA includes the EBITDA from the businesses and assets acquired during the last 12 months, including on a pro forma basis the period prior to it becoming a member of the Group.

Condensed consolidated income statement

		Six months ended 31 December 2018			Six months ended 31 December 2017		
(In £m)	Note	**Underlying**	**Non-underlying (note 4)**	**Total**	Underlying	Non-underlying (note 4)	Total
Revenue	3	**208.9**	**–**	**208.9**	167.8	–	167.8
Cost of sales		**(128.9)**	**–**	**(128.9)**	(103.9)	(1.1)	(105.0)
Gross profit	3	**80.0**	**–**	**80.0**	63.9	(1.1)	62.8
Administrative expenses		**(40.2)**	**(22.6)**	**(62.8)**	(30.7)	(13.5)	(44.2)
Profit from operations		**39.8**	**(22.6)**	**17.2**	33.2	(14.6)	18.6
Finance cost	5	**(3.7)**	**(1.0)**	**(4.7)**	(2.1)	(1.1)	(3.2)
Share of profit of joint venture		**0.4**	**–**	**0.4**	0.4	–	0.4
Profit before income tax		**36.5**	**(23.6)**	**12.9**	31.5	(15.7)	15.8
Income tax expense	6	**(7.2)**	**4.2**	**(3.0)**	(6.6)	2.8	(3.8)
Profit attributable to owners of the Company		**29.3**	**(19.4)**	**9.9**	24.9	(12.9)	12.0
Earnings per share (pence)							
Basic	7			**7.7p**			10.2p
Diluted	7			**7.6p**			10.1p

Condensed consolidated statement of comprehensive income

	Six months ended 31 December 2018			Six months ended 31 December 2017		
(In £m)	**Underlying**	**Non-underlying (note 4)**	**Total**	Underlying	Non-underlying (note 4)	Total
Profit for the period attributable to owners of the Company	**29.3**	**(19.4)**	**9.9**	24.9	(12.9)	12.0
Other comprehensive income items that may be reclassified to profit or loss						
Cash flow hedges	**(0.3)**	**–**	**(0.3)**	(0.1)	–	(0.1)
Currency translation differences	**0.6**	**–**	**0.6**	0.2	–	0.2
Total other comprehensive income for the period	**0.3**	**–**	**0.3**	0.1	–	0.1
Total comprehensive income attributable to owners of the Company	**29.6**	**(19.4)**	**10.2**	25.0	(12.9)	12.1

All amounts relate to continuing operations.

Condensed consolidated statement of financial position

(In £m)	Note	31 December **2018**	31 December 2017	30 June 2018
Assets				
Non-current assets				
Intangible assets	9	**681.3**	505.6	497.6
Property, plant and equipment		**13.4**	7.0	6.8
Investment in joint venture		**6.7**	8.1	6.6
Deferred tax assets		**2.4**	3.8	2.6
Total non-current assets		**703.8**	524.5	513.6
Current assets				
Inventories		**25.8**	20.5	21.3
Trade and other receivables		**96.7**	70.8	95.9
Derivative financial instruments		**0.1**	0.3	–
Cash and cash equivalents		**55.1**	46.9	36.3
Total current assets		**177.7**	138.5	153.5
Total assets		**881.5**	663.0	667.1
Liabilities				
Non-current liabilities				
Trade and other payables		**37.4**	1.3	–
Loans and borrowings	10	**247.3**	188.7	172.8
Finance lease liabilities	10	**0.2**	–	–
Deferred tax liabilities		**45.0**	33.2	31.0
Total non-current liabilities		**329.9**	223.2	203.8
Current liabilities				
Trade and other payables		**107.7**	94.0	106.5
Corporation tax liabilities		**6.6**	6.5	6.8
Derivative financial instruments		**0.9**	–	0.5
Total current liabilities		**115.2**	100.5	113.8
Total liabilities		**445.1**	323.7	317.6
Net assets		**436.4**	339.3	349.5
Equity attributable to owners of the Company				
Share capital	12	**0.1**	0.1	0.1
Share premium account		**240.0**	161.3	161.3
Merger reserve		**88.2**	86.0	86.0
Hedging reserve		**(0.7)**	0.2	(0.4)
Foreign exchange reserve		**8.2**	10.7	7.6
Retained earnings		**100.6**	81.0	94.9
Total equity		**436.4**	339.3	349.5

