





# **WE CONTINUE TO 'JOIN-THE-DOTS' TO BROADEN OUR SERVICE OFFERING TO EXPAND PATIENT** ACCESS AND TO EXTEND THE PRODUCT LIFECYCLE, **DELIVERING GREATER VALUE TO OUR STAKEHOLDERS.**

Clinigen Group plc is a trusted global leader in the pharmaceutical and services industry, with a unique combination of businesses focused on providing access to medicines. Our mission is to deliver the right medicine, to the right patient, at the right time.



For more information visit our website **www.clinigengroup.com** 

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Group results on an adjusted basis exclude amortisation of acquired intangibles and products, and other non-underlying items relating to acquisitions (see notes 4 and 7 of the consolidated financial statements). Adjusted net revenue excludes Managed Access pass through revenue which varies each period dependent on the mix of programs. Adjusted net revenue is a new alternative performance measure of top line performance which is now used to manage the business as it eliminates volatility in reported revenue which can arise as a result of the mix of Managed Access Programs. Adjusted net revenue of £466.2m excludes £11.6m of intercompany sales. Adjusted EBITDA includes the Group's share of EBITDA from its joint venture. Adjusted results include amortisation on software and internally developed IP. 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. Acquisitions completed in the previous financial year are included on a like-for-like basis including the results for the acquisition where it is included in the comparable historical period. Organic growth is presented to aid the reader's understanding of the underlying performance of the business. On a pro forma basis, the best estimate for organic adjusted EBITDA growth for the year ended 30 June 2020 is 12%. Bank covenant leverage i calculated by dividing adjusted EBITDA of the Group for the last 12 months, excluding the impact of IFRS 16, 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 year prior to it becoming a member of the Group.

#### **FINANCIAL HIGHLIGHTS**

ADJUSTED NET REVENUE (£M)

466.2 ^15%

2020		466.2
2019		407.0
2018	300.8	
2017	270.6	
2016	265.6	

#### ADJUSTED BASIC EARNINGS PER SHARE (PENCE)

65.6

**^20**%

2020		65.6
2019		54.4
2018	45.4	
2017	41.3	
2016	33.4	





ADJUSTED EBITDA (£M)

131.0 ~30<sup>0</sup>/

2018 76.0 2017 65.1	2019			100.8
	2018		76.0	
	2017	65.1		
2016 53.7	2016 53.7	1		

#### REVENUE (£M)

**504.3 ~10%** 2019 **504.3** 

2018	381.2
2017	302.3
2016	339.9

#### **DIVIDEND PER SHARE (PENCE)**



2020				7.61
2019			6.7	
2018		5.6		
2017	5.0			
2016	4.0			

- Adjusted net revenue up 15% (+8% on an organic basis) to £466.2m (2019: £407.0m)
- Adjusted EBITDA up 30% (+13% on an organic basis) to £131.0m (2019: £100.8m)
- Adjusted EPS up 20% to 65.6p (2019: 54.4p), continuing double-digit EPS growth each year since IPO
- Reported EPS of 10.3p (2019: 4.0p)
- Profit before income tax of £22.6m (2019: £12.3m)
- Net debt as at 30 June 2020 of £311.9m (£288.4m excluding IFRS 16), representing leverage of 2.3x (leverage including CSM consideration of US\$89.5m of 2.8x) with target leverage of 1.0–2.0x expected within 12–18 months
- Full year dividend increased 14% to 7.61p (2019: 6.7p)

#### **INVESTMENT CASE**

# THE TRUSTED GLOBAL LEADER IN ACCESS TO MEDICINES

In becoming the trusted global leader in access to medicines, the Group has consistently delivered healthy financial returns. We believe there are several reasons to invest in Clinigen.

#### **UNIQUE AND DIVERSE BUSINESS MODEL**

We offer access to medicines at the key stages of the pharmaceutical product lifecycle by utilising Clinigen's balanced portfolio, across the services and products businesses.





#### DISCIPLINED CORPORATE AND PRODUCT ACQUISITIONS

We have made a number of acquisitions, both of corporates to build out the infrastructure platform, and of niche hospital speciality medicines. Both have contributed towards double-digit EPS growth since IPO in 2012.

**CORPORATE ACQUISITIONS SINCE IPO IN 2012** 



Î

**PRODUCT ACQUISITIONS SINCE IPO IN 2012** 

#### **GLOBAL CAPABILITY**

We have organically built a global supply chain and distribution network, organically, through acquisitions and partnerships, providing local market knowledge supported by global expertise.

#### **EXPERIENCED MANAGEMENT TEAM**

We have an experienced management team both at the regional and Group level, with a track record of delivering strong growth every year since inception.

#### **MARKET-LEADING POSITIONS**

POSITION

We are the global leader in the management of early access programs to innovative new medicines. We are a global market leader in the specialist supply and management of quality-assured comparator medicines and services to clinical trials and Investigator Initiated Trials ('IITs').

#### INTERNATIONAL LOCATIONS

14

COUNTRIES SUPPLIED IN LAST THREE YEARS



# EXECUTIVE MANAGEMENT TEAM (TENURE)

2-4 years>6 years

#### BROAD CLIENT AND CUSTOMER BASE

We have deep, well-established relationships with pharmaceutical and biotech companies as clients and Healthcare professionals ('HCPs') as customers.

#### SIGNIFICANT LONG-TERM GROWTH POTENTIAL

We have a significant exposure to emerging pharmaceutical growth markets from building out our infrastructure platform, service capability and product offering through a combination of organic and acquisitional growth.

#### NUMBER OF PHARMACEUTICAL AND BIOTECH COMPANIES AS CLIENTS



# HCPS AS CUSTOMERS' **18,625**

#### ADJUSTED NET REVENUE BY REGION

54%	25%	21%
60%	22%	18%
52%	25%	23%
	60%	60% 22%



#### OPERATING CASH FLOW (£M)<sup>2</sup>

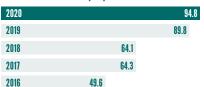
management.

**HIGHLY CASH GENERATIVE** 

We generate strong cash returns

which are underpinned by strong

credit control and working capital



1. HCPs as customers indicates the number of registered users on Cliniport.

2.Operating cash flow is net cash flow from operating activities before income taxes and interest.

\* % of adjusted EBITDA is before central

unallocated costs

**CHIEF EXECUTIVE OFFICER'S STATEMENT** 

# DOUBLE DIGIT ORGANIC BITDA GROWTH DELIVERED

We are executing on our strategy to build an integrated, international pharma product and services group with strong operational synergies and have also delivered a strong financial performance – both on a headline basis and on an organic basis.

"THE STRONG GROWTH IN EBITDA WAS DRIVEN BY BOTH THE ACQUISITIONS MADE IN FY19 AND A STRONG UNDERLYING PERFORMANCE."

SHAUN CHILTON Group Chief Executive Officer 16 September 2020 "FOLLOWING THE STRATEGICALLY TRANSFORMATIONAL CORPORATE AND PRODUCT ACQUISITIONS MADE IN FY19, THE FOCUS FOR THE GROUP IN FY20 HAS BEEN TO INTEGRATE THE ACQUISITIONS FURTHER AND TO CAPITALISE ON THE GROUP'S INTERNATIONAL PLATFORM TO SUPPORT SYNERGISTIC GROWTH IN FY21 AND BEYOND."

#### **ADJUSTED EPS (PENCE)**



OPERATING CASH FLOW ( $\pounds M$ )

94.8

**^6**%

#### **OVERVIEW**

Clinigen is dedicated to providing greater access to medicines around the world and in doing so delivering incremental value from pharmaceutical products by extending and expanding its lifecycle. Clinigen achieves this through operating as a pharmaceutical and pharma services group. Clinigen has three businesses; Clinical Services, Unlicensed Medicines and Commercial Medicines – each working synergistically to facilitate access to medicines at key points of a product's lifecycle.

Our strategy is to position ourselves as the most logical partner for two distinct customer groups: 1) pharmaceutical and biotech companies aiming to realise the long-term commercial value of their product(s) throughout the product lifecycle; and 2) enabling HCPs, particularly hospital pharmacists, to view Clinigen as the 'go to' source for hard to access medicines. In addition, we are also building our own portfolio of specialist, hospital medicines to further increase shareholder value by revitalising these products. This benefits from the insight of our unlicensed supply channel.

This year has seen unprecedented challenges in the form of the COVID-19 pandemic. Since its sudden emergence, the Group has had to be agile in its response. From the beginning, across its 14 international locations, we implemented a range of measures to prioritise keeping our employees safe, including extensive home working. In addition, we began working more closely with our pharmaceutical clients as well as our HCP customers to ensure that the supply of critical medicines to patients on a global basis continues uninterrupted.

During Q4, the Group experienced more meaningful disruption to its activities from COVID-19, but continued to deliver good progress overall. Clinical Services was impacted by clinical trials being delayed or cancelled. whilst both Commercial Medicines and Unlicensed Medicines saw reduced volume demand as treatments in the hospital setting, particularly for oncology, slowed. However, the Group quickly pivoted activities to support efforts against the pandemic, resulting in material contract wins, whilst containing costs to lessen the impact from a lower top line performance.

We estimate that the impact of COVID-19 to be between 5 to 7% to adjusted EBITDA in the financial year, with this primarily related to Proleukin as treatment centres shut and demand fell. As expected, these headwinds have continued into at least the first quarter of the current financial year. However, the Group has already seen signs of recovery in territories that have begun to relax restrictions related to the pandemic.

In October 2019, we implemented the Group's Enterprise Resource Planning ('ERP') system, which although faced several process issues from the beginning, were largely addressed by the end of the financial year. The Group will now be able to benefit from automation, streamlined operational activities and processes to increase the Group's efficiency and productivity. The Group is now working to maximise these benefits with the next stages of implementation to make the business ready for unified digitisation in FY21.

In April 2020, the Group announced its biggest ever Global exclusive licensing and distribution agreement signed with Porton Biopharma Limited ('PBL') to commercialise Erwinase®. Although the agreement will start on 1 January 2021, net sales aren't anticipated to begin until the second half of 2021. The Erwinase agreement fits with our strategy to partner with pharmaceutical companies to expand and extend the lifecycle of their products by utilising our global platform and expertise in the supply and distribution of both unlicensed and licensed medicines. As part of our portfolio in oncology and haematology, Erwinase strengthens our commercial offering in key markets and will be a priority product for the Group.

#### **FINANCIAL PERFORMANCE**

The Group this year, has once again delivered double-digit growth in each of our three key financial performance metrics – and has done so since IPO in 2012. Adjusted net revenue increased by 15%; adjusted EBITDA increased by 30%; and adjusted EPS increased by 20.

The strong growth in EBITDA was driven by both the acquisitions made in FY19 and a strong underlying performance. This performance was despite the difficult trading conditions in the last few months of the financial year due to COVID-19. On an organic basis, there were good performances in Commercial Medicines, from CSM in Clinical Services and in Unlicensed Medicines, from Global Access. These performances offset weaker performances from CTS in Clinical Services and in Unlicensed Medicines, from both Managed Access and the UK Specials business.

#### **CHIEF EXECUTIVE OFFICER'S STATEMENT CONTINUED**

"THE ERWINASE AGREEMENT FITS WITH OUR STRATEGY TO PARTNER WITH PHARMACEUTICAL COMPANIES TO EXPAND AND EXTEND THE LIFECYCLE OF THEIR PRODUCTS BY UTILISING OUR GLOBAL PLATFORM AND EXPERTISE IN THE SUPPLY AND DISTRIBUTION OF BOTH UNLICENSED AND LICENSED MEDICINES." In addition, after a weaker than normal cash flow performance in H1, cash generation improved meaningfully in H2, reverting back to historical levels.

Further details on our financial performance are covered by the Group Chief Financial Officer on pages 40 to 43.

#### PROGRESS AGAINST STRATEGIC OBJECTIVES

Following the strategically transformational corporate and product acquisitions made in FY19, the focus for the Group in FY20 has been to integrate the acquisitions further and to capitalise on the Group's international platform to support synergistic growth in FY21 and beyond. Integration of these acquisitions is either complete or well progressed, and the Group is already seeing the benefits through strong financial performance and operational synergies.

An important area of focus continues to be in strengthening the links between the Group's three business operations by deepening the relationships with both pharmaceutical and biotech companies (clients) and HCPs (customers). The Group is attempting to embed a culture that seeks to maximise value through extending the commercial relationship through the product lifecycle. The Group increased the number of pharmaceutical and biotech companies it works with during the year to 557 (2019: 532) and also expanded the number of registered users (HCPs) with which it interacts to 18,625 (2019: 15,580) on its digital platform, Cliniport. By linking the three business, what we call 'joining-thedots' more effectively, by identifying revenue generating opportunities that can move through the businesses, we will continue to drive growth.

In addition, as mentioned we implemented the Group's ERP system, expanded our portfolio of licensed assets in key territories, including the agreement signed with PBL to commercialise Erwinase, increased the number of Managed Access Programs ('MAPs') which will help to support growth in the Unlicensed Medicines business in the medium term and extended our global footprint by increasing the number of countries in which we distributed medicines.

#### **OPERATIONAL PERFORMANCE**

Supporting the strong financial performance were some areas which showed good organic growth that more than offset areas of weakness, demonstrating the benefit of having an international platform and balanced portfolio of complementary services and products.

Commercial Medicines, our largest business operation, showed excellent organic growth with good performances across the portfolio, despite growth being impacted in the final quarter due to COVID-19 disruption.

Foscavir<sup>®</sup>, which faced competition in recent years from a novel product, performed well in the second half with gross profit flat year on year. However, due to the approval of a generic in the EU, it is anticipated revenues will be impacted in FY21 and beyond. The Board has long anticipated the generic threat and has enacted its strategy to mitigate loss.

Proleukin®, the Group's largest product, faced difficult trading conditions in the final guarter largely as a result of COVID-19 within its current on-label indications. The use of Proleukin and aldesleukin, the active pharmaceutical ingredient ('API') used in Proleukin, in clinical development programs, continues to show promise. Proleukin is being investigated alongside Tumor Infiltrating Lymphocyte (TIL) therapies within a number of new and existing oncology indications and in July 2020, aldesleukin was granted Orphan Drug Designation ('ODD') for the treatment of Amyotrophic Lateral Sclerosis ('ALS'). The ODD recognises the potential therapeutic role of aldesleukin and could give Clinigen marketing exclusivity should we obtain marketing approval.

In the remainder of the Acquired Products portfolio in Commercial Medicines both Ethyol® and Savene performed very well. However, Ethyol faces some headwinds in FY21 following the failure of a manufacturing tech transfer process leading to an out of stock situation. This impact has been captured within management's forwardlooking guidance and expect the product to return to market in FY22.

Regionally, in the Licensed Products portfolio, as well as the Erwinase agreement mentioned above, further progress was made in increasing the number of local marketed licences. In addition, a New Drug Application ('NDA') was submitted to the Pharmaceuticals and Medical Devices Agency ('PMDA') in Japan for Hunterase (Idursulfase-beta) ICV under the strategic alliance with GC Pharma. Partnering with companies to commercialise their products outside of their home geography using Clinigen's regulatory expertise, is an important driver of growth for us in Japan.

#### STRATEGIC REPORT 07

"AGAINST THE BACKDROP OF THE COVID-19 PANDEMIC, THIS YEAR MORE THAN EVER, THE GROUP'S EMPLOYEES HAVE NAVIGATED THESE CHALLENGING TIMES WITH INCREDIBLE RESILIENCE AND AGILITY, HARD WORK AND PROFESSIONALISM ENABLING US AS A BUSINESS TO CONTINUE TO OPERATE SMOOTHLY AND SERVE OUR CUSTOMERS."

## employees **1,168**

Finally, in the Developed Products portfolio in Commercial Medicines, the portfolio's lead product, Melatonin and Glycopyrronium Bromide Oral Solution 1mg/5ml ('Glyco') both performed strongly and were a key driver of organic growth in the year.

In Unlicensed Medicines, Managed Access faced headwinds from two of its largest MAPs winding down and from reduced demand for treatments due to COVID-19. However, there were a record number of programs signed in the year helping to strengthen our market-leading position. In Global Access, organic growth was excellent, supported by an increase in the number of exclusive supply agreements and excellent performance in Asia, Australia, New Zealand and Europe. As previously highlighted, the UK Specials business continues to face a head wind due to modest pricing pressure from products going onto drug tariffs and cannibalisation from moving products through the unlicensed-to-licensed ('UL2L') pathway. This head wind is likely to continue in the medium term.

In addition, the Group's digital service offering (Cliniport and Clinigen Direct), which the Unlicensed Medicines business is the main beneficiary, continues to make good progress, with 18,625 registered users on Cliniport (2019: 15,580). Looking ahead, with the Group's ERP now implemented, once unified digitisation occurs this financial year, the Unlicensed Medicines business will be better placed to drive customer intimacy and will help to extend Clinigen's reach.

Following the implementation of Clinigen One, the Group's ERP system, the Group is working towards a unified digital platform. This will be a major contributor to the future success of the Unlicensed Medicines business, driving customer intimacy and extending and expanding Clinigen's reach. See pages 32 to 33 which provides a case study underlining the importance and impact of the Group's digital offering.

In Clinical Services, trading was also impacted by the pandemic with the market estimated to have declined c.30-50% in Q4. The performance was mitigated to some degree in CSM by offering a differentiated service in the form of the direct-to-patient model and by winning COVID-19 related business. Within CTS, a significant contract was won, the largest in the division's history, which is a multiyear contract and will help support the division in the medium term.

#### PEOPLE

The Group now has over 1,150 employees, with over half operating overseas from the UK in one of our 14 international locations in North America, Europe, Africa or Asia Pacific. Against the backdrop of the COVID-19 pandemic, this year more than ever, the Group's employees have navigated these challenging times with incredible resilience and agility, hard work and professionalism enabling us as a business to continue to operate smoothly and serve our customers. On behalf of the Board, I would like to take the opportunity to thank all our employees, helping the Group in its guiding principle to become the trusted global leader in access to medicines.

I would also like to thank my Board colleagues for their support and guidance over the past year.

I would finally like to thank all our stakeholders; employees, customers, shareholders and regulators whose continued support has contributed to our success.

#### OUTLOOK

We continue to see organic growth in line with our medium-term guidance, despite COVID-19 and expected competitive pressure to Foscavir (see Operational Review on pages 34 to 39). As we look beyond FY21, we see growth significantly accelerating as we onboard our new asset, Erwinase, and we continue to gain share in the end-markets we serve.

Group results on an adjusted basis exclude amortisation of acquired intangibles and products, and other non-underlying items relating to acquisitions. Adjusted EBITDA includes the Group's share of EBITDA from its joint venture.

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. Acquisitions completed in the previous financial year are included on a like-for-like basis including the results for the acquisition where it is included in the comparable historical period. Organic growth is presented to aid the reader's understanding of the underlying performance of the business. On a pro forma basis, the best estimate for organic adjusted EBITDA growth for the year ended 30 June 2020 is 12%.

#### **COMPANY OVERVIEW**

# 'JOINING-The-Dots'

Clinigen 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 ('AAA'). Clinigen now has over 1,150 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 21 of the top 25 pharmaceutical companies; interacting with over 18,000 registered users across 115 countries, shipping approximately 6.5 million units in the year.

 % of adjusted EBITDA is before central unallocated costs.

# **CLINICAL SERVICES**

Clinigen is the global market leader in the specialist supply, packaging, distribution and management of quality-assured comparator medicines and services to clinical trials and IITs.

#### CSM

CSM is a specialist provider of packaging, labelling, warehousing and distribution services with infrastructure in the US, Belgium and Germany.

#### CTS

CTS is the global market leader in the specialist supply and management of quality-assured comparator medicines and services to clinical trials and IITs.



Clinigen is the global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet medical need. The Group manages MAPs to innovative new medicines and provides global access to medicines which remain unlicensed at the point of care.

#### **MANAGED ACCESS**

Managed Access is the global market leader in providing exclusive, ethical worldwide access to the most promising innovative medicines on behalf of pharmaceutical and biotech companies in disease areas where there is a high unmet patient need.

#### **GLOBAL ACCESS**

Global Access ethically supplies unlicensed or short supply medicines to patients, via their physicians.



### **COMMERCIAL MEDICINES**

Clinigen acquires global rights to niche hospital-only and critical care products, revitalising these assets around the world and returning them back to sustained growth. It also provides access to licensed and branded generic medicines in the AAA region.

The Group also has a UL2L strategy, where it looks to take unlicensed medicines with commercial potential and licences them, helping to address unmet medical need and allowing the Group to capitalise on its market-leading positions.

#### ACQUIRED

The Acquired Products portfolio includes niche hospital-only and critical care products, which the Group has selectively acquired for the purpose of revitalising them back to sustained growth.

#### DEVELOPED

The Developed Products portfolio is based upon a UL2L strategy, where it looks to take unlicensed medicines with commercial potential and develops them into licensed medicines, addressing unmet medical need.

#### **LICENSED**

The Licensed Products portfolio provides access to licensed and branded generic medicines, acting as a commercial partner with the owner/innovator in regions such as AAA.









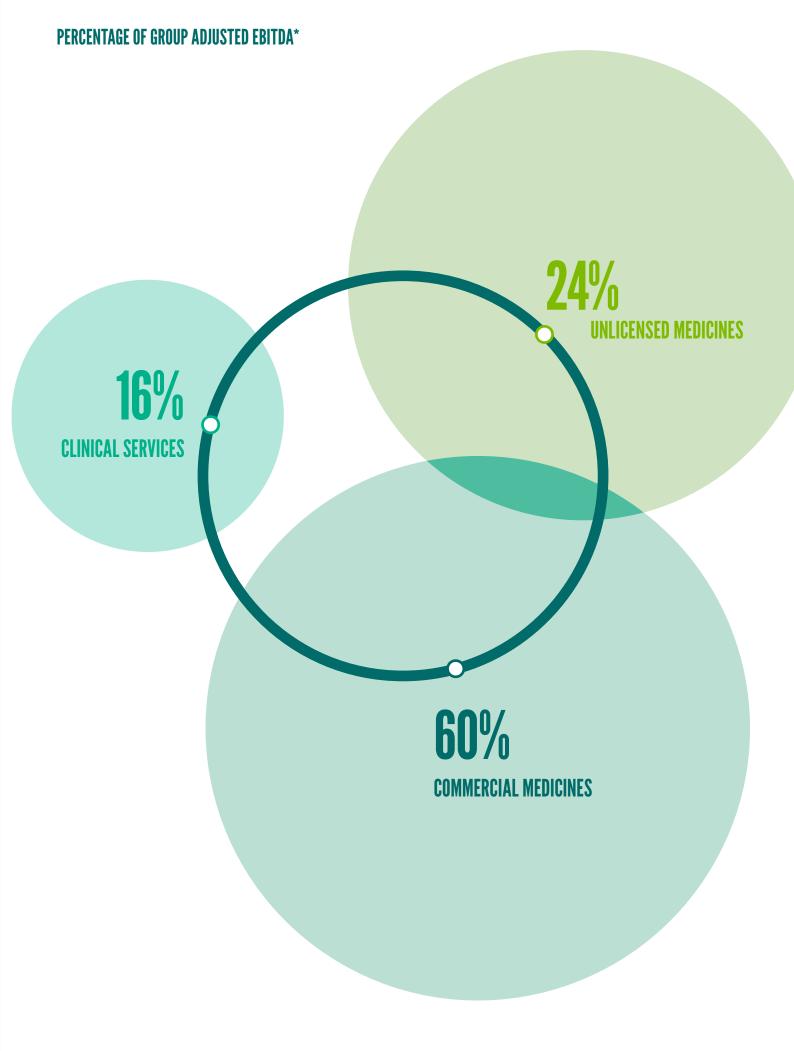
٦	See pages
	36 to 37











#### **BUSINESS MODEL**

# ENABLING ACCESS ACROSS THE LIFECYCLE

Clinigen has built an international platform which provides access to medicines across the pharmaceutical product lifecycle on a global scale. Its three business operations are supported by a central operating platform which provides supply chain expertise, quality assurance, customer services and support functions.

#### **OUR PROPOSITION**

#### **TO PHARMACEUTICAL AND BIOTECH CLIENTS**

Aim to be the logical partner for pharmaceutical and biotech companies to fully realise the commercial value of their assets

#### Specialist supply and distribution

- Global infrastructure
- Supply chain experience
- Sourcing capability

#### Partnership capability

- Project management and strategic guidance (including real-world data ('RWD'))
- Ability to partner throughout lifecycle
- Broad service and product offering

#### Expand and extend product lifecycles

- Facilitate early access to medicine
- Provide valuable insights resulting in sustained value
- Acquisition and revitalisation capability

#### **CLINIGEN'S VALUE PROPOSITION**

Clinigen sits between the pharmaceutical and biotech client who are looking for a partner to provide a service for their asset at key stages of the product lifecycle, and the HCP customer who is looking to source hard to find medicines



#### **TO HCP CUSTOMERS**

Aim to be the 'go to' company for HCPs to access hard to find medicines for their patients

#### Access to extensive portfolio of medicines

- Innovate new medicines
- Catalogue of hard to find medicines
- Unlicensed and licensed products

#### **Broad engagement offering**

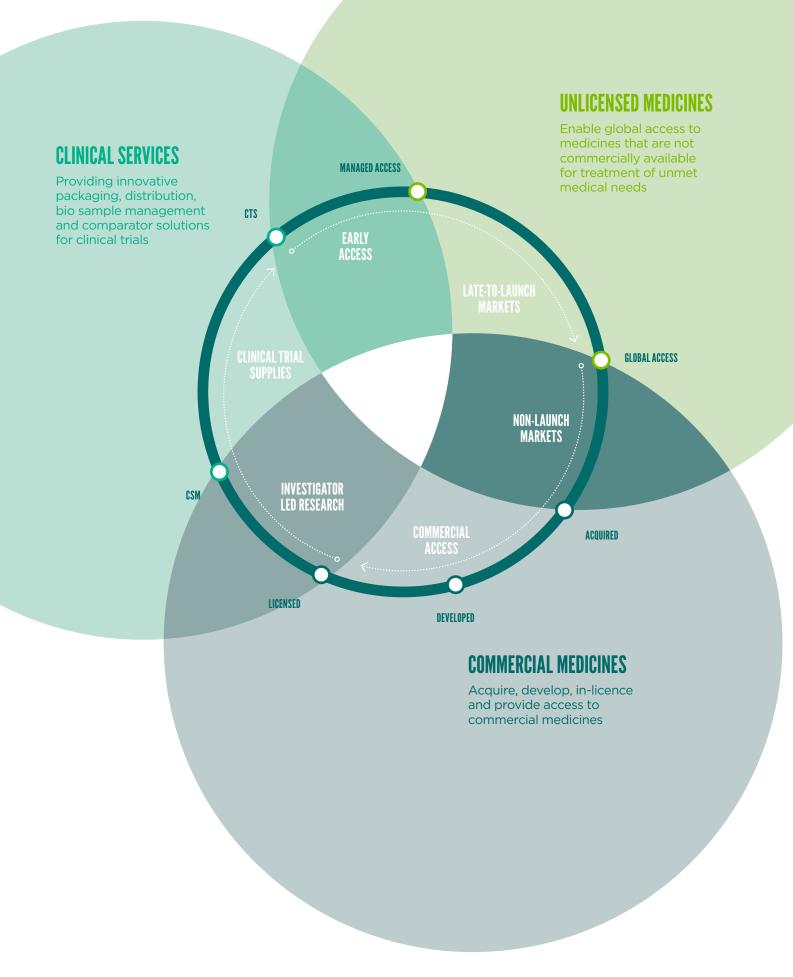
- Expert assistance
- Interactive engagement capability
- Comprehensive customer service model

#### Efficient service offering

- Rapid response times
- World-class quality standard

Clinigen is dedicated to providing greater access to medicines around the world and in doing so delivering incremental value from pharmaceutical products by extending and expanding its lifecycle.

Through organic growth and a buy and build strategy, we are able to provide solutions across the pharmaceutical product lifecycle and have positioned ourselves as the most logical partner for two distinct but directly connected customer groups, pharmaceutical and biotech clients, and HCPs.



#### **STAKEHOLDER ENGAGEMENT**

Since its inception, the Group has been building out its infrastructure platform, refining its value proposition and driving the synergies between its three business operations to deliver the right medicine, to the right patient, at the right time.

By investing in our business model, the Group is able to create sustained value for our stakeholders; patients, clients, customers, employees, shareholders and regulators.

The following table provides a list of the Group's stakeholders, as determined by the Board. It outlines why they are important for the Group, why we think we are important to them, how we engage and provides examples of our engagement throughout the year. Engagement with our key stakeholders is regularly reviewed to ensure we learn from these relationships for the benefit of both the Group and its key stakeholders.

#### **OUR STAKEHOLDERS**



Clinigen's mission is 'Right Medicine, Right Patient, Right Time', which demonstrates that the patient is at the heart of everything we do and is a key reason why many of its employees choose to work for the Group.

#### REPRESENTATIVE

"EACH OF US WORKING AT CLINIGEN KNOWS THAT EVERY REQUEST FOR ACCESS TO MEDICINES IS DESTINED FOR A PATIENT, WHERE THEY AND THEIR FAMILIES ARE LOOKING FOR OPTIONS, HOPING FOR A TREATMENT THEY OTHERWISE WOULD NOT HAVE. WE UNDERSTAND THE IMPACT THAT HAVING HOPE HAS ON FAMILIES AND THAT IS WHAT MOTIVATES US."

US Head of Program Management



Our pharmaceutical and biotech clients are broadening their relationship with Clinigen to enable ethical, secure and compliant global access to their medicines at the key stages of the product lifecycle. "OUR CLIENTS RECOGNISE THE THREAD THAT CONNECTS CLINICAL, UNLICENSED AND COMMERCIAL ACCESS. THEY WANT A PARTNER THAT CAN WORK ALONGSIDE THE WHOLE PRODUCT LIFECYCLE TO SECURE THIS THREAD AND DELIVER GREATER VALUE FOR THEMSELVES, HCPS AND PATIENTS."

Global Head of Business Development



We offer ethical access to medicines to HCPs through a combination of a global reach and local knowledge, providing a safe and compliant route for them to obtain hard to access medicines. "OUR WORLD CLASS REGIONAL TEAMS ARE DESIGNED TO DELIVER EXCEPTIONAL CUSTOMER SERVICES TO A GLOBAL BASE OF HCPS. THE KNOWLEDGEABLE ACCOUNT EXECUTIVES NOT ONLY SPEAK THE LOCAL LANGUAGE BUT ARE ALSO EXPERIENCED IN LOCAL REGULATORY REQUIREMENTS. THE SERVICE IS DESIGNED TO PROVIDE THE RIGHT MEDICINE TO THE RIGHT PATIENT AT THE RIGHT TIME."

Customer Service Director

#### WHY THEY ARE Important to the group

Patient demand is fundamental to the success of the business. There are only three ways to get a medicine into a patient, in a clinical trial, as an unlicensed medicine or as a licensed, commercial medicine, which is why Clinigen's three businesses are aligned as they are. Our business has international infrastructure, services and capabilities to be able to manage all three routes.

#### WHY THE GROUP Is important to them

By its very nature, Clinigen's business of providing ethical access to medicines, fundamentally impacts upon the health of patients across the globe, and we believe brings hope to those who have found themselves in a vulnerable position.

#### **HOW WE ENGAGE**

Clinigen engages with national and regional regulatory bodies and patient advocacy groups to support and improve access to medicines for patients. Specifically, Clinigen has created a Patient Innovation Lab ('PIL'), a global, internal network of representatives who are motivated to act as knowledge-sharers and mediators for the patientcentred activity that is undertaken, to share success stories where a patient's life has been impacted, and to champion patient advocacy for the Group as it grows.

#### We engage with our pharmaceutical and biotech clients as early as possible so we can understand the access needs for their medicines. The solutions Clinigen provide will vary depending on the client's long-term commercialisation plans, geographical footprint and internal capability. We flex the solution to fit the client's access needs.

#### **2020 EXAMPLES**

This year, in particular due to disruption caused by COVID-19, providing patients with access to medicines has become more acute, as traditional access via hospitals has been curtailed. Clinigen's direct-to-patient model in Clinical Services means that medicines are prepared, packaged, labelled, and then shipped directly to the home of the patient removing the challenge of having to visit the hospital.

We have deep, wellestablished relationships with pharmaceutical and biotech companies. Clinigen's client base consists of 557 clients, of which it interacts with 21 of the top 25 pharma companies.

clients are one of two customers where Clinigen is able to offer its services to provide access to medicines. Having a large pool of clients enables the Group to provide a differentiated service offering, which makes it the logical partner for pharmaceutical and biotech companies to fully realise the commercial value of their assets and allows the Group to link the pharmaceutical product with the other customer, the HCP.

Pharmaceutical and biotech

HCPs customers are one of two customers where Clinigen is able to offer its services to provide access to medicines. Having a large pool of customers enables the Group to provide a differentiated services offering which makes it the 'go to' company for HCPs to access hard to find medicines for their patients and allows the Group to link the HCP with the other customer, the pharmaceutical and biotech client. Partnering with Clinigen across the product lifecycle enhances value for our pharmaceutical and biotech clients by driving resource efficiencies, simplifying the supply chain model and mitigates the need for multiple vendors. The solution is replicated across the client's product portfolio to ensure the client fully benefits from Clinigen's expertise.

Cliniport and Clinigen Direct provide fast, accessible, and convenient access to our services for HCPs, increasing the number of HCPs in our community and ultimately improving access to medicines for patients in need. The majority of medicines available on Cliniport and Clinigen Direct are unlicensed medicines, and our digital systems ensure a safe and compliant way for HCPs to obtain access. We have built proprietary online ordering platforms, Cliniport and Clinigen Direct, designed to meet the specific needs of HCPs. Our platforms allow us to operate globally to build deep relationships with our customers and help ensure a HCP with a patient in need, anywhere in the world, can always get the right medicine for their individual patient – quickly, easily and safely. This year the Group continues to make good progress, with 18,625 registered users on Cliniport (2019: 15,580), enabling the Group to better interact with the HCP customer.

#### STAKEHOLDER ENGAGEMENT CONTINUED

#### SECTION 172(1) STATEMENT

Section 172 of the Companies Act 2006 requires each Director of the Company to act in the way he or she considers, in good faith, would most likely promote the success of the Company for the benefit of its members as a whole. In this way section 172 requires a Director to have regard, amongst other matters, to the:

- Likely consequences of any decisions in the long term
- Interests of the Company's employees
- Need to foster the Company's business relationships with suppliers, customers and other material stakeholders
- Impact of the Company's operations on local communities and the environment
- Desirability of the Company maintaining a reputation for high standards of business conduct
- Need to act fairly between members of the Company

In discharging its Section 172 duties the Board has considered the factors set out above and the views of key stakeholders. The Board acknowledges that some decisions will not necessarily result in a positive outcome for all our stakeholders. However, by considering the Company's purpose, mission, vision, values and commitment to responsible business together with its strategic priorities and having a process in place for decision-making, the Board aims to ensure that its decisions are in the best interests of the business.

Further information regarding the principal activities and decisions taken by the Board during the year can be found in the section entitled 'Board Leadership and Company Purpose' in the Corporate Governance Statement on page 56.

#### **OUR STAKEHOLDERS**



We employ over 1,150 people in 14 international locations and are committed to a policy of equal opportunities in the recruitment, engagement and retention of employees.



The Board realises that effective communication with shareholders on strategy and governance is an important part of its responsibilities. We have a dedicated investor relations resource focused on increasing awareness among the investor and analyst community.

#### REPRESENTATIVE

"WE ARE PROUD TO BE A TRULY PEOPLE CENTRIC BUSINESS. OUR DIVERSE GLOBAL WORKFORCE BRING TO LIFE OUR CLINIGEN WAY PRINCIPLES. WE ARE PASSIONATE About Employee Engagement and Career Development to Make Clinigen A great place to Work Across The Globe."

Global HR Director

"THE BOARD REALISES THAT EFFECTIVE Communication with shareholders on strategy and governance is an important part of its responsibilities and believes that appropriate steps are taken to ensure that they develop an understanding of the views of Major shareholders."

Head of Investor Relations



Clinigen engages with Competent Authorities including regulators and government departments in order to operate within the appropriate regulatory and legal framework. "CLINIGEN'S INTERACTIONS WITH COMPETENT AUTHORITIES ARE CRITICAL TO OUR SUCCESS AS A BUSINESS. BY CONDUCTING EFFECTIVE INTERACTIONS WITH COMPETENT AUTHORITIES AND OBTAINING NECESSARY APPROVAL WE ENSURE SMOOTH DAY-TO-DAY RUNNING OF THE BUSINESS, OPTIMISE RESOURCES AND SUPPORT GROWTH."

Head of Regulatory Affairs

#### WHY THEY ARE Important to the group

Our employees are vital to help us deliver on our strategic objectives and so we must continue to recruit, develop and retain the right people. We have appropriate remuneration packages to help recruit and retain key employees and our permanent employees are given the opportunity to become shareholders of the Company.

#### WHY THE GROUP Is important to them

Many of our employees are attracted to Clinigen due to the nature of the work in providing access to medicines. In addition, age, colour, race, gender, disability, ethnic origin, national origin, marital status, sexual orientation, religious or political views are not seen as barriers to employment and are evidenced by the Group's diverse employment base.

#### Shareholders play an important role in the success and growth of the Company and have provided a source of equity to help fund some of the acquisitions made. In addition, shareholders provide important feedback to the management team to be incorporated into future dialogue.

Clinigen has delivered long-term value to shareholders through share price appreciation and a progressive dividend policy. It's important for the Group to demonstrate risk management, good corporate governance practices, transparency and leadership.

#### **HOW WE ENGAGE**

We encourage a culture of open communication through a range of two-way mediums including: regular employee representative staff forums; a global intranet platform; newsletters; and regular Group and divisional performance updates from the CEO and CFO. In addition, we utilise Peakon, the world's leading platform for measuring and improving employee engagement.

The Executive Directors and investor relations resource communicate regularly with our shareholders engaging proactively with them and ensuring their views are communicated back to the Board. Interim and final results are communicated via formal meetings with roadshows, participation in conferences and additional dialogue with key investor representatives held in the intervening periods.

#### 2020 EXAMPLES

There were 36 employees who completed the Clinigen Management Academy training program during the year. In addition, the online recruitment platform was launched as well as the global wellbeing program.

The CEO and CFO have a regular dialogue with institutional shareholders engaging proactively with them and ensuring their views are communicated back to the Board. As a team, we engaged with over 160 institutional investors during the year, holding 180 meetings and attending nine international investor conferences. Included within these meetings, the Board also made themselves available prior to the AGM held in November 2019 to the Group's largest institutional investors and proxy companies to provide an opportunity for them to share their feedback on the resolutions past at the AGM and to cover questions more generally.

Competent Authorities are responsible for ensuring that medicines and medical devices meet applicable standards of safety, quality and efficacy. In addition, they are responsible for ensuring that the supply chain for medicines and medical devices is safe and secure. Competent Authorities grant licences and permits to allow the sale, supply, distribution and marketing of medicines and devices as well as performing ongoing vigilance.

Competent Authorities rely upon Clinigen to ensure compliance standards are met, to ensure that medicines and medical devices meet applicable standards of safety, quality and efficacy. In addition, requiring Clinigen to support the prevention of counterfeit and substandard products entering the supply chain. Clinigen engages with Competent Authorities via various routes, including submissions for Marketing Authorisations and process licences, obtaining approvals for supply of medicines and medical devices, requesting advice, and during periodic inspections. Clinigen keeps up to date with Competent Authority requirements via changes in legislation, training and attendance at symposia/conferences. In the past financial year, Clinigen has supported several inspections, from Competent Authorities around the world. Clinigen has also supported many Competent Authorities with the COVID-19 pandemic, in securing life-saving medications to meet supply shortages. Clinigen submitted and obtained new Marketing Authorisations to various Competent Authorities, successfully renewed and submitted licence variations and licence transfers. Clinigen also obtained a US ODD for aldesleukin and obtained approvals for compassionate use programs on behalf of clients.

#### **MARKET OVERVIEW**

Clinigen operates at the key stages of a pharmaceutical product's lifecycle as a specialist outsourced pharma service provider whilst marketing its own and partner products directly as a pharmaceutical company.

It has a unique business model that provides access to medicines and services across clinical trials, for early access purposes, on an unlicensed basis post-approval and for those that are commercially available. The Group operates in large, high growth international pharmaceutical markets with both macro trends which affect the industry and micro trends specific to each of the Group's three business operations. Some of the more common macro market trends and key market drivers for Clinigen are discussed in this Market Overview.

#### **KEY TO STRATEGIC OBJECTIVES**

- 1 Develop and retain talented people
- 2 Upgrade technology platform to drive organic growth
- **3** Expand and embed a global community of HCPs and opinion leaders
- 4 Expand portfolio of global, regional and licensed assets
- **5** Become the 'go to' leader in ethical access to unlicensed medicines
- 6 Extend global footprint into remaining key markets
- 7 Link the businesses to realise synergistic opportunities and increase pharmaceutical customer base

### **CLINIGEN'S MARKET DRIVERS AND DIFFERENTIATORS**

### **CLINICAL SERVICES**

#### MARKET DRIVERS

- Need for agility, flexibility and rapid response times to meet client demands
   Clients increasingly require more complex solutions (such as growth of IIT market) from fewer vendors
- Drive to reduce the cost of clinical development (i.e. comparator product sourcing) and time to market

#### UNLICENSED MEDICINES Market Drivers

- Increased role of patient advocacy groups and online resources leading to greater patient demand
- Clients increasingly wanting a global partner to manage supply and distribution beyond managed access
- Increased pressure to ensure integrity of supply chain including shortages to give patients continuity of supply
- Increased need for RWD to demonstrate value for market access and reimbursement

#### COMMERCIAL MEDICINES Market Drivers

- Portfolio rationalising by large pharmaceutical companies
- Clients increasingly looking to rationalise territories and partner with regional specialists to manage the lifecycle of products
- Increased pressure to have unlicensed products available as licensed products by regulatory authorities, HCPs and patients to improve access

#### CLINIGEN DIFFERENTIATORS

- Global supply chain and distribution network
- Qualified supply chain certifies product for authenticity
- Integrated service offering from clinical trial, to IITs to early access
- Regulatory expertise
- Broad and embedded relationships with both pharmaceutical and biotech clients and HCP customers
- Provide a range of innovative service capabilities ('ondemand', direct-topatient)

#### **CLINIGEN DIFFERENTIATORS**

- Broad and embedded relationships with pharmaceutical companies
- Expert understanding of complex regulatory environments globally
- Global supply chain and distribution network
- Proprietary online management platformAbility to manage
  - unlicensed supply from Managed Access to Global Access

#### **CLINIGEN DIFFERENTIATORS**

- Broad and embedded relationships with pharmaceutical companies to act as the preferred licensee of choice for non-core markets or as Global distributor
- Proven revitalisation capability
- Expert understanding of complex regulatory environments globally
- Capability to convert unlicensed medicines to licensed medicines
- Growing MSL and sales capability in the US, EU and selected AAA territories

### **GLOBAL MARKET TRENDS**

#### IMPACT FROM COVID-19 Strategic Link: 5 + 6

Impacts: CS/ULM/CM<sup>1</sup>

The sudden emergence of the COVID-19 pandemic has significantly impacted countries, industries and people around the world. In the pharmaceutical industry, many companies are currently focusing on treatments or vaccines with large investments in antiviral drugs and vaccines being funded by both industry and governments. However, the pandemic will reach beyond those companies searching for vaccines and is impacting the global pharmaceutical supply chain from drug manufacturing to operations, logistics and distribution both for large pharmaceutical companies, biotechs and those companies to which services are outsourced. It is not known how long this period of disruption and uncertainty will continue for, however, the trend in increased demand for access to medicines is unlikely to abate and those companies operating in the pharma industry will have to adapt and innovate in order to ensure prescribers and patients receive the right medicine at the right time.

Clinigen has worked closely with its pharmaceutical clients as well as its HCP customers to ensure that the supply of critical medicines to patients on a global basis continues uninterrupted. Although the Group has not been immune to the pandemic, it has lessened the impact by pivoting quickly its activities to support efforts against the pandemic, including in Clinical Services, increasing its direct-to-patient services and working with multiple pharmaceutical companies to get their medicines to market quicker and in Managed Access in Unlicensed Medicines, supporting access to COVID-19 related clinical studies via MAPs.

NUMBER OF COVID-19 RELATED CONTRACTS The group has won

# 26

#### STRUCTURAL GROWTH IN 'EMERGING' PHARMA MARKETS STRATEGIC LINK: 3 + 4 + 5 + 6 Impacts: CS/ULM/CM<sup>1</sup>

While pharmaceutical sales in 'mature' markets are showing anaemic growth, sales estimates in 'emerging' markets suggest continued growth with 'emerging' markets now accounting for over 30% of the total pharma market. The growth in 'emerging' markets is a consequence of several economic and demographic factors, including populations becoming larger and wealthier, increasing life expectancy and improved access to healthcare.

Although these 'emerging' markets may seem like sensible areas in which to expand into, doing so is not straightforward due to regulatory complexity, with every country in the world having extensive regulations, diverse infrastructures and complicated market dynamics.

As a consequence, many pharmaceutical companies consider it too difficult and uneconomic and instead their access to market strategy is focused on making medicines commercially available in a relatively small number of 'mature' pharmaceutical markets (c.25 markets). This leaves the remaining 'emerging' markets underserved leading to an unmet medical need which is often serviced by unlicensed medicines. Every country in the world has extensive regulations detailing how to manage access to unlicensed medicines. Unlicensed supply into these 'emerging' markets can account for 15-20% of a medicine's global revenues and profits and provides an alternative commercial access strategy. However, in order to fully benefit from this opportunity, a customised approach must be taken, which could include utilising the services of a niche and specialist service provide such as Clinigen.

Clinigen's strategy is to extend its global footprint into key markets and is ideally placed to improve access to medicines to HCPs and their patients, by utilising its sophisticated and complex global supply and distribution engine.

