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# IT'S ABOUT CONNECTIONS

Clinigen Group plc is a global pharmaceutical Services and Products company focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time.

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On 30 June 2021, the Group disposed of its UK Compounding business and the results of this business have been classified as discontinued operations. The results presented in the Overview and Strategic Report sections of this report are all from continuing operations and the comparative results have been restated accordingly. There has been no restatement of results for years before the prior year.

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 EBITDA includes the Group's share of EBITDA from its joint venture.

Organic growth is a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions and disposals. There were no acquisitions within the last 12 months of the reporting date and one disposal relating to the UK Compounding Business. Constant currency is derived by applying the prior year's actual exchange rate to this year's result. Organic growth is presented to aid the reader's understanding of the underlying performance of the business.

Bank covenant leverage is 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.

IFRS 16 'Leases' was adopted by the Group on 1 July 2019 with the recognition of lease liabilities for leases previously classified as operating leases. This adjustment to liabilities is excluded from borrowings for the purpose of leverage calculations under the banking facility covenant.

ADJUSTED NET REVENUE (£M)

**458**\_6

ADJUSTED EBITDA (£M)

**~7% 116.3** 

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

55.9

**~14% 523.6** 

REVENUE (£M)

NET DEBT (£M)

**DIVIDEND PER SHARE (PENCE)** 

0%

- Adjusted net revenue from continuing operations up 7% (+13% on an organic basis) to £458.6m (2020: £428.6m)
- Adjusted EBITDA from continuing operations down 10% (-5% on an organic basis) to £116.3m (2020: £129.8m)
- Adjusted EPS from continuing operations down 14% to 55.9p (2020: 65.3p)
- Reported EPS from continuing operations of 29.8p (2020: 10.8p)
- Profit before income tax from continuing operations of £51.8m (2020: £23.2m)
- Net debt as at 30 June 2021 of £335.8m (£316.9m excluding IFRS 16 liabilities) representing net debt leverage of 2.8x, meaningfully below the Group's temporary banking covenant of 3.5x
- Strong cash conversion with adjusted operating cash flow for the year from continuing operations up 6% to £99.9m (2020: £93.9m)

**INVESTMENT CASE** 

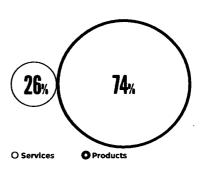
# WE'RE THE TRUSTED GLOBAL LEADER IN ACCESS TO MEDICINES

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

#### **UNIQUE AND FOCUSED 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.

#### **BUSINESS OPERATIONS BY ADJUSTED EBITDA\***



### 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.

CORPORATE ACQUISITIONS SINCE IPO IN 2012

6

PRODUCT ACQUISITIONS SINCE IPO IN 2012

6

#### **GLOBAL CAPABILITY**

We have built a global supply chain and distribution network, 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**

We are the global leader in the management of Managed 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** 

128

**EXECUTIVE MANAGEMENT TEAM (TENURE)** 

POSITION

#1

#### BROAD CLIENT AND CUSTOMER BASE

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

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

**577** 

HCPS AS CUSTOMERS

**25,127** 

### 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.

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

#### **CASH GENERATIVE**

We generate strong cash returns which are underpinned by operating strong credit control and working capital management.

ADJUSTED OPERATING CASH FLOW (£M)2

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

Adjusted operating cash flow is net cash flow from operating activities before income taxes and interest and excluding acquisition consideration.

 <sup>%</sup> of adjusted EBITDA is before central unallocated costs.

CHIEF EXECUTIVE OFFICER'S STATEMENT

# WE'RE BUILDING A PLATFORM FOR GROWTH

**ADJUSTED EPS (PENCE)** 

**55.9** 

**~14**%

ADJUSTED OPERATING CASH FLOW

999

**∧6**%

COVID-19 HAD A CONTINUED IMPACT ON OUR MARKETS LEADING TO A DECLINE IN EBITDA COMPARED TO PRIOR YEAR.

**SHAUN CHILTON** 

Group Chief Executive Officer 15 September 2021 The platform enables us to build long-term relationships with pharmaceutical and biotech companies and healthcare professionals at multiple points of a medicine's life, ensuring we fulfil our mission of delivering the right medicine, to the right patient, at the right time.

#### OVERVIEW

At Clinigen we are dedicated to enabling quicker and broader access to critical medicines around the world for patients with unmet needs. Our mission is to deliver the 'Right Medicine, to the Right Patient, at the Right Time'. We achieve this through a global platform offering pre and post-launch niche, innovative support for pharmaceutical and biotechnology companies to accelerate development and access to their medicines; and a 'go to' place for healthcare professionals to gain access to these critical medicines in licensed and unlicensed markets.

The Clinigen platform comprises two divisions, Services and Products, with more than 1,000 employees across 14 international locations who work together to make the Group's mission a reality, providing access to medicines in more than 120 countries for thousands of patients with unmet medical needs.