Condensed consolidated statement of cash flows

(In £m)	Note	Six months to 31 December 2018	2017	Year to 30 June 2018
Operating activities				
Profit before income tax		**12.9**	15.8	35.9
Share of profit of joint venture		**(0.4)**	(0.4)	(0.8)
Net finance costs	5	**4.7**	3.2	6.4
Profit from operations		**17.2**	18.6	41.5
Adjustments for:				
Amortisation of intangible fixed assets		**16.6**	9.7	22.6
Depreciation of property, plant and equipment		**1.0**	0.4	1.2
Dividends received from joint venture		**0.6**	1.2	2.9
Movement in fair value of derivatives		**–**	0.6	0.8
Release of fair value on acquired inventory	4	**–**	1.1	1.4
FX revaluation of deferred consideration	4	**0.3**	–	–
Equity-settled share-based payment expense		**1.2**	1.1	2.1
Operating cash flows before movements in working capital		**36.9**	32.7	72.5
Decrease/(increase) in trade and other receivables		**11.0**	9.6	(14.6)
(Increase)/decrease in inventories		**(4.2)**	0.1	(1.4)
(Decrease)/increase in trade and other payables		**(9.1)**	(8.1)	7.6
Cash generated from operations		**34.6**	34.3	64.1
Income taxes paid		**(6.1)**	(7.0)	(12.6)
Interest paid		**(3.4)**	(1.3)	(3.9)
Net cash flows from operating activities		**25.1**	26.0	47.6
Investing activities				
Purchase of intangible fixed assets		**(8.8)**	(4.7)	(11.1)
Purchase of property, plant and equipment		**(0.7)**	(0.4)	(1.2)
Purchase of subsidiaries, net of cash acquired	13	**(118.0)**	(56.4)	(62.1)
Purchase of products		**(23.2)**	(1.5)	(1.5)
Settlement of Quantum share awards on acquisition		**–**	(8.6)	(8.6)
Contingent consideration paid on the Link acquisition		**–**	(38.6)	(38.7)
Net cash flows used in investing activities		**(150.7)**	(110.2)	(123.2)
Financing activities				
Proceeds from issue of shares		**78.7**	0.1	0.1
Proceeds from increase in loan		**82.1**	130.6	135.6
Loan repayments		**(11.4)**	(23.0)	(45.0)
Dividends paid	8	**(5.1)**	(4.2)	(6.3)
Net cash flows from financing activities		**144.3**	103.5	84.4
Net increase in cash and cash equivalents		**18.7**	19.3	8.8
Cash and cash equivalents at beginning of the period		**36.3**	27.8	27.8
Exchange gains/(losses)		**0.1**	(0.2)	(0.3)
Cash and cash equivalents at end of the period		**55.1**	46.9	36.3

Condensed consolidated statement of changes in equity

(In £m)	Share capital	Share premium account	Merger reserve	Hedging reserve	Foreign exchange reserve	Retained earnings	Total equity
At 1 July 2018	**0.1**	**161.3**	**86.0**	**(0.4)**	**7.6**	**94.9**	**349.5**
Profit for the period	**–**	**–**	**–**	**–**	**–**	**9.9**	**9.9**
Currency translation differences	**–**	**–**	**–**	**–**	**0.6**	**–**	**0.6**
Cash flow hedges							
– Effective portion of fair value gains	**–**	**–**	**–**	**(0.7)**	**–**	**–**	**(0.7)**
– Transfers to income statement (revenue)	**–**	**–**	**–**	**0.4**	**–**	**–**	**0.4**
Total comprehensive income	**–**	**–**	**–**	**(0.3)**	**0.6**	**9.9**	**10.2**
Share-based payment scheme	**–**	**–**	**–**	**–**	**–**	**1.2**	**1.2**
Deferred taxation on share-based payment scheme	**–**	**–**	**–**	**–**	**–**	**(0.4)**	**(0.4)**
Tax credit in respect of tax losses arising on exercise of share options	**–**	**–**	**–**	**–**	**–**	**0.1**	**0.1**
Issue of new shares	**–**	**78.7**	**2.2**	**–**	**–**	**–**	**80.9**
Dividend paid (note 8)	**–**	**–**	**–**	**–**	**–**	**(5.1)**	**(5.1)**
Total transactions with owners of the Company, recognised directly in equity	**–**	**78.7**	**2.2**	**–**	**–**	**(4.2)**	**76.7**
At 31 December 2018	**0.1**	**240.0**	**88.2**	**(0.7)**	**8.2**	**100.6**	**436.4**