SIZE OF 'EMERGING' MARKETS AS % OF TOTAL PHARMA MARKET



#### RESEARCH & DEVELOPMENT TRENDS STRATEGIC LINK: 4 + 5 + 6 Impacts: ULM/CM<sup>1</sup>

There are three important research and development trends in the pharmaceutical industry:

a) Increase number of drugs in development and greater growth from preclinical to Phase II: The number of drugs in the R&D pipeline has consistently increased year on year for the past 20 years. In 2019, the number of drugs in development amounted to 16,181, an increase of 6% on the prior year. The greatest growth of drugs in development are those from preclinical to Phase II. These account for 83% of the total drug count and grew 7% in 2019. The remainder of the drugs in development from Phase III onwards account for only 17% and grew only 2% in 2019.

**b)** The rise of biotech: In 2011, the top ten pharmaceutical companies owned over c.13% of the total drug pipeline. This steadily decreased to c.6% in 2019. Whilst biotech companies, who have just one or two drugs in development, make up an increasing percentage of the pipeline. In 2011 they contributed c.15% of the total pipeline, which had increased to c.20% in 2019.

**c) Greater focus on oncology:** In 2011, c.28% of the drug pipeline was in oncology, this had increased to c.35% in 2019.

Collectively these trends demonstrate the structural growth drivers in the markets in which Clinigen operates. With CSM, the Group is now able to establish relationships early in the product lifecycle, where there are a greater number of drugs in development, with the greatest development growth rates and where there are a greater number of clients. CSM are then able to pass the client on to Clinigen's other businesses to extend and amplify the financial returns. In addition, Clinigen has an inherent expertise in oncology from Managed Access, where nine of its top ten MAPS are in oncology to its Commercial Medicines portfolio where in owns five oncology medicines.

#### % OF R&D PIPELINE REPRESENTED BY DRUGS IN ONCOLOGY

35%

 CS = Clinical Services ULM = Unlicensed Medicines CM = Commercial Medicines

#### Q&A WITH CLINIGEN CEO, SHAUN CHILTON

Clinigen CEO, Shaun Chilton, discusses the Group's performance in 2020 and addresses some common questions received from investors over the past year.



"AS A TEAM WE ATTENDED 180 INVESTOR MEETINGS IN THE YEAR. THESE MEETINGS ALLOW US TO COMMUNICATE THE GROUP'S PERFORMANCE AND STRATEGY BUT ALSO PROVIDE AN OPPORTUNITY FOR US TO LISTEN TO INVESTOR FEEDBACK AND CONCERNS DIRECTLY. THIS Q&A PROVIDES A FORUM TO ILLUSTRATE THE KEY QUESTIONS FROM THESE MEETINGS TO A WIDER AUDIENCE."

### WHAT IS THE CLINIGEN BUSINESS MODEL?

Clinigen is dedicated to providing greater access to medicines around the world and in doing so delivering incremental value from pharmaceutical products by extending and expanding its lifecycle.

Clinigen achieves this through operating as a pharmaceutical and pharma services group. Clinigen has three businesses; Clinical Services, Unlicensed Medicines and Commercial Medicines - each working synergistically, using the Group's global operating platform, to facilitate access to medicines at key points of a product's lifecycle. The Group's mission is 'Right Medicine, Right Patient, Right Time' (see pages 10 to 11 which illustrate the business model in more detail).

### CAN YOU EXPLAIN WHAT CLINIGEN'S **DIFFERENTIATED OFFERING IS?**

As the global leader in access to medicines, Clinigen's aim has been to create an international, integrated, synergistic business that positions itself as the most logical partner for two distinct but directly connected customer groups:

- 1) Pharmaceutical and biotech companies, increasing the value of their product(s) through lifecycle management; and
- 2) HCPs, particularly hospital pharmacists, giving them a 'go to' compliant, safe and ethical way to source hard to access medicines.

We operate in markets and geographies with long-term growth potential and underserved needs

#### WHAT HAS BEEN THE IMPACT OF COVID-19 ON THE GROUP?

During the COVID-19 pandemic, we immediately implemented a range of measures to prioritise keeping its employees safe, including extensive home working. The Group worked closely with its pharmaceutical clients and its hospital customers to ensure that the supply of critical medicines to patients on a global basis continued uninterrupted.

During the fourth quarter, the Group experienced more meaningful disruption to its activities from COVID-19. but continued to deliver good progress overall. Clinical Services was impacted by clinical trials being delayed or cancelled, whilst both Commercial Medicines and Unlicensed Medicines saw reduced volume demand as treatments in the hospital setting, particularly for oncology, slowed. However, the Group quickly pivoted activities to support efforts against the pandemic, resulting in material contract wins, whilst containing costs to lessen the impact from a lower top line performance.

We estimate that the impact of COVID-19 to be between 5 to 7% to adjusted EBITDA in FY20, with this primarily related to Proleukin as treatment centres shut and demand fell. As expected, these headwinds have continued throughout the first quarter of the current financial year and are expected to continue through the second quarter. The Group has seen signs of recovery, specifically from territories that have begun to relax restrictions related to the pandemic or have adapted to the new working environment, but as expected the recovery is protracted, shows variability by geography, and hospital demand in particular remains lower than normal.



I believe we have delivered a strong financial performance with organic net revenue growth of 8% and organic adjusted gross profit growth of 10%, at the top end of our guidance, despite difficult trading conditions due to the COVID-19 pandemic.

In Commercial Medicines, there were good performances across the portfolio, albeit growth in the final quarter was impacted due to COVID-19 disruption (see above). Within Unlicensed Medicines, Global Access performed

well despite continuing headwinds in the UK Specials business whilst in Managed Access, the performance was weaker despite an improved second half that was boosted by a material number of program wins. Within Clinical Services, whilst the pandemic led to a reduction in activity with clinical trials being delayed or cancelled, the performance of both CTS and CSM was encouraging against a tough market backdrop.

In addition, we achieved operational leverage with adjusted EBITDA growth higher than the growth in adjusted gross profit both at a headline level and on an organic basis, demonstrating the focus we have on driving efficiencies across the Group.

Therefore overall, I believe on an organic basis, the performance of the Group was strong and we are well positioned to drive further organic growth this year. A more detailed breakdown of organic growth by business is included in the Operational Review (see pages 34 to 39).

#### HOW WOULD YOU VIEW THIS YEAR'S PROGRESS AGAINST YOUR STRATEGIC OBJECTIVES. WHAT HAS **GONE WELL AND WHERE COULD IMPROVEMENTS BE MADE?**

Overall, I would view this year as having made good progress against the Group's strategic objectives.

We implemented the Group's ERP system (see overleaf), expanded our portfolio of licensed assets in key territories, including the agreement signed with PBL to commercialise Erwinase (see overleaf), increased the number of MAPs which will help to support growth in the Unlicensed Medicines business in the mid term, increased the number of both the pharmaceutical client base and HCP customers in which we interact with and extended our global footprint by increasing the number of countries in which we distributed medicines.

Our international platform and balanced portfolio of complementary services and products have shown real resilience against the backdrop of the COVID-19 pandemic.

However, as a Group there are always areas in which to improve that are centred around realising the synergistic opportunities that exist between the Groups three businesses by developing further the relationships and partnerships we have established with our clients and customers and utilising the international platform we have built to drive greater financial returns.

#### **Q&A WITH CLINIGEN CEO, SHAUN CHILTON CONTINUED**

#### "OVERALL, I WOULD VIEW THIS Year as having made good Progress against the group's Strategic objectives."

### WHERE ARE THE GROUP'S GREATEST OPPORTUNITIES?

Given the Group's international platform and balanced portfolio of complementary services and products, there are many opportunities.

I, and the Board, believe that the greatest opportunity is to realise the synergies that exist between the three business operations and central operating platform. Through our buy and build strategy, we now have the geographical footprint and infrastructure to offer a comprehensive service offering from Phase I through to commercial launch and the supply and distribution of commercial medicines. By leveraging the platform more effectively we will continue to drive growth.

As a result of building out the commercial platform both in the US, from the acquisition of Proleukin and in the EU, from the acquisition of iQone, the Group has, and is being presented with, many more opportunities to acquire products or partner with pharmaceutical companies to supply and distribute their assets, as demonstrated with the exclusive supply and distribution agreement for Erwinase. This type of agreement would not have been possible without the commercial infrastructure in the US and from having an international platform which is capable of supplying unlicensed medicines.

The Group also has a great opportunity from owning the global rights to Proleukin (see below).

#### **U** Would you be able to discuss The opportunities for proleukin?

Proleukin is currently being used in many active studies across multiple therapeutic areas and indications. This broad usage demonstrates the opportunity to increase sales into clinical trials but also provides a mid-term opportunity by increasing the market if any of these trials are successful. Two of the more immediate opportunities relate to emerging cell therapies such as TIL's and the use of aldesleukin (the API of Proleukin), in the treatment of ALS.

Proleukin is being investigated alongside TIL therapies within a number of new and existing oncology indications. Data for adoptive cell therapy has been presented

that showed significant benefit to patients within both metastatic melanoma and cervical cancer. If these treatments are approved, we see a significant commercial opportunity for Proleukin, with an immediate market opportunity of c.5k patients.

In July 2020, we announced that the US Food and Drug Administration ('FDA') Office of Orphan Products Development ('OOPD') granted ODD for aldesleukin in the treatment of ALS. Aldesleukin is the API used in Proleukin. An ODD in the US recognises the potential therapeutic role of aldesleukin in this devastating disease and could provide a number of benefits for Clinigen should it obtain a marketing approval for this indication. These benefits include seven years marketing exclusivity within the US upon launch, along with tax credits for clinical development costs and fee waivers.

In addition to the above, we continue to explore the use of Proleukin and aldesleukin in several other therapeutic areas where its use may have a beneficial clinical effect.

#### WHAT ARE CLINIGEN'S GREATEST Threats and challenges?

Operating in niche market segments has presented us with many opportunities. The greatest challenge is to decide which of these opportunities provides the Group with the best chance to realise our mission to deliver the right medicine, to the right patient, at the right time and to generate long-term shareholder value. The other significant challenge is to make sure we keep talent and develop it, a key strategic objective for the Group, whilst also adding key service capabilities to ensure we can continue to grow.

More immediate challenges relate to the uncertainty caused by the pandemic, the generic threat to Foscavir and the stock situation for Ethyol.

We are aware of an approval for a Foscavir generic in the EU but have not seen any formal product launch. It is not possible to quantify precisely the financial impact that the launch of a generic alternative to Foscavir will have on Clinigen's revenues, or how quickly such an impact would take effect. However, the Board has long anticipated the generic threat and are enacting its strategy to mitigate loss and expect the impact to be captured within its mediumterm organic gross profit guidance. Whilst for Ethyol, we expect no sales in FY21 following the failure of a manufacturing tech transfer process leading to an out of stock situation. This impact has been captured within management's forward-looking guidance and expect the product to return to market in FY22.

## COULD YOU EXPLAIN THE STRATEGIC RATIONALE BEHIND THE ERWINASE AGREEMENT?

In April 2020, the Group announced it had signed an exclusive global licensing and distribution agreement with PBL to commercialise Erwinase.

We will look to expand the market opportunity for Erwinase by driving awareness of the product's availability, ensuring uninterrupted patient access, launching in select new countries and increasing the global supply of the product into unlicensed markets utilising its global infrastructure through a global access program.

Erwinase will be the Group's third biologic and fits well within Clinigen's existing haematology and oncology product portfolio and customer base. It further strengthens and leverages Clinigen's newly established commercial infrastructure in both the EU and higher value US market where it currently owns the rights to Proleukin, Foscavir, Ethyol and Totect<sup>®</sup>.

Whilst the agreement will start on 1 January 2021, it is anticipated that net sales for Clinigen will begin in the second half of 2021 as the product is transitioned from PBL's current licensing partner.

### Q What can we expect on M&A going forward?

We will continue to focus primarily on organic growth but also continue to look at selective acquisitions to extend capability and create long-term growth opportunities underpinned by more extensive competitive advantage.

M&A also needs to fit within the Group's capital allocation framework which exists in order to prioritise the use of cash and maximise shareholder value whilst retaining the flexibility to make value enhancing acquisitions.

#### **U** The group launched its ERP system in October, how has that gone?

The Group's ERP system was implemented in October 2019. The ERP is designed to deliver automated, streamlined operational activities and processes to increase the Group's efficiency and productivity.

Upon implementation, several process issues were identified, from order creation to shipping and billing, and whilst most were resolved within weeks, some remain at year end, which is not unusual in a project of this scope and scale. The challenges faced included delays in invoicing and subsequent cash collection which led to a working capital outflow in H1, which partially reversed in H2 and should continue to reverse during FY21. The Group is now working to maximise the benefits of the ERP with the next stages of implementation to make the business ready for unified digitalisation in FY21 (see pages 32 to 33 which illustrates the path to unified digitalisation).

The ERP 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.

#### WHAT ARE THE MAJOR MILESTONES TO LOOK OUT For in Fy2021? What does success look like?

The Group remains in a good position to capitalise on the substantial opportunity in its markets and drive further growth in the year ahead.

Trading to date at this early stage of the current financial year is in line with market expectations, with the impact of COVID-19 continuing, but at an improved level from Q4 FY20. The Group's medium-term guidance is for future organic net revenue growth to be between 5-10%, with FY21 expected to be at the lower end due to the impact of COVID-19, which is expected to subside, and an expected launch of a generic Foscavir in the EU. Given the above and the timing of contracted Proleukin shipments, H1 is expected to be below the prior year followed by a return to growth in H2. This will be more evident within Commercial Medicines and Unlicensed Medicines where the impact of COVID-19 has been greater.

Growth in FY22 is then expected to significantly accelerate as new asset Erwinase is onboarded and the Group continues to gain share in the endmarkets it serves. Management sees the potential for higher organic growth as Proleukin revitalisation takes place and as it gains traction within new indications.

In addition, we aim to paydown and maintain net debt within a range of 1.0–2.0x EBITDA on an ordinary basis within 12–18 months.

As mentioned above, we have many exciting opportunities, but we also need to remain disciplined on making the expected progress against the core KPIs in each of the three businesses and for the Group as a whole.

### DOES THE BOARD HAVE ANY PLANS TO MOVE TO THE MAIN MARKET?

At Clinigen's IPO in 2012, the market capitalisation was £135m, since then Clinigen's growth has made it one of the largest companies on AIM. We have made six corporate and six product acquisitions, therefore, being on AIM has been useful for the Group and to many of our stakeholders.

We have in the past and continue to assess our status on AIM and take the appropriate counsel from our advisers. There are clearly some advantages of moving to the Main Market but we need to weigh these up with the advantages we have as an AIM-listed company to ensure that we make the right decision, at the right time.

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. Acquisitions completed in the previous financial year are included on a like-for-like basis including the results for the acquisition where it is included in the comparable historical period. Organic growth is presented to aid the reader's understanding of the underlying performance of the business. In previous reports, organic growth was calculated on a pro forma basis with the comparative period results before acquisition based on the vendors' previously reported results. The like-for-like basis now used has been necessary due to the limited reported financial information available for the products' results prior to acquisition by Clinigen. On a pro forma basis, the best estimate for organic adjusted EBITDA growth for the year ended 30 June 2020 is 12%

#### **OUR TRACK RECORD AND FUTURE GROWTH GUIDANCE**

#### **OUR HISTORICAL PERFORMANCE**

#### 2010

Clinigen Group formed by Peter George. Acquires its first product, Foscavir

#### 2011

Recognised as the fastestgrowing private company in the UK by the Sunday Times Virgin Fast Track 100

#### 2012

Lists on the AIM of the London Stock Exchange – the first UK healthcare company to list in London in five years

#### 2013

Wins Best Newcomer at the London Stock Exchange AIM Awards. Acquires its second product, Cardioxane

#### 2014

Extends headquarters in Burton-on-Trent, UK. Acquires its third product, Savene and fourth product, Ethyol

#### 2015

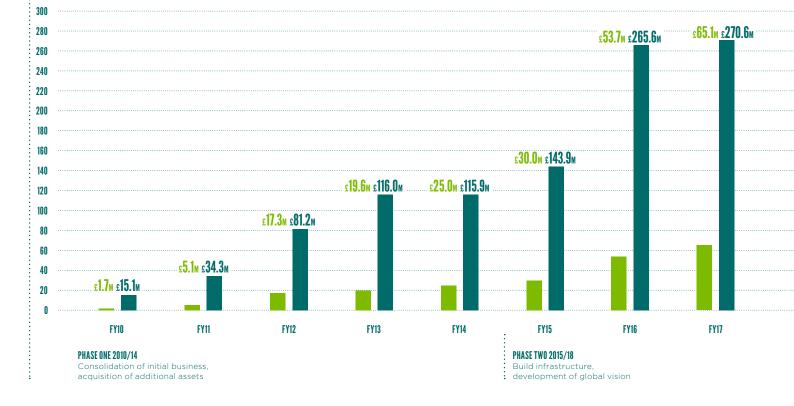
Acquires Idis to become the global leader in providing ethical compliant access to unlicensed medicines. Acquires Link Healthcare ('Link') to expand its ability to provide access to medicines for patients in the AAA region

#### 2016

Acquires its fifth product, Totect, and Foscavir bag line extension

#### 2017

Acquires IMMC, strengthening the Group's presence in Japan, the world's second largest pharmaceutical market. Acquires Quantum, strengthening Clinigen's position as global leader in ethical access to medicines







#### 2018

Acquires its sixth product, Proleukin (global rights outside the US) and its seventh product, Imukin (global rights outside the US, Canada and Japan). Acquires CSM, a specialist provider of packaging, labelling, warehousing and distribution. Acquires iQone, a Swissbased specialty pharmaceutical business providing EU MSL capability

#### 2019

Acquires the US rights to Proleukin, providing breadth and diversity to the portfolio and creating an ideal platform to expand existing footprint in higher value US market

#### 2020

Signs exclusive global licensing and distribution agreement to commercialise Erwinase, strengthening Clinigen's existing product portfolio and customer base

 CAGR growth covers the ten-year period between FY10 and FY20.



As announced at the full year results in September 2019, the Group has now changed its reporting structure to a divisional EBITDA profit-level model, akin to industry peers. Management believes this will lead to better internal cost control and P&L accountability whilst allowing for easier interpretation of results by external stakeholders.

#### **OUR FUTURE ASSUMPTIONS**

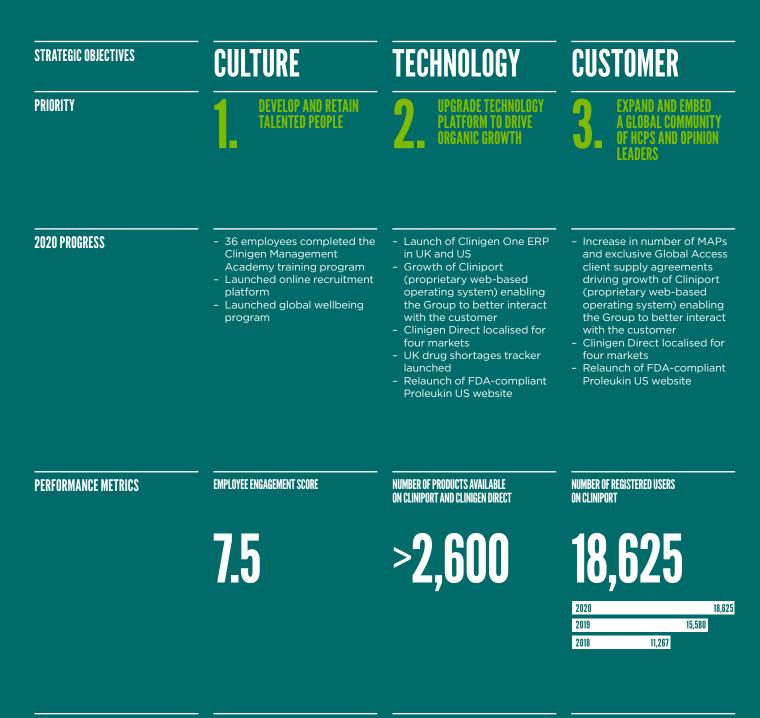
- Proleukin revitalisation within new indications would lead to above
- upper-end growth guidance achievedOnboarding of Erwinase commencing
- in FY21 with revenues from FY22
  Revenue synergies across the Group leading to top-end growth expectations
- Continued revitalisation of Acquired Products portfolio
- Further 'program' to 'partner' and regional partner agreements signed
- Underlying market dynamics remaining positive – some impact from COVID-19 but expected to be short term
- Continued delivery from Developed Products pipeline
- Modest expectations for lower revenue visibility businesses
- Modest decline in UK Specials' market
- Material decline to Foscavir following generic approval in EU and expected approval in US

# organic net revenue cagr 5-10%

PHASE THREE 2018 ONWARDS Global positioning, differentiation

of businesses, genuine lifecycle partnership

#### STRATEGY



#### 2021 OBJECTIVES

- Integrate culture and values across the Group
- Implement a global HR system
- Develop a strategic resourcing plan
- Improve people
- management capabilities
- Regionally based customer services
- Enhanced online ordering platform for Managed Access and 'on-demand' businesses in Unlicensed Medicines and for Commercial Medicines
- Enhanced UK online ordering platform for QPL and Aseptics businesses in Unlicensed Medicines
- Increase number of users and amount of activity through Cliniport and Clinigen Direct
- Expand MSL and commercial capability in the US and the EU
- Drive Key Opinion Leader ('KOL'), hospital pharmacist and pharmacy group engagement across markets
- . Number of local, regional and global assets under management includes all products in the Commercial Medicines portfolio.
- Number of exclusive supply agreements includes MAPs, exclusive Global Access client supply agreements and exclusive customer supply agreements in UK Specials business.

#### **BUSINESS** EXPAND PORTFOLIO Of Global, regional BECOME THE 'GO TO' LEADER IN ETHICAL **EXTEND GLOBAL** LINK THE BUSINESSES **FOOTPRINT INTO** TO REALISE SYNERGISTIC AND LICENSED ASSETS ACCESS TO UNLICENSED **REMAINING KEY** OPPORTUNITIES MARKETS AND INCREASE PHARMACEUTICAL CIISTOMER BASE Exclusive global licensing EU entity established to Exclusive global licensing Increase in the number of and distribution agreement maximise 'on-demand' and distribution agreement pharmaceutical and biotech signed with PBL to opportunity signed with Porton companies working with all commercialise Erwinase Increase in number of MAPs Biopharma to commercialise business operations strengthens commercial and exclusive Global Access Erwinase strengthens - iQone supporting offering in key markets client supply agreements commercial offering in key implementation and 'Shortage Scramble Team' management of MAPs Collaboration with GC markets Pharma in Japan to submit established to maximise the - Internationalisation of - Cross-divisional referrals new drug application for opportunity in fulfilling **Developed Products** driving pipeline and leading Hunterase global drug shortages portfolio to new business wins Exclusive agreement signed Rapidly flexed resources and with Cheplapharm in efforts to react to COVID-19 related MAPs and Global Australia and New Zealand to distribute Etopophos and Access 'on-demand' opportunity Venesid Internationalisation of Developed Products portfolio NUMBER OF LOCAL, REGIONAL AND GLOBAL NUMBER OF EXCLUSIVE SUPPLY AGREEMENTS ADJUSTED NET REVENUE BY REGION NUMBER OF PHARMACEUTICAL AND BIOTECH **ASSETS UNDER MANAGEMENT** IN UNLICENSED MEDICINES COMPANIES WHO HAVE WORKED WITH ALL THREE BUSINESS OPERATIONS 205 2892020 289 2020 205 2020 54% 25% 21% 2019 262 2019 192 18% 2019 60% 22% 2018 232 2018 208 2018 52% 25% 23% Europe ● US **O** RoW

- Further conversion of UL2L pipeline
   Further internationalisation
- of Developed Product
- Continue to search for selective acquisitions and in-licensing agreements
- Conversion of MAPs to regional licensing opportunities
- Expand and deepen our client base in Managed Access
- Grow and develop our portfolio of exclusive supply agreements
- Drive growth in EU entity by developing portfolio, pricing and customer experience in key EU markets
- Build RWD capability to provide a differentiated service to clients
- Ensure smooth delivery of enhanced digital ordering platforms
- Further partnership agreements signed to expand geographical reach, particularly in the LATAM and the Middle East
   Further expansion of
- commercial infrastructure in US and EU
- Increase the number of pharmaceutical and biotech companies working with all business operations
- Increase the number of companies working with at least two business operations
- Increase the number of top 50 companies in which the Group has a relationship
- Secure new business wins by moving a client or molecule through Clinigen's lifecycle platform

#### **KEY PERFORMANCE INDICATORS**

Our performance is measured against a number of KPIs.

### **FINANCIAL**

ADJUSTED NET REVENUE (£M)

466.2		<b>^15</b> %
2020		466.2
2019		407.0
2018	300.8	
2017	270.6	
2016	265.6	

Why we measure it: Adjusted net revenue is viewed by the Board as the preferred measure of topline performance. It allows management to assess the performance of the business after removing the impact of pass through revenue which varies dependent on the mix of 'charged-for' and 'free of charge' programs. Net revenue provides additional information to enable management and users of the accounts to assess growth in the business and improved comparability of margin year on year.

**Performance:** Adjusted net revenue increased by 15%, driven by both the acquisitions made in FY19 and a strong underlying performance.

#### **ADJUSTED BASIC EPS (PENCE)**



Why we measure it: Adjusted EPS growth allows management to assess the post-tax underlying performance of the business in combination with the impact of capital structure actions on the share base.

**Performance:** Adjusted EPS increased 20% reflecting the Group's higher adjusted profit from operations, partially offset by dilution and higher finance costs following the acquisitions.

These KPIs contribute to the success of the Group and form a component of the Executive Directors' and senior management's incentives. As previously guided, the Group has now changed its reporting structure to a divisional EBITDA profit-level model, akin to industry peers. Management believes this will lead to better internal cost control and P&L accountability whilst allowing for easier interpretation of results by external stakeholders.

#### ADJUSTED EBITDA (£M)



Why we measure it: Adjusted EBITDA provides management with an approximation of cash generation from operating activities after removing transactions that are not reflective of the underlying performance of the business.

**Performance:** Adjusted EBITDA increased 30% benefiting from the increase in net revenue, good operational leverage, and robust cost control.

**STRATEGIC LINK: 5** 

205

208

192

138

#### **NON-FINANCIAL STRATEGIC LINK: 4** NUMBER OF LOCAL, REGIONAL AND NUMBER OF EXCLUSIVE SUPPLY **GLOBAL ASSETS UNDER MANAGEMENT**<sup>1</sup> AGREEMENTS IN UNLICENSED MEDICINES<sup>2</sup> **~10**% 289 2020 2020 2019 2019 262 2018 232 2018 2017 197 2017 2016 180 136 2016 Why we measure it: Measures the quantity of Why we measure it: Measures the quantity products in the Commercial Medicines portfolio, of exclusive supply agreements in Unlicensed demonstrating the business's potential for Medicines, demonstrating the business's future growth. potential for future growth. **Performance:** Growth in the number of products Performance: The increase in the number of in the portfolio was driven by an increase in products in the portfolio was driven by the the number of local marketed licences and number of MAPs. branded generic products in the AAA region. **COMMUNITY OF REGISTERED STRATEGIC LINK: 3 KEY TO STRATEGIC OBJECTIVES USERS ON CLINIPORT** 1 Develop and retain talented people 2 Upgrade technology platform to 18,625 drive organic growth **~20**% 3 Expand and embed a global community of HCPs and opinion leaders 4 Expand portfolio of global, regional 2020 18,625 and licensed assets 2019 15,580 5 Become the 'go to' leader in ethical 2018 11.267 access to unlicensed medicines 6,593 2017 6 Extend global footprint into remaining key markets 2016 3.037 7 Link the businesses to realise synergistic opportunities and Why we measure it: Measures the progress made in increase pharmaceutical customer building a community of HCP customers. base Performance: Growth has been driven by an increase in the number of exclusive supply agreements in Unlicensed Medicines. 1. Number of local, regional and global assets under management includes all products in the Commercial Medicines portfolio.

2. Number of exclusive supply agreements includes MAPs, exclusive Global Access client supply agreements and exclusive customer supply agreements in the UK Specials business.

#### **STRATEGY IN ACTION**

# CSM INTEGRATION UNIQUELY POSITIONED

The acquisition of CSM in October 2018 gave the Group a broader complementary offering to the comparator sourcing service offered through CTS.

Collectively, CTS and CSM form the Clinical Services business and provide a diversified set of value-added clinical services: comparator and ancillary sourcing, 'on-demand' specialist packaging, labelling, supply and distribution, and biological sample management in the US, Belgium and Germany.

#### INTEGRATION WITH CTS AND THE WIDER GROUP

The earn-out period associated with CSM was completed on 31 December 2019 and more meaningful steps are now being undertaken to integrate CSM with CTS as Clinical Services (see the Financial Review on pages 40 to 43 for more details on the deferred consideration). In March 2020, an Executive Vice President was appointed to take the business to the next stage in its development. Business Development and strategic sourcing are working under one leadership and management structure, which has already led to revenue synergies with CTS, with the expectation that this will now increase. Since CSM's acquisition, 23 introductions have been made to Unlicensed Medicines and 18 introductions have been made from Unlicensed Medicines to Clinical Services, reinforcing the links between the Group's business operations.

CSM's financial year has now been aligned with Clinigen's, making consolidation easier and the Group's Clear Review performance management system has been implemented helping to bring the Group's wide HR processes to CSM employees.

A branding review is currently being undertaken to harmonise the CSM brand into Clinigen to ensure continuity with the Group's corporate communication and marketing strategy.

In addition, an IT strategy is being developed which is focused on improving standardisation with the Group and increasing automation.



LOCATIONS UNITED KINGDOM, UNITED STATES, AUSTRALIA, SINGAPORE

29

# 

CSM CLIENTS **3652** LOCATIONS

UNITED STATES, GERMANY, Belgium

#### BRINGING OF BROADER SERVICE OFFERING AND MARKET OPPORTUNITY

The market size in the niche in which Clinical Services operates is estimated to be between US\$4-5bn, growing between 5-8% per annum. Despite Clinigen's market-leading position in CTS, Clinical Services' market share is less than 5%, illustrating the size of the opportunity. Opportunities to increase financial returns, accelerate growth and increase market share include:

- Meeting unmet/underserved market need
- We now have a broad specialist service capability across the Clinical Services spectrum to offer to clients increasingly looking to outsource. This includes servicing the expanding IIT market and offering our unique platform to address client demand for 'on-demand packaging' and 'direct-topatient' services
- Strengthening market-leading positions by crossselling CTS and CSM specialist capabilities to clients
- Geographical expansion into Clinigen's other key regional hubs
- Strengthening the links between Clinigen's three businesses by cross-selling Clinigen's Unlicensed Medicines service capability to clients earlier in the product lifecycle and supporting packaging, labelling and distribution services in Clinigen's Unlicensed Medicines and Commercial Medicines business operations

The attributes within Clinical Services needed to seize the market opportunity include:

- Having a range of offerings and capabilities that are global yet nimble
- Offering unrivalled ethical access to branded and generic medicines
- Establishing and developing long-term relationships with clients early in the pharmaceutical product lifecycle
- Continually innovating service offering ('on-demand packaging', 'direct-to-patient')
- Focus on client satisfaction

Clinical Services provides a compelling service offering to pharmaceutical and biotech clients in the market in which it operates. In addition, establishing a client relationship early in the product lifecycle will lead to further financial opportunities with greater returns for Clinigen's Unlicensed Medicines and Commercial Medicines businesses.

#### LINK TO STRATEGIC OBJECTIVES

Become the 'go to' leader in ethical access to unlicensed medicines CSM was a complementary acquisition which has strengthened the service offering within Unlicensed Medicines and provide a further differentiation against the Group's competitors.

Extend global footprint into remaining key markets

CSM has added high-quality facilities in Belgium and Germany and complementary sites and warehouses in the US extending the Group's supply and distribution reach.

Link the businesses to realise synergistic opportunities and increase pharmaceutical customer base CSM increases size of customer base at early stage of product lifecycle and additional capabilities have enhanced proposition across the Group's three business operations.

#### STRATEGY IN ACTION CONTINUED

# PROLEUKIN POTENTIAL MARKET OPDORTUNITES DEPORTUNITES

Proleukin (aldesleukin or recombinant interleukin-2, 'IL-2') remains the only FDA-approved IL-2 and is indicated for the treatment of adults with metastatic renal cell carcinoma ('metastatic RCC') and in certain markets for treatment of adults with metastatic melanoma ('mM').

It is one of two biological therapeutics Clinigen owns which are more attractive than small molecule medicinal products due to their greater inherent protection against generic threat. Proleukin has significant potential for revitalisation, not only in the current indications but also for potential new indications across multiple therapeutic areas.

#### POTENTIAL MARKET OPPORTUNITIES

Demonstrating the potential to become an integral part of future oncologic combination therapies, Proleukin is currently being used in over 110 active studies across multiple therapeutic areas and indications. This investigational usage creates an opportunity to increase demand into clinical trials and also provides a mid-term opportunity by increasing the market potential for aldesleukin if any of these studies are successful.

The nearest on-market potential opportunity is where Proleukin is being investigated alongside novel cancer immunotherapies within a number of new and existing oncology indications. The most advanced being in relation to TIL therapy for the treatment of metastatic melanoma and cervical cancer. Both indications are in clinical development; the metastatic melanoma cohort being the most advanced with a FDA/(BLA) filing anticipated within CY20 potentially followed by a cervical cancer filing in CY21. SECOND LINE THERAP

metastatic melanoma c.20k

c 5–6l

PATIENTS, mM SECOND LINE POP<sup>®</sup>

PATIENTS ON THIRD To Fourth Line Therapy

> C.2-3k PATIENTS, MM THIRD AND FOURTH LINE POP\*



#### STAGE IV PATIENTS ON FIRST LINE THERAPY

STAGE IV PATIENTS ON SECOND AND THIRD LINE THERAPY

CERVICAL CANCER

C.12K PATIENTS, CERVICAL CANCER

C.6-7k PATIENTS, CERVICAL CANCER STAGE I-III POP<sup>N</sup> **C\_4-5k** PATIENTS, CERVICAL CANCER STAGE IV FIRST LINE POP<sup>44</sup>

#### **C.2k** PATIENTS, CERVICAL CANCER STAGE IV SECOND AND THIRD LINE POP<sup>#</sup>

Patient (Pt) numbers refer to 2019 in the US. Source: Kantar CancerMPact data and management information.

#### WHAT IS THE POTENTIAL TIL MARKET?

If TIL therapy within these two indications obtains approval, it would create a significant new commercial opportunity for Proleukin. The graphic in this case study illustrates where TIL therapy could sit within the treatment pathway.

For metastatic melanoma, if TIL therapy competes within third and fourth line therapy, the estimated patient population is c.2–3k. If TIL therapy is also utilised as second line therapy in this setting, the number of patients would increase to c.7k.

For cervical cancer, if TIL therapy competes within second and third line therapy, the estimated patient population is c.2k. If TIL therapy is also utilised as first line therapy in this setting, the number of patients would increase to c.4–5k.

#### WHAT DOES THIS MEAN FOR PROLEUKIN?

The clinical and regulatory outcome of these TIL therapies is dependent on leading biotechnology companies who are conducting the clinical development independent of Clinigen and therefore the Group has no control over the potential success and/or timelines to market. However, data for TIL therapy presented at ASCO in May 2020 demonstrated potential efficacy and durability of response for metastatic melanoma patients. TIL are extracted from the patient and expanded to billions in number by stimulating them ex vivo with IL-2. Therefore, if approved, TIL therapy would mean an increase in revenues for Clinigen above current guidance. Clinigen management are currently evaluating both the potential for improved reimbursement and optimal presentation for the product to support these new indications.

#### LINK TO STRATEGIC OBJECTIVES

**Expand portfolio of global, regional and licensed assets** Proleukin has significant potential for revitalisation, which if realised, could lead to material increases in revenues.

**Extend global footprint into key markets** Proleukin has provided the Group an ideal platform to expand the existing footprint in the higher value US market, enabling Clinigen to maximise other opportunities across the business.

Link the businesses to realise synergistic opportunities and increase pharmaceutical customer base The Group is not only supplying Proleukin as a commercial medicine, which it owns, in approved indications but is also supplying the product to a number of clients in a clinical development setting, for potential new indications and alternative usages.

#### STRATEGY IN ACTION CONTINUED

# JOURNEY TO UNIFIED DIGITISATION STRONG FOUNDATIONS

#### OUR TRANSFORMATION ROAD MAP

Investment in internal-facing platforms is essential to the realisation of external-facing differentiation.

This year saw the culmination of a multi-year project to embed a Tier 1 ERP in the business and we are now strongly positioned to leverage this technology to drive the next stage of our growth. This is a key milestone for Clinigen and alongside other global applications in the Finance, Quality and HR parts of the business, we have taken a significant step forwards in our development of a truly global operating platform. A multi-year road map is now in place and we will continue to invest in technology where it enhances our operational platform or differentiates our service from competitors.

> Strong foundations in place

Tier 1 ERP embedded (Clinigen One), including two warehouses, nine CMOs and over 40 third-party logistics providers

Global building blocks in place across Quality, Finance and HR Regionally-based customer services

Enhanced global online ordering platforms for Managed Access, 'On-Demand' and Commercial Medicines

Enhanced UK online ordering platforms for QPL and Aseptics

> Three additional warehouses to be integrated

Data warehouse and enhanced data capabilities

TODAY

#### **OUR EXTERNAL-FACING PLATFORMS**

# cliniport >400

#### PRODUCTS

- Primarily an ordering platform to allow HCPs to enrol on MAPs
- Customisable to individual program requirements
- Client reporting functionality

Cliniport is a safe and secure online ordering platform specifically designed to help HCPs enrol their patients in MAPs. It is customisable, scalable and is already an invaluable part of our service offering to clients.

# CLINIGEN DIRECT >2,600

- Public website and secure login area
- Three languages, >40,000 unique users
  - from 174 countries
- Shortages tracker

Clinigen Direct is a globally available service which helps clinicians, pharmacists and pharmacy technicians source hard to find medicines. It is the personal assistant every pharmacist wishes they had, delivering a service that pharmaceutical wholesalers can't match.

#### LINK TO STRATEGIC OBJECTIVES

Upgrade technology platform to drive organic growth The operational efficiency obtained from

The operational efficiency obtained from the launch of the Group's ERP will allow it to better compete on a global scale.

- Expand and embed a global community of HCPs and opinion leaders Clinigen Direct and Cliniport both make our services more accessible and convenient for HCPs and improving access to medicines.
  - Become the 'go to' leader in ethical access to unlicensed medicines Cliniport and Clinigen Direct ensure a safe and compliant way for HCPs to obtain access to unlicensed medicines.

Best-in-class online customer and client experience

**Global ERP integration** 

Supply chain optimisation

#### CRM

Enhanced global HR platform

#### **FUTURE ROAD MAP**

#### **OPERATIONAL REVIEW**

# LINKING THE BUSINESSES

#### ENABLING ACCESS ACROSS The product lifecycle

The greatest opportunity for Clinigen is by 'joining-the-dots' between each of the three business operations and central operating platform.

In recent years, the Group has expanded its service capabilities and extended its geographical footprint by making both transformational and bolt-on acquisitions, both corporate and product in nature. By 'joining-thedots' more effectively by identifying revenue generating opportunities that can move through the businesses, we will continue to drive growth.

#### **CLIENT OVERLAP**

Understanding the success the Group has had to date in cross-selling its services, and where the client overlaps currently exist, along with having the structure in place to focus on the opportunities, are all important in order to further increase the links between the Group's three business operations to drive an improved financial performance.

Establishing the relationship with the client early in the pharmaceutical product lifecycle is an important part of the strategy to develop the partnership for longer to extend revenue streams and amplify returns.

From the Group's client base of 557 pharmaceutical and biotech clients, 458 are clients in Clinical Services, giving the Group a solid base in which to establish the partnership. Within Clinical Services there are 13 clients which overlap between CSM and CTS, demonstrating the potential opportunity that still exists in integrating these two businesses further. There are a further 25 clients which overlap with Unlicensed Medicines and nine which overlap with Commercial Medicines both of which demonstrate the demand for Clinigen's niche services across the business operations but also the opportunity to unlock further synergies by increasing the number of clients which overlap from the large pool of clients which exist.

In addition, from the 101 clients in Unlicensed Medicines, there are 17 clients which overlap with Commercial Medicines, demonstrating the demand for Clinigen's UL2L capability but again the opportunity still to be unlocked. In total, there are 35 clients which work across two or more business operations, 14 of which are from the top 50 of the world's largest pharmaceutical companies, demonstrating the breadth and strength of Clinigen's client base, and eight which work across all three business operations.

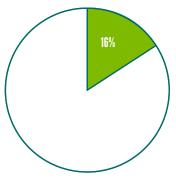
#### **PARTNERSHIPS**

A key to improving the client overlap is to establish long-term partnerships with pharmaceutical and biotech clients, built on shared values and goals. We have provided services to the same client from comparator sourcing and packaging, labelling and distribution in Clinical Services, through to providing consultancy on early access, managing post clinical study access, early access and global access programs in Unlicensed Medicines to being a licensing and distribution partner in Commercial Medicines – a true lifecycle partner.

#### **CASE STUDY**

To demonstrate that these partnerships exist, for one client alone, Clinigen has developed a relationship over 12 years, supported access to medicines in every continent for over 20,000 patients. We have supplied over 100 comparator medicines for more than 50 studies in Clinical Services. In Unlicensed Medicines, we have assisted in the development of a global policy for early access and provided access to over 25 different products in multiple therapy areas, helping over 7,000 patients. Finally, we have provided commercial access to over ten medicines in certain territories in Commercial Medicines. This is a key client for Clinigen but there are other current examples too, and many more opportunities in which to establish further partnerships if we are to 'join-the-dots'.

#### SHARE OF GROUP ADJUSTED EBITDA\*



# NET REVENUE (£M) 162.2 ~15%

# adjusted ebitda (£m) **222.6** ~14%

**458** NUMBER OF CLIENTS

**1.5** UNITS SHIPPED (M) **70** COUNTRIES SHIPPED TO

#### **ADJUSTED NET REVENUE BY PORTFOLIO**

FY20	63%	37%
FY19	68%	32%
● CTS O CSM		

#### **ADJUSTED NET REVENUE BY REGION**

FY20	57%	39% <mark>4%</mark>
FY19	65%	32% <mark>3%</mark>
<ul><li>Europe</li><li>Americas</li><li>AAA</li></ul>		

 % of adjusted EBITDA is before central unallocated costs.

# **CLINICAL SERVICES**

Clinical Services aims to be the market leader in servicing clinical trials and supplying quality-assured comparator medicines internationally. Its strategic focus is on:

- Establishing Clinigen with customer compounds earlier in the product lifecycle (Phase I/II)
- Improving visibility and quality of revenue streams through diversification of customer base, longer-term contracts and exclusive supply arrangements
- Presenting product opportunities to the Unlicensed Medicines business operation

Net revenue in Clinical Services increased 15% (+1% on an organic basis) to £162.2m (2019: £141.7m), whilst gross profit increased by 18% (-4% on an organic basis) to £39.2m (2019: £33.2m). The performance benefited from a full year's contribution from CSM. The marginal decline in organic gross profit was largely a consequence of clinical trials being delayed or cancelled due to COVID-19 and was against a market backdrop which management believes was down c.30-50% in Q4. Whilst the performance of Clinical Services has improved notably following wins to support the development of products against COVID-19 (both vaccines and products to treat the disease), the overall clinical trial market outlook remains uncertain given reduced activity by clients.

EBITDA increased 14% (-12% on an organic basis) to £22.6m (2019: £19.8m). The increase in EBITDA was largely due to full year effect of the CSM acquisition, with the overall organic performance impacted by the timing of investment in the CSM platform to support long-term growth which coincided with the outbreak of COVID-19.

The Clinical Services business continues to build capacity in its platform in Europe and the US for future growth. Work continues to harness the client synergies to bring together the package and labelling and legacy Clinigen comparator business to develop deeper client relationships at the start of the product lifecycle.

### CSM

The acquisition of CSM in October 2018 gives the Group a broader complementary offering to the comparator sourcing market within Clinical Services. It provides a diversified set of valueadded clinical services: comparator and ancillary sourcing, 'on-demand' specialist packaging, labelling, supply and distribution, and biological sample management, along with infrastructure in the US, Belgium and Germany.

Within CSM, the direct-to-patient model was a clear differentiator against competitors, particularly during the COVID-19 pandemic where more COVID-19 related work has been won than has been delayed or cancelled, including notable large contract wins in the final months of the financial year.

The earn-out period associated with CSM was completed on 31 December 2019 and since then more meaningful steps have and are being taken to integrate it into the Clinical Services business. Business Development and strategic sourcing were previously working under one leadership and management structure which has already led to revenue synergies with CTS, with the expectation that this will now increase. Since CSM's acquisition, 23 introductions have been made to Unlicensed Medicines and 18 introductions have been made from Unlicensed Medicines to Clinical Services, reinforcing the links between the Group's business operations.

Since its acquisition, CSM has outperformed management expectations, demonstrating excellent growth and has created a resilient and robust platform in which its reach can be extended across the other two of the Group's business. Post year end deferred consideration of US\$89.5m was paid to the sellers, with the upfront consideration of US\$151.9m representing 14.2x CY19 EBITDA as this outperformance lead to the maximum earn-out consideration being met.

# CTS

The performance of this business has been encouraging even though COVID-19 has led to a slowdown in customer enquiries. Clinigen signed and delivered a significant contract win in April 2020. This multi-year contract, the largest in the division's history, is with a large pharmaceutical company and will continue to support the division in the medium term. Alongside this, the business agreed terms on a Master Service Agreement with a large global biopharma client that should lead to strong mediumterm growth as clinical trial activity picks up.

The focus in CTS remains on improving service levels amongst the existing client base and becoming more competitive with sourcing in a highly competitive market. Business Development is focused on leveraging the existing client base and rejuvenating older relationships as well as developing revenue synergies with CSM.

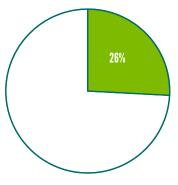
# **PIPELINE**

Clinical Services 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 operation well to take advantage of the rapidly developing market opportunity.