This supports the pharmaceutical and biotechnology companies at critical stages of a medicine's life effectively, protecting their reputations, minimising risks to their supply chain and extending relationships with their customers; the value to healthcare professionals is that it delivers significant time saving in accessing these critical medicines and ensuring a regulatory compliant and quality assured service.

#### **PLATFORM**

We are proud of the Services and Products platform we have built since we were formed in 2010. We also know that to remain successful we must continue to develop and adapt to the needs of our markets, and to that end we remain focused on areas where we are uniquely well positioned to deliver value for all of our stakeholders.

Over the past 12 months we have made great progress despite the challenges presented by the COVID-19 pandemic. We have further simplified our operating model, moving from three divisions to two to better align the platform with the end-market customer. We also announced the divestment of the UK Specials and Aseptics business. This further demonstrates our commitment to sharpening our focus on areas that drive the most value.

In response to the growing demand for services such as our Managed Access Programs, we will seek to accelerate our focus on those areas of the Group where we have growing and sustainable competitive advantage and, as we do so, continue to drive revenue and cost synergies. Clinigen's most differentiated offerings are from the Services division and the Partnering segment of the Products division where our platform provides market-leading solutions from the clinical phase through the commercial lifecycle phases of a drug product.

We are focused on streamlining and simplifying the Products division and optimising our core business, which we believe will strengthen our offering whilst creating greater shareholder value.

#### FINANCIAL PERFORMANCE

In FY2021 COVID-19 had a continued impact on our markets leading to a decline in EBITDA compared with the prior year. In spite of this, the business continues to meet challenges head on with a significant number of business wins across both the Services and Products Divisions and the roll-out of key products such as Erwinase and Hunterase.

The Group continues to be highly cash generative in spite of large investments in working capital for Erwinase coming earlier than expected.

Whilst net debt did rise slightly the Group made its final deferred payment for CSM in September 2020 meaning debt paydown can continue to be prioritised moving forward.



THE BUSINESS
CONTINUES TO MEET
CHALLENGES HEAD ON
WITH A SIGNIFICANT
NUMBER OF BUSINESS
WINS ACROSS BOTH THE
SERVICES AND PRODUCTS
DIVISIONS AND THE
ROLL-OUT OF KEY
PRODUCTS ERWINASE
AND HUNTERASE.

#### CHIEF EXECUTIVE OFFICER'S STATEMENT CONTINUED



AS A GLOBAL LEADER IN ETHICAL ACCESS TO MEDICINES THERE IS AN INCREASING EXPECTATION AMONGST STAKEHOLDERS THAT WE CONTRIBUTE, MEASURE AND COMMUNICATE THE IMPACT OUR STRATEGY HAS ON A RANGE OF SUSTAINABILITY ISSUES.

#### **OPERATIONAL PERFORMANCE**

In 2021 we further strengthened our leadership team with the appointment of Sam Herbert as Chief Operating Officer and head of the Products division. Sam brings a wealth of experience leading specialty logistics and distribution service providers and will be pivotal in ensuring we continue to deliver against our strategic objectives.

The Services division had another strong year adding a significant number of client wins, with an increase in both the number and the total value of business wins across the division. We are currently running more Managed Access Programs than at any point in time and we have booked more business across the specialist packaging, labelling, storage and distribution clinical business than ever before. It is especially promising to see the healthy mix of business coming from both new and existing clients as well as seeing Clinigen maintain and grow market share in these areas given the more competitive nature of the Services business. Despite the high number of wins across Services we continue to see a very healthy new business pipeline across both the Clinical and Managed Access parts of the division.

Within the Products division we have successfully grown our Partnered products segment by more than twenty five products, a key growth opportunity for us moving forward. A large proportion of this growth has been from the exclusive supply agreements to distribute pharma client's medicines into unlicensed markets. We have continued to see these agreements come from both large and small pharma companies

who have a commitment to enable broader access to their medicines and see Clinigen as a key part of their product lifecycle management strategy.

Erwinase, the product licensed from Porton Biopharma for the treatment of acute lymphoblastic leukaemia, was launched in the UK and is being supplied into multiple unlicensed countries.

We also saw multiple product launches across our AAA region the most significant being Hunterase (Idursulfase-beta) ICV in Japan which represented the first approval for Hunterase ICV in any country worldwide. This provides an important treatment option for patients with the rare enzyme deficiency condition Hunter syndrome. I am excited about the opportunity in front of us in terms of further partnering and in-licensing across all the regions we are present in.

Innovation and thought leadership remain critical to the development of the business and in 2021 we rolled out two new initiatives that recognise two of our key stakeholders: Pharmacists and Patients. We held the first 'Love Your Pharmacist' awards which were created to recognise and celebrate the significant role pharmacists play in enabling better access to medicines and improving people's lives.

We also launched the Patient Advocate Fellowship in early access, an initiative aimed at equipping patient groups and their leadership with the skills and experience they need to engage meaningfully within early access programs. I am extremely proud of these two initiatives, which I believe strongly align to our mission and values.