(In £m)	Share capital	Share premium account	Merger reserve	Hedging reserve	Foreign exchange reserve	Retained earnings	Total equity
At 1 July 2017	0.1	161.2	5.4	0.3	10.5	71.6	249.1
Profit for the period	–	–	–	–	–	12.0	12.0
Currency translation differences	–	–	–	–	0.2	–	0.2
Cash flow hedges							
– Effective portion of fair value gains	–	–	–	0.4	–	–	0.4
– Ineffective portion of fair value gains	–	–	–	(0.4)	–	–	(0.4)
– Transfers to income statement (revenue)	–	–	–	(0.1)	–	–	(0.1)
Total comprehensive income	–	–	–	(0.1)	0.2	12.0	12.1
Share-based payment scheme	–	–	–	–	–	1.1	1.1
Deferred taxation on share-based payment scheme	–	–	–	–	–	0.2	0.2
Tax credit in respect of tax losses arising on exercise of share options	–	–	–	–	–	0.3	0.3
Issue of new shares	–	0.1	80.6	–	–	–	80.7
Dividend paid (note 8)	–	–	–	–	–	(4.2)	(4.2)
Total transactions with owners of the Company, recognised directly in equity	–	0.1	80.6	–	–	(2.6)	78.1
At 31 December 2017	0.1	161.3	86.0	0.2	10.7	81.0	339.3

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 specialty global pharmaceutical 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 Alternative Investment 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 2018 were approved by the board of directors on 26 September 2018 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 2018 have been prepared in accordance with International Accounting Standard 34 'Interim financial reporting' ('IAS 34') as adopted by the European Union (the 'EU'). The condensed interim financial statements should be read in conjunction with the annual financial statements for the year ended 30 June 2018, which have been prepared in accordance with International Financial Reporting Standards ('IFRS' or 'IFRSs') as adopted by the EU.

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 financial information in the condensed consolidated financial statements has been prepared on a basis consistent with that adopted for the year ended 30 June 2018.

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 2018 in note 2 on page 56 and in the notes to these interim condensed consolidated financial statements.

From 1 July 2018, the Group adopted IFRS 15 'Revenue from Contracts with Customers' and IFRS 9 'Financial Instruments'. As disclosed in the Annual Report for the year ended 30 June 2018, the Group has not identified any material differences on adopting the new standards and therefore no restatement of prior periods has been made.

There have been no other 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 2018 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.

Following the acquisition of CSM, the Clinical Trial Services segment has been renamed to Clinical Services. There have been no other changes to the reported segments during the period.

Operating segment results

The Group evaluates performance of the operational segments on the basis of gross profit from operations.

	2018		2017	
(In £m)	**Revenue**	**Gross profit**	Revenue	Gross profit
Commercial Medicines	**46.0**	**32.8**	42.0	31.0
Unlicensed Medicines	**107.0**	**35.7**	96.4	26.3
Clinical Services	**55.9**	**11.5**	29.4	6.6
Segmental result	**208.9**	**80.0**	167.8	63.9
Adjustment for fair value of acquired stock sold in the period (note 4)	**–**	**–**	–	(1.1)
Reported results	**208.9**	**80.0**	167.8	62.8