The Clinical Services pipeline is broadly in line with the prior year.

# **OPERATIONAL REVIEW CONTINUED**

SHARE OF GROUP ADJUSTED EBITDA\*



NET REVENUE (£M) 158.9 <u>~2%</u>

# ADJUSTED EBITDA (£M)

**34.4** v<sub>2%</sub>



**UNITS SHIPPED (M)** 

NUMBER OF EXCLUSIVE

SUPPLY AGREEMENTS<sup>1</sup>



#### **ADJUSTED NET REVENUE BY PORTFOLIO**

FY20 16%	84%
FY19 17%	83%
Managed Access	

O Global Access

# ADJUSTED NET REVENUE BY REGION

FY20	69% <b>5%</b>	<b>26</b> %
FY19	71% 9%	20%
Europe		
Americas		
ΟΑΑΑ		

1. Number of exclusive supply agreements includes 131 MAPs (2019: 117), 44 exclusive Global Access client supply agreements (2019: 40) and 30 exclusive customer supply agreements in UK Specials business (2019: 35).

% of adjusted EBITDA is before central unallocated costs.

# **UNLICENSED MEDICINES**

Clinigen is the international leader in ethically sourcing, managing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet medical need. The Group contracts with pharmaceutical and biotech companies to provide MAPs for innovative new medicines and provides Global Access to medicines which remain unlicensed at the point of care.

Clinigen's aim is to be the first point of call for HCPs to source hard to access, unlicensed medicines through its strategy of:

- Developing a rich pipeline based on industry trends and innovation
- Providing a world-class customer service to HCPs through three distinct channels (online, telephony and in person), sourcing hard to access medicines for their patients
- Converting MAPs to long-term exclusive supply agreements in **Global Access**

Net revenue in Unlicensed Medicines increased 2% (+3% on an organic basis) to £158.9m (2019: £156.0m), whilst gross profit decreased by 4% (-3% on an organic basis) to £66.7m (2019: £69.7m). The performance represented excellent growth in Global Access despite ongoing headwinds in the UK Specials business and weakness in Managed Access caused by both the timing of programs starting and finishing and COVID-19 disruption, which has continued into the first quarter. Organic net revenue and gross profit growth excluding UK Specials was 14% and 7% respectively.

EBITDA in Unlicensed Medicines decreased 2% (-5% on an organic basis) to £34.4m (2019: £35.0m). The decline in EBITDA was greater than the decline in net revenue due to investment in the business to support the onboarding of new MAPs and lower utilisation at the UK Specials facility.

# PIPELINE

The business development teams in Unlicensed Medicines is focused on forming long-term relationships with clients to realise the full opportunity of following a molecule from an early access setting through to commercial launch. Given the lengthy nature of the product lifecycle, this opportunity is likely to be realised in the medium to long term.

At the end of period there were 70 programs in the Managed Access pipeline (2019: 52) and 47 partnered products in the Global Access pipeline which the business is looking to partner with on an exclusive basis (2019: 22).

# MANAGED ACCESS

Following a slow performance in Managed Access in H1, due to two of its largest programs beginning to wind down, the performance improved in H2 despite facing headwinds in the final quarter from COVID-19 as demand for treatments in the hospital setting, particularly for oncology, slowed.

Following the 16 programs signed in H1, which contributed to the improved H2, there were a further 25 programs signed in the second half - the highest in the Group's history. Some of these new programs are high profile and relate to the clinical development of products for COVID-19. Whilst these new program wins have led to an increase in market share and would ordinarily lead to meaningful revenue and profit growth, it is expected the disruption caused by COVID-19 will lead to a reduced first half performance based upon a lower than normal level of patients started on these novel therapies. Once hospital disruption ends and end-market demand returns to normal, the business expects to benefit more meaningfully from these program wins.

As at 30 June 2020, there were 131 MAPs (2019: 117), of which 91% 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 net revenue and gross profit as the preferred measures of top-line growth.

Collectively, the top 10 MAPs contributed 35% of the Managed Access gross profit (2019: 38%) with nine of the top 10 in the oncology therapy area (2019: six oncology).

# "FOLLOWING THE 16 PROGRAMS Signed in H1, which contributed to the improved H2, there were a further 25 programs signed in the second half – the highest in the group's history."

# **GLOBAL ACCESS**

In Global Access, the Group ethically supplies unlicensed or short supply medicines to patients via their HCPs; note, the hospital pharmacist is the main customer. There are 44 exclusive supply agreements for high demand or niche medicines covering 57 products under management (2019: 54). Contracting for exclusive supply agreements was delayed by COVID-19, but issues surrounding this have alleviated somewhat and the Group has signed 15 exclusive supply agreements post the year end.

On a regional basis, Asia once again delivered excellent growth, driven by expanding supply from the hub in Singapore into surrounding territories. Strong growth in Australia, New Zealand and Europe was supplemented by maximising the opportunity in fulfilling drug shortages. Although short term in nature, shortages are becoming an increasing challenge for pharmaceutical companies as they struggle to manage an imbalance in the demand and supply of medicines. In having the international infrastructure to provide access to medicines, this is an increasing area of growth for the division as well as serving a benefit to patients in need.

Within Global Access, the greatest disruption caused from COVID-19 was to those medicines supplied outside an exclusive agreement ('on-demand'), as demand for non-COVID-19 treatments reduced in the hospital setting. This disruption has continued in the first quarter of this financial year.

As previously highlighted, the niche UK Specials business within Unlicensed Medicines is facing modest pricing pressure from products going onto drug tariffs and volume pressure from increased competition. In addition, as a result of launching Melatonin in June 2019, the revenue associated with the product is now recognised in Commercial Medicines where it has been a key contributor of growth. The Aseptic Services business within UK Specials, which saw good growth in H1, was impacted by COVID-19 in the final quarter. Aseptic Services prepare and supply patient-specific, dosebanded and batch-made aseptically prepared products and until COVID-19, were benefiting from fulfilling a capacity constraint in the market. The Group is investing in its Aseptic capability (both incremental capacity and online ordering) and expects this to help the business return to EBITDA growth in the current financial year.

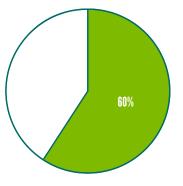
Following the implementation of Clinigen One, the Group's ERP system, the Group is working towards a unified digital platform. This will be a major contributor to the future success of the Unlicensed Medicines business, driving customer intimacy and extending and expanding Clinigen's reach. Currently the Group has a digital service oriented to Global Access, Clinigen Direct, and a complementary service, Cliniport, oriented to Managed Access.

Clinigen Direct is the Group's digital search tool for HCPs to source hard to access medicines with over 2,600 medicines available. It also provides customer service support to help HCPs navigate the regulatory hurdle in importing unlicensed medicines. Since its launch, Clinigen Direct has received interest from HCPs in over 150 countries.

This service is complementary to Cliniport, the Group's customisable, scalable web portal which continues to be an invaluable part of Clinigen's offering for its Managed Access clients and strengthens its interaction with the customer. The community of HCPs on Cliniport continues to build and now has 18,625 registered users (2019: 15,580).

# **OPERATIONAL REVIEW CONTINUED**

SHARE OF GROUP ADJUSTED EBITDA\*



# NET REVENUE (£M) **156.7** ~42%

# ADJUSTED EBITDA (£M) **84.3** ~ 55% **289** NUMBER OF LOCAL, REGIONAL AND GLOBAL ASSETS UNDER MANAGEMENT'

# 2.5

65

UNITS SHIPPED (M)

**COUNTRIES SHIPPED TO** 

### **ADJUSTED NET REVENUE BY PORTFOLIO**

FY20	55%	27%	8%
FY19	57%	27%	16%

• Acquired Products portfolio<sup>2</sup>

• Licensed Products portfolio<sup>3</sup>

O Developed Products portfolio<sup>4</sup>

#### **ADJUSTED NET REVENUE BY REGION**

FY20	33%	36%	31%
FY19	38%	28%	34%
● Euro	ne		

Americas

ΟΑΑΑ

 Number of local, regional and global assets under management includes all products in the Commercial Medicines portfolio.

2. Acquired Products refers to Foscavir, Ethyol,

- Cardioxane, Savene, Totect, Imukin and Proleukin. 3. Licensed Products refers to the local marketed licences including branded and generic products in the AAA region.
- Developed Products refers to the commercialised products developed through the UL2L regulatory
- process. \* % of adjusted EBITDA is before central unallocated costs.

# **COMMERCIAL MEDICINES**

The strategy for Commercial Medicines comprises three areas of focus in order to expand its diversified product portfolio that can deliver sustainable growth:

- Acquired: Continued revitalisation/ growth of current portfolio of niche hospital-only and critical care products, coupled with future, selective product acquisitions
- Licensed: Being the licensing partner of choice for pharmaceutical and biotech clients in their core or non-core territories through regional and global licensing agreements using Clinigen's scale and footprint
- Developed: Developing a pipeline of products using the U2L2 or regional model to support unmet medical need in the markets regionally or globally

Net revenue in Commercial Medicines increased 42% (+29% on an organic basis) to £156.7m (2019: £110.3m), whilst gross profit increased by 47% (+29% on an organic basis) to £116.5m (2019: £79.3m). The performance was due to strong underlying growth across the portfolio, particularly from the UL2L developments and from licensing agreements in the AAA regions. Growth was also supported by the acquisitions made in FY19. In the final quarter, growth was impacted by material headwinds to Proleukin caused by COVID-19 disruption. The impact of this disruption has continued into Q1, albeit at a reduced level, and management currently assumes it will subside fully in the second quarter as treatment centres reopen and patient referrals pick up to pre-COVID-19 levels.

EBITDA in Commercial Medicines increased 55% (+34% on an organic basis) to £84.3m (2019: £54.4m) due to the increase in net revenue. The growth in EBITDA was higher than the growth in net revenue due to improving sales mix and good cost control.

Gross margin was 74.4% (2019: 72.0%) with the increase due to the change in mix towards the higher margin Acquired Products portfolio.

# PIPELINE

The Group continues to seek selective product acquisitions that fit within the Acquired Products portfolio, and regional and global in-licensing opportunities to leverage the platform. In addition, the business continues to develop its pipeline of UL2L products, as well as complementary, larger, niche generic products. There are currently 14 products in the Developed Products pipeline which are due to be launched in the next two to three years (2019: 17) with a peak asset net revenue value of £39m.

## ACQUIRED PRODUCTS (BY THERAPEUTIC CATEGORY)

This includes the seven Acquired Products (Foscavir, Imukin, Proleukin, Cardioxane, Savene, Totect and Ethyol), along with iQone, the Swissbased specialty pharmaceutical business acquired in October 2018.

# Anti-infective portfolio (Foscavir and Imukin)

Foscavir, the Group's largest product prior to the acquisition of Proleukin, is an antiviral used to treat herpesvirus infections (typically CMV and HHV6) mainly in bone marrow transplant and HIV-infected patients. Foscavir performed well in H2 in spite of increased competition from a novel product, with gross profit flat year on year.

At the year end the Group became aware of a generic Foscavir approval in the EU but has not yet seen any formal product launch. It is not possible to quantify precisely the financial impact that the launch of a generic alternative to Foscavir will have on Clinigen's revenues, or how quickly such an impact would take effect. However, the Board has long anticipated the generic threat and management is enacting its strategy to mitigate loss and expects the impact to be captured within its medium term organic gross profit guidance.

Imukin has performed in line with management expectations despite disruption caused by COVID-19.

#### Oncology portfolio (Proleukin, Cardioxane, Savene, Totect and Ethyol)

Proleukin, one of the Group's two biologics, is indicated for use in metastatic RRC, as well as for metastatic melanoma in certain markets. It is Clinigen's largest product and has created the foundation from which to expand Clinigen's existing footprint in the higher value US market. Proleukin usage declined largely as a result of disruption caused by COVID-19 in the US and, whilst end-market demand has improved as treatment centres have reopened, volumes still remain below pre-COVID-19 levels and are expected to remain subdued until the situation resolves further. In addition, the timing of contracted shipments to clinical trial customers are weighted to the 2H of the financial year. Given this, it is anticipated that growth will be weighted to the 2H with the 1H expected to be below the prior year.

Whilst the FY21 impact of COVID-19 is impacting growth rates, management sees this as temporary in nature and continues to see meaningful potential from the revitalisation of Proleukin, particularly within new indications and alternative usages, and there were a number of positive developments in the period.

Proleukin is being investigated alongside TIL therapies within a number of new and existing oncology indications. During the period, data for adoptive cell therapy was presented at ASCO that showed significant benefit to patients within both metastatic melanoma and cervical cancer. If these therapies in these indications are approved, management sees a significant new commercial opportunity for Proleukin, with a market opportunity of c. 7k patients in metastatic melanoma alone. Separately, there has been research published evaluating the safety and efficacy of Proleukin with emerging cell therapies in metastatic Non-Small-Cell Lung Carcinoma ('mNSCLC') after evidence of progression on nivolumab. These opportunities are being evaluated by third parties independent from Clinigen which could open up another significant market opportunity for Proleukin. Management is evaluating both the potential for improved reimbursement and optimal presentation for the product to support these new indications.

Outside of oncology management also sees a significant medium term opportunity for aldesleukin (the active pharmaceutical ingredient (API) of Proleukin) within amyotrophic lateral sclerosis ('ALS'). In July 2020, Clinigen announced that the FDA Office of Orphan Products Development ('OOPD') granted Orphan Drug Designation ('ODD') for aldesleukin in the treatment of ALS. ALS is a severe, neurodegenerative disease which affects motor neurons leading to progressive muscle weakness, paralysis and ultimately death within a median time of two to four years from disease onset. Clinigen is supplying aldesleukin to the ongoing MIROCALS study evaluating its clinical potential within ALS, with data expected by Q3 2021, and is investigating the optimal pathway to support and submit an application for a marketing authorisation in the US and other key markets.

An ODD in the US recognises the potential therapeutic role of aldesleukin in this devastating disease and could provide a number of benefits for Clinigen should it obtain a marketing approval for this indication. These benefits include seven years marketing exclusivity within the US upon launch, along with tax credits for clinical development costs and fee waivers. Clinigen management is exploring developing a new product presentation for this indication and will update further in due course.

Ethyol benefited from the Group taking back direct control of the product in the US from its previous partner, and being able to sell directly into hospitals utilising its commercial infrastructure, formed and developed as a result of the acquisition of Proleukin. However, due to delays with the manufacturing tech transfer process between third party manufacturers, management expects to be without product for a prolonged period of FY21. Whilst disappointing, management remains committed to the product, the only product of its type in the US and EU, and has enlisted a top tier CDMO to take on the manufacturing moving forwards. This impact has been captured within management's forward-looking guidance.

From the dexrazoxane products (Cardioxane, Savene and Totect), Savene performed very well where the focus has been on the products replacement cycle and education of HCPs on its usage in the hospital setting to treat extravasation. The Group are currently evaluating the potential to amend the label on Totect, which if successful, would lead to increased revenues.

# **LICENSED PRODUCTS**

The Group continues to make good progress in extending the commercial strategy through utilising its international platform and expertise in being the ideal licensing partner for an increasing number of companies where they have no desire or infrastructure to commercialise their products.

In April 2020, Clinigen signed an exclusive licensing and distribution agreement with PBL to commercialise Erwinase/Erwinaze ('Erwinase'). Erwinase is approved for patients with acute lymphoblastic leukaemia ('ALL') who have developed hypersensitivity to E. coli-derived asparaginase in 19 countries, including the US, Europe and Japan.

Clinigen will look to expand the market opportunity for Erwinase by driving awareness of the product's availability, ensuring uninterrupted patient access, launching in select new countries and increasing the global supply of the product into unlicensed markets utilising its global infrastructure and experience in this field.

Erwinase will be the Group's third biologic and fits well within Clinigen's existing haematology and oncology product portfolio and customer base. It further strengthens and leverages Clinigen's established commercial infrastructure in the EU, the higher value US market and in other territories such as Japan.

In the year to 31 December 2019, net sales of Erwinase were US\$177m. Whilst the agreement will start on 1 January 2021, it is anticipated that net sales for Clinigen will not begin until the second half of 2021 as the product is transitioned from PBL's current licensing partner. PBL will maintain the trademarks and manufacturing of the product, whilst Clinigen will be responsible for marketing, packaging, labelling, storage and distribution of the Erwinase.

In the Africa and Asia Pacific region, the Group has 267 (2019: 241) local marketed licences including branded and generic products of variable strengths and dosages across multiple geographies. Growth was good across all regions, particularly from Asia where licences are held across six countries.

Management continues to actively review new in-licensing opportunities of both established and late-stage development molecules to launch from Clinigen's established platform. These late-stage development molecules have often been introduced from the Group's Managed Access business and represent a further strengthening of the platform, as management works to 'follow the molecule' from development to launch, partnering with those companies that do not have the required commercial infrastructure, or wish to benefit from accessing both the unlicensed and licensed market opportunities in full.

# **DEVELOPED PRODUCTS**

The Commercial Medicines business also develops, licenses and commercialises medicines that were previously prescribed as unlicensed medicines. Obtaining marketing authorisations for previously unlicensed products is an example of the UL2L strategy in Commercial Medicines. This strategy not only leads to a material uplift in revenues but also satisfies a previously unmet clinical need for patients and is why the business will continue to explore and invest to strengthen and diversify the portfolio on an international basis.

By year end, the business had 15 products in its portfolio (2019: 14).

Following its launch in June 2019, the portfolio's lead product, Melatonin, performed strongly as did the portfolio's first significant product taken through the UL2L regulatory pathway, Glyco. The performance of both these products was a key driver of organic growth in the year.

Although both these products initially were supplied on an unlicensed basis and subsequently launched in the UK, good progress has been made to internationalise revenues by utilising the Group's commercial infrastructure and working with partners to supply and distribute into new territories. Internationalisation of the Developed Products portfolio is a key part of the strategy in extending and expanding the lifecycle of medicines and help patient to get access to these products.

# **FINANCIAL REVIEW**

# A STRONG FINANCIAL PERFORMANCE

# HIGHLIGHTS

- Reported revenue up 10% to £504.3m (2019: £456.9m)
- Adjusted net revenue up 15% (+8% on an organic basis) to £466.2m (2019: £407.0m)
- Adjusted gross profit up 21% (+10% on an organic basis) to £220.0m (2019: £182.3m)
- Adjusted EBITDA up 30% (+13% on an organic basis) to £131.0m (2019: £100.8m)
- Adjusted EPS up 20% to 65.6p (2019: 54.4p), continuing double-digit EPS growth each year since IPO
- Reported EPS of 10.3p (2019: 4.0p)
   Profit before income tax of £22.6m (2019: £12.3m)
- Net debt as at 30 June 2020 of £311.9m, (£288.4m excluding IFRS 16 adjustment), representing leverage of 2.3x (leverage including CSM consideration of US\$89.5m of 2.8x) with target leverage of 1.0-2.0x expected within 12-18 months
- Full year dividend increased 14% to 7.61p (2019: 6.7p)

NICK KEHER Group Chief Financial Officer 16 September 2020 Nick joined Clinigen in March 2019 from Royal Bank of Canada ('RBC') where he was Managing Director and Head of RBC's European healthcare equity research team. Prior to joining RBC, Nick was a senior analyst at Investec. Nick is a qualified accountant (ACMA) and a qualified pharmacist (MPharm). A full biography can be read on page 52.

Clinigen has achieved a strong year of organic growth at net revenue, adjusted gross profit and adjusted EBITDA with adjusted gross profit growth in line with the Group's organic guidance. This is in spite of the disruption caused by COVID-19 in the final quarter, which impacted the Group by between 5 to 7% at adjusted EBITDA, with an acute effect on Proleukin in particular. On top of the strong organic growth we have seen operational leverage and the benefits of prior year acquisitions help deliver earnings per share (adjusted EPS) growth of 20%. Cash generation and cash conversion in the year of 72% was below historic levels, but represented a solid second half performance (123%) after the working capital headwinds seen in H1 that should continue to reverse during FY21. Management remains committed to achieving a leverage ratio of 1.0–2.0x within 12–18 months, with the delay to this caused by COVID-19, a generic to Foscavir and an increased earn out consideration for CSM.

By business operation, both Clinical Services and Unlicensed Medicines saw an impact from the COVID-19 pandemic that has continued to dampen growth rates, but both have continued to develop and broaden client relationships which bode well for the future. Within Commercial Medicines organic growth was extremely strong, and whilst the near-term outlook has been impacted by both COVID-19 and a generic entrant to Foscavir, the medium to long-term outlook remains very positive with the in-licensing of Erwinase and exciting new opportunities for Proleukin. On top of this, the Group is exploring new in-licensing opportunities to leverage across the platform, that will both underpin the business strategy of focusing on both unlicensed and licensed markets and demonstrate the synergistic link between the divisions.

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 and one-off impairments which are explained in note 7 of the condensed financial statements.

Overall, the Group delivered strong growth in revenues which increased by 10% (4% on an organic basis) to £504.3m (2019: £456.9m). Net revenues, adjusting for the pass through revenue in the Managed Access business in Unlicensed Medicines, grew by 15% (9% on an organic basis).

Group profits also grew strongly, with adjusted EBITDA up 31% on a constant currency basis and adjusted EPS up 20%.

# SUMMARY ADJUSTED INCOME STATEMENT

				GROWTH	
YEAR ENDED 30 JUNE ADJUSTED RESULTS	2020 £M	2019 £M	REPORTED	CONSTANT Currency <sup>4</sup>	ORGANIC <sup>5</sup>
Gross revenue	504.3	456.9	10%	10%	4%
Net revenue <sup>1</sup>	466.2	407.0	15%	15%	8%
Gross profit <sup>2</sup>	220.0	182.3	21%	21%	10%
Administrative expenses	(89.6)	(82.6)	(9)%		
EBITDA from joint venture	0.6	1.1	(46)%		
EBITDA <sup>3</sup>	131.0	100.8	30%	31%	13%
EBITDA <sup>3</sup> as % net revenue	28.1%	24.8%	330bps		
Depreciation and amortisation	(11.1)	(3.9)			
EBIT	119.9	96.9	24%		
Finance cost	(11.4)	(8.6)			
Profit before tax	108.5	88.3	23%		
Basic EPS	65.6p	54.4p	20%		
Dividend per share	7.61p	6.7p	14%		

This 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 4 and 7 of the consolidated financial statements).

# PROFITABILITY

As announced at the full year results in September 2019, the Group has now changed its reporting structure to a divisional EBITDA profit-level model, akin to industry peers. Management believes this will lead to better internal cost control and P&L accountability whilst allowing for easier interpretation of results by external stakeholders.

# **ADJUSTED EBITDA BY DIVISION**

				GROWTH	
YEAR ENDED 30 JUNE	2020 £M	2019² £M	REPORTED	CONSTANT Currency4	ORGANIC <sup>5</sup>
Commercial Medicines	84.3	54.4	55%	55%	34%
Unlicensed Medicines	34.4	35.0	(2)%	1%	(5)%
Clinical Services	22.6	19.8	14%	13%	(12)%
Central unallocated costs	(10.3)	(8.4)	(23)%	(23)%	(16)%
	131.0	100.8	30%	31%	13%

Adjusted EBITDA increased by 30% (13% on an organic basis) to £131.0m (2019: £100.8m). The growth in adjusted EBITDA was driven by both the acquisitions made in FY19 and a strong underlying performance. This performance was despite the difficult trading conditions in the last few months of the financial year due to COVID-19. On an organic basis, there were good performances in Commercial Medicines, from CSM in Clinical Services and in Unlicensed Medicines, from Global Access. These performances offset weaker performances from CTS in Clinical Services and in Unlicensed Medicines, from both Managed Access and the UK Specials business.

The growth in adjusted EBITDA was higher than the growth in net revenue due to operational leverage and the change in business mix following the acquisitions. Adjusted EBITDA on an organic basis increased by 13% benefiting from the higher growth of Commercial Medicines and controlled investment in underlying overheads. Towards the end of the period, management also carried out a number of structural changes to both commercial and operational personnel, with those cost savings to be reallocated towards higher growth opportunities, reflecting the continued focus on driving efficiencies across the Group.

Management continues to see further cost-saving opportunities from the enlarged platform, primarily from utilising the now embedded ERP, from sourcing opportunities on key spend lines and on challenging non-drug procurement costs.

See note 4 of the condensed financial statements for a reconciliation of adjusted EBITDA to the IFRS equivalent comparative.

- 1 Adjusted net revenue excludes Managed Access pass through revenue which varies each period dependent on the mix of programs. Adjusted net revenue is a new alternative performance measure of top line performance which is now used to manage the business as it eliminates volatility in reported revenue which can arise as a result of the mix of Managed Access Programs. Adjusted net revenue of £466.2m excludes £11.6m of intercompany sales.
- £466.2m excludes £11.6m of intercompany sales.2 Adjusted gross profit excludes the impact of exceptional charges from write down of inventories. Adjusted gross profit of £220.0m excludes £2.4m of gross profit related to intercompany sales.
- 3 Adjusted EBITDA includes the Group's share of EBITDA from its joint venture and is now shown after the adoption of IFRS 16. The Group implemented IFRS 16 'Leases' for the first time in FV20 using the modified retrospective approach. Comparatives have not been restated and therefore are not comparable to the prior year. Organic growth has been calculated excluding the Impact of IFRS 16.
  4 Constant currency growth is derived by applying the prior year's actual exchange
- rate to this year's result. 5 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. Acquisitions completed in the previous financial year are included on a like-for-like basis including the results for the acquisition where it is included in the comparable historical period. Organic growth is presented to aid the reader's understanding of the underlying performance of the business. In previous reports, organic growth was calculated on a pro forma basis with the comparative period results before acquisition based on the vendors' previously reported results. The like-for-like basis now used has been necessary due to the limited reported financial information available for the products' provide prior to acquisition by Clinigen. On a pro forma basis, the best estimate for organic adjusted EBITDA growth for the year ended 30 June 2020 is 12%.

# FINANCIAL REVIEW CONTINUED

# **FINANCE COST**

The adjusted net finance cost was £11.4m (2019: £8.6m) with the increase due to the Group's higher net debt position following the recent acquisitions and as the Group's debt facility was fully drawn down for the final quarter during the height of the COVID-19 period. The average interest charge on gross debt, excluding the impact of IFRS 16, was 2.6% (2019: 2.8%). The reported net finance cost was £19.7m (2019: £12.8m), after taking account of the non-cash £8.1m unwind of discount on the deferred and contingent consideration relating to the acquisitions (2019: £4.2m).

# RECONCILIATION OF ADJUSTED PROFIT BEFORE TAX TO REPORTED PROFIT BEFORE TAX

YEAR ENDED 30 JUNE	2020 £M	2019 £M
Adjusted profit before tax	108.5	88.3
Amortisation of acquired intangibles and products	(45.4)	(37.8)
Acquisition costs	(0.5)	(5.5)
Restructuring costs	(2.8)	(6.4)
Increase in the fair value of contingent consideration	(11.8)	(21.4)
Impairment of assets related to acquired products	(9.1)	
Impairment of investment in joint venture	(5.9)	
FX revaluation on deferred consideration	(2.0)	(0.4)
Unwind of discount on contingent consideration and other acquisition finance costs	(8.1)	(4.1)
Tax on joint venture in South Africa	(0.3)	(0.4)
Total adjustments	(85.9)	(76.0)
Reported profit before tax	22.6	12.3

The table above shows the reconciling items between the adjusted profit before tax of  $\pm 108.5m$  (2019:  $\pm 88.3m$ ) and the reported profit before tax of  $\pm 22.6m$  (2019:  $\pm 12.3m$ ).

The adjustments to profit before tax comprise costs relating to amortisation, acquisitions, impairments and the Group's share of the tax charge on the joint venture earnings of £0.3m (2019: £0.4m).

Total amortisation was £50.1m (2019: £39.3m), of which £30.4m (2019: £31.1m) related to acquired intangibles, £15.0m (2019: £6.7m) related to acquired product licences, £4.2m (2019: £1.1m) related to software and £0.5m (2019: £0.4m) related to internally developed product licences.

Acquisition costs amounted to £0.5m (2019: £5.4m) relating to the iQone, Proleukin and CSM acquisitions. Restructuring costs were £2.8m (2019: £6.4m), in respect of one-off redundancies primarily from the acquisition reorganisations as well as preparations for any potential Brexit impact.

Impairment charges have been recognised against the Totect IP, Totect short-dated stock and excess Foscavir active pharmaceutical ingredient totalling £9.1m. Totect is facing challenging market conditions with an increased number of generic competitors, and whilst management has successfully increased the number of indications for the product, the ability to achieve a suitable return has reduced. Alongside this, a generic entrant to Foscavir has required a review of the recoverability of the raw material holding resulting in an impairment charge.

The Group's joint venture in South Africa has been impaired following a reassessment of the likely future profitability of the business due in part to the introduction of constraints to the procurement policies related to broad-based black economic empowerment.

There was a £2.0m (2019: £0.4m) foreign exchange charge from revaluation of the contingent consideration on CSM and iQone which is denominated in foreign currency.

# **TAXATION**

Taxation was £8.9m (2019: £7.1m), based primarily on the prevailing UK and overseas tax rates. This charge is calculated as £21.5m based on the adjusted profit of £108.5m, offset by a credit of £12.6m in respect of the adjusted items.

The Group's adjusted effective tax rate ('ETR') was 19.8% (2019: 20.0%). Given the increasing proportion of ex-UK activity, the Group expects the ETR to increase c. 50–100bps in FY21.

#### EPS

Adjusted basic EPS, calculated excluding amortisation of acquired intangibles and products, and other non-underlying items, increased by 20% to 65.6p (2019: 54.4p). The increase reflects the Group's higher adjusted profit from operations, offset by dilution and higher finance costs following the acquisitions in FY19 and the related equity placing and debt re-financing.

Reported basic EPS was 10.3p (2019: 4.0p).

#### DIVIDEND

The Directors are proposing to increase the final dividend to 5.46p per share (2019: 4.75p), resulting in a 14% increase in the full year dividend to 7.61p per share (2019: 6.7p).

The final dividend will be paid, subject to shareholder approval, on 2 December 2020 to shareholders on the register on 6 November 2020.

# **CASH FLOW AND NET DEBT**

Operating cash flow of £94.8m (2019: £89.8m) reflects a materially improved performance overall in H2 after the working capital outflow seen in H1. Management expects the FY21 performance to improve upon that delivered in FY20, as the working capital headwinds seen in H1 FY20 continue to unwind.

Capital expenditure (excluding product acquisitions) was £23.0m (2019: £19.0m), which includes £5.9m related to warehouse, IT and other infrastructure investments, £10.7m related to the Group ERP system, and £6.4m on new product development. Capital expenditure for FY21 is expected to increase marginally versus the prior year due to increased spend on Proleukin product development more than offsetting reduced spend on the ERP system.

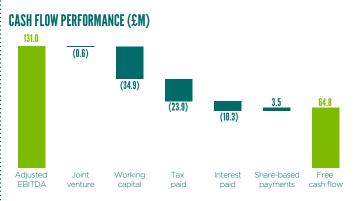
The Group made two deferred consideration payments of US\$30m for the rights to Proleukin US during the financial year.

For CSM, the Group paid initial consideration of £115.5m (US\$151.9m) in cash on completion in October 2018 and has, post year end, finalised and paid the additional contingent consideration to the sellers US\$89.5m.

The other main cash outflows were tax paid of  $\pm 23.9m$  (2019:  $\pm 13.6m$ ), interest paid of  $\pm 10.3m$  (2019:  $\pm 7.9m$ ) and dividends paid of  $\pm 9.2m$  (2019:  $\pm 7.7m$ ).

Net debt as at 30 June 2020 of £311.9m, (£288.4m excl. IFRS 16 adjustment) represented leverage of 2.3x. Net debt is expected to increase temporarily in H1 FY21 as operational cash flow is offset by the deferred consideration payment for CSM alongside planned capital expenditure. Leverage is therefore expected to peak at this point at between 2.5x to 3.0x before reducing thereafter, with FY21 set to end below 2.5x (broadly similar to FY20), and management targeting a range of 1.0x to 2.0x within

12-18 months. As a prudent measure, management has already obtained support from its banking syndicate to lift the net debt/adjusted EBITDA covenant limit from 3.0x to 3.5x for the next testing period.



# **USES OF CASH FLOW**

£M
58.4
23.0
9.2
4.3
(0.1)
94.8
64.8
30.0
94.8

# 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 year, the debt facility has been increased from £375m to £430m, comprising an unsecured £180m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £250m. The incremental debt facilities are to help cover the upcoming deferred consideration payments on CSM, whilst providing headroom for future acquisitions should they arise.

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 June 2020 covenant testing date as a precautionary measure (excluding IFRS 16). As at 30 June 2020, interest cover was 13.3x and the net debt/adjusted EBITDA leverage was 2.3x. The leverage ratio in the current financial year is expected to peak post the CSM earn-out payment in H1 and be broadly flat by the end of the financial year before reducing thereafter in FY22.

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. 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 long-term fundamentals of the business and its endmarkets remain strong even if COVID-19 leads to a degree of near-term uncertainty. As demonstrated in FY20, the Group is well positioned to capture further share from its service focused end-markets whilst revitalising and growing its product portfolio in the Commercial Medicines business and expect to see further signs of strategic progress in the coming year to support this outlook.

The Group's medium-term guidance is for future organic net revenue growth to be between 5–10%, with FY21 expected to be at the lower end due to the impact of COVID-19, which is expected to subside, and an expected launch of a generic Foscavir in the EU. Given the above and the timing of contracted Proleukin shipments, H1 is expected to be below the prior year followed by a return to growth in H2. This will be more evident within Commercial Medicines and Unlicensed Medicines, where the impact of COVID-19 has been greater. Management will provide a further update at the AGM on 26 November 2020.

Growth in FY22 and beyond is expected to significantly accelerate as Erwinase is onboarded and the Group continues to gain share in the end-markets it serves. Management sees the potential for higher organic growth as Proleukin revitalisation takes place and as it gains traction within new indications.

Further operational leverage is not expected in FY21 due to the headwinds of COVID-19 and a generic to Foscavir, alongside additional investment into the commercial platform ahead of onboarding Erwinase. Operational leverage is expected to increase in FY22.

# **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 to reduce the impact of this risk and therefore expect it will be broadly neutral for the current financial year. If the current exchange rates are assumed to apply throughout FY21, the Group estimates it would have a 0-1% negative impact on adjusted EBITDA. Current spot exchange rates to pound sterling as of 16 September 2020 are USD: 1.29; EUR: 1.09; ZAR: 21.15; AUD: 1.77.

# **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 1.0-2.0x 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 44 to 47.

# **PRINCIPAL RISKS**

The Group's approach to risk management is to identify principal risks and then to develop actions or processes within the business to eliminate or mitigate those risks to an acceptable level. The internal controls are designed to manage risk rather than eliminate it.

# **RISK MANAGEMENT FRAMEWORK**

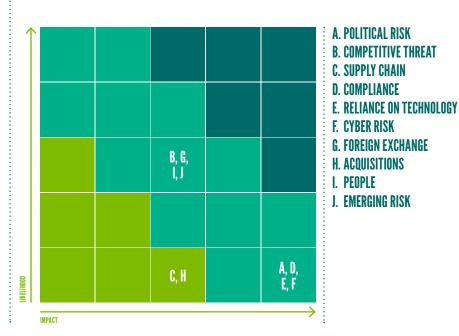
The Group's risk management framework provides the structure by which the principal risks are managed. Although the Board believe this risk management framework currently provides enough structure to ensure the risk assessment process is able to manage the current risks identified and has the appropriate procedures in place to identify emerging risks, during the year the Company engaged KPMG to conduct a top to bottom Governance, Risk and Internal Control Framework Gap Analysis. This was in recognition of the nature and size of the Group's operations and the rapid expansion through acquisition and organic growth. The objective of the analysis was to identify best practice and develop recommendations to drive consistency and quality in the governance processes and internal controls across the Group. This will underpin our growth ambitions and further enhance our ability to manage and respond to risks. Implementation of the recommendations is ongoing and will be an area of focus in 2021. The Group will report further on the changes made as a result of the KPMG analysis in next year's Annual Report.

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Î	BOARD - Ensures comprehensive risk management and internal controls are in place and operating effectively	<ul> <li>Reviews the principal risks</li> <li>Determines the Group's risk appetite</li> </ul>	IMPLEMENTATION
	AUDIT AND RISK COMMITTEE - Oversees the effectiveness of the Group's risk management and internal controls	<ul> <li>Monitors and has oversight of external audit</li> <li>Reviews and monitors the Group's principal risks</li> </ul>	
	<ul> <li>EXECUTIVE MANAGEMENT TEAM</li> <li>Responsible for consolidating the key risks across the Group</li> <li>Oversees the implementation and operation of the risk management and internal control systems</li> </ul>	- Reviews and monitors the Group's key risks	
	<ul><li>BUSINESS OPERATIONS</li><li>Identifies and assesses operational risk</li></ul>	<ul> <li>Implements risk management processes, procedures, controls and reporting</li> </ul>	

# **RISK HEAT MAP**

**AONITORING** 



The Directors have carried out a robust assessment of the principal risks facing the Group, including those that would threaten its business model, future performance, solvency or liquidity. The Group's principal risks, together with the management actions to mitigate the risk, are set out below. They are not in any order of priority and do not comprise all risks associated with the Group. Further risks not currently known or risks that have been considered to be less material may also have an adverse impact on the business.

RISK	MANAGEMENT ACTIONS TO MITIGATE RISK	TREND
<b>A. POLITICAL RISK</b> The Group's expanded global footprint has increased the exposure to adverse local political decisions, changes	The Group mitigates this risk by having an increasingly broad product, service and geographical range, limiting the impact of events in any single territory.	>
pharmaceutical industry, which may affect the ability to supply, local demand and/or pricing. The impact of Brexit could affect the Group's ability to ship product efficiently in and out of the UK and the EU. For example, in the immediate aftermath of the UK leaving the EU, it is possible that the capacity at major ports both in the UK and the EU may be materially reduced for a period. The longer-term effects of Brexit are difficult to predict, but could include financial instability and slower economic growth or economic downturn in the UK, the EU and/or the global economy. Brexit could also impact the Group's ability to recruit EU employees. STRATEGIC LINK 1+4+5+6	The Group regularly monitors developments in key geographies and maintains strong relationships with regulatory bodies to enable the Group to respond rapidly to local changes in circumstances or events. The Group also takes account of political risk when assessing new contracts or product acquisitions.	
	The Group have completed the majority of actions necessary to ensure it can continue to trade in a post-Brexit environment and continues to monitor the advice from the UK and EU governing bodies to ensure the plan is up to date. Clinigen's priority is to maintain continuity of supply of its products to its customers in the UK and EU, and it has acquired an Irish entity to support the supply of unlicensed medicines in the EU, as well as increased inventory accordingly on the continent where appropriate. The Group has previously completed a dry-run of its Brexit plan to ensure readiness ahead of any potential exit. The changes outlined below will enable us to continue supplying products to customers within the EU in the event that there will be no agreement in place regarding the supply or unlicensed and licensed products. The Group has transferred its UK registered Marketing Authorisations for products that are sold in the EU to a subsidiary in the Netherlands; acquired the remaining share of the QMS entity to ensure continued supply of unlicensed medicines into the EU; and established a relationship with a third-party warehouse agent to act as our EU distribution hub.	
<b>B. COMPETITIVE THREAT</b> The Group faces a threat to its owned products from generic products and/or the development of alternative therapies by competitors. The Group's products are not typically protected by patents and competitor threat could significantly erode sales of our products. The threat of	The continued diversification of the Group reduces the overall effect if one of its products or services is impacted by significant change in the competitive landscape. Finding and promoting new users of our products and services, and expanding into new geographies are a key part of our strategy and this helps mitigate the impact of competition in a particular geography treatment area or service.	>
significantly erode sales of our products. The threat of generic risk increases as the Group's product sales increase in size as increasing market size improves the viability for a potential generic product. The competitive landscape could also change during a product's development before commercialisation. The Group also faces competitive threat within the services operations.	The Group closely monitors the competitive landscape in key markets to ensure a rapid and appropriate response to changes in competition.	
STRATEGIC LINK 4+6		

### **C. SUPPLY CHAIN**

The Group's reputation could be undermined and profits impacted if its products go into shortage of supply or through the risk of counterfeit products.

In addition, the Group has obligations to comply with increased regulation on the serialisation of licensed pharmaceutical products.



The Group has effective supply chain management only working with trusted manufacturing and global distribution partners which the Group assesses regularly. The Group also seeks to maintain appropriate stock levels of its own products and related API to minimise the risk of shortage of supply. See page 39 for more information on the supply challenges for Ethyol and the steps the Group has taken to remedy.

To the extent possible, the Group supplies its own products directly to hospitals and HCPs. The Group also has industry-leading quality management systems and audits supply partners where appropriate.

The mandatory global serialisation of licensed pharmaceutical products is expected to reduce the trade of counterfeit medicines. As a pharmaceutical company with its own specialty product portfolio in its Commercial Medicines operation and a supplier of licensed comparator products in its Clinical Services operation, Clinigen is fully compliant with serialisation regulation. >

# **PRINCIPAL RISKS CONTINUED**

#### RISK

# **D. COMPLIANCE**

#### Failure to proactively identify and comply with industry laws and pharmaceutical regulatory changes across our value chain (including government mandated pricing), could result in fines, penalties, business disruption, reduced revenue, and/or potential exclusion from government programs.

Failure to comply with anti-corruption and anti-bribery laws/regulations, policies and standards governing the manufacturing, sales, and marketing of our products, could negatively impact the Group and/or its officers, Directors and employees, resulting in enforcement activity, civil and/ or criminal liability, fines, penalties, imprisonment, business restrictions, or damage to our reputation.

### STRATEGIC LINK 1+3+4+5+6

# **E. RELIANCE ON TECHNOLOGY**

The Group's dependence on technology in our day-to-day business means that systems failure and loss of data would have a high impact on our operations.

**STRATEGIC LINK** 

2

F. CYBER RISK The Group relies on technology in our day-to-day business. These systems are potentially vulnerable to service interruptions and data breaches from attacks by malicious third parties, or from intentional or inadvertent actions by our employees. Failure to protect against the threat of cyber-attack could adversely impact the systems performing critical functions which could lead to a significant breach of security, jeopardising sensitive information and financial transactions of the Group.

### STRATEGIC LINK

2

### **G. FOREIGN EXCHANGE**

The Group has significant operations and activities outside the UK and is therefore exposed to foreign exchange risk.

STRATEGIC LINK 4+5+6

The Group's main operational currencies are sterling, US dollar, euro and, to a lesser extent, the South African rand and Australian dollar. The Group reduces its exposure to currency fluctuation on translation

by typically managing currencies at Group level using bank accounts denominated in the principal foreign currencies for payments and receipts. The Group seeks to optimise the matching of currency surpluses generated to the foreign currency needs of the wider Group, and where there is a sufficient visibility of currency needs, forward contracts are used to hedge exposure to foreign currency fluctuations.

The Group does not issue or use financial instruments of a speculative nature and the Group's treasury function does not act as a profit centre.

The volatility of sterling as a result of Brexit discussions heighten the foreign exchange risk.

The Group's technology strategy is regularly reviewed to ensure that the

TRFND

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Ongoing asset lifecycle management programs mitigate risks of hardware obsolescence whilst back-up procedures mitigate risk of data loss.

The Group continues to embed the ERP system which was implemented last year in the UK and US (other than for the CSM and Quantum businesses). The ERP system is designed to make the business systems more efficient and scalable. Actions were taken to mitigate the risk by conducting a significant amount of planning work, utilising the services of a specialist implementation partner and operating a robust

the threat of cyber-attack. Cyber security procedures exist to minimise



systems it operates across the Group support its strategic direction.

We operate in numerous countries around the world and our industry

is also highly regulated. These circumstances increase our exposure

and Group-wide compliance structure which is continually assessed.

manufacturing practice activities, including pharmacovigilance, and

manufacturing and distribution, as well as legal policies including

employee code of conduct reinforces the Group's values of ethics,

whistleblowing, and anti-bribery and corruption. In addition, the

relating to Clinigen's approach to good distribution practice and good

trust and quality. The Group is also regularly audited by customers and

acts to address any recommendations. Senior management at Clinigen

has full responsibility for the quality management system undertaking periodic management reviews and maintains a close working

regulatory authorities to ensure compliance with relevant legislation and

to potential bribery or corruption risks. The Group has a business

Employees are regularly trained in key areas including policies

relationship with the competent authorities to ensure compliance.

**MANAGEMENT ACTIONS TO MITIGATE RISK** 

this risk

RISK	MANAGEMENT ACTIONS TO MITIGATE RISK	TREND
<b>H. ACQUISITIONS</b> The Group could fail to integrate acquisitions efficiently, leading to disrupted operations and reduced returns. In addition, the Group could make acquisitions which don't support the business as intended or could fail to identify potential acquisitions to drive future growth aspirations.	The Group utilises specialist advisers on all acquisitions and conducts the appropriate level of due diligence to ensure the costs and benefits are fully evaluated prior to acquisition. All acquisitions are thoroughly reviewed and approved by the Board and supported by experienced integration teams with detailed integration plans. These plans are then monitored regularly to raise any deviations and corrective action taken.	>
STRATEGIC LINK 4+5+6+7		
<b>I. PEOPLE</b> The Group's ability to deliver on its strategic objectives could be adversely impacted by failure to recruit, develop and retain the right people.	The Group has grown rapidly and now employs over 1,150 people in 14 international locations. The Group ensures effective and regular internal communications in order to communicate and update on strategy and objectives.	>
STRATEGIC LINK 1	The Group has appropriate remuneration packages to help recruit and retain key employees. In addition, all permanent employees are given the opportunity to become shareholders of the Company.	
	The Group provides significant opportunities for learning, development and leadership training, demonstrated by its management academy which is recognised by the Institute of Leadership and Management to assist with career development and improve competency.	
J. EMERGING RISK Given the current macroeconomic uncertainty, the Group have identified COVID-19 as an emerging risk. STRATEGIC LINK 1+3+4+5+6+7	<b>CIVID-19</b> The Group reacted immediately to government guidance by introducing 'at home' working for the majority of its personnel, as well as amending shift patterns and staffing rotas in our manufacturing, operating and logistics facilities to enable employees to continue to produce and supply essential medicines safely. Office workers were provided with the technology required to work from home as well as assessing the safety for 'at home' working. A Global Business Continuity Group ('GBCG') was established with weekly calls to review, discuss and manage the business impact of the pandemic with regular updates provided to both the executive management team and the Board. The GBCG provided health and safety guidance and procedures for the Group's employees, and prepared office locations to enable employees to return as lockdown restrictions were eased. Communication and engagement was increased both internally with staff and externally with investors. Finally, additional viability stress testing was conducted to assess the impact of a severe and sustained reduction in demand.	N
	Longer term, the pandemic may result in a global recession that continues to suppress patient demand at hospitals and increased trade restrictions, which could impact demand for the Group's products and increase costs. However, the pharmaceutical industry is resilient to economic downturns and once restrictions are fully lifted it is envisaged that hospital demand will return. On the subject of tariffs, pharmaceutical products are not subject to tariffs under the World Trade Organisation Pharmaceutical Tariff Elimination Agreement and so this risk is envisaged as minimal.	