	Six months ended 31 December 2018			Six months ended 31 December 2017		
(In £m)	**Underlying**	**Non-underlying**	**Total**	Underlying	Non-underlying	Total
Gross profit	**80.0**	**–**	**80.0**	63.9	(1.1)	62.8
Administrative expenses excluding amortisation and depreciation	**(38.8)**	**(6.4)**	**(45.2)**	(30.1)	(4.0)	(34.1)
EBITDA	**41.2**	**(6.4)**	**34.8**	33.8	(5.1)	28.7
Analysed as:						
Adjusted EBITDA including share of joint venture	**41.8**	**(6.4)**	**35.4**	34.4	(5.1)	29.3
Joint venture EBITDA	**(0.6)**	**–**	**(0.6)**	(0.6)	–	(0.6)
EBITDA excluding share of joint venture	**41.2**	**(6.4)**	**34.8**	33.8	(5.1)	28.7
Amortisation	**(0.4)**	**(16.2)**	**(16.6)**	(0.2)	(9.5)	(9.7)
Depreciation	**(1.0)**	**–**	**(1.0)**	(0.4)	–	(0.4)
Profit from operations	**39.8**	**(22.6)**	**17.2**	33.2	(14.6)	18.6
Net finance costs	**(3.7)**	**(1.0)**	**(4.7)**	(2.1)	(1.1)	(3.2)
Share of joint venture profit	**0.4**	**–**	**0.4**	0.4	–	0.4
Profit before income tax	**36.5**	**(23.6)**	**12.9**	31.5	(15.7)	15.8
Analysed as:						
Adjusted profit before tax excluding share of joint venture tax	**36.7**	**(23.8)**	**12.9**	31.7	(15.9)	15.8
Joint venture tax	**(0.2)**	**0.2**	**–**	(0.2)	0.2	–
Profit before tax including share of joint venture tax	**36.5**	**(23.6)**	**12.9**	31.5	(15.7)	15.8
Income tax expense	**(7.2)**	**4.2**	**(3.0)**	(6.6)	2.8	(3.8)
Profit after tax	**29.3**	**(19.4)**	**9.9**	24.9	(12.9)	12.0

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.

	Six months to 31 December	
(In £m)	**2018**	2017
Cost of sales		
a) Adjustment for fair value of acquired stock sold in the period	**–**	1.1
Administrative expenses		
b) Acquisition costs	**5.0**	3.7
c) Restructuring costs (relating principally to acquisitions)	**1.1**	1.3
d) Settlement of Quantum's legal claim	**–**	(1.0)
e) FX revaluation of deferred consideration on acquisitions	**0.3**	–
f) Amortisation of intangible fixed assets acquired through business combinations and acquired products	**16.2**	9.5
	22.6	13.5
Finance costs		
g) Unwind of discount on deferred consideration on acquisitions	**1.0**	1.1
Taxation		
h) Credit in respect of tax on non-underlying costs	**(4.2)**	(2.8)
	19.4	12.9

a) Under IFRS 3, inventory acquired in a business combination is valued at fair value on acquisition, which includes the profit margin in the inventory's carrying value. The £1.1m recognised in the prior period represents the profit margin on the inventory sold in that period which was acquired with the Quantum business.

b) The acquisition costs relate to CSM and iQone comprising legal, corporate finance, due diligence advice and costs for securing 'certain funds' for the CSM acquisition.

c) Restructuring costs have been incurred during the period in respect of the integration of acquired businesses primarily relating to redundancy costs.

d) Following the acquisition of Quantum in the prior period, a settlement was agreed in Quantum's favour in relation to a legal claim with the vendors of a business acquired by Quantum pre-acquisition.

e) Deferred consideration on Proleukin, Imukin, CSM, and iQone are all 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.

f) 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.

g) The non-cash unwind of the discount applied to the deferred consideration on the acquisitions of Foscavir Bags, Proleukin, Imukin, CSM, and iQone (2017: Link).

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

5. Net finance expense

(In £m)	Six months to 31 December 2018	2017
Bank interest expense	**3.3**	1.6
Borrowing costs	–	0.2
Amortisation of facility issue costs	**0.4**	0.2
Unwind of discount on deferred consideration on product acquisitions	–	0.1
Underlying finance cost	**3.7**	2.1
Unwind of discount on deferred consideration on acquisitions (note 4)	**1.0**	1.1
Total finance cost	**4.7**	3.2

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 23.8% (2017: 23.6%).

7. Earnings per share

(In £m)	Six months to 31 December 2018	2017
Profit after tax used in calculating reported EPS	**9.9**	12.0
Underlying profit after tax used in calculating adjusted EPS	**29.3**	24.9
Number of shares (million)		
Weighted average number of shares	**127.2**	117.4
Dilution effect of share options	**1.8**	1.9
Weighted average number of shares used for diluted EPS	**129.0**	119.3
Reported EPS (pence)		
Basic	**7.7p**	10.2p
Diluted	**7.6p**	10.1p
Adjusted EPS (pence)		
Basic	**23.0p**	21.2p
Diluted	**22.7p**	20.9p

8. Dividends

A final dividend in relation to the year ended 30 June 2018 of 3.84p (2017: 3.4p) per ordinary share was paid on 30 November 2018. This amounted to £5.1m (2017: £4.2m).

An interim dividend of 1.95p (2017: 1.76p) per ordinary share has been approved by the Board. This amounts to £2.6m (2017: £2.2m) and will be paid on 12 April 2019 to all shareholders on the register as at 22 March 2019.

9. Intangible assets

(In £m)	Brand	Contracts	Customer relationships	Trademarks & licenses	Computer software	Goodwill	Total
At 1 July 2018	55.2	10.3	60.0	82.4	11.2	278.5	497.6
Acquisition of subsidiaries	4.0	–	56.2	–	1.4	102.9	164.5
Additions	–	–	–	29.9	4.0	–	33.9
Amortisation charge	(2.0)	(1.3)	(9.1)	(3.8)	(0.4)	–	(16.6)
Exchange differences	–	–	0.8	–	(0.1)	1.2	1.9
At 31 December 2018	**57.2**	**9.0**	**107.9**	**108.5**	**16.1**	**382.6**	**681.3**

In July 2018, the Group acquired the global rights outside the US to Proleukin from Novartis and the global rights to Imukin outside the US, Canada and Japan from Horizon Pharma. In October 2018, the Group acquired the

entire share capital of CSM and iQone and has recognised goodwill and separately acquired intangibles. Further details are provided in note 13.

10. Net debt

	31 December		30 June
(In £m)	**2018**	2017	2018
Revolving credit facility	**98.9**	190.9	174.7
Term loan	**151.3**	–	–
Unamortised issue costs	**(2.9)**	(2.2)	(1.9)
Finance leases	**0.2**	–	–
Total borrowings	**247.5**	188.7	172.8
Cash	**(55.1)**	(46.9)	(36.3)
Net debt	**192.4**	141.8	136.5

During the period, the debt facilities have been refinanced as part of the financing arrangements for the acquisition of CSM. The new financing increased the debt facility from £220m to £300m, extending the facility to October 2023. The facility includes an unsecured £150m term loan with a single repayment in 2023 and an unsecured revolving credit facility (RCF) of up to £150m.

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 3.25x. As at 31 December 2018, interest cover was 14.1x and the net debt/adjusted EBITDA leverage was 2.2x. There were no instances of default, including covenant terms, in either the current or the preceding period.

Subsequent to the period end, the debt facilities have been increased to finance the acquisition of the US rights to Proleukin. The revised facility has been increased by £75m to £375m. This comprises an unsecured £150m term loan with a single repayment in 2023 and an unsecured RCF of up to £225m.

The Group's bank covenant leverage on completion of the acquisition of Proleukin in April 2019 is expected to be approximately 2.4x net debt / EBITDA. Given the Group's strong cash flow generation, leverage is expected to reduce towards 2.0x by 31 December 2019.

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 2018. There have been no changes in the risk management processes or in any risk management policies since the year end.