# **KEY TO STRATEGIC OBJECTIVES**

- 1 Develop and retain talented people
- 2 Upgrade technology platform to drive organic growth
- 3 Expand and embed a global community of HCPs and opinion leaders
- 4 Expand portfolio of global, regional and licensed assets
- **5** Become the 'go to' leader in ethical access to unlicensed medicines
- 6 Extend global footprint into remaining key markets
- **7** Link the businesses to realise synergistic opportunities and increase pharmaceutical customer base

ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE (ESG)

# DEVELOPING A Robust Strategy

The Clinigen mission is to address unmet medical needs and improve access to medicines and our intention is to do this whilst behaving in a socially and environmentally responsible manner. Our ESG strategy focuses on those areas that are material to our stakeholders and long-term business success and we intend to report on our continuing progress in subsequent annual reports.

"OUR ROLE AS A GLOBAL LEADER IN FACILITATING ACCESS TO MEDICINES INCLUDING OUR OWN, DRIVES EVERYTHING WE DO. OUR STAKEHOLDERS LIE AT THE HEART OF OUR STRATEGY AND DECISION-MAKING. WE HAVE A RESPONSIBILITY TO ENSURE THE GROUP BEHAVES IN A SOCIALLY AND ENVIRONMENTALLY RESPONSIBLE MANNER."

# **ENVIRONMENTAL**

The Group is an environmentally conscious organisation, which acknowledges the impact its operations and services may, potentially, have on the environment. The Group fully complies with applicable legal and other compliance obligations, whilst at all times striving for best practice. The Group is committed to continually investigating ways of minimising its impact on the environment. In order to help drive improvements in this area, managers within the Group are being given greater visibility on the environmental management steps we are taking under ISO 14001 (the relevant accreditation from the International Organization for Standardization), with a view to creating a positive culture where environmental issues are given due consideration wherever appropriate.

The Group aims to minimise energy and water consumption, and wherever practicable, reduce, recycle and reuse our resources to prevent the unnecessary waste of materials. This year we have focused on packaging, freight and our warehouse footprint. One of the main areas of focus within our Clinical Services business, in mainland Europe and the US, has been to fully implement, wherever possible, multiuse insulated shippers to avoid waste. From the Byfleet facility in the UK, we have also been working to significantly reduce the use of single-use passive temperature controlled shippers, moving to temperature controlled vehicles as a delivery solution for the majority of UK customer freight. We are working to make the same change in other regions.

In addition, the Group is registered with the Environment Agency in the UK as an approved packaging producer which demonstrates that we have met our recovery and recycling obligations under the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (as amended). We have also engaged Valpak Limited, a third-party environmental specialist, to gather information, to help us to develop new strategies and comply with ESOS (the Energy Savings **Opportunity Scheme Regulations 2014** (SI 2014/1643)), Streamlined Energy and Carbon Reporting ('SECR'), the energy and carbon reporting requirements under the Companies (Directors' Report) and Limited Liability Partnerships (Energy and Carbon Report) Regulations 2018 (SI 2018/1155) and PRN (the Packaging Recovery Note requirements under the Producer Responsibility (Packaging Waste) Regulations 2007).

### STREAMLINED ENERGY AND CARBON REPORTING

The new SECR regulations came into effect on 1 April 2019. Under these UK regulations, we are obliged to report UK energy use and associated greenhouse gas emissions. The collection and creation of the SECR report was facilitated externally by TEAM (Energy Auditing Agency Limited). The SECR report covers Scope 1 direct emissions, which includes company-owned vehicles, Scope 2 indirect emissions from electricity purchased and Scope 3 emissions from private vehicles for business use. The SECR report matches the financial year for the year ended 30 June 2020. Using the latest figures provided by The Department for Business, Energy and Industrial Strategy and The Department for Environment, Food and Rural Affairs, TEAM converted the data into tonnes of carbon dioxide equivalent ('tonnes of CO<sub>2</sub>e') and categorised into Scope 1, Scope 2 and Scope 3 emissions. The results are shown in the table overleaf.

YEAR ENDED 30 JUNE	SCOPE 1	SCOPE 2	SCOPE 3	TOTAL
Tonnes of CO <sub>2</sub> e	129	501	51	681
Percentage	19%	74%	7%	100%

The intensity measure variable that the Group has used is total carbon dioxide equivalent emissions (tonnes) per £m of turnover (using the turnover from the previous financial year ending June 2019). This is considered to be the best metric to alleviate any skew in the data as a result of the unprecedented impact of COVID-19. Furthermore, if the consumption increases due to an increase in business operation, i.e. generates more emissions and turnover during subsequent years, this metric allows for a good comparison across the years to determine whether the energy performance and carbon savings of the Group has improved.

The result for the year ending 30 June 2020 is an intensity ratio of 1.49 tonnes of  $CO_2e$  per £m of turnover (using the turnover from the previous financial year ending June 2019).

During the period, the Group implemented a number of energy saving measures in its UK offices. These included, ensuring that the majority of office space is now illuminated by PIR LED lights, with a phased approach to ensure all lighting is illuminated by PIR LED lights as soon as possible, and setting temperature limits at 21°C with a dead band of three to four degrees between heating and cooling set points in fully air-conditioned areas to avoid conflict between individual control units.

The Group is committed to reducing both energy usage and greenhouse gases. The UK HSE management system has been upgraded in accordance with ISO 14001 to allow employees to access information on HSE-related matters including energy consumption, ensuring there is both visibility and engagement from all staff to ensure the Group's carbon footprint can be improved. The new system was rolled out in September 2020 and UK staff will receive training through the year including information on how they can make a positive impact in this area. The Group is looking at rolling out similar initiatives in other locations around the world.

# **HEALTH AND SAFETY**

The Group recognises that health and safety has positive benefits for the organisation. It also recognises that health and safety is a legal requirement and must, therefore, continually improve, progress and adapt to change. To achieve this aim, appropriate levels of resource are allocated to ensuring a positive health and safety culture throughout the Group.

Clinigen prides itself on being people focused and empowering its staff to make change. This is demonstrated by the fact we have active HSE Committees and regular internal HSE inspections. New starter inductions include mandatory online modules for all UK staff relating to display screen equipment, workplace health and safety, environmental awareness, fire safety awareness and stress management. The results of these modules are assessed upon completion and responded to wherever necessary. Different regions work together to share information in order to improve the health and welfare of our staff and others.

The Group's approach to health and safety is based on the identification and control of risks. Adequate planning, monitoring and reviews of the health and safety policy are carried out to ensure continual improvement to our health and safety standards. In the UK, Clinigen continues to work closely with the British Safety Council to enhance our procedures, compliance and reporting. The Group recognises the importance of providing a safe working environment for all its employees and visitors, and strives for best practice standards. The Group also recognises that staff wellbeing is extremely important and provides free of charge health checks for employees and health promotion initiatives, employment assistance programs and activities are communicated and organised on a regular basis.

## **DELIVERING FOR OUR CLIENTS AND CUSTOMERS**

Our mission is to deliver the right medicine, to the right patient, at the right time and we regularly receive feedback on how our work has benefited patients directly.

We help HCPs to transform patient outcomes by enabling more patients in more places to access treatments to improve their condition. We believe every patient should have access to the medicine they need at the time they need it, with confidence in its quality.

Our digital platform, Clinigen Direct, is a globally available service which helps clinicians, pharmacists and pharmacy technicians to source hard to find medicines by connecting them with our specialist customer services team. By combining a passionate, multilingual customer service team and our in-house Medical Information, Quality, Pharmacovigilance and Regulatory experts, we aim to deliver real benefits to pharmacists.

Clinigen recognises the importance of balancing the interests of its customers, shareholders, employees, suppliers and the communities in which it operates. Management of the environmental and social issues that play a part in the business are key factors in the Group's strategy for success and in the practice of good corporate governance.

We expect our clients and customers to behave ethically and responsibly and to comply with their legal obligations at all times.

# ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE (ESG) CONTINUED

# **OUR PEOPLE**

The Group currently employs over 1,150 people in 14 international locations and is committed to a policy of equal opportunities in the recruitment, engagement, performance management and retention of employees. The multinational diversity of the Group's team supports its global service offering. In line with the Group's strategic objective of developing and retaining talented people, employees are encouraged and supported to undertake additional training, both internal and external, to develop their skills, which are then often transferred across departments or enable promotion.

The Group believes that the development of talent is important to achieve the long-term strategic goals of the business. The Clinigen Management Academy, a bespoke management development program which is formally recognised in the UK by the Institute of Leadership and Management, was successfully completed by 36 employees during the year, with a further 80 completing the program this year.

Age, colour, race, gender, disability, ethnic origin, national origin, marital status, sexual orientation, religious or political views must not be seen as barriers to employment and we are proud of the Group's diverse employment base. The Group is committed to providing equal opportunities for individuals in all aspects of employment and considers the skills and aptitudes of disabled persons in recruitment, career development, training and promotion. The Group supports employees with disabilities, ensuring the necessary reasonable adjustments are in place to support them. It is important the Group listens to its employees and understands their views on Clinigen as an employer. The Group operates a culture of open communication through a range of two-way mediums including: regular employee representative staff forums; a global intranet platform; newsletters; and regular Group and divisional performance updates from the CEO and CFO. The strategic objectives of the Group are communicated to employees through regular updates and this year, that included at virtual all-staff conferences.

The Group also uses Peakon, the world's leading platform for measuring and improving employee engagement. Peakon asks employees a small number of questions weekly and enables management to obtain realtime feedback. The external platform ensures anonymity and empowers management to take prompt and informed action. In the last 12 months we have used Peakon feedback to drive 'You Spoke, We Listened' action planning, with a particular focus on career paths, support and development.

As the Company grows it is important that the Group has a culture and set of values which are understood in each of the locations in which it operates. At Clinigen, this is called the 'Clinigen Way', and is captured in six clear and powerful principles that underpin everything the Group does (see below). They reflect the Group's rich and varied historic businesses and the common purpose employees all share today.

The Group recognises the importance of diversity, including gender, at all levels of the Company. The Group already has a strong female representation in the business leaders group where women comprise 35% of positions. In addition, out of 1,168 employees, approximately 58% are female. The Group continues to actively seek to recruit and advance women into its top management through manager training, application monitoring and robust, transparent selection processes.

# **COVID-19**

The Group has proactively supported and engaged with employees throughout the COVID-19 pandemic. Within a relatively short period, in March 2020, nearly 75% of the global workforce were working remotely with the remaining workforce continuing to attend Clinigen sites to support crucial activities across the Group's supply chain operations. Regular COVID-19 business continuity calls are held across the Group's 14 locations which feed into the global COVID-19 business continuity call. This has meant the Group has been able to adapt and implement national government and health authority requirements and share experiences and best practice. The focus throughout has been the safety and wellbeing of the Group's employees.

Employee engagement has been critical, and the Group's employee engagement platform, Peakon, has been updated to include specific feedback points around the Group's response to the pandemic. Feedback has been very positive, and employees have continued to work effectively despite the challenging and uncertain circumstances. In addition, managers have been provided with training resources on how to manage teams remotely. Individual teams have also worked hard to maintain good communication between colleagues and have made good use of video conferencing facilities. Remote working practices are being considered for the future.



MAKE A DIFFERENCE We go further for patients



**SHOW MUTUAL RESPECT** We treat others as we would like to be treated



NURTURE SUCCESS We reward, recognise and develop success





MAINTAIN INTEGRITY We're open and transparent

PUT BEST INTERESTS FIRST

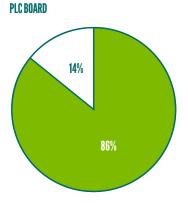
We manage for best interests, not self-interest

MEASURE PROGRESS We know where we are and where we're going

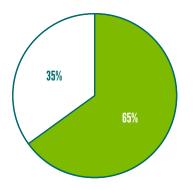
# STRATEGIC REPORT 51

# **GENDER RATIO**

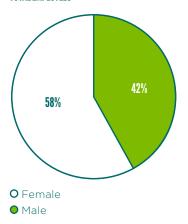
In 2019 we reported a pay gap of 5.1% in favour of our UK female employees whereas in the prior year we reported a pay gap of 0.6% in favour of our UK male employees. Our full report can be found on the Group website (https://www.clinigengroup.com/ uk-gender-pay-gap-report/).



**BUSINESS LEADERS GROUP** 



**TOTAL EMPLOYEES** 



#### **WORKING WITH OUR PARTNERS**

We aim to build strong, mutually beneficial relationships with the suppliers, distributors and partners who we rely on to meet the needs of our clients and customers. We require that those suppliers, distributors and partners to behave ethically and responsibly, and to demonstrate a culture of compliance. We expect our suppliers, distributors and partners to ensure all aspects of their businesses comply with applicable laws and regulations, and we include obligations to this effect in our standard contract templates.

The Group, through its Quality management team, audits our suppliers and manufacturers regularly. Quality compliance is a key part of the Group's Quality audit.

Our Quality team have been working this year to strengthen and improve the Quality questionnaires which we ask our suppliers to complete. They have also been reviewing certain other elements of the terms and conditions on which we engage suppliers. We expect these changes to enhance the quality standards of our suppliers, to the benefit of our clients and customers.

The Group fully supports the aims of the Modern Slavery Act 2015 to eradicate human slavery and trafficking. In particular, the Group wishes to ensure that no child labour or servitude of any kind or human trafficking has been involved in the supply and distribution of products or services. Further details of these steps can be seen in our Modern Slavery Statement, which is available on our website.

### CHARITY

During the year, there were various local fundraising activities across the different regions, supporting a number of important cancer charities. including Macmillan Cancer Support and Teenage Cancer Trust in the UK and Kick Cancer in Belgium. Colleagues from our US office volunteered at food banks and supported families in need with food parcels and Christmas gift initiatives. From an environmental perspective, Clinigen colleagues raised money and donated to the Australian Wildfire Relief Fund. Our South African office, recognising the devastating effect of plastic, made sure that each employee received a wheat straw bottle, which is durable, reusable, and offers an alternative to single-use plastics. We are proud to support different charitable and environmental projects and will continue to make a positive impact in the regions in which we serve HCPs and patients.

# APPROVAL

The Strategic Report was approved by the Board of Directors on 16 September 2020 and signed on its behalf by:

SHAUN CHILTON Group Chief Executive Officer 16 September 2020

# **BOARD OF DIRECTORS**



#### PETER ALLEN Independent Non-Executive Chairman

APPOINTED August 2012

#### COMMITTEES

Nomination (Chairman), Remuneration

#### PROFILE

Peter has a wealth of experience and has held key senior positions, including Chairman, CEO and CFO in a number of companies in the healthcare industry, and played a significant role in their growth. Peter spent 12 years at Celltech Group plc (1992/2004) as CFO and Deputy CEO, six years at ProStraken Group plc as Chairman (2007/13) and interim CEO (2010/11) and three years as Chairman of Proximagen plc (2009/12).



SHAUN CHILTON Chief Executive Officer

# APPOINTED

Director in July 2013 and CEO in November 2016 COMMITTEES None

#### PROFILE

Shaun has been the CEO of Clinigen since November 2016 and has the responsibility for the Group achieving its KPIs and plays a central role in setting the Group strategy. Shaun has played a pivotal role in the development of Clinigen, joining the Company in January 2012 as Chief Operating Officer, when it was a privately-owned company with a turnover of £82m.

He was a key part of the executive team that took Clinigen through IPO in September 2012 and has been a fundamental part of the leadership of the impressive strategic growth of the Company.

Prior to joining Clinigen, Shaun held senior global strategic, commercial and operational roles at Pfizer, Sanofi, Wolters Kluwer Health and the KnowledgePoint360 Group (now part of UDG Healthcare).



NICK KEHER Chief Financial Officer

APPOINTED March 2019

#### COMMITTEES

None

#### PROFILE

Nick joined Clinigen in March 2019 from RBC where he was Managing Director and Head of RBC's European healthcare equity research team.

Prior to joining RBC, Nick was a senior analyst at Investec. Cumulatively, Nick has covered the European healthcare space for over eight years at both RBC and Investec.

Nick began his career at Lloyd's Pharmacy, registering as a pharmacist before joining GlaxoSmithKline ('GSK'). At GSK, Nick worked within the Group's R&D, UK commercial operations and global manufacturing and supply strategy finance teams. Nick is a qualified accountant (ACMA) and a qualified pharmacist (MPharm) having completed his Master's degree in Pharmacy, Medicinal Chemistry, Pharmaceuticals, Biology and Maths from Aston University.



#### JOHN HARTUP

Senior Independent Non-Executive Director

APPOINTED June 2011

#### COMMITTEES

Nomination, Remuneration, Audit and Risk

#### PROFILE

John has over 30 years of experience as a corporate lawyer, dealing with corporate finance and commercial contract issues across a number of industries. He was formerly Managing Partner at Ricksons LLP and subsequently became a Partner at DWF LLP.

#### EXTERNAL APPOINTMENTS

Peter is currently Chairman of Abcam plc and Advanced Medical Solutions Group plc, and Non-Executive Director of Oxford Nanopore Technologies Limited and Istesso Limited.

The Board has undertaken a thorough review of each of the Chairman's external appointments and is satisfied that he has sufficient time to meet all of his Board responsibilities at Clinigen. The Board believes that the Chairman provides effective leadership and manages Board meetings extremely well. Further, the Board finds the additional insight gained by his participation on other Boards to be of enormous benefit.

#### EXTERNAL APPOINTMENTS

Shaun is currently Chairman of C7 Health Limited, a provider of software and services for the healthcare sector.

The Board is satisfied that this external appointment does not impact upon the CEO's ability to discharge his role at the Company effectively. EXTERNAL APPOINTMENTS None EXTERNAL APPOINTMENTS None



# IAN NICHOLSON

Independent Non-Executive Director

APPOINTED

September 2012

#### COMMITTEES

Remuneration (Chairman), Audit and Risk, Nomination

#### **PROFILE**

Ian has considerable experience as both an Executive Director and as a Non-Executive Director. Ian is CEO of F2G Limited.



#### **ANNE HYLAND**

Independent Non-Executive Director

APPOINTED January 2018

#### COMMITTEES

Audit and Risk (Chair), Remuneration

#### **PROFILE**

Anne has a strong track record within the biopharma sector, bringing with her over 25 years of financial experience with both public and private companies.

Anne is a Chartered Accountant (FCA), and corporate tax adviser (CTA - AITI) and holds a degree in Business Studies from Trinity College, Dublin. Anne's previous roles include CFO of BBI Diagnostics Group Limited and FTSE-listed Vectura Group plc. Prior to her role at Vectura, Anne held a number of senior finance positions at Celltech Group plc. Medeva plc and KPMG.



**ALAN BOYD** Non-Executive Director

APPOINTED November 2018

#### COMMITTEES

None

#### **PROFILE**

Professor Boyd has accumulated over 30 years of extensive medical and policy experience within the pharmaceutical sector, holding senior roles within some of the world's largest pharmaceutical companies

He began his pharmaceutical career with Glaxo Group Research Limited. From 1988, he led ICI's cardiovascular medical research team, and later assumed the role of Director of Clinical and Medical Affairs at ICI Pharma, Canada.

In 1999, after four years as Head of Medical Research for Zeneca Pharmaceuticals, he became Director of Research and Development for Ark Therapeutics Limited where he was responsible for delivering the majority of key development milestones.

In 2005, Professor Boyd left to set up Alan Boyd Consultants Limited, to focus on aiding and supporting early stage life-science based companies in Europe, North America and Japan.



# AMANDA MILLER

General Counsel and Company Secretary

APPOINTED June 2017

COMMITTEES None

#### **PROFILE**

Amanda trained and qualified as a UK solicitor at Freshfields Bruckhaus Deringer and has over 20 years of legal and governance experience. Before joining Clinigen in June 2017, she was Vice President and European General Counsel at Shire Pharmaceuticals Group plc where she had spent 14 years in positions of increasing responsibility in the UK and US. She began her professional career as a commodity trader for Cargill.

#### EXTERNAL APPOINTMENTS

Ian is currently Non-Executive Chairman of Bioventix plc. Ian is also Chairman of the Investment Committee at Cancer Research UK Pioneer Fund, Director of Casewell Consulting Limited, F2G Limited, and Wells Stores Limited, and an Operating Partner at Advent Life Sciences LLP.

#### EXTERNAL APPOINTMENTS

Anne is CFO of Kymab Ltd a private biopharmaceutical company. She is also a Non-Executive Director of Elementis plc, a global specialty chemicals company

#### EXTERNAL APPOINTMENTS

Professor Boyd is currently CEO of Alan Boyd Consultants Limited, a private specialist biopharmaceutical consultancy company. He is also a Director of BaxterBoyd Limited and Celentyx Limited.

# EXTERNAL APPOINTMENTS

None

**CHAIRMAN'S INTRODUCTION TO GOVERNANCE** 

# STRONG AND ROBUST Corporate Governance



# **DEAR SHAREHOLDER**

I am pleased to introduce the governance section of the Annual Report for the year ended 30 June 2020.

This year has seen continued focus on the Group's corporate governance arrangements, ensuring that we have strong and robust corporate governance at the heart of everything we do. The Board continues to adhere to the principles of integrity, respect, transparency and openness and Board members are expected to lead by example and exemplify the highest standards of propriety, diligence and accountability. The Board, and its Committees, play a key role in providing the necessary framework, challenge and support to the business and ensure that a culture of good governance exists throughout the Group.

# THE 2018 UK CORPORATE GOVERNANCE CODE

The new 2018 UK Corporate Governance Code (the "Code") applied to the Company from 1 January 2019. In response to the new Code, we undertook an assessment of our readiness and the changes we needed to make to embed the new requirements into our governance framework whilst ensuring that it continues to service our strategic priorities. I am pleased to report that we comply with all the principles of the Code.

The new Code highlights and reinforces the need for the Board to understand the views of the Company's key stakeholders and how their interests, and the matters set in Section 172 of the Companies Act 2006, have been considered in Board discussions and decision-making. A review of the Group's stakeholders and how we engage with them is set out on pages 12 to 15.

# "THE BOARD CONTINUES TO MAKE PROGRESS TO TAKE INTO ACCOUNT Developments in corporate Governance and best practice."

**PETER ALLEN** Independent Non-Executive Chairman 16 September 2020

#### **THROUGHOUT THE YEAR**

The Board met eight times during the year. All of the meetings were held in the UK.

As part of the focus on key stakeholders, the Board has spent some time discussing workforce engagement strategies. We reviewed and approved an amended version of the Employee Handbook and updated a number of key governance documents, policies and procedures. During the year, we appointed John Hartup as the designated Non-Executive Director for workforce engagement. Unfortunately, the arrival of COVID-19 and the subsequent lockdown has meant that our work on workforce engagement has been somewhat hampered but we have been updated regularly on the statistics generated from Peakon (the world's leading platform for measuring and improving employee engagement) and the steps taken to address the comments coming out of that. The weekly statistics generated by Peakon allow the Company and the Board to regularly temperature test culture, employee engagement and alignment with the Group's values. While the events of 2020 have undoubtedly created uncertainty, I am pleased to report that our employees demonstrated unwavering commitment. We value their feedback and we shall continue to focus on ways to engage with them effectively through 2021.

In June 2019, the Board took part in an externally facilitated board evaluation exercise. As Chairman, in order to facilitate the long-term sustainability and success of the Group, my role is to ensure that the Board operates in an open and transparent manner, allowing the Non-Executive Directors the opportunity to critically assess, challenge and support the Executive Directors and senior management team. I believe that this has been achieved and the Board has worked effectively. I am pleased that the evaluation confirmed this.

As in previous years, the implementation of the strategy has been a significant area of focus in our Board meetings during the year, and Shaun and his executive management team have provided us with regular updates allowing the Board to inform our view on the successes and challenges throughout the Group.

Principal risks facing the Group continue to be a focus. Details of our principal risks are set out on pages 44 to 47. All risks, along with the other principal risks are regularly assessed by the Audit and Risk Committee.

Further information regarding the principal decisions taken by the Board during 2020 are set out on page 56.

#### **BOARD CHANGES AND BOARD COMPOSITION**

John Hartup will not stand for re-election at the 2020 AGM. John has served as Non-Executive Director for the last nine years and I would like to thank him for his commitment to the Company. The Nomination Committee is currently seeking a replacement and considering who will take on John's responsibility for workforce engagement. Board composition is considered regularly by the Board. The question of 'overboarding' has increased in prominence over the last year, arising from concerns that Directors may not be able to properly fulfil their duties where they have too many competing commitments to other listed companies. The Board, always mindful of this, undertakes a regular and detailed review of the nature and scope of its Directors' external appointments, which consciously extends beyond the standard corporate governance guidelines of listed company directorships, and includes appointments to private companies and charities. Following the 2019 AGM, when 31.59% voted against my re-election, the Board engaged with the Group's largest institutional investors and proxy companies to provide an opportunity for them to share their views on corporate governance and to cover questions more generally. As a result, in May 2020, I relinquished my position as a member of the Audit and Risk Committee. I also stepped down as Chairman of the Board of Diurnal Group on 30 June 2020.

The Board is satisfied that none of its Directors are over committed and that each has sufficient time to meet their Board responsibilities at Clinigen. In June 2019 the Board evaluation exercise, which was led by the Senior Independent Director, John Hartup, and facilitated externally by Prism Cosec confirmed, not just the prevailing view that the Board operates efficiently and cohesively, but that none of the Directors is 'overboarded'. Further, the Board finds the additional insight gained by Directors' participation on other Boards to be of enormous benefit. Each of the Non-Executive Directors provides excellent, uncompromising service; that said, the Board maintains a watching brief and is actively engaged in succession planning.

The Board continues to believe that its membership has the right qualities required to operate within a robust governance structure which matches the requirements of the Group. This structure makes our business stronger to ensure the right decisions are made to help support and deliver the Group's strategy, and to protect shareholders interests.

#### LOOKING AHEAD

Priorities for the Board in 2021 include continually assessing progress against the strategic priorities, with particular attention on integration of the acquisitions and ensuring that they are supported by appropriate governance structures. We believe that our governance framework is robust and effective, but we recognise that we should look for continual improvement as we follow the Code.

Thank you for your continued support and I look forward to meeting any shareholders who can join us at our AGM on 26 November 2020. I should add that all shareholders planning to attend the meeting in person need to be aware that arrangements may be subject to change because of the ongoing pandemic. We will publish any changes on our website and through the regulatory news service.

# **CORPORATE GOVERNANCE STATEMENT**

As a company whose shares are traded on AIM, the Company is subject to the AIM Rules for Companies. Pursuant to (amended) AIM Rule 26, with effect from 28 September 2018, every company whose shares are traded on AIM is required to state on its website which corporate governance code it applies, how it complies with that code, and where it departs from its chosen corporate governance code an explanation of the reasons for doing so (Corporate Governance Statement).

The Board has elected to report against the UK Corporate Governance Code 2018 (published July 2018 and applying to accounting periods beginning on or after 1 January 2019) (the "Code"). Whilst the Group is not required to comply with the Code (which has been drafted with larger, main-market listed companies in mind), we have voluntarily chosen to formally adopt the Code as representing best practice in UK corporate governance. The Board also uses the revised Guidance on Board Effectiveness to help guide best practice when applying the Code. Published by the Financial Reporting Council ('FRC'), the Code is much shorter than the previous version and focuses on board leadership and company purpose; division of responsibilities; composition, succession and evaluation; audit, risk and internal control; and remuneration. At its heart, the Code emphasises the value of good corporate governance to long-term sustainable success. Although AIM listed companies are not required to comply with the Code (unlike those with a premium listing), the Board's election underpins its belief that effective corporate governance as best business practice will assist the delivery of the Group's corporate strategy, the management of risk and the generation of shareholder value, improve Board efficiency, boost investor confidence, reduce cost of capital and help protect our shareholders' long-term interests. Clinigen values corporate governance highly, not only in the boardroom but across the whole business of the Group.

The Company's Corporate Governance Statement sets out how it complies with the Code and is available from the Company's website at www.clinigengroup.com.

The following section outlines in broad terms how the Board has managed and applied standards of corporate governance that are appropriate for the Group's size and circumstances.

# **BOARD LEADERSHIP AND COMPANY PURPOSE**

The Board's role is to establish the vision and strategy for the Group and the Board is responsible for the long-term success of the Company. The individual members of the Board have equal responsibility for the overall stewardship, management and performance of the Group and for the approval of its long-term objectives and strategic plans.

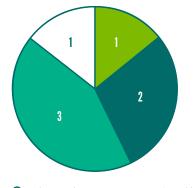
The Board is responsible to the Company's shareholders with its main objective to increase the sustainable value of assets and long-term viability of the Company. The Board reviews business opportunities and determines the risks and control framework. It also makes decisions on budgets, Group strategy and major capital expenditure. The day-to-day management of the business is delegated to the Executive Directors.

The Board has a schedule of matters specifically reserved for its approval. These matters are delegated to the Board Committees, Executive Directors, executive management team and senior management where appropriate. The schedule of matters reserved for the Board and terms of reference for each of its Committees can be found on the website, www.clinigengroup.com.

Matters considered by the Board in 2020 included:

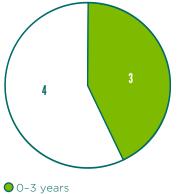
TOPIC	DISCUSSION	CONSIDERATIONS
STRATEGY	<ul> <li>Strategic Review</li> <li>Acquisition Strategy</li> </ul>	The need to ensure the long-term sustainable success of the business
CULTURE	<ul> <li>Regular review of the output from the Peakon employee engagement platform</li> </ul>	The need for the Board to ensure that the workforce is engaged, is aligned with the Company culture and that the Board is alert to any concerns employees may have
FINANCE	<ul> <li>Approval of the financial statements</li> <li>Annual budget</li> </ul>	The need to provide transparent and accurate information to the market and the need to ensure that the Company generates and preserves value over the long term
RISK	<ul> <li>Governance, risk and internal control framework gap analysis</li> <li>Insurance review</li> <li>Review and approval of an updated Global Delegation of Authority Matrix</li> </ul>	The need for the Board to establish formal and transparent policies and procedures to ensure the effectiveness of its internal controls systems and the integrity of financial statements
WORKFORCE	<ul> <li>Gender pay gap reporting</li> <li>Review and approval of an updated Global Clinigen</li> <li>Employee Handbook</li> </ul>	The need to ensure external reporting is accurate and that the Company strives to address any imbalances within pay and conditions. The need to ensure that all employees are treated fairly and have clear guidance on Company policies and procedures
GOVERNANCE	<ul> <li>Approval of a US Healthcare Policies Compliance Manual</li> <li>Consideration of reporting Directors' duties under Section 172 of the Company Act 2006</li> <li>Approval of mandatory global anti-bribery and corruption training for all employees</li> </ul>	To ensure high standards of governance and adherence to applicable regulations throughout the Group

# **BOARD COMPOSITION**



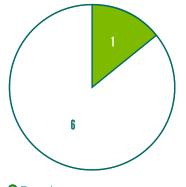
- Independent Non-Executive Chairman
   Executive Directors
- Independent Non-Executive Directors
- O Non-Executive Director

# **BOARD TENURE**



O-5 years
O>6 years

# **GENDER DIVERSITY OF THE BOARD**



FemaleMale

### **DIVISION OF RESPONSIBILITIES**

There is a clear division of responsibilities between the Chairman and the CEO of the Company.

The role of the Chairman is to lead and manage the Board, ensuring the Board's effectiveness in all aspects. They should facilitate active engagement by all members, promoting a culture of challenge, openness and scrutiny.

The CEO manages the Group's business and develops its strategy. The CEO leads the senior management team in delivering the Group's strategic objectives.

The Non-Executive Directors' responsibilities are to challenge and contribute towards the Group's strategy, and to ensure that the financial controls and systems around risk management are suitably robust.

The Company Secretary supports the Board and advises on all governance matters. All Directors have access to the advice of the Company Secretary. The appointment of the Company Secretary is a matter for the Board.

# **BOARD COMPOSITION, SUCCESSION AND EVALUATION**

The Board consists of two Executive Directors, an Independent Non-Executive Chairman, three Independent Non-Executive Directors and a Non-Executive Director. During the year, John Hartup was the Company's Senior Independent Director, acting as a sounding board for the Chairman and a trusted intermediary for the other Directors. He was also available as an additional point of contact for shareholders.

The names of the Directors and the Company Secretary, and their biographies are set out on pages 52 and 53.

In accordance with the provisions of the Code, during the year, at least half the Board is comprised of Independent Non-Executive Directors.

The Code sets out criteria designed to assist the Board in determining whether there are circumstances that might affect, or could appear to affect, a Director's judgement and therefore their independence. In accordance with recommendations of the Code, the Board have concluded that the majority of Board members are independent Non-Executive Directors.

The Board continues to assess that its membership has the right qualities required to operate within a robust governance structure which the Board believes fits the requirements of the Group. Priorities for the Board in 2020/21 include continually assessing progress against the strategic priorities and strengthening the Board membership with Independent Non-Executive Directors where it is deemed necessary.

# CORPORATE GOVERNANCE STATEMENT CONTINUED

In June 2019, the Board conducted an internal Board evaluation : The Articles of Association state that one-third of the Directors which was led by the Senior Independent Director, John Hartup, and facilitated externally by Prism Cosec. The evaluation concluded that the Board operates efficiently and cohesively. The key recommendations and the actions taken are set out below:

RECOMMENDATION	ACTION
Schedule an annual review of the attendance and time commitments of each Director by the Nominations Committee to ensure that any concerns are addressed	An annual review has been put in place. The Board is satisfied that none of its Directors are over committed and that each has sufficient time to meet their Board responsibilities at Clinigen
Consider options for improving the structure of the agenda and papers within the Board pack	The Company Secretary facilitated the introduction of an online Board portal to manage Board and Committee packs
Ensure that the roles and responsibilities of the Chairman, CEO and Senior Independent Director are documented and published in line with the requirements of the 2018 Code	The Board has approved written job descriptions for the Chairman, CEO and Senior Independent Director
In light of new reporting requirements, Directors review their duties under Section 172 of the Companies Act 2006	The Company Secretary facilitated a discussion about Section 172 and ensured that the Directors (i) had a clear view on how they discharged their duties under Section 172; (ii) determined who the key stakeholders were and how they should engage with; and (iii) were clear on how they should report on their responsibilities under Section 172 in the Annual Report
When preparing the agendas for Board and Committee meetings, the Secretary and Chair should agree proposed timings for each discussion topic and note those timings on the meeting agenda	This has been implemented
In light of Code requirements, consider the governance and review of reports arising from the Company's arrangement for employees to raise concerns in confidence	This takes place using the Peakon employee engagement platform. We also have a Whistleblowing Policy
Formalise the annual programme of work for the Nomination Committee	This is in the process of being formalised

# APPOINTMENT. REMOVAL AND RE-ELECTION OF DIRECTORS

The Group seeks to recruit the best candidates at Board level and considers candidates on merit and against objective criteria. The process for the appointment of Directors is managed by the Nomination Committee.

Appointments are made with due regard for the benefits of diversity on the Board (including gender). The Group supports the Code in respect of diversity.

The Board takes care that appointees have sufficient time available to allocate to the position. Each Non-Executive Director is expected to allow the necessary time to conduct their duties which involves attending all Board and Committee meetings of which they are members.

Effective procedures are in place to deal with conflicts of interest. Other interests and commitments of Directors are known by the Board and any changes to their commitments are reported.

must stand for re-election by shareholders annually in rotation and that each Director appointed by the Board is subject to election by the shareholders at the first AGM after their appointment. However, to underline their accountability to shareholders and the Board's commitment to appropriate corporate governance, each Director, other than John Hartup, will stand for re-election at the upcoming AGM. Following advice from the Nomination Committee, the Board has concluded that each Director is gualified for election or re-election

# **BOARD AND COMMITTEE MEETINGS**

The Board meets on a formal basis regularly throughout the year and met eight times in the year ended 30 June 2020. The Committee meetings are scheduled around the Board meetings. Agendas, Committee papers and other appropriate information are distributed prior to each meeting to allow the Board to meet its duties.

The Directors' attendance during the year ended 30 June 2020 are as follows:

	BOARD	AUDIT AND RISK Committee	REMUNERATION Committee	NOMINATION Committee
S Chilton	8	3 <sup>1</sup>	21	11
N Keher	8	3 <sup>1</sup>	2 <sup>1</sup>	-
P Allen	8	3	3	1
J Hartup	8	3	3	1
I Nicholson	8	3	3	1
A Hyland	8	3	2 <sup>1</sup>	11
A Boyd	8	3 <sup>1</sup>	2 <sup>1</sup>	-

1. By invitation.

# INDUCTION AND DEVELOPMENT

On joining the Board, new Directors receive a comprehensive formal induction, involving meetings with senior management and external advisers. Individual training and development needs are reviewed regularly and provided as required. All Directors receive regular updates in legal, regulatory and governance matters by the Group General Counsel and Company Secretary, independent external auditors and advisers. The Group General Counsel and Company Secretary attends all Board meetings and has the responsibility of advising the Board on corporate governance matters and assisting with the flow of information to and from the Board.

During the year, the Board received refresher training on the AIM Rules for Companies as part of the transition which took place with the change in NOMAD.

Occasionally Board meetings are held at operational sites outside the UK to enhance the Board's understanding of the business but travel restrictions due to COVID-19 has meant that this was not possible this year. The face-to-face Board meetings which were possible this year have all taken place in the UK. The Board is also provided with regular updates on strategy from senior management throughout the year including a virtual strategy day held in June 2020.

### **BOARD COMMITTEES**

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The Board has established a Nomination Committee, Audit and Risk Committee, and Remuneration Committee, each having separate duties and responsibilities.

#### NOMINATION COMMITTEE

The Chairman of the Nomination Committee is Peter Allen, with John Hartup and Ian Nicholson the other members of the Committee. The primary role of the Committee is regularly to review the structure, size and composition of the Board, give full consideration to succession planning for Directors and other senior executives and evaluate the balance of skills, knowledge, experience and independence on the Board. The Committee meets at such times as the Chairman of the Committee requires. The Committee met once during the year to discuss succession planning and board composition. Topics for the coming year will include the Company's approach to diversity and inclusion and how that links to company strategy.

## **AUDIT AND RISK COMMITTEE**

The Chair of the Audit and Risk Committee is Anne Hyland. with John Hartup and Ian Nicholson being the other members of the Committee. As announced in May 2020, the Board recognises that it is best practice for the Chairman of the Group not to be a member of the Audit Committee. With this in mind, Peter Allen relinquished his position as a member of the Audit and Risk Committee with immediate effect. The primary role of the Committee is to monitor, review and challenge the financial statements and regulatory environment, monitor the relationship with the external auditors, monitor the Group's internal control and risk management, and ensure compliance with laws and regulations. The Committee meets at such times as the Chairman of the Committee requires. The Committee carefully considers the key judgements applied in preparation of the consolidated financial statements including the estimated future discounted cash flows supporting the carrying value of goodwill and intangibles and the going concern assumption. Each of the relevant estimates and judgements have been confirmed as appropriate.

The Board believes that the Chair, who is a Chartered Accountant, has highly relevant experience to contribute to the Committee discussions.

# **REMUNERATION COMMITTEE**

The Chairman of the Remuneration Committee is Ian Nicholson, with Peter Allen, John Hartup and Anne Hyland being the other members of the Committee. Anne was appointed to the Committee on 23 June 2020. The primary role of the Committee is to determine and agree the remuneration of the Company's Chairman, CEO, Executive Directors and senior managers, with the objective to ensure there is an appropriate remuneration strategy in place to encourage enhanced performance and reward for individual contributions to the success of the Company. The Committee also reviews the design of all Group share incentive plans and oversees major changes to employee benefit structures across the wider business. The Committee reviews the performance targets regularly to ensure that they are both challenging and closely linked to the Group's strategic priorities. The level of remuneration of the Directors is set out in the Group's Remuneration Report on pages 62 to 71.

#### **RISK MANAGEMENT AND INTERNAL CONTROL**

The Board has responsibility for establishing and maintaining the Group's internal control systems. The Board regularly reviews, and evaluates internal controls, ensuring they meet the needs of the Group. The internal controls are designed to manage risk rather than eliminate it and therefore cannot provide absolute assurance against material misstatement or loss. Primary responsibility for reviewing internal controls has been delegated to the Audit and Risk Committee.

#### **COMMUNICATION WITH INVESTORS**

The Board realises that effective communication with shareholders on strategy and governance is an important part of its responsibilities. The CEO and CFO have a regular dialogue with institutional shareholders engaging proactively with them and ensuring their views are communicated back to the Board. The Investor Relations department acts as a focal point for contact with investors throughout the year. The Chairman and Non-Executive Directors continue to be available to discuss matters of concern as requested. Interim and final results are communicated via formal meetings with roadshows, participation in conferences and additional dialogue with key investor representatives held in the intervening periods.

Prior to the AGM held in November 2019, the Board contacted the Group's largest institutional investors and proxy companies and provided an opportunity for them to share their feedback on the resolutions past at the AGM and to cover questions more generally. Peter Allen, John Hartup and Ian Nicholson met with the governance representatives and fund managers from these institutions and communicated the feedback back to the wider Board.

The Board believes that appropriate steps are taken to ensure that the Board, and in particular the Non-Executive Directors, develop an understanding of the views of major shareholders. Prior to each Board meeting, an Investor Relations report is circulated which includes analysts' and brokers' briefings and following results roadshows, broker and adviser feedback is also passed to the Board.

#### SHARE DEALING

The Company has a Group share dealing code which complies with all applicable legislation, and all the Directors of the Group understand the importance of compliance with the Code.

#### AGM

The Company's AGM is used by the Board to communicate with shareholders, who are all entitled to attend. The presentation of the results will be given by the CEO, followed by the formal business of the meeting. The meeting provides an opportunity to ask questions of each of the Board members as part of the agenda, or more informally after the meeting.

The Notice of AGM and all related papers are sent to each shareholder at least 20 working days before the meeting. The outcomes of the voting on resolutions are announced to the London Stock Exchange via the Regulatory News Service and added to the Clinigen website.

## WHISTLEBLOWING

The Group operates a whistleblowing policy which allows all employees to raise concerns to senior management in strict confidence about any unethical business practices, fraud, misconduct or wrongdoing.

# AUDIT AND RISK COMMITTEE REPORT

# PROVIDING OVERSIGHT OF FINANCIAL REPORTING

# "AS THE GROUP CONTINUES TO Develop the committee plays A key role in the governance Around Audit and Risk."

# <image>

# **DEAR SHAREHOLDER**

As Chair of the Audit and Risk Committee, I am pleased to present you with the Committee's report for the year ending 30 June 2020. This report details the work of the Committee over the past year in fulfilling our responsibilities to provide effective governance over the Group's financial and risk affairs, to ensure that shareholders' interests are properly protected in relation to internal controls, financial reporting and risk management.

In meeting these responsibilities, the Committee continues to consider the provisions of the Code and the FRC Guidance on Audit Committees.

As has already been mentioned, this year the Group has delivered strong organic growth despite the difficult trading conditions in the last few months of the financial year due to COVID-19. As the Group continues to develop the Committee plays a key role in the governance around audit and risk.

# **COMPOSITION**

The Audit and Risk Committee was chaired by me throughout the year and my co-members were, Senior Non-Executive Director, John Hartup and Non-Executive Director, Ian Nicholson. As announced in May 2020, the Board recognises that it is best practice for the Chairman of the Group not to be a member of the Audit Committee. With this in mind, Peter Allen relinquished his position as a member of the Audit and Risk Committee. The Committee met three times formally in 2020. Other Board members and representatives from the Group's external auditors, PwC, are invited to attend the Audit and Risk Committee meetings.

A. Mad

ANNE HYLAND Chair of the Audit and Risk Committee 16 September 2020

As I am a Chartered Accountant with over 25 years' financial, risk and commercial experience in listed companies, the Board has determined that I meet the Code requirements for the Committee to include at least one member with recent and relevant financial experience.

# ROLE

My role and that of the Committee is to monitor, review and challenge the financial statements and regulatory environment, monitor the relationship with the external auditors, monitor the Group's internal control and risk management, ensure compliance with laws and regulations, and to report to the Board on all of these matters.

# **MAIN COMMITTEE ACTIVITIES**

- Reviewed the annual and half-yearly financial reports and related statements including clarity and completeness of disclosures and use of alternative performance measures
   Approving the annual external audit plan and risk
- identification
- Approving the level of fees paid to the external auditors for audit and non-audit services
- Discussed the key findings of the external auditors on the interim and annual consolidated financial statements
- Reviewed the independence, objectivity, performance and effectiveness of the external auditors
- Reviewed the integrity and consistency of the key accounting judgements
- Considering if the Annual Report and Accounts taken as a whole are fair, balanced and understandable
- Reviewed principal risks to ensure effective and continual improvement
- Reviewed the Group's accounting for the acquisition of products and corporate acquisitions
- Review of support for the going concern assumption
- Review of the effectiveness and integrity of the internal financial controls framework which underpins financial reporting by considering reports on internal control
- Monitoring progress on the Group ERP implementation

As part of the half and full year reporting we carefully consider the key judgements applied in preparation of the consolidated financial statements including the estimated future discounted cash flows supporting the carrying value of goodwill and intangibles and the going concern assumption along with the critical accounting estimates and judgments detailed in note 2 of the financial statements.