11. Financial risk management and financial instruments (continued)

Financial instruments

At 31 December 2018 (In £m)	**Designated at fair value**	**Amortised cost**	**Total carrying value**	**Fair value**
Cash and cash equivalents	**–**	**55.1**	**55.1**	**55.1**
Trade and other receivables	**–**	**84.0**	**84.0**	**84.0**
Derivative financial instruments	**0.1**	**–**	**0.1**	**0.1**
Total financial assets	**0.1**	**139.1**	**139.2**	**139.2**
Trade and other payables	**–**	**(139.5)**	**(139.5)**	**(139.5)**
Borrowings	**–**	**(247.3)**	**(247.3)**	**(247.3)**
Finance lease liabilities	**–**	**(0.2)**	**(0.2)**	**(0.2)**
Derivative financial instruments	**(0.9)**	**–**	**(0.9)**	**(0.9)**
Total financial liabilities	**(0.9)**	**(387.0)**	**(387.9)**	**(387.9)**

At 31 December 2017 (In £m)	**Designated at fair value**	**Amortised cost**	**Total carrying value**	**Fair value**
Cash and cash equivalents	–	46.9	46.9	46.9
Trade and other receivables	–	55.7	55.7	55.7
Derivative financial instruments	0.3	–	0.3	0.3
Total financial assets	0.3	102.6	102.9	102.9
Trade and other payables	–	(85.3)	(85.3)	(85.3)
Borrowings	–	(188.7)	(188.7)	(188.7)
Total financial liabilities	–	(274.0)	(274.0)	(274.0)

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 date; and Level 3 instruments are those valued using information other than observable market data.

Derivative financial instruments at 31 December 2018 and 31 December 2017 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 2018, and there have been no transfers between valuation levels nor changes in valuation techniques during the period.

12. Share capital

Issued and fully paid (Ordinary shares of 0.1p each)	**Number (m)**	**Cost (£m)**
At 1 July 2017	115.2	0.1
Issue of new shares	7.1	**–**
At 30 June 2018	**122.3**	**0.1**
Issue of new shares	10.1	**–**
At 31 December 2018	**132.4**	**0.1**

On 27 September 2018, the Group issued 9,467,456 ordinary shares to institutional investors at a price of 845p per share. On 9 October 2018, 241,744 ordinary shares were issued as consideration for the acquisition of iQone which required the application of merger relief under the Companies Act 2006. As a result, the difference between the nominal value and fair value of shares issued has been recognised in the merger reserve.

13. Business combinations

On 2 October 2018, the Group acquired the entire share capital of CSM Parent, Inc., a company registered in the United States, and its subsidiaries with a presence in the US, Belgium and Germany. The acquisition expands Clinigen's value added capabilities, diversifies Clinical Services' global client and customer base, adds important continental EU infrastructure, and reinforces the links between the Group's three business operations.

On 9 October 2018, the Group acquired the entire share capital of iQone Healthcare Holding, a company registered in Switzerland, and its subsidiaries with a presence in France, Germany, Switzerland, Italy and Spain. This acquisition supports growth of Clinigen's Commercial Medicines portfolio in the EU, differentiates the early access business from its competitors by providing EU medical scientific liaison ('MSL') capability to support and secure long-term unlicensed agreements, and enhances the Group's proposition as a commercial partner for pharmaceutical companies.

In order to fund the cash element of the consideration, the Group's borrowing facilities were increased as detailed in note 10.

The provisional fair value of assets acquired and liabilities assumed on the acquisitions are as follows:

(In £m)	CSM	iQone	Total
Intangible assets	60.4	1.2	**61.6**
Property, plant and equipment	6.7	–	**6.7**
Inventories	0.2	0.1	**0.3**
Trade and other receivables	10.5	0.8	**11.3**
Corporation tax recoverable	0.5	–	**0.5**
Cash and cash equivalents	2.1	2.3	**4.4**
Trade and other payables	(7.0)	(1.2)	**(8.2)**
Borrowings	(1.0)	–	**(1.0)**
Finance lease liabilities	(0.3)	–	**(0.3)**
Deferred tax liabilities	(16.7)	(0.2)	**(16.9)**
Net assets acquired	**55.4**	**3.0**	**58.4**
Goodwill arising on acquisition	91.6	11.3	**102.9**
Total consideration	**147.0**	**14.3**	**161.3**
Satisfied by:			
Cash consideration paid	115.5	6.9	**122.4**
Consideration settled by shares in Clinigen Group plc	–	2.2	**2.2**
Discounted fair value of contingent consideration	31.5	5.2	**36.7**
Other information:			
Revenue from date of acquisition	12.7	0.6	**13.3**
Loss before tax from date of acquisition	(2.2)	(0.6)	**(2.8)**
Pro forma revenue for the 6-month period ended 31 December 2018	24.7	1.2	**25.9**
Pro forma loss before tax for the 6-month period ended 31 December 2018	(5.7)	(0.9)	**(6.6)**

The total consideration for CSM of £147.0m is made up of initial cash consideration of £114.0m (US$150.0m), payment for working capital of £1.5m (US$1.9m) and contingent consideration of £31.5m (US$40.2m).

The contingent consideration is payable in the year ending 30 June 2020 and is contingent on the adjusted EBITDA generated by CSM in the 12 months to 31 December 2019. The undiscounted fair value of the contingent consideration as of the acquisition date has been estimated at US$45.7m based on current forecasts and could be in the range of nil to US$90m.

13. Business combinations (continued)

The total consideration for iQone of £14.3m is made up of initial cash consideration of £6.9m (€7.7m) cash, an issue of 241,744 shares in Clinigen Group plc which had a fair value of £2.2m (€2.5m), and contingent consideration of £5.2m (€5.8m).

The contingent consideration is payable in the years ending 30 June 2023 and 2024 which is contingent on the adjusted EBITDA generated by iQone in the 12 months to 31 December 2022 and 2023. The undiscounted fair value of the contingent consideration as of the acquisition date has been estimated at €12.3m and could be in the range of nil to €50.0m.

As all of the contingent consideration is payable in more than 1 year from the balance sheet date it is included in non-current liabilities. The liability falls within Level 3 of the fair value hierarchy.

The fair value of the acquired identifiable intangible assets in CSM consists of £4.0m attributable to brand, £55.0m attributable to customer relationships and £1.4m attributable to some proprietary software together with a related deferred tax liability of £16.7m. In iQone, the only identifiable acquired intangible assets are customer relationships which have been valued at £1.2m with an associated £0.2m deferred tax liability. These values have been assessed by an independent third party valuation expert.

Goodwill represents the synergies, assembled workforces and future growth potential of the acquired businesses. The goodwill arising in the period of £102.9m is not deductible for tax purposes.

The loss before tax is stated after the charge for amortisation of acquired intangibles.

14. Post balance sheet events

Subsequent to the period end, the Group signed an agreement to acquire the US rights and assignment of the current distribution and promotion agreement of Proleukin from Novartis. On acquisition, which is expected to take place in April subject to US anti-trust clearance, the Group will be the only global supplier of Proleukin and with its current sales revenues, it will become the largest product in the Commercial Medicines portfolio.
Although Proleukin is indicated for metastatic melanoma and metastatic renal cell carcinoma within the US, it is also being used in around 80 active studies within the US across multiple disease areas indicating its potential application in the treatment of other cancers and future potential for revitalisation. The acquisition further diversifies the Group's oncology and infectious disease portfolio of acquired niche hospital-only and critical care products.

Total consideration is up to US$210m, comprising initial consideration of US$120m, deferred consideration of US$60m over the 12 months following completion, and a further $30m contingent consideration based on sales milestones. In the year to 30 June 2018, in the US, Proleukin generated revenue of US$60m according to IQvia (IMS). Gross profit margin is expected to be similar to other specialty medicines within the Commercial Medicines division. The acquisition will be modestly EPS accretive in the current financial year as the product transitions to Clinigen, and at least 25% accretive in the first full financial year.

In order to finance this acquisition, the debt facilities available to the Group have been increased. The revised facility of £375m is composed of an unsecured £150m term loan with a single repayment in 2023 and an unsecured RCF of up to £225m.

The Group's bank covenant leverage on completion of the acquisition of Proleukin in April 2019 is expected to be approximately 2.4x net debt / EBITDA. Given the Group's strong cash flow generation, leverage is expected to reduce towards 2.0x by 31 December 2019.

Independent review report to 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 2018. 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 2018;

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 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.

PricewaterhouseCoopers LLP
Chartered Accountants
East Midlands
27 February 2019