# **INTERNAL AUDIT**

The Company, to date, has not had an internal audit function. However, following the recent increases in the size and scope of the Group's business, the Committee has recommended the creation of an internal audit function. Subsequent to the year end an experienced Head of Internal Audit and Risk management has been appointed. A co-sourced internal audit model has been identified as being most appropriate to enable the Group to access specialist skills and resource through a third-party provider. A process is currently under way to determine who Clinigen will partner with to provide this function.

# **EXTERNAL INDEPENDENT AUDITORS**

Both the Board and the external independent auditor (PwC) have safeguards in place to protect the independence and objectivity of the external auditors. These were reviewed by the Committee during the year and remain appropriate. In accordance with International Standards on Auditing (UK), PwC formally confirmed to the Board its independence as auditors of the Company. Non-audit services require approval by the Committee.

The Committee undertakes an annual assessment of the effectiveness of the external auditors. The assessment considered:

- Delivery of a thorough, robust and efficient global audit, complying with plan and timescales
- Provision of accurate, robust and perceptive advice on key accounting and audit judgements, technical issues and best practice
- Strict adherence to independence policies and other regulatory requirements

The Committee concluded that the above factors had been met and that it continued to be satisfied with PwC's performance and effectiveness.

# **RISK MANAGEMENT**

The Committee oversees the effectiveness of the Group's risk management and internal controls, and reviews and monitors the key risks in order to eliminate or mitigate against those risks. The risk management framework is the mechanism by which the current risks identified are managed and that appropriate procedures are in place to identify emerging risks.

# CONCLUSIONS

The Committee has had another productive year providing oversight of financial reporting, external audit and the further development of the control and risk environments. This will continue as the Group grows and develops in line with its strategy, and we will ensure that finance and risk management capability is enhanced to manage in an increasingly complex business.

# **REMUNERATION REPORT**

# PROVIDING Accountability To shareholders

"AS AN AIM-LISTED COMPANY WE VOLUNTARILY SEEK ADVISORY SHAREHOLDER APPROVAL FOR OUR REMUNERATION REPORT TO PROVIDE Accountability and for shareholders to Express their views on the remuneration Policy and its implementation."



# **DEAR SHAREHOLDER**

On behalf of the Board, I am pleased to present you with the Remuneration Committee's report for the year ended 30 June 2020.

The Remuneration Committee was chaired by me throughout the year and my co-members were Peter Allen, John Hartup and Anne Hyland who was appointed to the Committee on 23 June 2020 with immediate effect. The Committee met three times formally in 2020.

As one of the larger listed companies on the AIM market, the Board and Remuneration Committee take governance seriously and this report is put to advisory vote each year at the AGM. During the year, I and other members of the Board have engaged with the Group's largest institutional investors and proxy voting agencies on various governance matters, including remuneration. Engagement with our stakeholders has been invaluable to the Committee, who has taken into consideration the balance of feedback received. The Committee also uses independent remuneration consultants to advise on best practice and to ensure appropriate disclosure in this Remuneration Report.

In order to deliver the Group's strategy, the Committee believes Clinigen must continue to attract, motivate and retain the highest calibre talent in the sector. The Committee therefore must ensure that the remuneration policy is appropriate for a diverse and unique team working in a dynamic and successful business with over 1,150 employees in 14 international locations. The governance of the remuneration policy is equally important to ensure it is appropriate for a business the size and profile of the Group.

# **PERFORMANCE HIGHLIGHTS**

The Group has once again delivered another strong set of financial results, with:

- Adjusted net revenue of £466.2m up 15%
- Adjusted EBITDA of £131.0m up 30%
- Adjusted EPS up 20% to 65.6p

The growth in adjusted EBITDA was driven by both the acquisitions made in FY19 and a strong underlying performance. This performance was despite the difficult trading conditions in the last few months of the financial year due to COVID-19. On an organic basis, there were good performances in Commercial Medicines, from CSM in Clinical Services and in Unlicensed Medicines, from Global Access. These performances offset weaker performances from CTS in Clinical Services and in Unlicensed Medicines, from both Managed Access and the UK Specials business.

# J.h.

IAN NICHOLSON Chairman of the Remuneration Committee 16 September 2020

# **REMUNERATION FOR 2020**

Reflecting the performance in 2020 set out above and the performance of the Group over the last three years, annual bonus payouts and Long-Term Incentive Plan ('LTIP') vesting for the Executive Directors were as follows:

#### **ANNUAL BONUS**

The Company related performance condition for the annual bonus for the last financial year was based on the achievement of stretching adjusted Group EBITDA targets (70%) and personal objectives (30%). In view of performance, the Committee has determined that:

- Adjusted EBITDA of £131.0m was below the maximum stretch target of £156.2m, resulting in 45% out of 70% payout for this element
- The personal objectives for both Shaun Chilton and Nick Keher are set on an individual basis and are linked to the corporate, financial, strategic and other non-financial objectives of the Group (further details are set out in the annual bonus section of this report). In the Committee's view, these objectives were met in full
- Shaun Chilton and Nick Keher will receive 64% and 100% of the maximum award for financial and personal measures respectively. This amounts to an annual bonus payout of 75% of their maximum opportunity. In line with the stated policy, 20% in excess of 50% of base salary is deferred for one year

#### LTIP

Shaun Chilton was granted LTIP awards in October 2017 and November 2017. The November 2017 award was a one off award following the Quantum Pharmaceuticals acquisition. These awards will vest in October 2020 and November 2020, shortly after the end of the 2020 financial year.

The performance criteria and weightings attached to these awards are as follows:

- TSR performance condition (40%) the performance period for this part of the award is due to end on 21 October 2020 and 5 November 2020 - TSR based on performance to 30 August 2020 was 6% below the Index and provides an estimated vesting of 0% out of 40% vesting
- Cumulative EPS (40%) cumulative EPS over the three financial years to 30 June 2020 period was 164.2p which is above the maximum target of 127.4p and therefore 40% out of 40% will vest
- 20% was subject to personal objectives for this element
   20% out of 20% will vest for Shaun Chilton reflecting strong
   personal performance over the three year period
- Therefore, it is estimated that 60% of Shaun Chilton's award will vest in October 2020 and November 2020. The final vesting position will depend on the TSR vesting outcome which will not be known until after this report is signed off. The final position will be shown in next year's report

In last year's report it was estimated that the October 2016 LTIP would vest at 100% for Shaun Chilton. The final TSR performance was 25% ahead of the Index and therefore, we can confirm that the October 2016 LTIP vested in full in October 2019.

The Remuneration Committee believes the above incentive outcomes are fair reflections of the very strong Company performance and shareholder value creation over the relevant performance periods.

#### **IMPLEMENTATION OF POLICY IN 2021**

Due to the uncertainty that the COVID-19 pandemic could have on the Company, the Committee took the prudent and responsible step to mitigate any potential financial impact on the Company by postponing the April 2020 salary review process until September 2020. Following the review in September 2020, Shaun Chilton's annual base salary remained unchanged at £600,000 (no change since 1 November 2017). Nick Keher's annual base salary remains unchanged at £300,000.

Due to the continuing focus and prevailing market practice in relation to executive remuneration, the Committee regularly reviews the remuneration policy to ensure it remains appropriate for the business. The Committee has determined that the policy does not require fundamental changes to the way our Executive Directors are remunerated. Therefore, the annual bonus and LTIP schemes will continue to apply as follows:

- Annual bonus opportunity shall be 100% for Shaun Chilton and Nick Keher. 70% will be based on stretching EBITDA targets with the balance based on personal and strategic goals
- The Committee intends to grant Shaun Chilton and Nick Keher an LTIP award with a face value of 125% of salary. 40% of the award will be based on TSR, 40% based on EPS and 20% based on personal objectives. The Committee considered the level of award in light of the prevailing share price and felt that no discretion was required to adjust the 125% of salary award level

### **COMPLIANCE WITH THE CODE**

As one of the larger AIM-listed companies in the market and reflecting the Board's approach to governance, Clinigen follows the 2018 Code on a comply or explain basis.

The Code asks companies when determining its Policy to have considered the following six factors:

#### CLARITY

- Our Policy has a clear aim; to incentivise and reward for the delivery of our strategy
- There have been minimal changes to the Policy overtime, so it is well understood both internally and externally
- Each component of remuneration is clearly explained in the Policy table, including its purpose, how it is operated, the maximum potential and any relevant performance measures
- Full disclosure of performance measures and assessments is provided for shareholders' consideration

#### SIMPLICITY

- The Policy reflects standard UK market practice, with the operation of an annual incentive and a single long-term share plan, full details of which are set out in the Policy table
- All payments are in the form of cash or Clinigen Group plc shares, there are no artificial structures used to deliver remuneration

# **REMUNERATION REPORT CONTINUED**

#### RISK

- The Committee has the ability to use its discretion to override the formulaic outturns of the incentive plans if it is felt appropriate
- Malus and clawback provisions operate in the LTIP plan, providing the ability to recover or withhold payments if appropriate
- There is an appropriate mix of financial, non-financial and share price measures to avoid minimise undue risk taking

#### PREDICTABILITY

- Appropriate individual (and where necessary aggregate) limits are set out in the Policy and within the respective plan rules so outcomes can be predicted
- In operating the Policy, the Committee continually monitors the performance of in-flight incentive awards so that it is well aware of potential outcomes

#### PROPORTIONALITY

- The outcomes of our incentive plans are directly aligned to the delivery of our strategy
- Outcomes are assessed against multiple metrics to ensure performance is considered on a broad basis

#### ALIGNMENT OF CULTURE

- A key focus of our Policy is long-term sustainable performance which is reflective of the business culture

As an AIM-listed company we voluntarily seek advisory shareholder approval for our Remuneration Report to provide accountability and for shareholders to express their views on the remuneration policy and its implementation. All feedback provided by shareholders helps form the Committee's approach to governance of the remuneration policy. The Committee welcomes any feedback on the remuneration policy. If you have any comments, then please let me know via Amanda Miller, General Counsel and Company Secretary (amanda.miller@clinigengroup.com).

I hope you find the Remuneration Report useful and the Committee looks forward to your continued support.

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. Acquisitions completed in the previous financial year are included on a like-for-like basis including the results for the acquisition where it is included in the comparable historical period. Organic growth is presented to aid the reader's understanding of the underlying performance of the business. In previous reports, organic growth was calculated on a pro forma basis with the comparative period results before acquisition based on the vendors' previously reported results. The like-for-like basis now used has been necessary due to the limited reported financial information available for the products' results prior to acquisition by Clinigen. On a pro forma basis, the best estimate for organic adjusted EBITDA growth for the year ended 30 June 2020 is 12%.

As an AIM-listed company, Clinigen is not subject to the UK Listing Rules and makes the following disclosures voluntarily.

The Group's Remuneration Report will be put forward, on an advisory basis, for shareholder approval at the AGM to be held on 26 November 2020. The current policy set out below came into effect following the AGM on 26 November 2019 and remains unchanged for 2020/21.

#### **REMUNERATION POLICY**

The remuneration policy has been constructed to offer appropriate, competitive remuneration to attract, retain and motivate senior executives to avoid excessive or inappropriate risk-taking and encourage them to implement the Group's strategy for the benefit of long-term shareholder value.

The Board believes in pay for performance against challenging targets and stretching goals. The approach is to set base salaries around the median for our comparator group. A significant proportion of the total remuneration package is variable and linked to corporate performance. In setting Directors' remuneration, the Committee takes account of the remuneration of other companies of similar size and complexity. The Committee also takes into account the pay and employment conditions of all our employees.

The Remuneration Committee determines the remuneration policy for the Chairman, Executive Directors and senior managers. The remuneration for the Chairman is determined by the Committee (with the Chairman not present for any discussions). The remuneration of the Non-Executive Directors is determined by the Chairman and the Executive Directors.

The Committee reviews the performance targets regularly to ensure that they are both challenging and closely linked to the Group's strategic priorities. Furthermore, because a large part of the remuneration package is delivered in shares, they are directly exposed to the same gains or losses as all other shareholders.

The Committee ensures that the incentive structure for senior executives does not raise environmental, social or governance risks by inadvertently motivating irresponsible behaviour. Part of the annual bonus depends upon an assessment of each senior executive's personal contribution to Company measures, including results of the regular employee surveys and health and safety outcomes.

### **SHAREHOLDERS' VIEWS**

The Committee considers the views expressed by shareholders during the year, including at the AGM, and encourages open dialogue with its largest shareholders. In addition, in determining the remuneration policy, the Committee takes into account guidance issued by shareholder representative bodies, including The Investment Association, the Pensions and Lifetime Savings Association and Institutional Shareholder Services ('ISS').

# **EXECUTIVE DIRECTORS**

The Executive Directors' remuneration consists of five components to ensure there is a balance between fixed and performance-related remuneration. The table opposite sets out a summary of our remuneration policy:

	PURPOSE AND LINK TO STRATEGY	OPERATION	MAXIMUM OPPORTUNITY	PERFORMANCE METRICS
BASE SALARY	To provide a core reward for undertaking the role, positioned at a level needed to recruit and retain the talent required to develop and deliver the business strategy.	<ul> <li>The Remuneration</li> <li>Committee sets base</li> <li>salaries taking into account</li> <li>a range of factors including:</li> <li>The individual's skills,</li> <li>performance and</li> <li>experience</li> <li>Internal relativities and</li> <li>wider workforce salary</li> <li>levels</li> <li>External benchmark data</li> <li>The size and</li> <li>responsibility of the role</li> <li>The complexity of the</li> <li>business and</li> <li>geographical scope</li> <li>Economic indicators</li> </ul>	There are no maximum levels set although increases will normally be in line with the typical level of increases awarded to other employees at Clinigen and will be a reflection of the individual's performance. The Remuneration Committee may award increases above this level in certain circumstances, including if there is an increase in the scope of roles and responsibilities. Base salaries are usually reviewed annually.	
ANNUAL BONUS	To support the delivery of the Group's annual business plan. The focus is on the delivery of the annual financial, strategic, customer and people KPIs.	Performance targets are approved annually by the Remuneration Committee. The Remuneration Committee exercises its judgement to determine payout levels after the year end, based on performance against targets. This ensures that the outcome is fair in the context of overall Group performance and against personal goals. For Executive Directors, 20% of any bonus above 50% of salary will be deferred. For example: this would relate to 10% of total for those receiving 100% bonus, 5% for those getting 75%. The deferral period will be one year.	The maximum award opportunity in respect of any financial year is based on role and is up to 100% of base salary.	Performance is measured against a range of key financial metrics, strategic, customer and people indicators, and personal performance. Stretch targets are set for maximum payout. Performance is measured over 12 months.
LTIP	To reward participants for the delivery of the Group's goals of driving shareholder value through measures such as the Group's adjusted EPS and TSR.	Award of shares subject to performance measured over a three-year period. Performance targets are set annually for each three-year cycle by the Remuneration Committee. Awards are subject to review by the Remuneration Committee at the end of the three- year performance period to confirm that vesting of the award is appropriate. Unvested awards can be reduced or withheld in certain circumstances.	The maximum award opportunity is based on role. The maximum award possible under the plan rules is usually 125% of salary but may rise to 400% in exceptional circumstances.	<ul> <li>Vesting of the award is based on a combination of the following performance measures:</li> <li>Cumulative Group adjusted EPS compared to targets</li> <li>Cumulative Group TSR compared to FTSE Small Cap Index (ex Investment Trusts); FTSE 250 Index (ex Investment Trusts) for awards granted from 1 July 2019</li> <li>Personal objectives</li> <li>The split between measures, for each grant, is set annually by the Remuneration Committee. In 2020, 40% of the award was based on EPS, 40% on TSR and 20% on personal objectives. The personal objectives component can only vest if a minimum EPS target is achieved. In future years, the Committee may choose alternative measures and weightings aligned to the strategic priorities in place at the time.</li> </ul>

# **REMUNERATION REPORT CONTINUED**

	PURPOSE AND LINK TO STRATEGY	OPERATION	MAXIMUM OPPORTUNITY	PERFORMANCE METRICS
PENSION	To provide a competitive, flexible retirement benefit in a way that does not create an unacceptable level of financial risk or cost to the Group.	Executive Directors are auto-enrolled into a defined contribution pension plan and are offered the alternative of a cash allowance. Legacy arrangements will continue to be honoured.	Employer contribution into the Group's defined contribution pension plan of up to 10% of salary.	
OTHER BENEFITS	To provide market- competitive monetary and non-monetary benefits, in a cost-effective manner, to assist employees in carrying out their duties efficiently.	Executive Directors are provided with a package of core benefits, including private healthcare, health screening, death in service protection and reimbursement of membership fees of professional bodies. The Company also operates a sharesave scheme.	There is no maximum value of the core benefit package as this is dependent on the cost to the Company and the individual's circumstances.	

# **SHARE OWNERSHIP GUIDELINE**

Executive Directors are expected to build and maintain a significant shareholding in the Company, with a minimum value of 200% of base salary. It is expected that any vested share awards are retained (after the sale of any shares for the payment of tax) until the guideline has been achieved. The Committee will monitor the level of Directors' shareholdings regularly.

# **PAYMENT FOR LOSS OF OFFICE**

In a departure event, the Committee will typically consider whether any element of bonus should be paid for the financial year. Generally, any bonus, if paid, will be limited to the period served during the financial year in which the departure occurs. The Committee will consider whether any of the share element of deferred bonus awarded or LTIP in prior years should be preserved either in full or in part and whether any deferred cash payments should be preserved either in full or in part.

The Committee has a discretionary approach to the treatment of leavers, on the basis that the facts and circumstances of each case are unique. The overriding approach to payments for loss of office is to act in the shareholders' interests. The default position is that an unvested share award, LTIP or cash entitlement lapses on cessation of employment. This provides the Committee with the maximum flexibility to review the facts and circumstances of each case, allowing differentiation between good and bad leavers, and avoiding payment for failure. When considering a departure event, there are a number of factors which the Committee takes into account. These include:

- The position under the relevant plan documentation
- The individual circumstances of the departure
- The performance of the Company/individual during the year to date
- The nature of the handover process

If the Committee, at its discretion, permits an award to vest in a departure event, awards which would otherwise lapse by default may vest either on the normal vesting date or on cessation of employment, under the rules of the relevant plan. These circumstances may include death, injury, ill-health, disability, redundancy or sale of the Company or business.

# **NON-EXECUTIVE DIRECTORS**

The Board aims to recruit high-calibre Non-Executive Directors, with broad commercial, international or other relevant experience. Each Non-Executive Director has an appointment letter setting out the terms of his or her appointment. They do not have service contracts. The letter includes membership of any Board Committees, the fees to be paid and the time commitment expected. Appointments are for an initial period of three years. During that period, either party can give the other at least three months' notice of termination. All Board appointments automatically terminate in the event of a Director not being elected or re-elected by shareholders at the AGM each year. The appointment of a Non-Executive Director is terminable on notice by the Company without compensation. At the end of the period, the appointment may be continued by mutual agreement. The appointment letter also covers matters such as confidentiality. data protection and Clinigen's share dealing code.

Non-Executive Directors cannot individually vote on their own remuneration. Non-Executive Director remuneration is reviewed by the Chairman and the Executive Directors, and discussed and agreed by the Board. Non-Executive Directors may attend the Board discussion but may not participate in it.

Details of the service agreements for the Executive Directors and letters of appointment for the Non-Executive Directors are set out below:

	DATE OF CONTRACT	UNEXPIRED TERM (Months) or Rolling Contract	NOTICE PERIOD (Months)
S Chilton	3 January 2012	Rolling	12
N Keher	19 March 2019	Rolling	6
P Allen	1 August 2012	Rolling	3
J Hartup	1 June 2011	Rolling	3
l Nicholson	1 September 2012	Rolling	3
A Hyland	1 January 2018	Rolling	3
A Boyd	15 November 2018	Rolling	3

#### **REMUNERATION GOVERNANCE**

The Remuneration Committee consists of three independent Non-Executive Directors. The table below provides each member's attendance record at Committee meetings during the year. The Committee members' biographies are set out on pages 52 to 53.

COMMITTEE MEMBER	POSITION	APPOINTED	ATTENDANCE
l Nicholson	Committee Chair	September 2012	3/3
P Allen	Non-Executive Director	August 2012	3/3
J Hartup	Non-Executive Director	June 2011	3/3

The key areas of focus for the Remuneration Committee during 2020 included:

- Approved the Remuneration Report
- Reviewed and approved UK and international sharesave plans
- Reviewed performance conditions and targets for 2020 bonus and LTIP
- Reviewed 2019 personal objectives and set 2020 personal objectives for the Executive Directors
- Reviewed and approved the Company's Gender Pay Gap Report
- Reviewed and approved base salary increases for the Executive Directors, senior managers and the Chairman
- Reviewed wider market trends and best practice reporting in remuneration
- Engaged with the Group's largest institutional investors and proxy companies

The key areas of focus for the Remuneration Committee for the year ahead include:

- Prepare and publish the Remuneration Report
- Determine performance conditions and targets for 2020 bonus and LTIP
- Review and approve base salary increases for the Executive Board, senior managers and the Chairman
- Consider advice from FIT Remuneration Consultants LLP ('FIT') who are independent advisers to the Committee
- Review and approve the Gender Pay Gap Report

FIT advised on market trends, corporate governance, Remuneration Report disclosures and on Directors' remuneration arrangements in 2020/21. FIT is a member of the Remuneration Consultants' Group and complies with its Code of Conduct which sets out guidelines to ensure that its advice is independent and free of undue influence. FIT carries out no other work for Clinigen or its subsidiaries.

#### ANNUAL REPORT ON REMUNERATION

The table below sets out the Single Figure of Total Remuneration for the Executive Directors' and Non-Executive Directors' for 2020 and 2019:

	2020			2019						
£000	SALARY/FEES	BONUS	LTIP <sup>1</sup>	<b>BENEFITS</b> <sup>2</sup>	TOTAL	SALARY/FEES	BONUS	LTIP	OTHER	TOTAL
S Chilton	600	450	377	62	1,489	600	450	1,439	69	2,558
N Keher	300	225	-	31	556	85	49	-	-	134
P Allen	140	-	-	3	143	140	-	-	3	143
J Hartup	70	-	-	-	70	70	-	-	-	70
l Nicholson	70	-	-	-	70	70	-	-	-	70
A Hyland	70	-	-	-	70	70	-	-	-	70
A Boyd	60	-	-	-	60	39	-	-	-	39

1. The 2020 LTIP figure relates to the October 2017 and November 2017 award which is due to vest in October 2020 and November 2020. These awards are subject to a TSR performance period ending on 16 October 2020 and 5 November 2020. In line with the reporting regulations for Main Market companies, the table above provides an estimate of the vesting value based on TSR performance to 30 August 2020. The value is based on 0% of the TSR element of the award vesting and using the average share price for the period 1 July 2020 to 30 August 2020. The actual vesting value will be updated in next year's report to reflect the share price on vesting date. The 2019 LTIP value relates to the award that was granted on 21 October 2016 and vested on 21 October 2019.

2.Payment in lieu of pension, employer pension contribution and private medical insurance for Shaun Chilton and Nick Keher. Private medical insurance for Peter Allen.

Two Directors (2019: two) are members of the defined contribution pension scheme.

As mentioned on page 63, Shaun Chilton's annual base salary has remained at £600,000 this year (no change since 1 November 2017), whilst Nick Keher's annual base salary has remained at £300,000 this year (no change since his appointment on 19 March 2019).

The amount payable to the highest paid Director in respect of emoluments was £1,489,000 (2019: £2,558,000), comprising basic salary and bonus of £1,050,000 (2019: £1.050,000), long-term share-based incentives vesting of £377,000 (2019: £1,439,000) and other benefits of £62,000 (2019: £69,000).

The bonus and LTIP outcomes are explained in more detail overleaf.

# **REMUNERATION REPORT CONTINUED**

#### **ANNUAL BONUS**

The Executive Directors were eligible to earn an annual bonus of up to 100% of salary, based on the achievement of stretching adjusted Group EBITDA targets and personal objectives. Adjusted Group EBITDA targets unlock up to 70% of maximum bonus potential, whilst personal objectives unlock up to 30%.

The bonus calculation in relation to adjusted Group EBITDA for 2020 are set out below:

THRESHOLD LEVEL OF ADJUSTED GROUP EBITDA £M	TARGET LEVEL OF ADJUSTED GROUP EBITDA £M	MAXIMUM LEVEL OF ADJUSTED GROUP EBITDA £m	ACTUAL LEVEL OF ADJUSTED GROUP EBITDA £M	BONUS EARNED (% OF MAXIMUM)
127.8	142.0	156.2	131.0	64%
40% payable	100% payable	130% payable		

The personal objectives determining the other 30% of the bonus are set on an individual basis and are linked to the corporate, financial, strategic and other non-financial objectives of the Group.

For the 2020 financial year for Shaun Chilton, these related to the implementation of Clinigen One ERP and the improvement of customer service and product offering, expansion of our medical scientific liaison and commercial capabilities across the EU and US, and the development of our business and client base, including, where appropriate, M&A. The Committee determined that 30% out of 30% would become payable.

For Nick Keher, relating to the financial year 2020, personal objectives included the development of a five-year digital strategy across the Group, a number of operational efficiency and business value creation programs and the development of a long-term business plan covering all divisions. The Committee determined that 30% out of 30% would become payable.

The annual bonuses awarded for the 2020 financial year were as follows:

£000	BONUS PAYABLE (% of Salary	TOTAL BONUS Awarded In September 2020 (Relating to 2020 Financial Year)	CASH BONUS TO BE Paid in September 2020 (Relating to 2020 Financial Year)	DEFERRED BONUS TO BE PAID IN SEPTEMBER 2021 (Relating to 2020 Financial Year)
S Chilton	75%	450	420	30
N Keher	75%	225	210	15

For the 2020 financial year, the annual bonus awarded to Shaun Chilton and Nick Keher was 75% of their base salary. 20% of the bonus earned in excess of 50% of base salary is deferred for one year in line with the stated policy.

The deferred element of the bonus relating to the 2019 financial year was paid in September 2020.

#### LTIP AWARDS VESTING IN THE YEAR OCTOBER 2016 AWARD

Nil cost share options were granted to Shaun Chilton in October 2016 and these vested in October 2019. This award was subject to a performance condition of TSR (40%) for the period from 21 October 2016 to 21 October 2019, cumulative EPS (40%) for the three financial years ending 30 June 2019, and personal objectives (20%).

MEASURE	THRESHOLD VESTING	MAXIMUM VESTING	OUTCOME	VESTING (% OF MAXIMUM)	
Relative TSR	Equal to the FTSE SmallCap Index (ex Investment Trusts)	Index plus 15% outperformance or higher	Index plus 24.7%	40%	
EPS growth	5% p.a.	10% p.a.	21% p.a.	40%	
Personal objectives	sonal objectives - Seeking further acquisitions to extend global footprint - Improving the Company's information technology platforms - Increasing the profile of Clinigen with key stakeholders				
		•••••••••••••••••••••••••••••••••••••••	· · · · · · · · · · · · · · · · · · ·	100%	

A total performance score of 100% was achieved by Shaun, made up of 40% TSR, 40% EPS and 20% personal objectives.

The terms agreed with Martin Abell in respect to his pro-rated share options are as stated in last year's report. Martin Abell, a former Director departed the Company on 31 March 2019.

#### OCTOBER 2017 AND NOVEMBER 2017 AWARDS

Nil cost share options were granted to Shaun Chilton in October 2017 and November 2017 and these will vest in October 2020 and November 2020. These awards are subject to a performance condition of TSR (40%) for the period from 16 October 2017 to 16 October 2020 and 5 November 2017 to 5 November 2020, Cumulative EPS (40%) for the three financial years ending 30 June 2020, and personal objectives (20%).

MEASURE	THRESHOLD VESTING	MAXIMUM VESTING	OUTCOME	VESTING (% OF MAXIMUM)
Relative TSR	Equal to the FTSE SmallCap Index (ex Investment Trusts)	Index plus 15% outperformance or higher	Index minus 6% – based on an estimate to 30 August 2020	0%
EPS growth	5% p.a.	10% p.a.	18% p.a.	40%
Personal objectives	<ul> <li>Broaden service capability</li> <li>Utilise international platfor</li> <li>Drive performance of port</li> </ul>	20%		
				Estimated 60%

It is expected that 60% of awards will vest on 16 October 2020 and 5 November 2020.

#### LTIP AWARDS GRANTED IN THE YEAR

Awards were granted to Shaun Chilton and Nick Keher in October 2019, with vesting of the awards subject to the performance conditions, as set out below, in October 2022. The split between these measures, for each grant, is set annually by the Remuneration Committee. 40% of the award is based on TSR against the FTSE 250 Index (ex Investment Trusts), 40% against EPS growth targets (with a 5–10% p.a. (threshold and maximum range)) and 20% based on personal objectives. The personal objectives component can only vest if a minimum EPS target is achieved.

The face value of Shaun Chilton's awards was equal to 125% of base salary and 100% for Nick Keher.

	NUMBER OF AWARDS Granted	FACE VALUE <sup>1</sup>	AMOUNT OF BASE Salary	VESTING DATE
Shaun Chilton	95,238	£750,000	125%	28 October 2022
Nick Keher	38,095	£300,000	100%	28 October 2022

1. Valued using the share price on grant.

The performance conditions applying to these awards are as follows:

#### TSR

0%
25%
20/0
aight-line basis between 25% and 100%
100%
-

CUMULATIVE EPS OVER THE PERFORMANCE PERIOD (WHICH ARE THE THREE FINANCIAL YEARS COMMENCING WITH THE 2019/2020 FINANCIAL YEAR)	PERCENTAGE OF AWARD THAT VESTS
Less than 180.1p	O%
Equal to 180.1p	25%
Between 180.1p but less than 198.1p	Calculated on a straight-line basis between 25% and 100%
Equal to or greater than 198.1p	100%

#### **Personal objectives**

The element of the award relating to personal objectives shall only vest if the personal objectives have been achieved and the minimum EPS threshold, shown above, is achieved. The personal objectives are based on; enhancing the Company's Acquired Products portfolio, especially in the oncology therapeutic area, ensuring that improvements to the information technology platform are implemented and the successful integration of newly acquired businesses into the Group.

# **REMUNERATION REPORT CONTINUED**

# **OUTSTANDING SHARE AWARDS**

Details of outstanding share options held by the Executive Directors as part of the LTIP are set out in the table below:

	DATE OF GRANT	30 JUNE 2019	GRANTED	EXERCISED	LAPSED	30 JUNE 2020
S Chilton	LTIP - 19 June 2015 - vested	43,811	-	-	-	43,811
	LTIP – 30 November 2015 – vested	34,452	-	-	-	34,452
	LTIP - 21 October 2016 - vested	159,893	-	-	-	159,893
	LTIP – 16 October 2017	34,904	-	-	-	34,904
	LTIP – 6 November 2017	43,630	-	-	-	43,630
	LTIP - 31 October 2018	106,007	-	-	-	106,007
	LTIP – 28 October 2019	-	95,238	-	-	95,238
N Keher	LTIP - 29 May 2019	96,256	_	_	_	96,256
	LTIP – 28 October 2019	-	38,095	-	-	38,095
	Clinigen Group Sharesave Plan	-	2,538	-	-	2,538

# **DIRECTORS' INTERESTS**

The interests of the Directors over the ordinary share capital of the Company as at 30 June 2020 are as follows:

	NUMBER OF SHARES Owned Outright	NUMBER OF SHARE Options with Performance Conditions	NUMBER OF SHARE Options without Performance Conditions	NUMBER OF VESTED But unexercised Options
S Chilton	330,044	279,779	-	238,156
P Allen	47,232	-	-	-
N Keher	10,100	134,351	2,538	-
J Hartup	5,000	-	-	-
I Nicholson	10,000	-	-	-
A Hyland	4,142	-	-	-
A Boyd	-	-	-	-
Total	406,518	414,130	2,538	238,156

There has been no change in the interests set out above between 30 June 2020 and 16 September 2020.

The Group has used Alan Boyd Consultants Limited, a company owned by Professor Alan Boyd, for regulatory services in relation to the maintenance of country product licence approvals over the course of the year.

# TSR

In the eight years since IPO on 24 September 2012 until 28 August 2020, the Group's TSR, defined as share price growth including reinvested dividends, has outperformed the FTSE All-Share Index by 291%, the FTSE 350 Pharma and Bio Index by 195% and the FTSE SmallCap Index (ex Investment Trusts) by 255%.

### **CEO REMUNERATION**

The total remuneration for the CEO during each of the last four financial years is shown in the table below. The total remuneration includes base salary, annual bonus (based on previous year's performance), LTIPs and other benefits. The annual bonus payout on that year's performance and LTIP vesting level as a percentage of the maximum is also shown.

	FINANCIAL YEAR 2016	FINANCIAL YEAR 2017	FINANCIAL YEAR 2018	FINANCIAL YEAR 2019	FINANCIAL YEAR 2020	PERCENTAGE Change	PERCENTAGE CHANGE For all employees
Total remuneration (£000)	6,103	1,266	1,202	2,558	1,489	(42)%	6%
Annual bonus (% of maximum)	0% <sup>1</sup>	100%	58%	75%	75%	0%	4%
LTIP vesting (% of maximum)	100%	100%	95%	100%	60%	(40)%	(50)%

1. For the year ended 30 June 2016, the annual performance bonus for the Executive Directors' paid at 95% of their basic salary. Peter George waived his entire bonus.

### **RELATIVE IMPORTANCE OF SPEND ON PAY**

The table below shows the Group's actual spend on pay (for all employees) relative to dividends, and adjusted profit before tax for the year.

YEAR ENDED 30 JUNE 2020	2019 £M	2020 £M	CHANGE %
Total employee pay	52.3	58.5	12%
Dividends	7.7	9.2	19%
Adjusted profit before tax	88.3	108.5	23%

# **GENDER PAY GAP REPORTING**

The Group recognises the importance of diversity and inclusion, including gender, at all levels of the Company. For further details on gender pay gap reporting, please see pages 48 to 51.

### **IMPLEMENTATION OF REMUNERATION POLICY IN 2021**

Along with the salary review timetable for the Company as a whole, the Executive Directors' salaries for 2020 are scheduled to be reviewed in September 2021. Any increases to the Executive Directors' salaries are expected to be in line with the average UK employee, other than where a larger increase is awarded to reflect additional duties.

Shaun Chilton's and Nick Keher's pension contribution is 10% of salary. They will both receive standard benefits in line with those provided to the workforce.

The annual bonus opportunity for Shaun Chilton and Nick Keher is 100% of salary, with 70% based on EBITDA and 30% on personal objectives. The actual targets and objectives are commercially sensitive at this time but will be disclosed when they cease to be so.

It is expected that an LTIP award with a face value of 125% of salary will be granted to Shaun Chilton and Nick Keher. 40% will be based on relative TSR against the FTSE 250 Index (ex Investment Trusts), 40% against EPS growth targets (with a 5% p.a. to 10% p.a. (threshold and maximum range)) and 20% based on personal objectives.

No changes are proposed to the Non-Executive Directors' fees for 2021.

# **REPORT OF THE DIRECTORS** For the year ended 30 June 2020

The Directors present their report together with the Strategic Report and the audited consolidated financial statements for the year ended 30 June 2020.

Clinigen Group plc is a public limited company, which is listed on AIM, incorporated and domiciled in the UK and registered in England and Wales.

# **PRINCIPAL ACTIVITIES**

Clinigen is a specialty global pharmaceutical and services company headquartered in the UK, with offices in the US, South Africa, Australia, New Zealand, Japan, Hong Kong, Singapore, Germany, France, Switzerland, Belgium, Greece and Ireland. The Parent Company is a holding company for the Group, holding the product portfolio of intangible assets of the Group and providing management services for the other Group companies which undertake the Group's three operations.

Clinical Services is the global market leader in the specialist supply, packaging, distribution and management of qualityassured comparator medicines and services to clinical trials and IITs.

Unlicensed Medicines is the global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet medical need. The operation manages MAPs to innovative new medicines and provides global access to medicines which remain unlicensed at the point of care.

Commercial Medicines acquires global rights to niche hospitalonly and critical care products, revitalising these assets around the world and returning them back to sustained growth. The operation also provides access to licensed and branded generic medicines in the AAA region and has an UL2L strategy, where it looks to take unlicensed medicines with commercial potential and licenses them, helping to address unmet medical need and allowing the Group to capitalise on its market-leading positions.

The three operations work in synergy to attain our primary aim of supplying the right medicine, to the right patient, at the right time.

# **STRATEGIC REPORT**

Strategic Report on pages 4 to 51, as the Board considers them to be of strategic importance. Specifically, these are Risk Management on pages 44 to 47, Business Review and Future Developments on pages 34 to 39, and Environmental, Social and Corporate Governance on pages 48 to 51. The Strategic Report forms part of this Report of the Directors and is incorporated into it by cross-reference. Both the Strategic Report and the Report of the Directors have been drawn up and presented in accordance with and in reliance upon applicable English company law, and the liabilities of the Directors in connection with those reports shall be subject to the limitations and restrictions provided by such law.

# **KPIS**

The Group's KPIs are discussed in the Strategic Report. The Directors consider the Group KPIs as adjusted gross profit, adjusted EBITDA and adjusted basic EPS. The KPIs for the business operations are the number of local, regional and global assets under management, the number of exclusive supply agreements in Unlicensed Medicines and the community of registered users on Cliniport.

# **FINANCIAL INSTRUMENTS**

The Group's operations expose it to a variety of financial risks that include credit risk, liquidity risk and foreign exchange risk. The Group has a risk management program that seeks to limit the adverse effects on the financial performance of the Group by monitoring levels of debt finance and related finance costs and managing foreign currency transactions. The Group has implemented policies that require appropriate credit checks before a sale is made. The Group reduces its exposure to currency fluctuations on translation by 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 its exposure to foreign currency fluctuations.

Further detail is provided in note 21 of the consolidated financial statements.

# **CREDITOR PAYMENT POLICY**

It is the policy and normal practice of the Group to make payments due to suppliers in accordance with agreed terms and conditions, generally 30 days. Where suppliers offer early settlement discounts, these may be taken advantage of. The policy will also be applied for 2021.

# **MAJOR SHAREHOLDERS**

As at 30 June 2020, the following shareholders held an interest of 3% or more of the Company's issued share capital:

	% OF TOTAL VOTING Rights
Rathbones	6.1%
Janus Henderson Investors	5.6%
Octopus Investments	4.9%
Merian Global Investors	4.7%
AXA Investment Managers	4.6%
Invesco	3.6%
Leaver family	3.2%

# DIVIDEND

As explained in the CFO statement, the Directors propose a final dividend of 5.46p per share, subject to approval at the AGM on 26 November 2020. The dividend will be payable on 2 December 2020 to all shareholders on the register on 6 November 2020. Together with the interim dividend of 2.15p per share paid on 17 April 2020, this makes a combined dividend for the year of 7.61p per share (2019: 6.7p per share).

# **EVENTS AFTER THE REPORTING DATE**

There have been no significant events to report since the date of the balance sheet.

# **DIRECTORS AND APPOINTMENT OF DIRECTORS**

The Directors who served during the year and up to the date of signing the financial statements were, unless otherwise stated, as follows:

S Chilton	
N Keher	
P Allen	(Independent Non-Executive Chairman)
J Hartup	(Senior Independent Non-Executive)
l Nicholson	(Independent Non-Executive)
A Hyland	(Independent Non-Executive)
A Boyd	(Non-Executive)

With regard to the appointment of Directors, the Company is governed by its Articles of Association, the Companies Act and related legislation. Directors are subject to re-election at intervals of not more than three years. However, as a matter of best practice, all Board members will resign and submit themselves for re-election annually in line with the Code.

# DIRECTORS' RESPONSIBILITIES STATEMENT

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare financial statements for each financial year. Under that law, the Directors have prepared the Group financial statements in accordance with IFRS as adopted by the EU and the Parent Company financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 'Reduced Disclosure Framework' and applicable law). Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and the Company and of the profit or loss of the Group for that period. In preparing these financial statements, the Directors are required to:

- Select suitable accounting policies and then apply them consistently
- Make judgements and accounting estimates that are reasonable and prudent
- State whether applicable IFRS as adopted by the EU have been followed for the Group financial statements and UK Accounting Standards, comprising FRS 101, have been followed for the Company financial statements, subject to any material departures disclosed and explained in the financial statements
- Prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and the Group, and enable them to ensure that the financial statements and the Directors' Remuneration Report comply with the Companies Act 2006 and, as regards the Group financial statements, Article 4 of the IAS Regulation. They are also responsible for safeguarding the assets of the Company and the Group, and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the Company's website. Legislation in the UK governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

The Directors consider that the Annual Report and Accounts, taken as a whole, is fair, balanced and understandable and provides the information necessary for shareholders to assess the Company's performance, business model and strategy.

Each of the Directors, whose names and functions are listed in the Report of the Directors confirm that, to the best of their knowledge:

- The Group financial statements, which have been prepared in accordance with IFRS as adopted by the EU give a true and fair view of the assets, liabilities, financial position and profit of the Group
- The Strategic Report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal risks and uncertainties that it faces

# **DIRECTORS' INDEMNITIES**

The officers of the Company and its subsidiaries would be indemnified in respect of proceedings which might be brought by a third party. No cover is provided in respect of any fraudulent or dishonest actions.

#### GOING CONCERN AND VIABILITY STATEMENT ASSESSMENT OF PROSPECTS AND VIABILITY

The Group operates a strategic planning process which includes monthly reviews of business and financial performance, regular financial projections and an annual planning review for the next financial year. Medium term business and planning and financial projections for the next three years are prepared and reviewed taking into account known strategic changes in that time frame. The three-year plan considers the Group's growth potential, cash flows and key financial ratios. The strategic planning process is managed centrally, led by the executive management team.

The Directors have assessed the Group's prospects and resilience with reference to its current financial position, its recent and historical financial performance and forecasts, the Board's risk appetite, and the principal risks and mitigating factors. The Group is operationally and financially strong and has a track record of consistently generating profits and cash, and this is expected to continue.

### VIABILITY STATEMENT

Based on this assessment, the Directors confirm that they have a reasonable expectation that the Company will be able to continue in operation and meet its liabilities as they fall due over the next three years.

### **GOING CONCERN**

The Group's strategy and forecasts, taking account of sensitivities within the trading projections and possible changes in trading performance, show that the Group has adequate resources to continue in operational existence for the foreseeable future. The Group is not immune from COVID-19, however, the impact on trading has been relatively limited and is therefore not impacting on the Group's ability to continue as a going concern. At 30 June 2020, the Group had £143m of cash balances available which combined with the Group's positive cash generation from each of its operations, provides sufficient funding for the near term settlement of deferred consideration liabilities along with sufficient liquidity for ongoing trading.

After making appropriate enquires, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for at least twelve months from the date of approval of the financial statements. Therefore, the Company and Group continues to adopt the going concern basis in preparing its financial statements. Further information on the Group's borrowing facilities is given in note 20.

# **REPORT OF THE DIRECTORS CONTINUED** For the year ended 30 June 2020

# **EMPLOYEES**

The policies relating to employees are discussed in the Environmental, Social and Corporate Governance section of the Strategic Report. See pages 12 to 15 for disclosure of the employee engagement and other stakeholder engagement statements.

# **POLITICAL DONATIONS**

In line with the established policy, the Group made no political donations.

Although the Group does not make, and does not intend to make, political donations, the definition of political donations under the Companies Act 2006 includes broad and potentially ambiguous definitions of the terms 'political donation' and 'political expenditure', which may apply to some normal business activities which would not generally be considered to be political in nature.

As in previous years, a resolution will be proposed at the AGM seeking shareholder approval for the Directors to be given authority, to make political donations and/or to incur political expenditure, in each case within the meaning of the Companies Act 2006 for no more than £50,000. The Directors wish to emphasise that the proposed resolution is sought on a purely precautionary basis in order to avoid inadvertent contravention of the Companies Act 2006. The Board has no intention of entering into any party political activities.

# **PROVISION OF INFORMATION TO THE INDEPENDENT AUDITORS**

Each of the Directors at the time when this Report of the Directors is approved has confirmed that:

- So far as that Director is aware, there is no relevant audit information of which the Company's and the Group's auditors are unaware
- That the Director has taken all the steps that ought to have been taken as a Director in order to be aware of any information needed by the Company and the Group's auditors in connection with preparing their report and to establish that the Company and the Group's auditors are aware of that information

# **AGM NOTICE**

The notice convening the AGM to be held on 26 November 2020, together with an explanation of the resolutions to be proposed at the meeting, is contained in a separate circular to shareholders.

# **INDEPENDENT AUDITORS**

The independent auditors, PwC, have expressed their willingness to continue in office and a resolution to reappoint them will be proposed at the forthcoming AGM.

This report and the Strategic Report was approved by the Board and signed on behalf of the Board:

NICK KEHER Group Chief Financial Officer 16 September 2020

# **INDEPENDENT AUDITORS' REPORT** To the members of clinigen group PLC

# **REPORT ON THE AUDIT OF THE GROUP FINANCIAL STATEMENTS**

#### OPINION

In our opinion, Clinigen group plc's group financial statements (the 'financial statements'):

- give a true and fair view of the state of the group's affairs as at 30 June 2020 and of its profit and cash flows for the year then ended:
- have been properly prepared in accordance with International Financial Reporting Standards ('IFRSs') as adopted by the European Union; and
- have been prepared in accordance with the requirements of the Companies Act 2006

We have audited the financial statements, included within the Annual Report and Accounts 2020 (the 'Annual Report'), which comprise: the consolidated statement of financial position as at 30 June 2020; the consolidated income statement and consolidated statement of comprehensive income; the consolidated statement of cash flows; and the consolidated statement of changes in equity for the year then ended; and the notes to the financial statements, which include a description of the significant accounting policies.

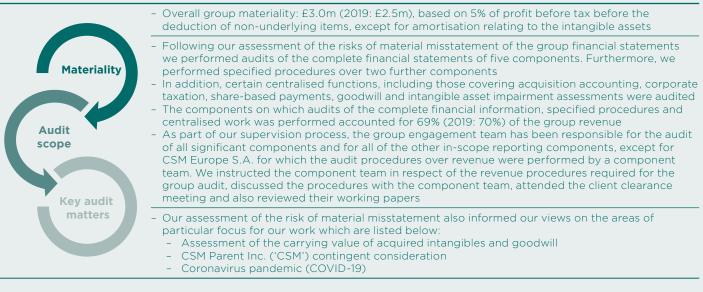
#### **BASIS FOR OPINION**

We conducted our audit in accordance with International Standards on Auditing (UK) ('ISAs (UK)') and applicable law. Our responsibilities under ISAs (UK) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Independence

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, which includes the FRC's Ethical Standard, as applicable to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

#### OUR AUDIT APPROACH Overview



#### The scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the Directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the Directors that represented a risk of material misstatement due to fraud.

#### **Key audit matters**

Key audit matters are those matters that, in the auditors' professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

# INDEPENDENT AUDITORS' REPORT CONTINUED to the members of clinigen group PLC

KEY AUDIT MATTER	HOW OUR AUDIT ADDRESSED THE KEY AUDIT MATTER
Assessment of the carrying value of acquired intangibles and goodwill. Refer to the critical accounting estimates and judgements in note 2 to the consolidated financial statements, and note 12 (intangible assets). We focused on this area because the Directors' assessment of whether impairment triggers have been identified that could give rise to an impairment charge in relation to intangible assets and goodwill, involved complex and subjective judgements and assumptions including the progress and future performance of individual products, in addition to the ongoing business activities of acquired entities. The Directors have prepared impairment assessment models which include a number of assumptions. The assumptions which are deemed to be the most significant in respect of these models are the short and long term growth and discount rates.	For each separate intangible asset, including goodwill, we focused on the key assumptions relating to future revenue forecasts, margin expectations and associated selling costs. We were able to evaluate the reasonableness of the Directors' forecasts and expectations, including the impact upon terminal values by agreeing changes in growth assumptions to corroborating evidence and assessing the margin and selling costs expected to be achieved by reference to historical margins realised, and where relevant, consideration of actual performance against prior year forecasts. We validated the inputs used by the Directors to calculate the discount rate applied by using our valuation specialists to compare this to the cost of capital for the group and a selection of comparable organisations. The Directors' key assumptions for long-term growth rates were also compared to economic and industry forecasts for reasonableness. We assessed, through the performance of sensitivity analysis over the key assumptions above, the extent of change in those assumptions that either individually or collectively would be required for any potential impairment charges, to have a material impact on the carrying value of the acquired intangible assets and goodwill. We also assessed the likelihood of such changes occurring.
	charge for goodwill is required to be recognised. We consider that the associated judgements taken were supportable.
CSM contingent consideration Refer to the critical accounting estimates and judgements in note 2 to the consolidated financial statements. The Directors have reconsidered their estimate of the contingent consideration to be payable in relation to the October 2018 acquisition of CSM. The amount of contingent consideration payable was sensitive to relatively small movements in EBITDA and therefore represented an area of focus during our audit fieldwork. Subsequently, on 3 September 2020, Clinigen reached agreement with the previous owners of CSM to finalise the contingent consideration which has been updated in these consolidated financial statements.	We understood the basis of the contingent consideration liability and the related CSM EBITDA in the earn-out period, from 1 January 2019 to 31 December 2019, including the driving factors in the EBITDA performance and how this judgement had changed since the previous financial year. We validated the final liability to the settlement agreement reached with the vendors on 3 September 2020. We considered the presentation of the contingent consideration as a non-underlying administrative expense in the consolidated income statement and concluded that it met the definition of non-underlying given the size and one-off nature of it.
<ul> <li>Coronavirus pandemic (COVID-19)</li> <li>Refer to page 60 (Audit and Risk Committee Report). During the financial year, the COVID-19 pandemic has had a significant impact globally, with lockdown measures being implemented widely. However, the impact of COVID-19 has been less significant on the group, which has continued to operate well through these uncertain times.</li> <li>As at the year-end date and the date of signing the financial statements, whilst there continues to be significant uncertainty over the future impact of COVID-19, management's assessment is that the impact on Clinigen is not expected to be significant.</li> <li>Notwithstanding that, management has considered implications for the group's going concern assessment, potential impairment of certain assets and associated disclosure in the financial statements. The results of these scenarios did not indicate any significant issues as a result of the impact of COVID-19.</li> </ul>	<ul> <li>In respect of going concern:</li> <li>We evaluated management's base case, plausible sensitivity scenarios, challenging key assumptions including the forecast cash flows. We further sensitised management's forecasts to understand the impact of any further downside scenarios</li> <li>checked the integrity of management's model, as well as agreeing underlying data to source documents</li> <li>assessed whether management's mitigating actions are reasonably achievable based on our understanding of the business, including the nature of its cost base</li> <li>obtained evidence to support disclosures within the financial statements and checked that the disclosures within the annual report are consistent with the financial statements and knowledge gained on the audit</li> <li>Our conclusion in respect of going concern is included in the 'Conclusions relating to going concern' section on page 77.</li> <li>In respect of impairment, refer to separate key audit matter above relating to 'Assessment of the carrying value of acquired intangibles and goodwill'.</li> </ul>

#### How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the group, the accounting processes and controls, and the industry in which it operates.

#### Materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

<b>Overall group materiality</b>	£3.0m (2019: £2.5m).
How we determined it	5% of profit before tax before the deduction of non-underlying items, except for amortisation relating to the intangible assets.
Rationale for benchmark applied	We believe that profit before tax before the deduction of non-underlying items, except for amortisation relating to the intangible assets provides a consistent basis for determining materiality as it eliminates the impact of these items which fluctuate year on year and can have a disproportionate impact on the consolidated income statement.

For each component in the scope of our group audit, we allocated a materiality that is less than our overall group materiality. The range of materiality allocated across components was between £0.2m and £2.3m.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £150,000 (2019: £125,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

#### **Going concern**

In accordance with ISAs (UK) we report as follows:

REPORTING OBLIGATION	OUTCOME
We are required to report if we have anything material to add or draw attention to in respect of the Directors' statement in	We have nothing material to add or to draw attention to.
the financial statements about whether the Directors considered it appropriate to adopt the going concern basis of accounting in preparing the financial statements and the Directors' identification of any material uncertainties to the group's ability to continue as a going concern over a period of at least 12 months from the date of approval of the financial statements.	However, because not all future events or conditions can be predicted, this statement is not a guarantee as to the group's ability to continue as a going concern.

# **INDEPENDENT AUDITORS' REPORT CONTINUED** To the members of clinigen group plc

#### **REPORTING ON OTHER INFORMATION**

The other information comprises all of the information in the Annual Report other than the financial statements and our auditors' report thereon. The Directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Strategic Report and Report of the Directors, we also considered whether the disclosures required by the UK Companies Act 2006 have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, the Companies Act 2006 ('CA06') and ISAs (UK) require us also to report certain opinions and matters as described below (required by ISAs (UK) unless otherwise stated).

### **Strategic Report and Report of the Directors**

In our opinion, based on the work undertaken in the course of the audit, the information given in the Strategic Report and Report of the Directors for the year ended 30 June 2020 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements. (CA06)

In light of the knowledge and understanding of the group and its environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic Report and Report of the Directors. *(CA06)* 

# The Directors' assessment of the prospects of the group and of the principal risks that would threaten the solvency or liquidity of the group

As a result of the Directors' reporting on how they have applied the UK Corporate Governance Code (the 'Code'), we are required to report to you if we have anything material to add or draw attention to regarding:

- The Directors' confirmation on page 45 of the Annual Report that they have carried out a robust assessment of the principal risks facing the group, including those that would threaten its business model, future performance, solvency or liquidity
- The disclosures in the Annual Report that describe those risks and explain how they are being managed or mitigated
   The Directors' explanation on page 73 of the Annual Report as to how they have assessed the prospects of the group, over what period they have done so and why they consider that period to be appropriate, and their statement as to whether they have a reasonable expectation that the group will be able to continue in operation and meet its liabilities as they fall due over the

period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions

We have nothing to report in respect of this responsibility.

#### **Other Code Provisions**

As a result of the Directors' reporting on how they have applied the Code, we are required to report to you if, in our opinion:

- The statement given by the Directors, on page 73, that they consider the Annual Report taken as a whole to be fair, balanced and understandable, and provides the information necessary for the members to assess the group's position and performance, business model and strategy is materially inconsistent with our knowledge of the group obtained in the course of performing our audit
- The section of the Annual Report on page 61 describing the work of the Audit Committee does not appropriately address matters communicated by us to the Audit Committee

We have nothing to report in respect of this responsibility.

#### **RESPONSIBILITIES FOR THE FINANCIAL STATEMENTS AND THE AUDIT Responsibilities of the Directors for the financial statements**

As explained more fully in the Directors' Responsibilities Statement, the Directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view. The Directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the group or to cease operations, or have no realistic alternative but to do so.

#### Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the FRC's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditors' report.

#### Use of this report

This report, including the opinions, has been prepared for and only for the parent company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, 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.

# **OTHER REQUIRED REPORTING**

### COMPANIES ACT 2006 EXCEPTION REPORTING

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- we have not received all the information and explanations we require for our audit; or
- certain disclosures of Directors' remuneration specified by law are not made.

We have no exceptions to report arising from this responsibility.

# **OTHER MATTER**

We have reported separately on the parent company financial statements of Clinigen Group plc for the year ended 30 June 2020.

# PAUL NORBURY BSC FCA (SENIOR STATUTORY AUDITOR)

for and on behalf of PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors East Midlands 16 September 2020

# **CONSOLIDATED INCOME STATEMENT** FOR THE YEAR ENDED 30 JUNE 2020

			2020			2019	
(IN £M)	NOTE	UNDERLYING	NON-UNDERLYING (Note 7)	TOTAL	UNDERLYING	NON-UNDERLYING (Note 7)	TOTAL
Revenue	4	504.3	-	504.3	456.9	-	456.9
Cost of sales	•	(284.3)	(4.9)	(289.2)	(274.6)	-	(274.6)
Gross profit	4	220.0	(4.9)	215.1	182.3	-	182.3
Administrative expenses		(100.7)	(72.4)	(173.1)	(86.5)	(71.4)	(157.9)
Profit from operations	4	119.3	(77.3)	42.0	95.8	(71.4)	24.4
Finance income	8	-	-	-	0.1	-	0.1
Finance expense	8	(11.4)	(8.3)	(19.7)	(8.7)	(4.2)	(12.9)
Share of profit of joint venture	15	0.3	-	0.3	0.7	-	0.7
Profit before income tax		108.2	(85.6)	22.6	87.9	(75.6)	12.3
Income tax expense	9	(21.2)	12.3	(8.9)	(17.3)	10.2	(7.1)
Profit attributable to owners of the Company		87.0	(73.3)	13.7	70.6	(65.4)	5.2
EPS (pence)							
Basic	10			10.3			4.0
Diluted	10			10.2			4.0

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2020

	2020			2019		
(IN £M)	NON-UNDERLYING Underlying (Note7)		TOTAL	UNDERLYING	NON-UNDERLYING (Note 7)	TOTAL
Profit attributable to owners of the Company	87.0	(73.3)	13.7	70.6	(65.4)	5.2
Other comprehensive income						
Items that may be subsequently reclassified to profit or loss					•••••	
Cash flow hedges	0.2	-	0.2	0.1	-	0.1
Currency translation differences	2.7	-	2.7	7.4	-	7.4
Total other comprehensive income for the year	2.9	-	2.9	7.5	-	7.5
Total comprehensive income attributable to owners of the Company	89.9	(73.3)	16.6	78.1	(65.4)	12.7

All amounts relate to continuing operations.

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION** As at 30 June 2020

(IN £M)	NOTE	2020	2019
Assets			
Non-current assets			
Intangible assets		788.3	811.9
Property, plant and equipment	13	13.4	13.6
Right-of-use assets		20.4	-
Investment in joint ventures and associates		-	6.5
Deferred tax assets	22	7.2	2.8
Total non-current assets		829.3	834.8
Current assets			
Inventories	16	43.5	35.4
Trade and other receivables		125.9	110.2
Derivative financial instruments	21	0.2	2.2
Cash and cash equivalents	18	143.1	83.5
Total current assets		312.7	231.3
Total assets		1,142.0	1,066.1
Liabilities			
Non-current liabilities			
Trade and other payables	19	8.9	7.3
Borrowings and lease liabilities	20	450.7	335.9
Deferred tax liabilities	22	33.6	41.1
Total non-current liabilities		493.2	384.3
Current liabilities			
Trade and other payables	19	194.9	235.7
Corporation tax liabilities		3.7	7.3
Borrowings and lease liabilities	20	4.3	0.1
Derivative financial instruments	21	0.3	0.4
Total current liabilities		203.2	243.4
Total liabilities		696.4	627.7
Net assets		445.6	438.4
Equity attributable to owners of the Company			
Share capital	23	0.1	0.1
Share premium account	24	240.2	240.2
Merger reserve	24	88.2	88.2
Hedging reserve	24	(0.1)	(0.3)
Foreign exchange reserve	24	17.7	15.0
Retained earnings	24	99.5	95.2
Total equity		445.6	438.4

The notes on pages 84 to 112 form an integral part of the consolidated financial statements.

The financial statements on pages 80 to 112 were approved and authorised for issue by the Board of Directors on 16 September 2020 and were signed on its behalf by:

SHAUN CHILTON Director

N.L

**NICK KEHER** Director

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2020

(IN £M)	NOTE	2020	2019
Operating activities			
Profit for the year before tax		22.6	12.3
Share of profit of joint venture		(0.3)	(0.7)
Net finance costs	8	19.7	12.8
Profit from operations		42.0	24.4
Adjustments for:			
Amortisation of intangible fixed assets	12	50.1	39.3
Impairment of intangible fixed assets	12	4.2	-
Depreciation of property, plant and equipment	13,14	6.4	2.45
Impairment of investment in joint venture	15	5.9	-
Dividends received from joint venture	15	-	0.8
Movement in fair value of derivative financial instruments		0.1	0.2
Increase in fair value of contingent consideration	7	11.8	21.4
Currency revaluation on deferred consideration	7	2.0	0.4
Equity-settled share-based payment expense	6	3.5	3.0
		126.0	91.9
Increase in trade and other receivables		(15.6)	(2.1)
Increase in inventories		(8.6)	(13.4)
(Decrease)/increase in trade and other payables		(7.0)	13.4
Cash generated from operations		94.8	89.8
Income taxes paid		(23.9)	(13.6)
Interest paid		(10.3)	(7.9)
Net cash flows from operating activities		60.6	68.3
Investing activities			
Purchase of intangible fixed assets (excluding products)	12	(20.1)	(17.0)
Purchase of property, plant and equipment	13	(2.9)	(2.0)
Purchase of specialty pharmaceutical products	12	(58.4)	(114.3)
Purchase of subsidiaries, net of cash acquired		-	(118.0)
Net cash used in investing activities		(81.4)	(251.3)
Financing activities			
Proceeds from issue of shares		-	78.9
Proceeds from increase in Ioan	20	107.6	179.1
Loan repayments	20	(17.1)	(20.5)
Principal element of lease payments	20	(3.4)	-
Dividends paid	11	(9.2)	(7.7)
Net cash flows generated from financing activities		77.9	229.8
Net increase in cash and cash equivalents		57.1	46.8
Cash and cash equivalents at beginning of year	18	83.5	36.3
Foreign exchange gains		2.5	0.4
Cash and cash equivalents at end of year	18	143.1	83.5

# **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY** For the year ended 30 June 2020

	SHARE Capital	SHARE Premium	MERGER	HEDGING	FOREIGN Exchange	RETAINED	TOTAL
(IN £M)	(NOTE 23)	ACCOUNT	RESERVE	RESERVE	RESERVE	EARNINGS	EQUITY
At 30 June 2019	0.1	240.2	88.2	(0.3)	15.0	95.2	438.4
Impact of adopting IFRS 16	-	-	-	-	-	(2.2)	(2.2)
At 1 July 2019	0.1	240.2	88.2	(0.3)	15.0	93.0	436.2
Profit for the year	-	-	-	-	-	13.7	13.7
Currency translation differences	-	-	-	-	2.7	-	2.7
Cash flow hedges							
- Effective portion of fair value movements	-	-	-	0.3	-	-	0.3
- Transfers to the income statement (revenue)	-	-	-	(0.1)	-	-	(0.1)
Total comprehensive income	-	-	-	0.2	2.7	13.7	16.6
Share-based payment scheme	-	-	-	-	-	3.5	3.5
Step-acquisition of QM Specials	-	-	-	-	-	(1.6)	(1.6)
Deferred taxation on share-based payment scheme	-	-	-	-	-	0.1	0.1
Dividends paid (note 11)	-	-	-	-	-	(9.2)	(9.2)
Total transactions with owners of the Company, recognised directly in equity	_	-	-	-	-	(7.2)	(7.2)
At 30 June 2020	0.1	240.2	88.2	(0.1)	17.7	99.5	445.6
(IN £M)	SHARE Capital (Note 23)	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 year	-	-	-	-	-	5.2	5.2
Currency translation differences	-	-	-	-	7.4	-	7.4
Cash flow hedges	•••••	•••••	•••••	•••••	•••••	•••••	
- Effective portion of fair value movements	-	-	-	(1.1)	-	-	(1.1)
- Ineffective portion of fair value movements	-	-	-	0.1	-	-	0.1
- Transfers to the income statement (revenue)	-	-	-	1.1	-	-	1.1
Total comprehensive income	_	_	-	0.1	7.4	5.2	12.7
Share-based payment scheme	-	-	-	-	-	3.0	3.0
	•••••	•••••	_	•••••	•••••	(0.4)	(0.4)
Deferred taxation on share-based payment scheme	-	-		-		(0.4)	
Deferred taxation on share-based payment scheme Tax credit in respect of tax losses arising on exercise of share options	-	-	_			0.2	0.2
Tax credit in respect of tax losses arising on		78.9	- 2.2			·····	0.2
Tax credit in respect of tax losses arising on exercise of share options		- - 78.9 -	- 2.2 -			·····	
Tax credit in respect of tax losses arising on exercise of share options Issue of new shares		- 78.9 - 78.9	- 2.2 - 2.2	- - - -	- - - -	0.2	81.1

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2020

# **1. ACCOUNTING POLICIES**

The principal accounting policies adopted by the Group and applied in the preparation of these consolidated financial statements are set out below. The policies have been consistently applied to all years presented, unless otherwise stated.

### **BASIS OF PREPARATION**

The consolidated financial statements of Clinigen Group plc have been prepared in accordance with IFRS, as adopted for use in the European Union and IFRS Interpretations Committee interpretations (together 'adopted IFRS') and with those parts of the Companies Act 2006 that are applicable to companies that prepare financial statements in accordance with IFRS. The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities (including derivative instruments) at fair value through profit or loss.

The preparation of financial statements in conformity with adopted IFRS requires the use of certain critical accounting estimates. It also requires Group management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 2.

The accounting policies set out below have, unless otherwise stated, been applied consistently throughout the year presented in these financial statements. These financial statements are presented in pounds sterling, which is the Group's functional currency. All financial information presented in pounds sterling has been rounded to the nearest £100,000.

#### **GOING CONCERN**

The Group's strategy and forecasts, taking account of sensitivities within the trading projections and possible changes in trading performance, show that the Group has adequate resources to continue in operational existence for the foreseeable future. The Group is not immune from COVID-19, however, the impact on trading has been relatively limited and is therefore not impacting on the Group's ability to continue as a going concern. At 30 June 2020, the Group had £143m of cash balances available which combined with the Group's positive cash generation from each of its operations, provides sufficient funding for the near-term settlement of deferred consideration liabilities along with sufficient liquidity for ongoing trading.

After making appropriate enquires, the directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for at least twelve months from the date of approval of the financial statements. Therefore, the Company and Group continues to adopt the going concern basis in preparing its financial statements. Further information on the Group's borrowing facilities is given in note 20.

### CHANGES IN ACCOUNTING POLICIES

#### (a) New and amended standards, interpretations and amendments adopted by the Group IFRS 16 - Leases

The Group adopted IFRS 16 on 1 July 2019 using the modified retrospective approach. Under the specific transitional provisions in the standard, comparative information has not been restated. The reclassifications and the adjustments arising from the new leasing rules have been recognised in the opening balance sheet on 1 July 2019 (see note 29).

Until 30 June 2019, leases of property, plant and equipment were classified as either finance or operating leases. Payments made under operating leases were charged to profit or loss on a straight-line basis over the period of the lease. From 1 July 2019, leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between reducing the liability and a finance cost. The finance cost is charged to the income statement over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

On adoption of IFRS 16, the Group recognised additional lease liabilities in relation to leases which had previously been classified as operating leases under the previous principles of IAS 17 'Leases'. These liabilities were measured at the present value of the remaining lease payments, discounted using the Group's incremental borrowing rate as of 1 July 2019 which was deemed to be 2.75%.

The associated right-of-use are measured on a retrospective basis as if the new rules had always been applied. As above, the Group's incremental borrowing rate has been used. In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- on initial application, IFRS 16 was only applied to contracts that were previously classified as leases, the Group has elected not to reassess whether a contract is, or contains, a lease at the date of initial application. Instead, for contracts entered into before the transition date the Group has relied on its assessment made applying IAS 17 and IFRIC 4
- lease contracts with a duration of less than 12 months will continue to be expensed to the income statement on a straight-line basis over the lease term
- the lease term has been determined with the use of hindsight where the contract contains options to extend the lease
- reliance on previous assessments on whether or not leases are onerous

### IFRIC 23 - Uncertainty over Income Tax Treatment

The Group adopted IFRIC 23 on 1 July 2019. The interpretation clarifies how to apply the recognition and measurement requirements in IAS 12 Income Taxes when there is uncertainty over income tax treatments. The Group has measured the effect of relevant uncertain income tax positions using either the most likely amount or the expected value amount depending on which method is expected to better reflect the resolution of the uncertainty. Adoption of this interpretation did not have a material impact on the Group's financial statements.

There were no other new standards, interpretations or amendments to standards that are effective for the financial year beginning 1 July 2019 that have a material impact on the Group's consolidated financial statements.

#### (b) New standards, interpretations and amendments not yet adopted

There are amendments to a number of existing standards which have been endorsed by the EU but not yet adopted. These amendments are not expected to have a material impact on the Group's consolidated financial statements.

#### **BASIS OF CONSOLIDATION**

The consolidated financial statements present the results of the Company and its subsidiaries as if they formed a single entity. Subsidiaries are those entities where the Company has the ability to control the activities of and decisions made by that entity, and to receive economic benefits that can be affected by that control.

The results of subsidiaries acquired during the year are included in the Group results from the date on which control is transferred to the Group. Accounting policies of subsidiaries are changed when necessary to ensure consistency with the accounting policies adopted by the Group. There are no significant restrictions on the Group's ability to access or use assets and settle liabilities of the Group.

The Group applies IFRS 11 'Joint Arrangements' to all joint arrangements. Investments in joint arrangements are classified as either joint operations or joint ventures. The classification depends on the contractual rights and obligations of each investor, rather than the legal structure of the joint arrangement. Clinigen has assessed the nature of its joint arrangements and determined them all to be joint ventures or associated. Joint ventures and associated are accounted for using the equity method.

Intercompany transactions and balances are eliminated on consolidation.

#### **BUSINESS COMBINATIONS**

The Group uses the acquisition method to account for business combinations. The consideration transferred for the acquisition of a subsidiary is equal to the fair value of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Acquisition-related costs are expensed as incurred. Identifiable assets acquired, and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date.

On an acquisition-by-acquisition basis, the Group recognises any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets. The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If this is less than the fair value of the net assets of the subsidiary acquired in the case of a bargain purchase, the difference is recognised directly in the income statement.

Acquisition costs for business combinations and post-acquisition restructuring costs are recognised as non-underlying costs in the income statement as adjusting items as they do not relate to normal trading activities and to reflect their one-off nature.

### FOREIGN CURRENCY

#### (a) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the 'functional currency'). The consolidated financial statements are presented in sterling, being the currency of the primary economic environment in which the Company operates. This is the Group's presentation currency.

#### (b) Transactions and balances

Transactions entered into by Group entities in a currency other than the currency of the primary economic environment in which they operate (their 'functional currency') are recorded at the exchange rates prevailing at the dates of the transactions or valuation where items are remeasured. Foreign currency monetary assets and liabilities are translated at the exchange rates prevailing at the reporting date. All foreign exchange gains and losses are presented in the income statement within administrative expenses.

#### (c) Group companies

The results and financial position of all the Group entities that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- (a) Assets and liabilities for each balance sheet presented are translated at the closing exchange rate on the date of that balance sheet.
- (b) Income and expenses for each income statement are translated at average exchange rates for the financial year.
- (c) All resulting exchange differences are recognised in other comprehensive income and accumulated in the foreign exchange reserve.

On disposal of a foreign operation, the cumulative exchange differences recognised in the foreign exchange reserve relating to that operation up to the date of disposal would be transferred to the income statement as part of the profit or loss on disposal.

#### SEGMENT REPORTING

Operating segments are reported in a manner consistent with the internal reporting provided to the Group's Chief Operating Decision Maker ('CODM'). The CODM has been identified as the Executive Directors.

The Group has changed the key profit measure that is reviewed by the CODM at the segmental reporting level from gross profit to adjusted EBITDA. Therefore the segmental disclosures in note 4 have been amended with the restatement of comparatives.

# 1. ACCOUNTING POLICIES CONTINUED

### SHARE-BASED PAYMENTS

Where equity-settled share options are awarded to employees, the fair value of the options at the date of grant is charged to the income statement over the vesting period. Non-market vesting conditions are taken into account by adjusting the number of equity instruments expected to vest at each reporting date so that, ultimately, the cumulative amount recognised over the vesting period is based on the number of options that eventually vest. Non-vesting conditions are satisfied, a charge is made irrespective of whether the market vesting conditions are satisfied. The cumulative expense is not adjusted for failure to achieve a market vesting condition or where a non-vesting condition is not satisfied.

Where the terms and conditions of options are modified before they vest, the increase in the fair value of the options, measured immediately before and after the modification, is also charged to the income statement over the remaining vesting period.

#### **NON-UNDERLYING ITEMS**

Non-underlying items are material items of income or expense which the Directors consider are not related to the normal trading activities of the Group and are therefore separately disclosed as non-GAAP measures to enable full understanding of the Group's financial performance. These include one-off items relating to acquisitions e.g. acquisition costs and the costs of restructuring post-acquisition; amortisation of intangible assets arising on acquisition and acquired products; movements of deferred or contingent consideration; and the release of the fair value adjustment made to inventory acquired through a business combination. The associated tax impact of these items is also reported as non-underlying.

# INTANGIBLE ASSETS

#### Goodwill

Goodwill represents the excess of the cost of a business combination over, in the case of business combinations completed prior to 1 July 2010, the Group's interest in the fair value of identifiable assets, liabilities and contingent liabilities acquired.

For business combinations completed after 1 July 2010, goodwill represents the excess of the cost of a business combination over the Group's interest in the fair value of identifiable assets, liabilities and contingent liabilities including those intangible assets identified under IFRS 3 'Business Combinations'.

Goodwill is capitalised as an intangible asset with any impairment in carrying value being charged to the income statement. Where the fair value of identifiable assets, liabilities and contingent liabilities exceed the fair value of consideration paid, the excess is credited in full to the income statement on the acquisition date as a non-underlying item.

Goodwill is not amortised, but is assessed for impairment annually or more frequently if events or changes indicate a potential impairment. Goodwill arising on business combinations is allocated to the associated cash-generating units ('CGUs') based on the particular segment that it relates to. This is then assessed against the discounted cash flows of the CGUs for impairment.

#### Brand

The brand reflects the cash flows associated with the Idis brand acquired in April 2015; the Link, Homemed and Equity brands purchased in October 2015; the Quantum brand purchased in November 2017; and the CSM brand purchased in October 2018. Each brand was recognised following the associated business combination and is initially recognised at the fair value of the asset at the acquisition date. The carrying value of the brand is calculated as cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the fair value cost of the asset over its estimated useful life. The estimated useful lives range between ten and 20 years. The amortisation expense is recognised within non-underlying administrative expenses in the income statement.

#### Contracts

Contracts acquired in a business combination are recognised at fair value on the acquisition date. The contracts recognised as intangible assets relate to those with key suppliers which were identified as important to the trade of the acquired business. The supply of product on a contractual and often exclusive basis is a key value driver and was a key element in the decision to acquire the Idis and Link businesses.

The contracts have a finite life and are amortised over the contractual term. Amortisation is scheduled to follow the expected economic benefits, recognising the fair value cost of acquiring these contracts against the revenues generated from them. This is normally on a straight-line basis over the term of the contract, except for MAPs which, due to their nature, have a short period of economic benefit i.e. until the product is licensed and becomes commercially available. The economic benefits from MAP contracts are weighted to the early stages of the contract. The amortisation expense is recognised within non-underlying administrative expenses in the income statement on a reducing balance basis.

#### **Customer relationships**

The customer relationships within acquired operating businesses can be separately identified. The customer relationships have been initially recognised following a business combination at the fair value of the asset at the acquisition date.

Amortisation is scheduled to follow the expected economic benefits of each asset over their estimated useful lives, as follows:

- Link between 6 and 9 years (straight-line)
- CTS 7 years (straight-line)
- Idis between 7 and 14 years (straight-line)
- Quantum 13 years (reducing balance)
- CSM 15 years (reducing balance)
- iQone 15 years (reducing balance)

The amortisation expense is recognised within non-underlying administrative expenses in the income statement.

#### Trademarks and licences

Separately acquired trademarks and licences are initially recognised at cost, being the fair value of the purchase price of the asset and any directly attributable cost of acquiring the asset and preparing it for its intended use.

Expenditure on development activities is capitalised if the product or process is technically and commercially feasible and the Group intends, has the technical ability and has sufficient resources to complete development, future economic benefits are probable and if the Group can measure reliably the expenditure attributable to the intangible asset during its development. Development activities involve a plan or design for the production of new or substantially improved products or processes. The expenditure capitalised includes the cost of materials, direct labour and an appropriate proportion of overheads and capitalised borrowing costs. Other development expenditure is recognised in the consolidated income statement as an expense as incurred. Internally developed trademarks and licences are held as assets under construction during development and amortisation commences when the development is complete and the asset is available for use.

The carrying value of trademarks and licences is calculated as cost less accumulated amortisation and impairment losses. Amortisation is calculated using the straight-line method to allocate the cost of the trademarks and licences over their estimated useful lives of between five and 15 years. The amortisation expense is recognised within underlying administrative expenses in the income statement, apart from where the trademarks or licences are acquired as part of a business combination or product acquisition which is recognised within non-underlying administrative expenses.

#### **Computer software**

Computer software is capitalised and recognised at cost, being the purchase price of the asset and any directly attributable costs of developing the asset for its intended use including internal staff costs for time spent specifically on development activities. The carrying value of computer software is calculated as cost less accumulated amortisation and impairment losses. Amortisation begins when the computer software comes into use and is calculated using the straight-line method to allocate the cost over its estimated useful life of three to 7 years. The amortisation expense is recognised within underlying administrative expenses in the income statement.

#### **Impairment reviews**

Goodwill is assessed for impairment annually or more frequently if events or changes indicate a potential impairment. Other intangibles are reviewed for impairment if a trigger is identified. The carrying value of individual intangible and tangible assets are compared to the recoverable amount, which is the higher of value-in-use and the fair value less costs to sell. An impairment loss is recognised for the amount by which the asset's carrying value exceeds its recoverable amount.

Where it is not possible to estimate the recoverable amount of an individual asset, the impairment test is carried out on the smallest group of assets to which it belongs for which there are separately identifiable cash flows (the CGUs). Goodwill is allocated on initial recognition to each of the Group's CGUs that are expected to benefit from the synergies of the combination giving rise to the goodwill.

Non-financial assets, other than goodwill, that suffered an impairment are reviewed for possible reversal of the impairment at each reporting date.

#### **PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment are stated at historical cost less accumulated depreciation and any recognised impairment loss. Cost comprises the purchase price and directly attributable amounts to bring the asset into operation.

Depreciation is provided on all items of property, plant and equipment at rates calculated to write off the cost of each asset on a straight-line basis over its expected useful economic life, as follows:

- Land and buildings
- 25 years - Leasehold improvements - remaining term of lease to which the improvements relate
- Plant and machinery
- Fixtures, fittings and equipment 20% to 33% straight-line

#### LEASES

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- Fixed payments less any lease incentive receivable
- Variable lease payments that are based on an index or a rate
- Amounts expected to be payable by the Group under residual value guarantees

- 20%

- The exercise price of a purchase option if the Group is reasonably certain to exercise that option
- Payments of penalties for termination of the lease, if the lease term reflects the Group exercising that option

Where leases commence after the initial transition date, the lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be determined, the Group's incremental borrowing rate is used, being the rate that the Group would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions. Lease liabilities are revalued at each reporting date using the spot exchange rate.

Right-of-use assets are measured at cost comprising the following:

- The amount of the initial measurement of lease liability or a revaluation of the liability
- Any lease payments made at or before the commencement date less any lease incentives received
- Any initial direct costs
- Restoration costs

# **1. ACCOUNTING POLICIES CONTINUED**

Each right-of-use asset is depreciated over the shorter of its useful economic life and the lease term on a straight-line basis unless the lease is expected to transfer ownership of the underlying asset to the Group, in which case the asset is depreciated to the end of the useful life of the asset.

Payments associated with the short-term leases are recognised on a straight-line basis as an expense in the income statement. Short-term leases are leases with a lease term of 12 months or less.

### INVESTMENTS

Investments in subsidiaries are recorded at historical cost, less any provision for impairment.

Investments in joint ventures are accounted for using the equity method of accounting. Under the equity method, the investment is initially recorded at cost, and the carrying amount is increased or decreased to recognise the investor's share of the profit or loss of the investee after the date of acquisition.

#### **INVENTORIES**

Inventories are initially recognised at cost and subsequently stated at the lower of cost and net realisable value. Individual units of drugs cannot be interchanged as they are determined by the customer's requirements for product name, dosage strength, pack size, batch number and expiry date. In accordance with IAS 2 'Inventories', items are recorded at their individual actual cost. To minimise obsolescence, cost is selected using first expiry, first out method. Cost comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition. In the case of manufactured inventories and work in progress, cost includes an appropriate share of overheads based on normal operating capacity. Net realisable value is the estimated selling price less applicable variable selling expenses. Provisions are made for slow moving and damaged inventories. Inventories which have expired are fully provided for until they are destroyed, when they are written off.

A number of arrangements exist where the Group holds inventories on consignment. Under these arrangements such inventories are only recognised in the statement of financial position when the risks and rewards of ownership are transferred to the Group.

#### DERIVATIVE FINANCIAL INSTRUMENTS AND HEDGING ACTIVITIES

The Group uses derivative financial instruments to mitigate its exposure to foreign currency exchange risk on cash flow transactions. Derivative financial instruments are recognised initially at their fair value and remeasured at fair value at each period end. Where appropriate the Group designates hedge relationships for hedge accounting under IFRS 9 'Financial Instruments'.

Where hedge accounting has been applied, changes in the fair value of derivative financial instruments designated as cash flow hedges are recognised in other comprehensive income to the extent that the hedge is effective. To the extent that the hedge is ineffective, changes in fair value are recognised immediately in the income statement. If the hedging instrument no longer meets the criteria for hedge accounting, expires or is sold, terminated or exercised, then hedge accounting is discontinued prospectively. The cumulative gain or loss previously recognised in other comprehensive income remains there until the forecast transaction occurs. When the hedged item is a non-financial asset, the amount recognised in other comprehensive income is transferred to the carrying amount of the asset when it is recognised. In other cases, the amount recognised in other comprehensive income is transferred to the income statement in the same period that the hedged item affects profit or loss. The designation is re-evaluated at each reporting date.

The gain or loss on remeasurement to fair value of derivatives that have not been designated for hedge accounting is recognised immediately in the income statement. Foreign forward exchange derivative gains and losses are recognised net.

Hedges of net investments in foreign operations are accounted for similarly to cash flow hedges. Any gain or loss on the hedging instrument relating to the effective portion of the hedge is recognised in other comprehensive income and accumulated in reserves.

### TRADE AND OTHER RECEIVABLES

Trade receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. Trade receivables are recognised initially at the amount of consideration that is unconditional, unless they contain significant financing components, where they are recognised at fair value. The Group holds trade receivables with the objective of collecting the contractual cash flows and therefore measures them subsequently at amortised cost using the effective interest method.

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. The expected loss rates are based on payment profiles and historic credit losses. The historic loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors to the extent they are relevant to the customers' ability to settle. For trade receivables, which are reported net, such provisions are recorded in a separate allowance account with the movement in the provision being recognised within administrative expenses in the income statement. The gross carrying value of the asset is written off against the associated provision when the Group's right to the cash flows expires.

#### CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash in hand, deposits held at call with banks and other highly-liquid cash investments.

#### BORROWINGS

Borrowings are initially recognised at fair value net of transaction costs, including facility fees incurred. Such interest-bearing liabilities are subsequently measured at amortised cost using the effective interest rate method, which ensures that any interest expense over the period to repayment is at a constant rate on the balance of the liability carried in the consolidated statement of financial position. Facility fees paid on the establishment of facilities and for the maintenance of the facility are capitalised against the loans and borrowings balance. These are amortised as the loan is repaid with the associated amortisation expense recognised in finance costs.

#### TRADE AND OTHER PAYABLES

Trade payables are obligations to pay for goods and services that have been acquired in the ordinary course of business from suppliers. They are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities. Trade payables are initially recognised at fair value and subsequently carried at amortised cost using the effective interest method.

#### DEFERRED AND CONTINGENT CONSIDERATION

Deferred consideration payable in cash in respect of the acquisition of intangible assets is recognised initially at its fair value at the date of acquisition. The difference between the fair value of the deferred consideration and the amounts payable in the future is recognised as a finance cost over the deferment period.

Contingent consideration on business combinations is initially measured at fair value and is payable in cash. The fair value of the contingent liability is remeasured at each period end and the change in fair value is recognised in the income statement as a non-underlying item.

The contingent consideration liability is classified as a current liability if payment is due within one year or less. If not, it is presented as a non-current liability.

#### **RETIREMENT BENEFITS: DEFINED CONTRIBUTION SCHEMES**

Contributions to defined contribution pension schemes are charged to the income statement in the year to which they relate. The Group has no further payment obligations once the contributions have been paid.

#### PROVISIONS

A provision is recognised in the balance sheet when the Group has a present legal or constructive obligation as a result of a past event, it is more likely than not that an outflow of economic benefits will be required to settle the obligation and the obligation can be estimated reliably. Provisions are discounted if the impact on the provision is deemed to be material.

#### DIVIDENDS

Dividends are recognised when they become legally payable. In the case of interim dividends to equity shareholders, this is when paid. In the case of final dividends, this is when approved by the shareholders.

#### **CURRENT AND DEFERRED TAX**

The tax expense for the year comprises current and deferred tax. Tax is recognised in the income statement, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly.

The current tax charge, including UK corporation tax and foreign tax, is calculated on the basis of the laws that have been enacted or substantively enacted by the balance sheet date. Provisions are established, where appropriate, on the basis of amounts expected to be paid.

Deferred tax assets and liabilities are recognised where the carrying amount of an asset or liability in the consolidated statement of financial position differs from its tax base, except for differences arising on:

- The initial recognition of goodwill
- The initial recognition of an asset or liability in a transaction which is not a business combination and at the time of the transaction affects neither accounting nor taxable profit
- Investments in subsidiaries and jointly-controlled entities where the Group is able to control the timing of the reversal of the difference and it is probable that the difference will not reverse in the foreseeable future

Deferred income tax assets are recognised only to the extent that it is probable that future taxable profit will be available against which the differences can be utilised.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the deferred tax liabilities or assets are settled or recovered, respectively.

Deferred tax assets and liabilities are offset when the Group has a legally enforceable right to offset current tax assets and liabilities relate to taxes levied by the same tax authority on either:

- The same taxable Group company, or
- Different company entities which intend either to settle current tax assets and liabilities on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax assets and liabilities are expected to be settled or recovered

#### **SHARE CAPITAL**

Financial instruments issued by the Group are treated as equity only to the extent that they do not meet the definition of a financial liability. The Group's ordinary shares are classified as equity instruments.

#### REVENUE

Revenue represents amounts receivable for goods and services provided in the normal course of business, net of trade discounts, VAT and other sales-related taxes.

#### **Supply of products**

Revenue from the supply of products is recognised, at a point in time, when the Group has transferred control to the buyer and it is probable that the Group will receive the previously agreed upon payment. These criteria are normally considered to be met when the goods are delivered to the buyer, or on fulfilment of a prescription. Revenue is recognised at the fair value of consideration received or receivable.

# **1. ACCOUNTING POLICIES CONTINUED**

Revenue from the supply of products in relation to charged for Managed Access programs is recognised based on Clinigen being the principal in the transaction given the Group takes title and bears the inventory risk. The revenue and cost of sales on these arrangements are typically the same value and is therefore referred to as 'pass through revenue'. Net revenue defined as revenue excluding the pass through from Managed Access is an Alternative Performance Measure used by the group as it allows management to assess the performance of the business after removing the distortion of pass through revenue which varies depending on the mix of 'charged for' and 'free of charge' programs in the period.

### Service fees

All services provided in relation to MAPs and product development contracts are contractually agreed with the product originator. Revenue for these services is recognised in the period in which the services are provided. For fixed-price contracts, revenue is recognised based on the actual service provided to the end of the reporting period as a proportion of the total services to be provided, because the customer receives and uses the benefits simultaneously. Estimates of revenues, costs or extent of progress toward completion are reviewed if circumstances change. Any resulting increase or decrease in estimated revenues or costs are reflected in profit or loss in the period in which the circumstances that give rise to the review become known to management.

Contracted program setup fees can be either for the whole project or triggered by milestones being achieved which are laid out in the contract. Revenue is recognised in relation to these fees, at a point in time, when the contracted milestones are achieved.

Monthly management fees are recognised as revenue, at a point in time, in the month to which they relate and once contractual services have been provided.

Revenue in respect of program management fees is recognised, at a point in time, when goods, provided under the program, have been dispatched to the customer for whom the management fee relates. Revenue is recognised at the fair value of consideration received or receivable.

### **Royalties**

Royalty income is earned on product distribution agreements based upon a percentage of sales, the income is recognised based on volumes sold by the third parties involved. Revenues from the licensing of intellectual property are recognised based on a right to use the intellectual property.

Revenue in all years principally arises from the three income streams discussed above. Further information is available in note 4.

# 2. CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The Group makes certain estimates and assumptions regarding the future. Estimates and judgements are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

### (A) BUSINESS COMBINATIONS

In accounting for business combinations, the identifiable assets, liabilities and contingent liabilities acquired have to be measured at their fair values. In particular, some judgement is required in estimating the fair value of inventory with reference to current selling prices and an assessment of obsolescence and demand for inventory; the fair value of trade debtors with reference to the ageing and recoverability of these and judgements in estimating the valuation of intangible assets with reference to forecast future sales under the pre-existing contracts and relationships where legal contracts are not in place.

### (B) IMPAIRMENT OF GOODWILL

The Group tests annually whether goodwill has suffered any impairment, in accordance with the accounting policy stated in note 1. The recoverable amount is determined based on value-in-use calculations. The use of this method requires the estimation of future cash flows and the choice of a discount rate in order to calculate the present value of the cash flows. Actual outcomes may vary. More information including carrying values is included in note 12.

### (C) CARRYING VALUE OF INTANGIBLE ASSETS EXCLUDING GOODWILL

The carrying value of intangible assets is at cost less amortisation and any impairment. Annual impairment trigger reviews are undertaken at the end of the financial year, or more frequently if events or changes in circumstances indicate a potential impairment. Trademarks and licences are not traded in an active market hence the fair value of the asset is determined using discounted cash flows which involves the Group using judgement and assumptions.

### (D) INVENTORY PROVISIONING

The Group's principal activities during the year related to the management, sale and distribution of pharmaceutical products which have associated expiry dates. As a result it is necessary to consider the recoverability of the cost of the inventory and the associated provisioning required. Management consider the nature and condition of inventory, the remaining expiry period, as well as applying assumptions around expected future demand for the inventory, when calculating the level of inventory provisioning. See note 16 for the net carrying value of inventory and associated provision.

### (E) IMPAIRMENT OF TRADE RECEIVABLES

The Group makes an estimate of the recoverable value of trade and other debtors. When assessing impairment of trade and other receivables, management considers factors including the credit rating and age profile of the receivable and historic experience. See note 17 for the net carrying amount of the receivables and the associated impairment provision.

#### (F) SALE OF PRODUCTS WHOLESALE

Certain products are sold to wholesalers with provisions to return product as a result of expiry dates being reached and for reimbursement from Clinigen for sale of product at below Wholesaler Acquisition Cost ('WAC'), known as chargebacks, where agreements are in place with healthcare providers. Revenue is recognised net of an estimate of reimbursements expected. Accumulated experience is used to estimate and provide for the reimbursements and revenue is only recognised to the extent that it is highly probable that a significant reversal will not occur. A liability (included in trade and other payables) is recognised for expected returns, rebates and chargebacks payable to customers in relation to sales made until the end of the reporting period.

The adjustment to revenue during the year for returns, chargebacks and rebates is £8.3m (2019: £7.5m). A 1% change in the overall estimated reimbursement would result in a £0.1m (2019: £0.3m) additional adjustment to revenue.

#### (G) DEFERRED TAXATION

Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profit will be available against which the difference can be utilised. The future taxable profits are based on forecasts and thus actual may vary.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the deferred tax liabilities or assets are settled or recovered. A change in rate would change these calculations.

The deferred tax asset recognised on share options, not yet exercised, is calculated based on the market price of the shares at the end of the reporting period. The market price at the exercise date would be expected to be different, hence the actual asset recognisable at exercise is likely to differ to the one recognised at the reporting date.

#### (H) MANAGED ACCESS JUDGMENT OF BEING A PRINCIPAL

Managed Access Programs provide a service for clients to distribute unlicensed products before the product is licensed in key markets. Clinigen charges the end customer for the product supplied at the price determined by the client which results in a pass through of revenue. A judgment is taken by management that Clinigen is operating as principal in the transaction based on the Group taking title to the product and bearing inventory risk. As a result, Clinigen recognises the amounts charged to customers for this activity as revenue.

#### (I) CONTINGENT CONSIDERATION

Contingent consideration is initially measured at the net present value of the expected future cash flows, discounted using an appropriate discount rate, to be paid pursuant to the relevant agreements. The discount rate used is pre-tax and reflects the current market assessments of the time value of money and the risks specific to the liability. The fair value of the contingent liability is remeasured at each period end utilising the latest financial forecasts. The change in fair value is recognised in the income statement as a non-underlying item.

### **3. ALTERNATIVE PERFORMANCE MEASURES**

The Group's performance is assessed using a number of non-GAAP financial measures which are not defined under IFRS. These measures are therefore considered alternative performance measures.

Management uses the adjusted or alternative measures as part of their internal financial performance monitoring and when assessing the future impact on operating decisions.

The measures allow 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.

The measures used in the Annual Report are defined in the table below and reconciliations to the IFRS measure are included in note 4.

ALTERNATIVE PERFORMANCE Measure	RELATED IFRS Measure	DEFINITION	USE/RELEVANCE
Net revenue	Revenue	Revenue excluding the pass through revenue from Managed Access.	The year on year growth in revenue can be impacted by a change in the mix of 'charged for' and 'free of charge' Managed Access Programs. Net revenue allows management and users of the accounts to assess the performance of the business after removing the pass through revenue. A reconciliation to the related IFRS measure is set out in note 4.
Adjusted gross profit	Gross profit	Gross profit excluding exceptional charges from write down of inventories.	Allows management to assess the performance of the business after removing the distortion of large/unusual items or transactions that are not reflective of the routine business operations. A reconciliation to the related IFRS measure is set out in note 4.
EBITDA	Profit from operations	Consolidated earnings before interest, tax, depreciation and amortisation.	Provides management with an approximation of cash generation from operational activities.

# **3. ALTERNATIVE PERFORMANCE MEASURES CONTINUED**

ALTERNATIVE PERFORMANCE Measure	RELATED IFRS Measure	DEFINITION	USE/RELEVANCE
Adjusted EBITDA	Profit from operations	<ul> <li>Consolidated earnings before interest, tax, depreciation, amortisation and adjusting items:</li> <li>Adjustment for fair value of acquired inventory sold in the year</li> <li>Adjustments to contingent consideration arising from earnouts on acquisitions</li> <li>Exceptional impairments</li> <li>Including share of joint venture EBITDA</li> </ul>	Provides management with an approximation of cash generation from operational activities after removing he distortion of large/unusual items or transactions that are not reflective of the underlying performance of the business. It is used in the covenant calculations for the revolving credit facility. A reconciliation to profit from operations is included in note 4.
Adjusted profit before tax	Profit before tax	<ul> <li>Profit before tax excluding adjusting items:</li> <li>As detailed above for adjusted EBITDA</li> <li>Amortisation of acquisition-related intangible assets</li> <li>Unwind of discount on contingent consideration</li> <li>Joint venture tax charge</li> </ul>	Allows management to assess the performance of the business after removing the distortion of large/unusual items or transactions that are not reflective of the routine business operations. A reconciliation to the related IFRS measure is set out in note 4.
Adjusted profit after tax	Profit after tax	<ul> <li>Profit after tax excluding adjusting items:</li> <li>As detailed above for profit before tax but including joint venture tax charge</li> <li>Related tax on the adjusting items</li> <li>Adjustments to tax charges relating to pre-acquisition periods</li> </ul>	
Adjusted EPS	Basic EPS	Adjusted profit after tax as defined above divided by the weighted average number of shares in issue during the year, consistent with the number of shares used in the calculation of basic EPS.	The growth versus previous periods allows management to assess the post-tax underlying performance of the business in combination with the impact of capital structuring actions on the share base. The components used in the calculation of adjusted EPS are detailed in note 10.
Net debt		Net debt comprises the carrying value of all bank loans and drawn revolving credit facilities net of unamortised loan issue costs and cash and cash equivalents. All amounts are closing balances as at the relevant balance sheet date.	Provides management with the level of leverage in the business and is used in the covenant calculations for the revolving credit facility.
Constant exchange rate ('CER')		CER is achieved by applying the prior year's average actual exchange rates to the current year's results.	Allows management to identify the relative year-on-year performance of the business by removing the impact of currency movements which are outside of management's control.
Operating cash flow	Cash flow from operating activities	Operating cash flow is net cash flow from operating activities before income taxes and interest.	Provides management with a view of the level of EBITDA converted into cash.
Free cash flow	Cash flow from operating activities	<ul> <li>Free cash flow is the cash generated from operating activities excluding the cash impact of adjusting items:</li> <li>Acquisition costs and related restructuring costs</li> <li>Acquisition-related income from settlement of contingent legal claims outstanding at acquisition</li> </ul>	Provides management with an indication of the amount of cash available for discretionary investing or financing after removing the distortion of large/unusual expenditures that are not reflective of the routine business operations A reconciliation to adjusted EBITDA is included on page 43.

### **4. 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 CODM during the reporting year. The CODM has been identified as the Executive Directors. The Group's operating segments are Commercial Medicines, Unlicensed Medicines and Clinical Services.

#### **OPERATING SEGMENT RESULTS**

The segmental performance measures have been changed from revenue and gross profit to net revenue and adjusted EBITDA. These are the segmental measures reported to and used by the CODM to manage the business. Net revenue eliminates the volatility in reported revenue which can arise from the pass through revenue as the mix of charged and free of charge MAPs changes. Segmental adjusted EBITDA is now used as it will lead to better internal cost control and accountability whilst allowing for easier interpretation of profitability of each segment by external stakeholders.

		2020			2019	
(IN £M)	<b>REPORTED REVENUE</b>	NET REVENUE	ADJUSTED EBITDA	REPORTED REVENUE	NET REVENUE	ADJUSTED EBITDA
Commercial Medicines	156.7	156.7	84.3	110.3	110.3	54.4
Unlicensed Medicines	197.0	158.9	34.4	205.9	156.0	35.0
Clinical Services	162.2	162.2	22.6	141.7	141.7	19.8
Central unallocated costs & eliminations	(11.6)	(11.6)	(10.3)	(1.0)	(1.0)	(8.4)
Segmental result	504.3	466.2	131.0	456.9	407.0	100.8

Net revenue is presented after excluding pass through revenue of £38.1m (2019: £49.9m) from the Managed Access business within Unlicensed Medicines.

		2020			2019	
(IN £M)	UNDERLYING	NON-UNDERLYING (Note 7)	TOTAL	UNDERLYING	NON-UNDERLYING (Note 7)	TOTAL
Reconciliation to reported profit						
Gross profit	220.0	(4.9)	215.1	182.3	-	182.3
Administrative expenses excluding amortisation and depreciation	(89.6)	(22.8)	(112.4)	(82.6)	(33.6)	(116.2)
EBITDA	130.4	(27.7)	102.7	99.7	(33.6)	66.1
Analysed as:						
Adjusted EBITDA including joint venture result	131.0	(27.7)	103.3	100.8	(33.6)	67.2
Joint venture EBITDA	(0.6)	-	(0.6)	(1.1)	-	(1.1)
EBITDA excluding joint venture result	130.4	(27.7)	102.7	99.7	(33.6)	66.1
Amortisation and impairment	(4.7)	(49.6)	(54.3)	(1.5)	(37.8)	(39.3)
Depreciation	(6.4)	-	(6.4)	(2.4)	-	(2.4)
Profit from operations	119.3	(77.3)	42.0	95.8	(71.4)	24.4
Net finance costs	(11.4)	(8.3)	(19.7)	(8.6)	(4.2)	(12.8)
Share of profit of joint venture	0.3	-	0.3	0.7	-	0.7
Profit before income tax	108.2	(85.6)	22.6	87.9	(75.6)	12.3
Analysed as:						
Adjusted profit before tax excluding share of joint venture tax	108.5	(85.9)	22.6	88.3	(76.0)	12.3
Joint venture tax	(0.3)	0.3	-	(0.4)	0.4	-
Profit before tax including share of joint venture tax	108.2	(85.6)	22.6	87.9	(75.6)	12.3
Income tax	(21.2)	12.3	(8.9)	(17.3)	10.2	(7.1)
Profit after income tax	87.0	(73.3)	13.7	70.6	(65.4)	5.2

# 4. SEGMENT INFORMATION CONTINUED

(IN £M)	2020	2019
Breakdown of revenues by type:		
Products	397.3	410.7
Services	99.5	38.0
Royalties	7.5	8.2
Total	504.3	456.9

All revenue arises from contracts with customers and is recognised at a point in time in accordance with the Group accounting policies.

# **GEOGRAPHICAL ANALYSIS**

(IN £M)	2020	2019
Revenue arises from the location of the customers as follows:		
UK	144.1	159.6
Europe	135.8	107.9
USA	121.4	90.7
South Africa	32.2	26.9
Australia	24.8	20.4
Rest of the world	46.0	51.4
Total	504.3	456.9

Assets and liabilities are reported to the Executive Directors at a Group level and are not reported on a segmental basis.

# 5. EXPENSES 5.1 EXPENSES

Profit from operations is stated after charging:

(IN £M)	2020	2019
Cost of inventories recognised as an expense in cost of sales	241.1	235.6
Employee benefit expense (net of capitalised costs of £1.6m (2019: £0.9m))	56.9	51.4
Amortisation and depreciation (notes 12, 13 and 14)	56.5	41.7
Impairment of intangible assets	4.2	-
Impairment of investment in joint venture	5.9	-
Operating lease charges	-	3.7
Foreign exchange gains	0.9	0.3

# 5.2 AUDITORS' REMUNERATION

During the year, the Group (including its overseas subsidiaries) obtained the following services from the Company's auditors and its associates:

- (N.S.M)	2020	2019
Fees payable to the Company's auditors for the audit of the Parent Company and consolidated financial statements	0.3	0.3
Fees payable to the Company's auditors for other services:		
- The audit of the Company's subsidiaries	0.4	0.3
- Audit related assurance services	0.1	0.1
- Tax advisory services	0.5	0.3

### 6. EMPLOYEES 6.1 EMPLOYEE BENEFIT EXPENSE

(IN £M)	2020	2019
Wages and salaries	49.0	43.9
Share-based payments	3.5	3.0
Social security costs	4.0	4.1
Other pension costs	2.0	1.3
Gross expense	58.5	52.3
Capitalised labour	(1.6)	(0.9)
Net expense	56.9	51.4

# 6.2 AVERAGE NUMBER OF PEOPLE EMPLOYED

The average monthly number of people employed by the Group (on an FTE basis) during the financial year amounted to:

NUMBER	2020	2019
Directors	2	2
Staff	1,166	1,106
Total	1,168	1,108

### 6.3 DIRECTORS' EMOLUMENTS

Details of the remuneration, shareholdings, share options and pension contributions of the Directors are included in the Remuneration Report on pages 62 to 71.

### 6.4 KEY MANAGEMENT PERSONNEL COMPENSATION

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Group. This is considered to be the Board of Directors.

(IN £M)	2020	2019
Directors' remuneration included in staff costs:		
Wages and salaries	2.1	2.0
Share-based payment expense	0.8	0.9
Total	2.9	2.9

# 7. 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 arising on acquisition and acquired products, one-off costs including business and product acquisition costs, restructuring costs, changes in deferred and contingent consideration, impairments and unwind of discount on contingent consideration. The associated tax impact is also reported as non-underlying.

(IN £M)	2020	2019
Cost of sales		
a) Impairment of Totect and Foscavir inventories	4.9	-
Administrative expenses		
b) Acquisition costs	0.3	5.4
c) Restructuring costs (relating principally to acquisitions)	2.8	6.4
d) Increase in the fair value of contingent consideration	11.8	21.4
a) Impairment of IP related to Totect	4.2	-
e) Impairment of investment in joint venture (note 15)	5.9	-
f) Foreign exchange revaluation on deferred and contingent consideration	2.0	0.4
g) Amortisation of intangible fixed assets acquired through business combinations and acquired products	45.4	37.8
	72.4	71.4
Finance costs	••••	
h) Unwind of discount on deferred and contingent consideration	8.1	4.1
b) Acquisition costs	0.2	0.1
	8.3	4.2
Taxation		
j) Credit in respect of tax on non-underlying costs	(12.3)	(10.2)
Total non-underlying items	73.3	65.4

- a) Impairment charges have been recognised against the Totect IP, Totect short-dated stock and excess Foscavir active pharmaceutical ingredient totalling £9.1m. Totect is facing challenging market conditions with an increased number of generic competitors, and whilst management have successfully increased the number of indications for the product, the ability to achieve a suitable return has reduced. Alongside this, a generic entrant to Foscavir has required a review of the recoverability of the raw material holding resulting in an impairment charge.
- b) Acquisition costs relate to legal fees and financing costs for the Group's recent product and business acquisitions.
- c) Restructuring costs have been incurred during the period in respect of the one-off integration of acquired businesses as well as preparations for any potential Brexit impact.
- d) The increase in the fair value of contingent consideration relates to the final earn-out calculation for the CSM acquisition.e) A fair value exercise was undertaken on the Group's joint venture undertaking Novagen Pharma Pty Limited and as a result of
- this valuation and future expectations for the business, management has taken the decision to fully impair the investment. f) Contingent consideration on CSM and iQone 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. g) 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 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.
- h) The non-cash unwind of the discount applied to the deferred and contingent consideration on the acquisitions of Proleukin, CSM, and iQone.
- i) The tax credit in respect of non-underlying items reflects the tax benefit on the costs incurred.

# **8. FINANCE INCOME AND COSTS**

(IN £M)	2020	2019
Bank interest expense	9.6	7.6
Borrowing costs	0.1	0.2
Amortisation of facility issue costs	1.1	0.9
Unwind of discount on lease liabilities	0.6	-
Underlying finance costs	11.4	8.7
Unwind of discount on deferred and contingent consideration on acquisitions	8.1	4.1
Acquisitions finance costs	0.2	0.1
Total finance costs	19.7	12.9
Bank interest income	-	(0.1)
Net finance expense	19.7	12.8

# **9. INCOME TAX EXPENSE**

(IN £M)	2020	2019
Current tax expense		
UK corporation tax	12.8	9.9
Overseas tax at local prevailing rates	6.7	5.8
Adjustment in respect of prior years	0.6	(1.1)
Total current tax expense	20.1	14.6
Deferred tax credit		
Origination and reversal of temporary differences	(13.6)	(7.5)
Adjustment in respect of prior years	0.1	-
Adjustments in respect of tax rates	2.3	-
Total deferred tax credit	(11.2)	(7.5)
Total income tax expense	8.9	7.1

The tax on the Group's profit before income tax differs from the theoretical amount that would arise using the standard rate of corporation tax in the UK applied to profit for the year as follows:

(M.S.M)	2020	2019
Profit before income tax	22.6	12.3
Expected tax charge based on corporation tax rate of 19.0%	4.3	2.3
Expenses not deductible for tax purposes other than amortisation on acquired intangibles	2.7	5.8
Tax relief for employee share schemes	(0.9)	(0.3)
Adjustments to tax charge in respect of prior years	0.7	(1.1)
Foreign tax credit	(0.2)	-
Recognition of previously unrecognised tax losses	(0.5)	-
Change in deferred tax rate	2.3	-
Higher rates of taxes on overseas earnings	0.5	0.4
Total income tax expense	8.9	7.1

In line with Finance Act 2016, from April 2020, the UK corporate tax rate was to reduce to 17.0%. The Government announced in the Budget on 11 March 2020, that the rate applicable from 1 April 2020 would remain at 19.0% rather than reduce to 17.0% and this was enacted on 17 March 2020. This 19% rate has been applied in the deferred tax valuations based on the expected timing of when such assets and liabilities will be recovered.

# 9. INCOME TAX EXPENSE CONTINUED

AMOUNTS RECOGNISED DIRECTLY IN EQUITY

The income tax credited/(charged) directly to equity during the year is as follows:

(IN £M)	2020	2019
Unexercised share options and losses recognised directly in equity	0.1	(0.2)

### TAX LOSSES

(INEM)	2020	2019
Unused tax losses for which no deferred tax asset has been recognised	-	2.3
Potential tax benefit at 25%	-	0.6

The unused tax losses have been incurred in the US subsidiary, Clinigen Inc. During the year, it has been determined that these tax losses can be utilised against future profits and so a deferred tax asset of £0.5m has been recognised in respect of losses of £2.4m.

# 10. EPS

(IN £M)	2020	2019
Profit after tax used in calculating reported EPS	13.7	5.2
Underlying profit after tax used in calculating adjusted EPS	87.0	70.6
Number of shares (million)		
Weighted average number of shares	132.7	129.8
Dilution effect of share options	2.0	2.2
Weighted average number of shares used for diluted EPS	134.7	132.0
Reported EPS (pence)		
Basic	10.3p	4.0p
Diluted	10.2p	4.0p
Adjusted EPS (pence)		
Basic	65.6p	54.4p
Diluted	64.6p	53.5p

EPS is calculated based on the share capital of the Parent Company and the earnings of the combined Group.

Diluted EPS takes account of the weighted average number of outstanding share options being 1,996,046 (2019: 2,225,514).

# 11. DIVIDENDS

(INEM)	2020	2019
Final dividend in respect of the year ended 30 June 2019 of 4.75p (2019: 3.84p) per ordinary share	6.3	5.1
Interim dividend of 2.15p (2019: 1.95p) per ordinary share paid during the year	2.9	2.6
	9.2	7.7

The Board proposes to pay a final dividend of 5.46p per ordinary share, subject to shareholder approval, on 2 December 2020, to shareholders on the register on 6 November.

# **12. INTANGIBLE ASSETS**

		ACQUIRED INT	ANGIBLES		DEVELOPED TRADEMARKS AND LICENCES			
(IN £M)	BRAND	CONTRACTS	CUSTOMER Relationships	ACQUIRED TRADEMARKS AND LICENCES		COMPUTER Software	GOODWILL	TOTAL
Cost								
At 1 July 2018	64.4	28.9	79.4	105.0	3.5	13.6	278.5	573.3
Acquisition of subsidiaries	4.0	-	56.2	-	-	1.4	102.9	164.5
Additions	-	-	-	172.4	4.0	8.4	-	184.8
Disposals	-	-	-	-	-	(0.1)	-	(0.1)
Exchange differences	-	(0.1)	1.0	2.1	-	-	1.6	4.6
At 30 June 2019	68.4	28.8	136.6	279.5	7.5	23.3	383.0	927.1
Additions	-	-	-	8.6	2.8	13.7	-	25.1
Disposals	-	-	-	(0.5)	-	(1.8)	-	(2.3)
Exchange differences	(0.1)	(0.3)	1.0	4.1	-	0.1	1.4	6.2
At 30 June 2020	68.3	28.5	137.6	291.7	10.3	35.3	384.4	956.1
Accumulated amortisation								
At 1 July 2018	9.2	18.6	19.4	26.0	0.1	2.4	-	75.7
Charge for the year	4.3	2.5	21.8	9.1	0.4	1.2	-	39.3
Disposals	-	-	-	-	-	(0.1)	-	(0.1)
Exchange differences	-	-	0.3	-	-	-	-	0.3
At 30 June 2019	13.5	21.1	41.5	35.1	0.5	3.5	-	115.2
Charge for the year	4.5	1.6	21.2	17.9	0.5	4.4	-	50.1
Impairment	-	-	-	4.2	-	-	-	4.2
Disposals	-	-	-	(0.5)	-	(1.8)	-	(2.3)
Exchange differences	-	(0.1)	0.5	0.2	-	-	-	0.6
At 30 June 2020	18.0	22.6	63.2	56.9	1.0	6.1	-	167.8
Net book value								
At 30 June 2020	50.3	5.9	74.4	234.8	9.3	29.2	384.4	788.3
At 30 June 2019	54.9	7.7	95.1	244.4	7.0	19.8	383.0	811.9
At 1 July 2018	55.2	10.3	60.0	79.0	3.4	11.2	278.5	497.6

#### BRAND

The brands represent the Idis, Link, Equity, Homemed, Quantum and CSM brands acquired as part of business combinations. Each brand has been fair valued at the acquisition date by reference to the operating businesses acquired which utilise each brand. The fair value is based on a Relief-from-Royalty-Method which calculates the value of the brand as equivalent to the royalty savings accrued over time, as the brand is owned and royalties are not required to be paid to a third party for the branding of products. The remaining amortisation periods are:

- Idis - 14 years 10 months

- 15 years 4 months - Link
- Equity - 10 years 4 months

- Homemed - 5 years 4 months

Quantum - 7 years 4 months
CSM - 3 years 3 months

### CONTRACTS

Contracts acquired with the Idis business combination related to client contracts within the Idis Managed Access business fair valued at the acquisition date based on the discounted value of future cash flows. These contracts enable the Group to manage the access programs on behalf of large pharma businesses. The remaining amortisation period is less than one year.

The acquired Link business has a number of supplier contracts which provide for the availability of product to Link on a contractual, exclusive supply basis. This accessibility to product is a key driver in growing the business. These exclusive supply contracts have been fair valued at the acquisition date based on the discounted value of future cash flows. The remaining amortisation period is between three and six years.

# **12. INTANGIBLE ASSETS CONTINUED**

### CUSTOMER RELATIONSHIPS

The nature of the acquired businesses is that there are no contracts with customers, however there are long-standing relationships with significant repeat business. These relationships have been fair valued at the acquisition date using a discounted valuation of future cash flows. The customer relationships for each area of the business are being amortised over different useful economic lives (see note 1). The remaining amortisation period is between three and 15 years.

### TRADEMARKS AND LICENCES

A total of 649 (2019: 690) trademarks and licences are held. £4.5m (2019: £4.5m) of internally developed trademarks and licences are assets in the course of development at the year end. During the year, due to the performance of the product, the decision was taken to fully impair the book value of the IP related to Totect which had a remaining net book value of £4.2m.

### COMPUTER SOFTWARE

The Group is undertaking the development and implementation of a new Oracle ERP system, the costs for which are being recognised as incurred. Amortisation started when the first major phase of the new system was brought into use.

#### GOODWILL

The goodwill is deemed to have an indefinite useful life. It is carried at cost and is reviewed annually for impairment. Where the recoverable amount is less than the carrying value, an impairment results. During the year, goodwill was tested for impairment, with no impairment charge arising.

The Group allocates goodwill to CGUs which are based on the reportable segments as defined by IFRS 8 (see note 4) as these segments are deemed to be the lowest level at which independent cash flows can be generated. Goodwill has been allocated as laid out in the table below.

(INEM)	2020	2019
Commercial Medicines	110.4	110.6
Unlicensed Medicines	144.8	145.0
Clinical Services	129.2	127.4
	384.4	383.0

The recoverable amount of all CGUs has been determined based on value-in-use calculations. These calculations use pre-tax cash flow projections over a period of 5 years and a pre-tax discount rate of 10.5% (2019: 10.5%), equivalent to the Group's weighted average cost of capital.

For each CGU, a terminal growth rate of 2.0% (2019: 2.0%) has been used. Cash flow forecasts have been based on gross profit growth assumptions which are based on approved budgets for the upcoming year and strategic projections representing the best estimate of future performance utilising the Group's current asset base. The long-term assumptions on gross profit growth used in each CGU are laid out in the table below.

	2020	2019
Commercial Medicines	1%	4%
Unlicensed Medicines	7%	9%
Clinical Services	8%	5%

The Group has applied sensitivities to assess whether any reasonably possible changes in assumptions rate could cause an impairment that would be material to these financial statements. Management does not consider any of the downside sensitivities required for an impairment to result, as detailed below, to be probable.

	2020 2019			19
	RATE REQUIRED TO ELIMINATE HEADROOM IN IMPAIRMENT ASSESSMENT			
	DISCOUNT Rate	TERMINAL Growth Rate	DISCOUNT Rate	TERMINAL Growth Rate
Commercial Medicines	14.9%	(6.2)%	20.9%	(30.4)%
Unlicensed Medicines	18.2%	(15.5)%	23.8%	(51.2)%
Clinical Services	20.1%	(22.4)%	19.9%	(23.5)%

# 13. PROPERTY, PLANT AND EQUIPMENT

	LAND AND Buildings	LEASEHOLD Improvements	PLANT AND Machinery	FIXTURES, FITTINGS AND EQUIPMENT	TOTAL
Cost				·	
At 1 July 2018	2.1	2.6	1.2	3.9	9.8
Acquisition of subsidiaries	2.4	1.7	-	3.1	7.2
Additions	0.1	0.3	0.2	1.4	2.0
Disposals	-	-	-	(0.3)	(0.3)
Exchange differences	-	-	-	0.2	0.2
At 30 June 2019	4.6	4.6	1.4	8.3	18.9
Additions	-	1.4	0.2	1.3	2.9
Disposals	-	(0.3)	(0.1)	(1.2)	(1.6)
Exchange differences	0.1	0.1	-	-	0.2
At 30 June 2020	4.7	5.8	1.5	8.4	20.4
Accumulated depreciation					
At 1 July 2018	0.1	0.7	0.2	2.0	3.0
Charge for the year	0.1	0.7	0.3	1.4	2.5
Disposals	-	-	-	(0.3)	(0.3)
Exchange differences	-	-	-	0.1	0.1
At 30 June 2019	0.2	1.4	0.5	3.2	5.3
Charge for the year	0.2	0.9	0.2	1.7	3.0
Disposals	-	(0.1)	(0.1)	(1.1)	(1.3)
At 30 June 2020	0.4	2.2	0.6	3.8	7.0
Net book value					
At 30 June 2020	4.3	3.6	0.9	4.6	13.4
At 30 June 2019	4.4	3.2	0.9	5.1	13.6
At 1 July 2018	2.0	1.9	1.0	1.9	6.8

# 14. RIGHT-OF-USE ASSETS

	LAND AND Buildings	PLANT AND Machinery	FIXTURES, FITTINGS AND EQUIPMENT	TOTAL
Cost				
Impact of adopting IFRS 16 (note 29)	16.5	0.5	0.5	17.5
At 1 July 2019	16.5	0.5	0.5	17.5
Additions	6.1	0.3	-	6.4
Disposals	(0.2)	-	-	(0.2)
Exchange differences	(0.1)	-	-	(0.1)
At 30 June 2020	22.3	0.8	0.5	23.6
Accumulated depreciation				
Charge for the year	3.0	0.3	0.1	3.4
Disposals	(0.2)	-	-	(0.2)
At 30 June 2020	2.8	0.3	0.1	3.2
Net book value				
At 30 June 2020	19.5	0.5	0.4	20.4

The Group adopted IFRS 16 on 1 July 2019 using the modified retrospective approach and therefore no comparative numbers are presented.

# **15. INVESTMENT IN JOINT VENTURES AND ASSOCIATES**

(IN £M)	2020	2019
At 1 July	6.5	6.6
Share of profit	0.3	0.7
Impairment	(5.9)	-
Dividends received	-	(0.8)
Cumulative currency losses	(0.9)	-
At 30 June	-	6.5

During the year, Clinigen South Africa Pty Limited, a subsidiary of the Group, acquired a 24.5% interest in an associate company in South Africa, Novagen BBBEE Invest Co Pty Limited for £nil consideration. This associate company was given an option to acquire 20% of the shares of the Group's existing joint venture undertaking, Novagen Pharma Pty Limited. As a result, the overall shareholding in Novagen Pharma Pty Limited was diluted from 50% to 45%. As a result of this transaction and a reassessment of the future profitability of the Novagen business due in part to the introduction of constraints to the procurement policies related to broad-based black economic empowerment, the carrying value has been impaired.

The registered office is also the principal place of business.

NAME	YEAR END	COUNTRY OF INCORPORATION AND REGISTERED OFFICE	MEASUREMENT METHOD	OWNERSHIP
Novagen Pharma Pty Limited	31 March	100 Sovereign Drive, Nellmapius Drive, Irene 0157, Pretoria, South Africa	Equity	45%
Novagen BBBEE Invest Co Pty Limited	31 March	100 Sovereign Drive, Nellmapius Drive, Irene 0157, Pretoria, South Africa	Equity	24.5%

The Group has no commitments and there are no contingent liabilities relating to the Group's interest in the joint venture.

Set out below is the aggregated summarised financial information for the Group's joint ventures and associates.

(IN £M)	2020	2019
Summarised statement of financial position		
Non-current assets	1.9	1.7
Cash and cash equivalents	0.9	0.7
Other current assets	2.3	3.3
Current liabilities	(1.4)	(2.0)
Net assets	3.7	3.7
Summarised income statement	· · · · · ·	
Revenue	8.5	12.6
Profit after tax	0.6	1.4
Reconciliation of the summarised financial information to the carrying amounts in the joint ventures and associates		
Opening net assets	3.7	4.0
Profit for the year	0.6	1.4
Dividend paid	-	(1.6)
Cumulative currency losses	(0.6)	(0.1)
Closing net assets	3.7	3.7
Interest in joint ventures and associates	1.9	1.9
Goodwill	-	(1.6)
Accumulated impairment	(1.9)	-
Carrying value	-	6.5

# **16. INVENTORIES**

(N.2.M)	2020	2019
Raw materials and consumables	15.6	4.8
Work in progress	0.1	2.5
Finished goods and goods for resale	27.8	28.1
	43.5	35.4

The cost of inventories recognised as an expense and included in cost of sales amounted to £241.1m (2019: £235.6m).

During the year, due to the performance of the product, the decision was taken to fully impair the value of the IP and the inventory related to Totect. Furthermore as the Directors have been made aware of a generic entrant for Foscavir, a supply agreement for raw material which was entered into as a defence against a generic is now considered to have no value and so has also been fully provided for. The total value of the inventory written down was £4.9m which has been classified as a non-underlying item in cost of sales.

# **17. TRADE AND OTHER RECEIVABLES**

(N2N)	2020	2019
Trade receivables	98.0	74.8
Less: provision for impairment of trade receivables	(1.0)	(1.6)
Trade receivables - net	97.0	73.2
Prepayments and accrued income	16.2	13.7
Payments made on account	1.1	16.2
Other receivables	11.6	7.1
Total trade and other receivables	125.9	110.2

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. The expected loss rates are based on payment profiles and historic credit losses. The historic loss rates are adjusted to reflect current and forward-looking information on macroeconomic factors to the extent they are relevant to the customers' ability to settle. Due to the short-term nature of trade and other receivables, the book value approximates to their fair value save for where specific provision for impairment has been made.

The following table provides information on the movement in the provision for impairment in the year:

(N.2M)	2020	2019
At 1 July	1.6	2.4
Acquisition of subsidiaries	-	0.3
Utilised in respect of debts written off	-	(0.4)
Released to the income statement	(0.9)	(1.0)
Charged to the income statement	0.3	0.3
At 30 June	1.0	1.6

The ageing analysis of the gross trade receivables balances and loss allowances is as follows:

		S	LOSS ALLOWANCE	
(IH £M)	2020	2019	2020	2019
Not past due	63.8	51.7	-	-
Up to three months past due	27.4	18.5	-	-
Three to six months past due	4.3	2.5	-	0.2
fore than six months past due	2.5	2.1	1.0	1.4
	98.0	74.8	1.0	1.6

# **18. CASH AND CASH EQUIVALENTS**

(IH£M)	2020	2019
Cash at bank and in hand	143.1	83.5

Due to the short-term nature of cash at bank and short-term deposits, the carrying value approximates to their fair value. The credit risk of the banks was very low and therefore the carrying amount has not been adjusted; their S&P credit ratings were RBS: A-1, HSBC: A-, ABSA: AA and JP Morgan: A+.

# **19. TRADE AND OTHER PAYABLES**

(M)	2020		2019	
	CURRENT	NON-CURRENT	CURRENT	NON-CURRENT
Trade payables	61.9	-	69.5	-
Payments received on account	0.3	-	9.2	-
Tax and social security	5.7	-	4.3	-
Other payables	0.9	-	1.0	-
Accruals and deferred income	51.9	2.0	47.9	1.5
Deferred consideration	1.6	-	48.8	-
Contingent consideration	72.6	6.9	55.0	5.8
	194.9	8.9	235.7	7.3

Contingent consideration is payable on the CSM and iQone acquisitions based on the adjusted earnings of the business. The final consideration of US\$89.5m has been paid post year end. The contingent consideration on the iQone acquisition 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 is €12.3m.

Due to the short-term nature of current trade and other payables, the fair value approximates to their book value. Creditors are unsecured.

# **20. BORROWINGS AND LEASE LIABILITIES**

The book value of loans and borrowings are as follows:

(IN £M)	2020	2019
Bank borrowings	431.3	335.7
Lease liabilities	23.7	0.2
Total borrowings and lease liabilities	455.0	335.9

During the year, the multi-currency debt facility was increased from £375m to £430m comprising an unsecured £180m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £250m. At 30 June 2020, the facility is denominated in £264m sterling (2019: £219m), €90m euros (2019: €90m), and US\$108m US dollars (2019: US\$48m).

At the year 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 3.5x (excluding IFRS 16), 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 30 June 2020, interest cover was 13.3x and the net debt/ adjusted EBITDA leverage was 2.3x. There were no instances of default, including covenant terms, in either the current or the prior year.

During the year, interest was payable on a tiered scale based on the level of borrowing. The applicable interest rate on amounts drawn down was up to 2.0% plus LIBOR.

#### MATURITY OF BORROWINGS AND LEASE LIABILITIES

The maturity profile of the carrying amount of the Group's borrowings and lease liabilities at the year end was as follows:

	2020			2019		
(IN EM)	GROSS Borrowings	UNAMORTISED Issue costs	NET Borrowings	GROSS Borrowings	UNAMORTISED Issue costs	NET Borrowings
Within one year	4.3	-	4.3	-	-	-
In more than one year but less than two years	4.2	-	4.2	0.2	-	0.2
In more than two years but less than five years	449.0	(2.5)	446.5	338.8	(3.1)	335.7
	457.5	(2.5)	455.0	339.0	(3.1)	335.9

The term loan and RCF are revalued at the period end foreign exchange rates for reporting purposes. However the banking facility position is based on exchange rates prevailing at the time the facility is drawn in the foreign currency.

#### FAIR VALUE OF BORROWINGS

The fair values of the Group's borrowings are the same as the carrying amount and are within Level 2 of the fair value hierarchy.

#### **RECONCILIATION OF MOVEMENTS IN NET DEBT**

	TERM LOAN	REVOLVING CREDIT Facility	LEASE LIABILITIES	UNAMORTISED Issue costs	TOTAL Borrowings	CASH AND CASH Equivalents	NET DEBT
At 30 June 2019	151.3	187.5	0.2	(3.1)	335.9	(83.5)	252.4
Impact of adopting IFRS 16	-	-	20.7	-	20.7	-	20.7
At 1 July 2019		187.5	20.9	(3.1)	356.6	(83.5)	273.1
Cash flow before borrowings	-	-	-	-	-	30.0	30.0
Amendment of facility	30.0	(30.0)	-	(0.5)	(0.5)	-	(0.5)
Lease liability additions	-	-	6.3	-	6.3	-	6.3
Proceeds from increase in loan	-	107.6	-	-	107.6	(107.6)	-
Repayments of borrowings	-	(17.1)	(3.4)	-	(20.5)	20.5	-
Amortisation of facility issue costs	-	-	-	1.1	1.1	-	1.1
Exchange differences	1.7	2.8	(0.1)	-	4.4	(2.5)	1.9
At 30 June 2020	183.0	250.8	23.7	(2.5)	455.0	(143.1)	311.9

The term loan and RCF are revalued at the period end foreign exchange rates for reporting purposes. However the banking facility position is based on exchange rates prevailing at the time the facility is drawn in the foreign currency.

# 21. FINANCIAL INSTRUMENTS – RISK MANAGEMENT

The Group is exposed through its operations to the following financial risks:

- Credit risk
- Foreign exchange risk
- Liquidity risk

In common with all other businesses, the Group is exposed to risks that arise from its use of financial instruments. This note describes the Group's objectives, policies and processes for managing those risks and the methods used to measure them. Further quantitative information in respect of these risks is presented throughout these financial statements.

#### **PRINCIPAL FINANCIAL INSTRUMENTS**

The principal financial instruments used by the Group, from which financial instrument risk arises, are as follows:

- Trade and other receivables
- Cash and cash equivalents
- Trade and other payables
- Loans and borrowings
- Derivative financial instruments

The Group does not issue or use derivative financial instruments of a speculative nature.

# 21. FINANCIAL INSTRUMENTS - RISK MANAGEMENT CONTINUED

A summary of the financial instruments held by category is provided below:

(IN £M)	2020	2019
Financial assets measured at amortised cost		
Cash and cash equivalents	143.1	83.5
Trade and other receivables	101.4	91.7
Derivatives used for hedging		
Derivative financial instruments	0.2	2.2
Total financial assets	244.7	177.4
Financial liabilities measured at amortised cost		
Trade and other payables	198.1	238.7
Borrowings and lease liabilities	457.5	339.0
Derivatives used for hedging		
Derivative financial instruments	0.3	0.4
Total financial liabilities	655.9	578.1

#### **RISK MANAGEMENT**

A description of the Group's treasury policy and controls is included in the Financial Review on page 43.

#### **Credit risk**

Credit risk is the risk of financial loss to the Group if a customer or a counterparty to a financial instrument fails to meet its contractual obligations. The Group is mainly exposed to credit risk from credit sales to customers. It is Group policy, implemented locally, to assess the credit risk of new customers by obtaining credit ratings before entering contracts or offering credit terms. The credit terms are then continually assessed on an individual basis, and amended accordingly, as a trading history is developed with the customer. Purchase limits are established for each customer, which represents the maximum open amount without requiring approval from the Group Financial Controller or Chief Financial Officer.

Quantitative disclosures of the credit risk exposure in relation to financial assets are set out below. Further disclosures regarding trade and other receivables at the end of the financial year, which are past due but not impaired, are provided in note 17.

(IN £M)	2020	2019
Financial assets – maximum exposure		
Cash and cash equivalents	143.1	83.5
Trade and other receivables	101.4	91.7
Derivative financial instruments	0.2	2.2
Total financial assets	244.7	177.4

### Foreign exchange risk

Foreign exchange risk arises because the Group has operations located in various parts of the world whose functional currency is not the same as the functional currency in which the Group companies are operating. The Group's overseas subsidiaries contribute approximately 44% (2019: 35%) to the Group's revenue, all of which is transacted in non-sterling currencies. The overseas subsidiaries operate separate bank accounts, which are used solely for that subsidiary, thus managing the currency in that country. The Group's net assets arising from such overseas operations are exposed to currency risk resulting in gains or losses on retranslation into sterling.

Foreign exchange risk also arises when individual Group entities enter into transactions denominated in a currency other than their functional currency. The Group hedges currency transactions internally through currency bank accounts and by managing Group-wide currency requirements centrally. This reduces the currency risk exposure and allows retranslation of these balances into sterling to be planned in order to minimise the exposure to foreign exchange rate fluctuations. The Group uses forward contracts on large transactions where there is adequate visibility and the contract is not naturally hedged. This reduces the risk to fluctuating foreign exchange rates and permits the management better visibility and certainty of gross profit margins.

At the reporting date the Group had entered into time option contracts with the bank for US dollars, euros, Japanese yen, Hong Kong dollars and Australian dollars. These options all mature within 12 months of the reporting date. Forward exchange contracts are formally designated as hedges and hedge accounting is applied to the extent that the relationship between the hedged items and the hedging instrument allows it. Derivative financial instruments are carried at fair value. The mark-to-market valuation at the reporting date has been recognised in the balance sheet as a financial instrument asset or liability as appropriate.

The derivative financial instruments held by the Group are summarised as follows.

	2020		201	9
(N £M)	ASSETS	LIABILITIES	ASSETS	LIABILITIES
Forward foreign exchange contracts – cash flow hedges	0.2	0.3	2.2	0.4

The notional principal amounts of the outstanding forward foreign exchange contracts at 30 June 2020 were US\$5m and  $\in 6m$  (2019: US\$90m and  $\in 12m$ ). The maturity dates range from July 2020 to March 2021. The foreign currency forwards are denominated in the same currency as the highly probable hedged transactions, therefore the hedge ratio is 1:1. The weighted average hedged rate for the year was US\$1.28:£1 and  $\notin 1.11$ :£1.

In FY19, the Parent Company drew down €90m of its multi-currency debt facility to fund the CSM acquisition which is treated as a net investment hedge against the consolidated euro functional net assets of CSM, including goodwill.

The valuation of financial instruments at the reporting date is impacted by the foreign exchange rate at that date, primarily in respect of the US dollar and euro. At 30 June 2019, if sterling had weakened/strengthened by 10% against both the US dollar and euro with all variables held constant, profit for the year would have been £10.5m (2019: £3.9m) higher/lower as a result of foreign exchange gains/losses on translation of US dollar/euro trade receivables, cash and cash equivalents, and trade payables. The figure of 10% used for sensitivity analysis has been chosen because it represents a range of reasonable fluctuations in exchange rates.

#### LIQUIDITY RISK

Liquidity risk arises from the Group's management of working capital and the finance charges and principal repayments on its debt instruments. It is the risk that the Group will encounter difficulty in meeting its financial obligations as they fall due.

The Group's policy is to ensure that it will always have sufficient cash to allow it to meet its liabilities when they become due.

The Board receives cash flow projections based on working capital modelling, as well as information regarding cash balances and net debt monthly. At the end of the financial year, these projections indicated that the Group expected to have sufficient liquid resources to meet its obligations under all reasonably expected circumstances.

The following table sets out the contractual maturities (representing undiscounted contractual cash flows) of financial liabilities:

(IN £M)	LESS THAN 3 Months	BETWEEN 3 Months And 1 year	BETWEEN 1 AND 2 YEARS	BETWEEN 2 and 5 years
At 30 June 2020				
Trade and other payables	191.1	1.4	0.8	11.2
Lease liabilities	1.0	3.3	4.2	8.0
Borrowings	-	-	-	433.9
At 30 June 2019				
Trade and other payables	130.1	108.2	1.6	11.1
Borrowings (including finance lease liabilities)	-	0.1	0.1	338.8

#### **Valuation hierarchy**

The table below shows the financial instruments carried at fair value by valuation method:

	2020 LEVEL 1	2020 LEVEL 2	2020 LEVEL 3	2019 LEVEL 1	2019 LEVEL 2	2019 LEVEL 3
Assets/(liabilities)						
Derivative financial instruments - forward foreign exchange contracts	-	(0.1)	-	-	1.8	-
Contingent consideration	-	-	(79.5)	-	-	(60.8)

The Level 2 forward foreign exchange valuations are derived from mark-to-market valuations as at 30 June 2020. Fair value gains of £2.3m (2019: losses of £1.0m) relating to the movement on open forward foreign exchange contracts have been recognised in underlying administrative expenses. The Level 3 contingent consideration liability is the discounted amount payable in respect of the CSM and iQone acquisitions. The amounts payable have been calculated based on the latest forecast of earnings during the respective earn-out periods.

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED For the year ended 30 June 2020

# 21. FINANCIAL INSTRUMENTS - RISK MANAGEMENT CONTINUED

#### Capital management

The Group monitors 'adjusted capital' which comprises all components of equity (i.e. share capital, share premium account, merger reserve, foreign exchange reserve, hedging reserve and retained earnings) as disclosed in the statement of changes in equity and long-term debt as detailed in note 20.

The Group's objectives when maintaining capital are:

- To safeguard the entity's ability to continue as a going concern, so that it can continue to provide returns for shareholders and benefits for other stakeholders
- To ensure the Group has the cash available to develop the products and services provided by the Group in order to provide an adequate return to shareholders

Pricing, sale and acquisition decisions are made by assessing the level of risk in relation to the expected return.

The Group sets the amount of capital it requires in proportion to risk. The Group manages its capital structure and makes adjustments to it in the light of changes in economic conditions and the risk characteristics of the underlying assets. In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

Net debt is calculated as total borrowings (as detailed in note 20) less cash and cash equivalents.

### **22. DEFERRED INCOME TAX**

Deferred tax assets and liabilities are analysed after offset, to the extent there is a legally enforceable right, of balances within countries as follows:

(IN EM)	2020	2019
Deferred tax assets	7.2	2.8
Deferred tax liabilities:		
Deferred tax liabilities to be settled after more than 12 months	27.6	34.0
Deferred tax liabilities within 12 months	6.0	7.1
	33.6	41.1

The movement on the deferred income tax account is as shown below:

	BALANCE AT 30 JUNE 2019	RECOGNISED IN Income statement	RECOGNISED In Equity	ADOPTION OF IFRS 16	FOREIGN EXCHANGE Adjustments	BALANCE AT 30 June 2020
Intangible assets	(39.6)	4.9	-	-	(0.1)	(34.8)
Property, plant and equipment	1.1	(0.1)	-	-	-	1.0
Inventories	0.3	5.8	-	-	-	6.1
Leases	-	(0.1)	-	0.7	-	0.6
Share-based payments	1.1	0.7	0.1	-	-	1.9
R&D tax credits	(1.5)	(0.2)	-	-	-	(1.7)
Losses	0.3	0.2	-	-	-	0.5
Net deferred tax liability	(38.3)	11.2	0.1	0.7	(0.1)	(26.4)

(IN £M)	BALANCE AT 30 JUNE 2018	RECOGNISED IN Income statement	RECOGNISED In Equity	ACQUISITION OF Subsidiaries	FOREIGN EXCHANGE Adjustments	BALANCE AT 30 June 2019
Intangible assets	(29.9)	7.3	-	(16.9)	(0.1)	(39.6)
Property, plant and equipment	0.9	0.2	-	-	-	1.1
Inventories	-	0.3	-	-	-	0.3
Share-based payments	1.4	0.1	(0.4)	-	-	1.1
R&D tax credits	(1.1)	(0.4)	-	-	-	(1.5)
Losses	0.3	-	-	-	-	0.3
Net deferred tax liability	(28.4)	7.5	(0.4)	(16.9)	(0.1)	(38.3)

Deferred income taxes are recognised for tax losses carried forward to the extent that the realisation of the related tax benefit through future taxable profits is probable. During the year, the Group recognised a deferred income tax asset of £0.5m in respect of previously unrecognised tax losses of £2.4m in Clinigen Inc., a subsidiary company registered in the US, as it has been determined that these can now be utilised against future taxable income.

Deferred tax is calculated in full on temporary differences under the liability method using the enacted tax rate for the period when the temporary difference is expected to reverse.

A deferred tax asset is being recognised in relation to profit in stock arising on intra-group sales of inventory on the basis Clinigen Inc. (the acquirer of the inventory) will generate sufficient taxable profits against which the temporary difference will reverse.

### **23. SHARE CAPITAL**

		NUMBER OF SHARES (ODOS)
ISSUED AND FULLY PAID	_	ORDINARY SHARES OF 0.1P EACH
At 1 July 2018		122,286
Issue of new shares		10,193
At 30 June 2019		132,479
Issue of new shares		420
At 30 June 2020		132,899
(IN £M)	2020	2019
Ordinary shares of 0.1p each	0.1	0.1

The Company does not have a limited amount of authorised share capital. The ordinary shares entitle the holder to participate in dividends and to share in the proceeds of winding up the company in proportion to the number of and amounts paid on the shares held. Every holder is entitled to vote with each share entitled to one vote.

### **24. RESERVES**

The following describes the nature and purpose of each reserve within equity:

RESERVE	DESCRIPTION AND PURPOSE
Share premium account	Amount subscribed for share capital in excess of nominal value, except where recognition in merger reserve is used (see below).
Merger reserve	Amount subscribed for share capital in excess of nominal value when shares are issued in exchange for at least a 90% interest in the shares of another company.
Hedging reserve	Gains/losses arising on cash flow hedges.
Foreign exchange reserve	Gains/losses arising on retranslating the net assets of overseas operations into sterling.
Retained earnings	All other net gains and losses and transactions with owners (e.g. dividends) not recognised elsewhere.

Included within the retained earnings reserve as at 30 June 2020 is £8.7m (2019: £6.1m) relating to unexercised share options which is not distributable.

### **25. CAPITAL COMMITMENTS**

At 30 June 2020, the Group had no capital commitments (2019: £1.1m relating to the design and implementation of the Oracle ERP system).

### **26. POST-EMPLOYMENT BENEFITS**

The Group operates a defined contribution pension scheme for the benefit of its employees. The assets of the scheme are held separately from those of the Group in an independently administered fund. Pension costs represent the contributions payable by the Group to the funds and amounted to £2.0m (2019: £1.3m).

# **NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED** For the year ended 30 June 2020

# **27. SHARE-BASED PAYMENTS**

An equity-settled share-based payment charge of £3.5m (2019: £3.0m) has been recognised in the year.

The Company operated the following schemes which are all equity-settled:

PLAN	TAX AUTHORITY STATUS	EMPLOYEES	GRANTING, VESTING CONDITIONS AND EXERCISE OF SHARE OPTIONS
Clinigen Group LTIP	Unapproved	All employees	Subject to performance criteria comparing TSR versus the FTSE SmallCap Index (excluding investment companies) over a three- year period.
			If the individual leaves earlier than the earliest vesting date, they may, if certain conditions are met, be still entitled to a proportion of the shares.
Clinigen Group Sharesave Plan	HMRC approved	All UK employees	Options are exercisable at a price equal to the average opening price as published in the Financial Times on the date of invitation and the two dealing days preceding the date of invitation, less 20%.
			Three-year vesting period.
			If options remain unexercised after a period of six months from the vesting date the options expire.
			If monthly contributions are not made for more than six months over the three-year period, the options lapse.
Clinigen Group Company Share Option Plan	HMRC approved for UK employees	All employees	Options granted to employees who have invested in the shares of the Company.
Option Plan	Unapproved for US employees		Options are granted to match the shares acquired by the employee or those granted through the initial grant under the Sharesave or US Stock Purchase Plan.
			Three-year vesting period.
			Options vest if employee still owns shares in three years or exercises their options under the Sharesave or US Stock Purchase Plan.
Clinigen Group US Stock Purchase Plan	US tax authority approved	All US employees	Options are exercisable at a price equal to the average opening price as published in the Financial Times on the date of invitation and the two dealing days preceding the date of invitation, less 15%.
			Two-year vesting period.
Clinigen Group LTIP 2015	Unapproved	All employees	Subject to performance criteria comparing TSR versus the relevant index (FTSE SmallCap Index (excluding investment companies) for grants in FY16 to FY19 and the FTSE 250 for grants in FY20) over a three-year vesting period and a performance condition measuring the EPS of the Group against target EPS over a three-year period. For certain individuals, vesting is also subject to achievement of personal objectives.
			If the individual leaves earlier than the earliest vesting date, entitlement is at the discretion of the Remuneration Committee.
Clinigen Group All Staff LTIP	Unapproved	All employees	Subject to performance criteria comparing TSR versus the FTSE SmallCap Index (excluding investment companies) over a three- year vesting period and a performance condition measuring the EPS of the Group against target EPS over a three-year period.
			If the individual leaves earlier than the earliest vesting date, their share option lapses.

Details of the share options granted are as follows:

	2020		2	1019
	WEIGHTED AVERAGE Exercise price (P)	NUMBER	WEIGHTED AVERAGE Exercise price (P)	NUMBER
As at 1 July		2,279,105		1,553,074
Granted during year	0.97	887,285	1.03	1,370,359
Forfeited during the year	1.30	(415,241)	1.11	(310,455)
Exercised during year		(220,116)		(333,873)
As at 30 June	0.82	2,531,033	0.93	2,279,105
Vested and exercisable at 30 June	1.12	386,714	1.16	162,021

The weighted average share price (at the date of exercise) of options exercised during the year was £7.87 (2019: £9.10).

The exercise price of options outstanding at 30 June 2020 ranged between nil and £9.25 and their weighted average contractual life was two years 11 months.

The weighted average fair value of each option granted during the year was £5.12 (2019: £6.70).

The following information is relevant in the determination of the fair value of options granted during the year under the equitysettled share-based remuneration schemes operated by the Group. A stochastic valuation model is used to value awards with market-based conditions, and the Black-Scholes pricing model is used for all other schemes.

2020	2019
Weighted average share price at grant date (£)£7.68	£9.13
	nil to £9.25
Weighted average contractual life (in years)   2.8	2.8
Expected volatility (%) 30.0	30.0
Expected dividend yield (%)	N/A
Risk-free interest rate (%) 0.5 to 0.8	

Expected volatility was determined by calculating the historical volatility of the Company's share price over the performance period immediately prior to the date of grant.

The Group did not enter into any share-based payment transactions with parties other than employees during the current or previous year.

#### **28. RELATED PARTY TRANSACTIONS** ULTIMATE CONTROLLING PARTY

The Company's shares are listed on AIM and are widely held. There is no one controlling party or group of related parties who have control of the Group.

#### TRANSACTIONS WITH RELATED PARTIES

The remuneration payable to the Directors of the Company is disclosed in note 6.

Novagen Pharma Pty Limited ('Novagen') is a joint venture in which the Group has a 45% interest. During the year, the Group charged distribution fees of £0.5m (2019: £0.9m) to Novagen, and recharged costs of £0.4m (2019: £0.5m) for goods and services provided. At 30 June 2020, the Group had no amounts receivable owing from Novagen (2019: £0.1m).

During the year, the Group received services amounting to £0.2m from Alan Boyd Consultants Limited, a company owned and managed by Alan Boyd, one of the Group's Non-Executive Directors.

There were no other transactions with related parties during the year.

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED For the year ended 30 June 2020

### **29. LEASES**

On 1 July 2019, the Group adopted IFRS 16 'Leases' using the modified retrospective approach. Under the specific transitional provisions in the standard, comparative information has not been restated and the adjustments arising from the new standard have been recognised in the opening balance sheet on 1 July 2019.

The Group leases various offices, warehouses, equipment and vehicles. Rental contracts are typically made for fixed periods of three to ten years but in the case of property, they often have extension options which are normally exercised. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets cannot be used as security for borrowing purposes.

Until the end of the previous financial year, leases of property, plant and equipment were classified as either finance or operating leases. Payments made under operating leases (net of any incentives received from the lessor) were charged to profit or loss on a straight-line basis over the period of the lease.

From 1 July 2019, leases are recognised as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the liability and finance cost in the cash flow statement. The finance cost is charged to profit or loss over the lease period (through underlying finance costs) so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

On adoption of IFRS 16, the Group recognised lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 'Leases'. These liabilities were measured at the present value of the remaining lease payments, discounted using the Group's incremental borrowing rate as of 30 June 2019 which was 2.75%.

For leases previously classified as finance leases, the carrying amount of the lease asset and lease liability immediately before transition are recognised as the carrying amount of the right-of-use asset and the lease liability at 1 July 2019.

(IN £M)	
Operating lease commitments disclosed as at 30 June 2019	22.6
Leases previously recognised as finance leases under IAS 17	0.2
Discounted using the borrowing rate as at 30 June 2019 (2.75%)	(1.8)
Short-term leases recognised on a straight-line basis	(0.3)
Lease liabilities recognised as at 1 July 2019	20.7
New lease liabilities recognised from new contracts and contract modifications	6.4
Unwind of discount recognised in finance costs	0.6
Repayment of capital element and payment of accrued interest	(4.0)
Lease liabilities recognised at 30 June 2020	23.7

The associated right-of-use assets were measured on a retrospective basis as if the new rules had always been applied.

(M2M)	30 JUNE 2020	1 JULY 2019
Land and buildings	19.5	16.5
Other	0.9	1.0
	20.4	17.5

Due to the differences arising between the lease liabilities and the right-of-use assets on transition, an adjustment of £2.9m has been recognised through retained earnings. As a result of this adjustment, an associated £0.7m deferred tax asset has also been recognised through retained earnings.

In applying IFRS 16 for the first time, the Group has used the following practical expedients permitted by the standard:

- Reliance on previous assessments of whether a contract is or contains a lease
- Reliance on previous assessments of whether leases are onerous
- The accounting for operating leases, with a remaining lease term of less than 12 months as at 1 July 2019, as short-term leases
- The exclusion of initial direct costs for the measurement of the right-of-use asset at the date of initial application
- The use of hindsight in determining the lease term where the contract contains options to extend or terminate the lease

The expense recognised relating to short-term leases during the year was £0.3m. At 30 June 2020 there were no outstanding commitments for short-term or low-value leases. The total cash outflow in respect of lease liabilities during the year was £4.0m.

The impact of the new standard on the income statement for the financial year was an increase in EBITDA of £4.0m (2019: £3.8m) reflecting the removal of the lease charge recognised under IAS 17 through administrative expenses, offset by increased depreciation of £3.4m (2019: £3.1m) on the right-of-use assets, and an increase in finance costs of £0.6m (2019: £0.5m) relating to the unwind of the discount on the lease liabilities.

### **INDEPENDENT AUDITORS' REPORT** To the members of clinigen group PLC

### **REPORT ON THE AUDIT OF THE PARENT COMPANY FINANCIAL STATEMENTS**

#### **OPINION**

In our opinion, Clinigen Group plc's parent company financial statements (the 'financial statements'):

- give a true and fair view of the state of the parent company's affairs as at 30 June 2020;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 'Reduced Disclosure Framework', and applicable law); and
- have been prepared in accordance with the requirements of the Companies Act 2006

We have audited the financial statements, included within the Annual Report and Accounts 2020 (the 'Annual Report'), which comprise: the company balance sheet as at 30 June 2020; the company statement of changes in equity for the year then ended; and the notes to the financial statements, which include a description of the significant accounting policies.

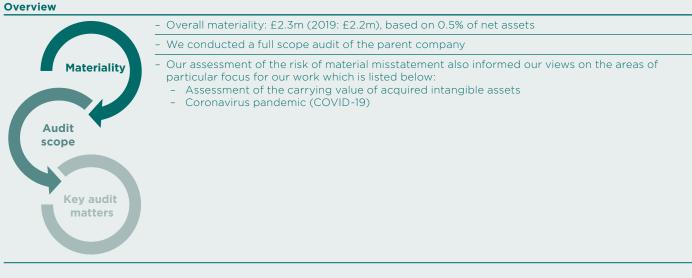
#### **BASIS FOR OPINION**

We conducted our audit in accordance with International Standards on Auditing (UK) ('ISAs (UK)') and applicable law. Our responsibilities under ISAs (UK) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Independence

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, which includes the FRC's Ethical Standard, as applicable to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.

# OUR AUDIT APPROACH



#### The scope of our audit

As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the Directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the Directors that represented a risk of material misstatement due to fraud.

#### **Key audit matters**

Key audit matters are those matters that, in the auditors' professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.

### INDEPENDENT AUDITORS' REPORT CONTINUED to the members of clinigen group plc

#### KEY AUDIT MATTER

# Assessment of the carrying value of acquired intangible assets

Refer to the critical accounting estimates and judgements in note 2 and note 12 (intangible assets) to the consolidated financial statements.

We focused on this area because the Directors' assessment of whether impairment triggers have been identified that could give rise to an impairment charge in relation to intangible assets, involved complex and subjective judgements and assumptions including the progress and future performance of individual products.

The Directors' have prepared impairment assessment models which include a number of assumptions. The assumptions which are deemed to be the most significant in respect of these models are the revenue forecasts.

#### Coronavirus pandemic (COVID-19)

Refer to page 60 (Audit and Risk Committee Report).

During the financial year, the COVID-19 pandemic has had a significant impact globally, with lockdown measures being implemented widely. However, the impact of COVID-19 has been less significant on the group, which has continued to operate well through these uncertain times.

As at the year-end date and the date of signing the financial statements, whilst there continues to be significant uncertainty over the future impact of COVID-19, management's assessment is that the impact on Clinigen is not expected to be significant.

Notwithstanding that, management has considered implications for the group's going concern assessment, potential impairment of certain assets and associated disclosure in the financial statements. The results of these scenarios did not indicate any significant issues as a result of the impact of COVID-19.

#### HOW OUR AUDIT ADDRESSED THE KEY AUDIT MATTER

For each separate intangible asset we focused on the key assumptions relating to future revenue forecasts, margin expectations and associated selling costs. We were able to evaluate the reasonableness of the Directors' forecasts and expectations by corroborating evidence and assessing the margin and selling costs expected to be achieved by reference to historical margins realised, selling cost improvement plans and, where relevant, consideration of actual performance against prior year forecasts.

As a result of our audit work, we agreed with the Directors' assessment that no impairment triggers for acquired intangible assets were identified. We consider that the associated judgements taken were supportable.

In respect of going concern:

- We evaluated management's base case, plausible sensitivity scenarios, challenging key assumptions including the forecast cash flows. We further sensitised management's forecasts to understand the impact of any further downside scenarios
- Checked the integrity of management's model, as well as agreeing underlying data to source documents
- Assessed whether management's mitigating actions are reasonably achievable based on our understanding of the business, including the nature of its cost base
- Obtained evidence to support disclosures within the financial statements and checked that the disclosures within the annual report are consistent with the financial statements and knowledge gained on the audit

Our conclusion in respect of going concern is included in the 'Conclusions relating to going concern' section on page 115.

In respect of impairment, refer to separate key audit matter above relating to 'Assessment of the carrying value of acquired intangibles'.

#### How we tailored the audit scope

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the parent company, the accounting processes and controls, and the industry in which it operates.

#### Materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

Overall materiality	£2.3m (2019: £2.2m).
How we determined it	0.5% of net assets.
Rationale for benchmark applied	We believe that net assets are an appropriate basis for determining materiality as the parent company is not a profit orientated entity.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £115,000 (2019: £109,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

#### **Going concern**

In accordance with ISAs (UK) we report as follows:

REPORTING OBLIGATION	OUTCOME
We are required to report if we have anything material to add or draw attention to in respect of the Directors'	We have nothing material to add or to draw attention to.
statement in the financial statements about whether the Directors considered it appropriate to adopt the going concern basis of accounting in preparing the financial statements and the Directors' identification of any material uncertainties to the parent company's ability to continue as a going concern over a period of at least 12 months from the date of approval of the financial statements.	However, because not all future events or conditions can be predicted, this statement is not a guarantee as to the parent company's ability to continue as a going concern.

#### **REPORTING ON OTHER INFORMATION**

The other information comprises all of the information in the Annual Report other than the financial statements and our auditors' report thereon. The Directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Strategic Report and Report of the Directors, we also considered whether the disclosures required by the UK Companies Act 2006 have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, the Companies Act 2006 ('CA06') and ISAs (UK) require us also to report certain opinions and matters as described below (required by ISAs (UK) unless otherwise stated).

#### **Strategic Report and Report of the Directors**

In our opinion, based on the work undertaken in the course of the audit, the information given in the Strategic Report and Report of the Directors for the year ended 30 June 2020 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements. (CA06)

In light of the knowledge and understanding of the parent company and its environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic Report and Report of the Directors. *(CA06)* 

The Directors' assessment of the prospects of the parent company and of the principal risks that would threaten the solvency or liquidity of the parent company

As a result of the Directors' reporting on how they have applied the UK Corporate Governance Code (the 'Code'), we are required to report to you if we have anything material to add or draw attention to regarding:

- The Directors' confirmation on page 45 of the Annual Report that they have carried out a robust assessment of the principal risks facing the parent company, including those that would threaten its business model, future performance, solvency or liquidity
- The disclosures in the Annual Report that describe those risks and explain how they are being managed or mitigated
- The Directors' explanation on page 73 of the Annual Report as to how they have assessed the prospects of the parent company, over what period they have done so and why they consider that period to be appropriate, and their statement as to whether they have a reasonable expectation that the parent company will be able to continue in operation and meet its liabilities as they fall due over the period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions

We have nothing to report in respect of this responsibility.

#### **Other Code provisions**

As a result of the Directors' reporting on how they have applied the Code, we are required to report to you if, in our opinion:

- The statement given by the Directors, on page 73, that they consider the Annual Report taken as a whole to be fair, balanced and understandable, and provides the information necessary for the members to assess the parent company's position and performance, business model and strategy is materially inconsistent with our knowledge of the parent company obtained in the course of performing our audit
- The section of the Annual Report on page 61 describing the work of the Audit Committee does not appropriately address matters communicated by us to the Audit Committee

We have nothing to report in respect of this responsibility.

### INDEPENDENT AUDITORS' REPORT CONTINUED to the members of clinigen group plc

### RESPONSIBILITIES FOR THE FINANCIAL STATEMENTS AND THE AUDIT

Responsibilities of the Directors for the financial statements

As explained more fully in the Directors' Responsibilities Statement, the Directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view. The Directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Directors are responsible for assessing the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the parent company or to cease operations, or have no realistic alternative but to do so.

#### Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the FRC's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditors' report.

#### Use of this report

This report, including the opinions, has been prepared for and only for the parent company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, 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.

### **OTHER REQUIRED REPORTING**

### COMPANIES ACT 2006 EXCEPTION REPORTING

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- We have not received all the information and explanations we require for our audit; or
- Adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- Certain disclosures of Directors' remuneration specified by law are not made; or
- The financial statements are not in agreement with the accounting records and returns

We have no exceptions to report arising from this responsibility.

### **OTHER MATTER**

We have reported separately on the group financial statements of Clinigen Group plc for the year ended 30 June 2020.

### PAUL NORBURY BSC FCA (SENIOR STATUTORY AUDITOR)

for and on behalf of PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors East Midlands 16 September 2020

# **COMPANY BALANCE SHEET** As at 30 June 2020

(N £M)	NOTE	2020	2019
Assets			
Non-current assets			
Intangible assets	4	61.3	57.7
Tangible assets	5	1.1	0.9
Investments	6	744.9	744.9
Deferred tax assets	11	1.9	1.4
Total non-current assets		809.2	804.9
Current assets			
Debtors	7	341.7	362.4
Derivative financial instruments		-	2.3
Corporation taxes recoverable		1.3	-
Cash and cash equivalents		50.4	1.9
Total current assets		393.4	366.6
Total assets		1,202.6	1,171.5
Current liabilities			
Creditors: amounts falling due within one year	8	176.3	218.3
Loans and borrowings	10	0.3	-
Total current liabilities		176.6	218.3
Net current assets		216.8	148.3
Total assets less current liabilities		1,026.0	953.2
Non-current liabilities			
Creditors: amounts falling due after more than one year	9	6.9	5.8
Loans and borrowings	10	431.6	335.1
Total non-current liabilities		438.5	340.9
Net assets		587.5	612.3
Capital and reserves			
Called up share capital	12	0.1	0.1
Share premium account		240.2	240.2
Merger reserve		88.2	88.2
Hedging reserve		-	(0.1)
At 1 July		283.9	332.0
Loss for the year attributable to the owners		(19.4)	(43.2)
Other changes in retained earnings		(5.5)	(4.9)
Retained earnings		259.0	283.9
 Total equity		587.5	612.3

The financial statements on pages 117 to 126 were approved by the Board of Directors on 16 September 2019 and were signed on its behalf by:

X (A)

SHAUN CHILTON Director

N.L

NICK KEHER Director

# COMPANY STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2020

(IN £M)	SHARE Capital (Note 12)	SHARE Premium Account	MERGER RESERVE	HEDGING Reserve	RETAINED Earnings	TOTAL Equity
At 30 June 2019	0.1	240.2	88.2	(0.1)	283.9	612.3
Impact of adopting IFRS 16	-	-	-	-	0.1	0.1
At 1 July 2019	0.1	240.2	88.2	(0.1)	284.0	612.4
Loss for the year	-	-	-	-	(19.4)	(19.4)
Cash flow hedges	-	-	-	0.1	-	0.1
Share-based payment scheme	-	-	-	-	3.5	3.5
Deferred taxation on share-based payment scheme	-	-	-	-	0.1	0.1
Dividends paid	-	-	-	-	(9.2)	(9.2)
Total contributions by, and distributions to, owners of the Company, recognised directly in equity	-	-	-	-	(5.6)	(5.6)
At 30 June 2020	0.1	240.2	88.2	-	259.0	587.5

	SHARE Capital (Note 12)	SHARE Premium Account	MERGER Reserve	HEDGING Reserve	RETAINED Earnings	TOTAL Equity
At 1 July 2018	0.1	161.3	86.0	-	332.0	579.4
Loss for the year	-	-	-	-	(43.2)	(43.2)
Cash flow hedges	-	-	-	(0.1)	-	(0.1)
Share-based payment scheme	-	-	-	-	3.0	3.0
Deferred taxation on share-based payment scheme	-	-	-	-	(0.4)	(0.4)
Tax credit in respect of tax losses arising on exercise of share options	-	-	-	-	0.2	0.2
Dividends paid	-	-	-	-	(7.7)	(7.7)
Issue of new shares	-	78.9	2.2	-	-	81.1
Total contributions by, and distributions to, owners of the Company, recognised directly in equity	-	78.9	2.2	_	(4.9)	76.2
At 30 June 2019	0.1	240.2	88.2	(0.1)	283.9	612.3

The following describes the nature and purpose of each reserve within equity:

RESERVE	DESCRIPTION AND PURPOSE
Share premium account	Amount subscribed for share capital in excess of nominal value, except where recognition in merger reserve is used (see below).
Merger reserve	Amount subscribed for share capital in excess of nominal value when shares are issued in exchange for at least a 90% interest in the shares of another company.
Retained earnings	All other net gains and losses and transactions with owners (e.g. dividends) not recognised elsewhere.

The issue of new equity share capital on the acquisition of iQone 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.

## NOTES TO THE COMPANY FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2020

### **1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

The financial statements of the Parent Company present information about the Company as a separate entity and not about its Group.

The accounting policies, set out in the consolidated financial statements, unless otherwise stated have been applied consistently to the period presented in these Company financial statements.

The Company financial statements have been prepared and approved by the Directors in accordance with FRS 101.

#### **BASIS OF PREPARATION**

The Company financial statements are prepared on the going concern basis under the historical cost convention and in accordance with Financial Reporting Standard 101 'Reduced Disclosure Framework'. In preparing these financial statements, the Company applies the recognition, measurement and disclosure requirements of International Financial Reporting Standards as adopted by the EU ('Adopted IFRS'), but makes amendments where necessary in order to comply with Companies Act 2006. The financial statements are presented in sterling and all values are rounded to the nearest £100,000 except when otherwise stated.

No income statement is presented for the Company as permitted by section 408(2) and (3) of the Companies Act 2006. Fees paid to PricewaterhouseCoopers LLP and its associates for audit and non-audit services to the Company itself are not disclosed in the individual financial statements of Clinigen Group plc because the Group financial statements are required to disclose such fees on a consolidated basis (see note 5.2 of the consolidated financial statements).

#### **INVESTMENTS**

Investments in subsidiaries are recorded at historical cost, less any provision for impairment.

The Company has elected to apply the exemption in section 408 of the Companies Act and has not presented its separate statement of comprehensive income and related notes. It has also taken advantage of the exemptions under FRS 101 not to disclose related party transactions entered into between two or more members of the Group and not to prepare a cash flow statement. The Company has elected not to prepare disclosures under IFRS 7 in accordance with the exemptions under FRS 101. The Company's information relating to these disclosures are included within the consolidated financial statements of Clinigen Group plc.

Judgements made by the Directors in the application of these accounting policies that have significant effect on the financial statements, and estimates with a significant risk of material adjustment in the next year, are discussed in note 2 of the consolidated financial statements.

### 2. STAFF COSTS

(IN £M)	2020	2019
Staff costs (including Directors) comprise:		
Wages and salaries	5.1	8.3
Social security costs	0.6	1.5
Share-based payment expense	3.5	3.0
Other pension costs	0.1	0.2
Gross staff costs	9.3	13.0
Capitalised labour	(1.2)	(0.5)
Net staff costs	8.1	12.5

Contracts of employment for UK staff across the Group are held by Clinigen Group plc. Employees are allocated to subsidiary companies as appropriate and the cost of the employees' services is charged to the relevant subsidiary. The disclosures for staff costs and employee numbers relate to those employees which are not recharged to subsidiary entities.

#### EMPLOYEE NUMBERS

The average monthly number of staff working for the Company (not reallocated to subsidiary companies) during the financial year amounted to:

NUMBER	2020	2019
Directors	2	2
Staff	23	128
	25	130

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED For the year ended 30 June 2020

### **2. STAFF COSTS CONTINUED**

### KEY MANAGEMENT PERSONNEL COMPENSATION

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company. This is considered to be the Board of Directors.

(N £M)	2020	2019
Directors' remuneration included in staff costs:		
Wages and salaries	2.1	2.0
Share-based payment expense	0.8	0.9
	2.9	2.9

Total emoluments of Directors (including pension contributions) amounted to £2.9m (2019: £2.9m). Information relating to Directors' emoluments, share options and pension entitlements is set out in the Remuneration Report on pages 62 to 71.

### 3. DIVIDENDS

(INEM)	2020	2019
Final dividend in respect of the year ended 30 June 2019 of 4.75p (2019: 3.84p) per ordinary share	6.3	5.1
Interim dividend of 2.15p (2019: 1.95p) per ordinary share paid during the year	2.9	2.6
	9.2	7.7

The Board proposes to pay a final dividend of 5.46p per ordinary share, subject to shareholder approval, on 2 December 2020, to shareholders on the register on 6 November.

## **4. INTANGIBLE FIXED ASSETS**

TRADEMARKS AND LICENCES	COMPUTER Software	TOTAL
61.6	14.8	76.4
2.4	10.9	13.3
(0.5)	(0.1)	(0.6)
63.5	25.6	89.1
18.5	0.2	18.7
3.5	1.9	5.4
4.2	-	4.2
(0.5)	-	(0.5)
25.7	2.1	27.8
37.8	23.5	61.3
43.1	14.6	57.7
-	61.6 2.4 (0.5) 63.5 18.5 3.5 4.2 (0.5) 25.7 37.8	61.6       14.8         2.4       10.9         (0.5)       (0.1)         63.5       25.6         18.5       0.2         3.5       1.9         4.2       -         (0.5)       -         25.7       2.1         37.8       23.5

During the year, due to the performance of the product, the decision was taken to fully impair the book value of the IP related to Totect which had a remaining net book value of £4.2m.

# **5. TANGIBLE FIXED ASSETS**

	RIGHT-OF-USE Asset	LEASEHOLD Improvement	PLANT AND Machinery	FURNITURE, FITTINGS And Equipment	TOTAL
Cost					
At 30 June 2019	-	0.7	0.1	1.4	2.2
Impact of adopting IFRS 16	0.9	-	-	-	0.9
At 1 July 2019	0.9	0.7	0.1	1.4	3.1
Additions	-	-	-	-	-
Disposals	-	(0.1)	(0.1)	(0.7)	(0.9)
At 30 June 2020	0.9	0.6	-	0.7	2.2
Accumulated depreciation					
At 1 July 2019	-	0.3	0.1	0.9	1.3
Charge for the year	0.3	0.1	-	0.2	0.6
Disposals	-	-	(0.1)	(0.7)	(0.8)
At 30 June 2020	0.3	0.4	-	0.4	1.1
Net book value					
At 30 June 2020	0.6	0.2	-	0.3	1.1
At 30 June 2019	-	0.4	-	0.5	0.9

The right-of-use asset relates to property leased by the Company for office and warehouse use.

### **6. INVESTMENTS**

(H £ M)	2020	2019
Cost or valuation		
At 1 July	744.9	444.8
Additions	-	300.1
At 30 June	744.9	744.9

The Company directly holds interests in the whole of the issued share capital of the following undertakings:

NAME	COUNTRY OF INCORPORATION	NATURE OF BUSINESS
Clinigen Holdings Limited	UK	Holding company
Clinigen Pharma Limited	UK	Holding company
Clinigen Asia Pte. Limited	Singapore	Holding company
Quantum Pharma Holdings Limited	UK	Holding company
CSM Parent, Inc.	US	Holding company
Clinigen Healthcare Holding (Suisse) SA	Switzerland	Holding company

All shareholdings in subsidiaries are owned 100% (2019: 100%) through the subsidiaries' ordinary share capital. A full list of the Company's subsidiary undertakings and their registered addresses is presented in note 14.

# 7. DEBTORS

(IN £M)	2020	2019
Amounts owed by Group undertakings	340.9	359.8
Prepayments and other debtors	0.8	2.6
	341.7	362.4

Amounts owed by Group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED For the year ended 30 June 2020

## 8. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

(IN £M)	2020	2019
Trade creditors	1.5	2.5
Amounts owed to Group undertakings	97.7	154.2
Tax and social security	1.8	1.7
Other creditors	0.1	0.1
Accruals and deferred income	2.6	3.3
Deferred consideration	-	1.5
Contingent consideration	72.6	55.0
	176.3	218.3

Amounts owed to Group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

# 9. CREDITORS: AMOUNTS FALLING DUE AFTER MORE THAN ONE YEAR

(IN £M)	2020	2019
Contingent consideration	6.9	5.8
	6.9	5.8

Contingent consideration relates to the iQone acquisition and is payable in the years ending 30 June 2023 and 2024 based on the adjusted EBITDA generated by iQone in the 12 months to 31 December 2022 and 2023.

### **10. BORROWINGS AND LEASE LIABILITIES**

The book value of loans and borrowings are as follows:

	2020			2019		
(IN £M)	CURRENT	NON-CURRENT	TOTAL	CURRENT	NON-CURRENT	TOTAL
Bank borrowings	-	431.3	431.3	-	335.1	335.1
Lease liabilities	0.3	0.3	0.6	-	-	-
	0.3	431.6	431.9	-	335.1	335.1

During the year, the debt facilities were increased from £375m to £430m comprising an unsecured £180m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £250m.

At the year 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 3.5x (excluding IFRS 16) 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 30 June 2020, interest cover was 13.3x and the net debt/ adjusted EBITDA leverage was 2.3x. There were no instances of default, including covenant terms, in either the current or the prior year.

During the year, interest was payable on a tiered scale based on the level of borrowing. The applicable interest rate on amounts drawn down was up to 2.0% plus LIBOR.

### **11. DEFERRED TAX**

The movement on the deferred tax account is as shown below:

DEFERRED TAX ASSETS (IN EM)	LOSSES	UNEXERCISED Share options	TOTAL
At 1 July 2018	0.2	1.4	1.6
Credit to the income statement	0.1	0.1	0.2
Charge recognised in equity	-	(0.4)	(0.4)
At 30 June 2019	0.3	1.1	1.4
(Charge)/credit to the income statement	(0.3)	0.7	0.4
Credit recognised in equity	-	0.1	0.1
At 30 June 2020	-	1.9	1.9

# **12. CALLED UP SHARE CAPITAL**

		NUMBER OF SHARES (000S)
ISSUED AND FULLY PAID		ORDINARY SHARES OF 0.1P EACH
At 1 July 2018		122,286
Issue of new shares		10,193
At 30 June 2019		132,479
Issue of new shares		420
At 30 June 2020		132,899
(III £M)	2020	2019
Ordinary shares of 0.1p each	0.1	0.1

The Company does not have a limited amount of authorised share capital.

### **13. FAIR VALUE MEASUREMENT**

The table below analyses the fair value of the Company's assets and liabilities, into a fair value hierarchy based on the valuation technique used to determine fair value.

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2: inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices)
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs)

	2020 Level 1	2020 Level 2	2020 LEVEL 3	2019 Level 1	2019 LEVEL 2	2019 LEVEL 3
Assets/(liabilities)						
Derivative financial instruments - forward foreign exchange contracts	-	-	-	-	2.3	-
Contingent consideration	-	-	72.6	-	-	55.0

The Level 2 forward foreign exchange valuations are derived from mark-to-market valuations as at 30 June 2020. Fair value losses of £nil (2019: £nil) relating to the movement on open forward foreign exchange contracts have been recognised in underlying administrative expenses. The Level 3 contingent consideration liability is the discounted amount payable in respect of the CSM and iQone acquisitions. The amounts payable have been calculated based on the latest forecast of earnings during the respective earn-out periods.

There have been no transfers between Level 1, Level 2 or Level 3 during the year.

#### FAIR VALUES OF FINANCIAL INSTRUMENTS

The fair values of all financial assets and financial liabilities by class together with their carrying amounts shown in the balance sheet are as follows:

(IN £M)	FAIR Value 2020	CARRYING Amount 2020	FAIR VALUE 2019	CARRYING Amount 2019
Loans and receivables		2020	2013	2013
Cash and cash equivalents	50.4	50.4	1.9	1.9
Debtors excluding prepayments and taxes (note 7)	341.0	341.0	359.8	359.8
Total loans and receivables	391.4	391.4	361.7	361.7
Total financial assets	391.4	391.4	361.7	361.7
Financial liabilities measured at amortised cost				
Borrowings and lease liabilities	(431.9)	(431.9)	(335.1)	(335.1)
Creditors: amounts falling due within one year (note 8)	(174.5)	(174.5)	(216.6)	(216.6)
Creditors: amounts falling due after more than one year (note 9)	(6.9)	(6.9)	(5.8)	(5.8)
Total financial liabilities measured at amortised cost	(613.3)	(613.3)	(557.5)	(557.5)
Total financial liabilities	(613.3)	(613.3)	(557.5)	(557.5)
Total financial instruments	(221.9)	(221.9)	(195.8)	(195.8)

Management considers that the carrying amount of financial assets and liabilities recognised at amortised cost in the financial statements approximate their fair value. The fair value of the financial assets and liabilities is included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED For the year ended 30 June 2020

# **14. RELATED PARTY TRANSACTIONS**

### ULTIMATE CONTROLLING PARTY

The Company's shares are listed on AIM and are widely held. There is no one controlling party or group of related parties who have control of the Group.

### TRANSACTIONS WITH RELATED PARTIES

The remuneration payable to the Directors of the Company is disclosed in note 2.

There were no transactions with related parties, other than the Company's subsidiaries, during the year or the preceding year.

#### **SUBSIDIARIES**

The subsidiaries of Clinigen Group plc at each reporting date have been included in these consolidated financial statements.

Subsidiaries at the end of the reporting year were as follows:

NAME	NATURE OF BUSINESS	COUNTRY OF INCORPORATION
Clinigen Holdings Limited*	Holding company	UK <sup>1</sup>
Clinigen International Holdings Limited*	Holding company	UK <sup>1</sup>
Clinigen Healthcare Limited*	Supply of pharmaceutical products and services	UK <sup>1</sup>
Clinigen Inc.	Supply of pharmaceutical products and services	US <sup>1</sup>
Clinigen SP Limited*	Supply of pharmaceutical products	UK <sup>1</sup>
Clinigen Healthcare B.V.	Holding company	Netherlands
Clinigen Clinical Trials Limited	Holding company	UK <sup>1</sup>
Clinigen Pharma Limited*	Holding company	UK <sup>1</sup>
Clinigen GAP Limited	Dormant	UK <sup>1</sup>
Clinigen CTS Limited	Dormant	UK <sup>1</sup>
Clinigen Consulting Limited	Dormant	UK <sup>1</sup>
Keats Healthcare Limited	Dormant	UK <sup>1</sup>
Clinigen GAP Inc.	Dormant	US <sup>2</sup>
dis Group Holdings Limited*	Holding company	UK <sup>1</sup>
dis Group Limited*	Holding company	UK <sup>1</sup>
dis Limited*	Dormant	UK <sup>1</sup>
dis MA Limited	Dormant	UK <sup>1</sup>
dis GA Limited	Dormant	UK <sup>1</sup>
dis Pharma Private Limited	Dormant	India
Clinigen Asia Pte. Limited	Holding company	Singapore
ink Healthcare Singapore Pte. Limited	Supply and distribution of pharmaceutical products	Singapore
ink Healthcare KK	Supply and distribution of pharmaceutical products	Japan
Clinigen KK	Supply and distribution of pharmaceutical products	Japan
MMC	Supply and distribution of pharmaceutical products	Japan
ink Healthcare Sdn Bhd	Supply and distribution of pharmaceutical products	Malaysia
ink Healthcare Hong Kong Limited	Supply and distribution of pharmaceutical products	Hong Kong
_ink Medical Products (Pty) Limited	Supply and distribution of pharmaceutical products	Australia
ink Pharmaceuticals Limited	Supply and distribution of pharmaceutical products	New Zealand
Clinigen South Africa (Pty) Limited	Holding company	South Africa
Homemed Pty Limited	Supply and distribution of pharmaceutical products	South Africa
Equity Pharmaceuticals (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
Equity Medical Technologies (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
Equipharm Specialised Distribution (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
Clinigen Kenya Limited	Supply and distribution of pharmaceutical products	Kenya
ink Healthcare (Pty) Limited	Holding company	Australia
ink Holding 1 (Pty) Limited	Holding company	Australia
ink Holding 2 (Pty) Limited	Holding company	Australia
PMIP (Pty) Limited	Dormant	Australia
Plurilinx (Pty) Limited	Dormant	South Africa

NAME	NATURE OF BUSINESS	COUNTRY OF INCORPORATION
Chloromix (Pty) Limited	Dormant	South Africa
Quantum Pharma Holdings Limited*	Holding company	UK <sup>2</sup>
Quantum Pharma 2014 Limited*	Holding company	UK <sup>2</sup>
Quantum Pharma Group Limited*	Holding company	UK <sup>2</sup>
Quantum Pharmaceutical Limited	Manufacture and supply of pharmaceutical products	UK <sup>2</sup>
JL Medicines Limited*	Supply and distribution of pharmaceutical products	UK <sup>2</sup>
Colonis Pharma Limited*	Development of pharmaceutical and related products	UK <sup>2</sup>
Pern Consumer Products Limited*	Supply and distribution of body care products	UK <sup>2</sup>
Protomed Limited	Supply and distribution of pharmaceutical products	UK <sup>2</sup>
amda Pharma Limited*	Holding company	UK <sup>2</sup>
_amda UK Limited*	Development of pharmaceutical and related products	UK <sup>2</sup>
amda Laboratories SA	Development of pharmaceutical and related products	Greece
amda Pharma SA	Development of pharmaceutical and related products	Greece
QM Specials Limited	Manufacture and supply of pharmaceutical products	Ireland
Quantum Specials Trustee Limited	Corporate trustee	UK <sup>2</sup>
Quantum Specials Limited	Dormant	UK <sup>2</sup>
NuPharm Group Limited	Dormant	UK <sup>2</sup>
NuPharm Laboratories Limited	Dormant	UK <sup>2</sup>
CSM Parent, Inc.	Holding company	US³
Clinical Supplies Management Holdings, Inc.	Provision of packaging, labelling, warehousing, and distribution services	US³
Clinical Supplies Management Europe SA	Provision of packaging, labelling, warehousing, and distribution services	Belgium
Clinical Supplies Management Europe GmbH	Provision of packaging, labelling, warehousing, and distribution services	Germany <sup>1</sup>
CSM Biomedical Sample Management, Inc.	Provision of packaging, labelling, warehousing, and distribution services	US <sup>4</sup>
Clinical Supplies Management Belgium SPRL	Holding company	Belgium
3&C Group Holding SA	Holding company	Belgium
Clinigen Healthcare Holding (Suisse) SA	Provision of medical information services	Switzerland
Clinigen Healthcare Switzerland Sàrl	Provision of medical information services	Switzerland
Clinigen Healthcare France Sàrl	Provision of medical information services	France
Clinigen Healthcare France SA	Supply of pharmaceutical services	France
Clinigen Healthcare Europe GmbH	Provision of medical information services and supply of medical products	Germany <sup>2</sup>
Clinigen Healthcare Italy Srl	Provision of medical information services	Italy
Clinigen Healthcare Spain S.L.	Provision of medical information services	Spain

\* The subsidiaries marked with an asterisk are companies which are incorporated in England and Wales, and are exempt from the requirements of the Companies Act 2006 relating to the audit of individual accounts by virtue of section 479A of the Act.

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED For the year ended 30 June 2020

### **14. RELATED PARTY TRANSACTIONS CONTINUED**

COUNTRY OF INCORPORATION	REGISTERED OFFICE
UK <sup>1</sup>	Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WW
JK <sup>2</sup>	Quantum House, Hobson Industrial Estate, Burnopfield, Co Durham, NE16 6EA
JK <sup>3</sup>	Unit 3, Ardane Park, Phoenix Avenue, Green Lane Industrial Estate, Featherstone, WF7 6EP
US <sup>1</sup>	Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808
JS²	Registered Office Service Company, 203 NE Front Street, Suite 101, Milford, Delaware 19963
JS³	Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801
JS⁴	180 Gordon Dr Suite 109, Exton, Pennsylvania 19341
Singapore	9 Raffles Place #27-00 Republic Plaza, 048619
Japan	1-16-3, Nihonbashi, Chuo-Ku, Tokyo, 103-0027
Malaysia	Upper Penthouse, Wisma RKT, No. 2 Jalan Raja Abdullah, 50300 Kuala Lumpur
Hong Kong	Room 1901, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay
Australia	5 Apollo Street, Warriewood NSW 2102
New Zealand	RSM New Zealand, Ford Building, 86 Highbrook Drive, Highbrook, Auckland 2013
South Africa	100 Sovereign Drive, Nellmapius Drive, Irene 0157, Pretoria
Vetherlands	WTC Schiphol Airport, D Tower, 11th floor, Schiphol Boulevard 359, 1118 BJ Amsterdam Schiphol
Belgium	Rue Granbonpré 11, 1435 Mont-Saint-Guibert
France	24 Avenue Joannes Masset, 69009 Lyon
Germany <sup>1</sup>	Am Kronberger Hang 3, 75824 Schwalbach
Germany <sup>2</sup>	Stefan-George-Ring 2, 81929 Munich
taly	Viale Abruzzi, 94, 20131 Milan
Spain	Plaza de Castilla, 3 - 15º E2, 28046 Madrid
Switzerland	Modulis Business Park, Route de Suisse 162, 1290 Versoix
reland	Mayfield Business Park, Lismore, County Waterford
Greece	59, Ioannou Metaxa str., 19400 Koropi
Kenya	Sameer Business Park, Mombasa Road, PO Box 10032 - 00100 - G.P.O Nairobi
ndia	302, 3rd Floor, A-Wing, Rutu Business Park, Thane West, Mumbai 400606

QM Specials Limited is now owned 100% (2019: 50%) following the exercise of an option to buy the remaining 50% holding in the business. In the prior year it was also treated as a subsidiary as it was determined that the Group had control of the entity as defined by IFRS 10. All other shareholdings in subsidiaries are owned 100% (2019: 100%) through the subsidiaries' ordinary share capital.

## **15. CAPITAL COMMITMENTS**

At 30 June 2020, the Company had no capital commitments (2019: £1.1m relating to the design and implementation of the Oracle ERP system).

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NOTES

# **COMPANY INFORMATION**

Clinigen Group plc is a public limited company, incorporated and registered in the UK with company number 06771928.

#### DIRECTORS

- S Chilton
- N Keher
- P Allen (Independent Non-Executive Chairman)
- J Hartup (Senior Independent Non-Executive)
- I Nicholson (Independent Non-Executive)
- A Hyland (Independent Non-Executive)
- A Boyd (Non-Executive)

### COMPANY SECRETARY AND REGISTERED OFFICE

A Miller Pitcairn House Crown Square Centrum 100 Burton-on-Trent Staffordshire DE14 2WW

# **ADVISER AND INVESTOR CONTACTS**

### INDEPENDENT AUDITORS

PricewaterhouseCoopers LLP Donington Court Pegasus Business Park Herald Way East Midlands DE74 2UZ

### NOMINATED ADVISER

J.P. Morgan Cazenove 25 Bank Street Canary Wharf London E14 5JP

#### JOINT BROKERS

J.P. Morgan Cazenove 25 Bank Street Canary Wharf London E14 5JP

RBC Capital Markets LLC Thames Court One Queenhithe London EC4V 3DQ

#### Clinigen Group plo

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