We dealt effectively with the challenges presented by Brexit, proving ourselves to be well-prepared with no impact on our business. We have continued to drive towards operational excellence and have expanded key capabilities with numerous examples, such as the expansion of our cold storage capacity in the Germany and Belgium hubs which are key to supporting the rapidly-developing cell and gene therapy market. A global review of our supply chain has also been conducted to enable us to build a blueprint for how we optimise our current wholly owned distribution centres alongside our partner network.

Technology continues to be a key focus across the business improving the customer experience, driving synergies and becoming more efficient operationally. This year we have rolled out phase one of a new customer relationship management (CRM) system that will continue in 2022 and ultimately create a central tool for pharma and biotech relationship management, supporting our 'Join-The-Dots' strategy (i.e. maximising the synergies between different parts of the platform).

We have seen the further roll-out of Clinigen Direct which now offers full online self-service to On-Demand, Partnered and Owned customers in the UK. We now have the building blocks in place to support further online services roll-out and localisation. In the H1 2022 financial year we also expect to see a material upgrade to our Cliniport portal and integration into Clinigen Direct.

#### SUSTAINABILITY

As a global leader in ethical access to medicines there is rightly an increasing expectation amongst our stakeholders that we contribute, measure and communicate the impact our strategy has on a range of sustainability issues.

This year Clinigen conducted a full review of how our strategy aligns to stakeholder values to ensure that our business model, objectives and growth plans are clearly aligned to the sustainability agenda. As a result of this we rolled out our Environment, Social and Governance (ESG) framework where we make 17 key commitments under the four pillars of Environment, Products and Services, Our People and Responsible Business.

Alongside this, Clinigen has signed up to the United Nations Global Compact ('UNGC') and UN Sustainable Development Goals ('SDGs') and formalised our commitment to sustainability. Of course the SDG of 'Good heath and well-being' is central to our mission and purpose.

**EMPLOYEES** 

1,069



THE GROUP HAS OVER
1,000 EMPLOYEES ACROSS
THE GLOBE HELPING US TO
FULFIL OUR MISSION. IT
IS VITAL WE CONTINUE TO
CREATE A THRIVING AND
HIGH PERFORMANCE
CULTURE IN WHICH
TO OPERATE.

We are at the beginning of our ESG journey, but we are already making a large contribution to important social and economic issues such as access to healthcare in developing countries and the importance of acting in a compliant and responsible way in everything that we do across the Group. For example, in the last three years we have supplied critical medicines into 128 countries of which sixty six are developing countries across Latin America, Africa and Asia. We now enable access to more than 1,400 medicines across our Managed Access, Partnered and On-Demand channels. Further detail of our ESG platform can be seen on page 32. We look forward to continuing to build on our ESG efforts in the future.

#### PEOPLE

The Group has over 1,000 employees operating across the globe helping us to deliver on our mission. It is vital we continue to create a thriving and high-performance culture. I am encouraged to see a further 110 people from six different countries complete the Clinigen Management Academy this year.

In these challenging times it is also vital we look after our people and give them the support they need. Mental health is a key part of that and in 2021 we rolled out mental health awareness training to all managers. We will continue to focus on this area in 2022 with further mental health initiatives.

We have increased our average training spend per employee, signalling our commitment to developing our people and supporting their growth. We have also made further commitments to ensure we have a culture that actively encourages diversity, and signing up to the Valuable 500 initiative was another key step towards creating even greater diversity at Clinigen.

Our employees' continued hard work, professionalism and commitment enables Clinigen to operate smoothly, serve our customers and, most importantly, help patients around the world.

#### **BOARD AND GOVERNANCE**

Peter Allen has been succeeded by Elmar Schnee as Group Chairman. I would like to thank Peter for his valued leadership over the past nine years and I look forward to working with Elmar to continue to grow the Company and deliver value.

Nick Keher stepped down from his position as Chief Financial Officer and a search to find his replacement is underway. Sharon Curran and Ian Johnson joined the Board bringing additional UK Plc and pharmaceutical experience and further transforming the Board.

In 2021 we also rolled out an Internal Audit and Risk function – more details on this can be found on page 52. This function is vital for better identifying, monitoring and mitigating risks across the business and something that we know is vital for all our stakeholders.

On behalf of the Board, I would like to take the opportunity to thank all our employees for their help in enabling the Group to achieve its guiding principle of being 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.

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

#### OUTLOOK

The Group is guiding to EBITDA growth of 5% to 10% in FY2022.

In Services, business wins secured in FY2O21 are being integrated as expected, the pipeline is strong with a number of new high value projects are already underway. Our Services business is positioned to become a focal growth area for Clinigen in the future particularly as we work to further refine our strategy.

In Products, specific risks remain from COVID-19, as demand remains subdued for some products but has not worsened. There is continued momentum across the Developed portfolio and Partnering deals signed in FY2021 are contributing to growth alongside the anticipated further roll-out of Erwinase.

The long-term fundamentals of the business and its end-markets remain strong despite the near-term uncertainty created by COVID-19, and we are confident that we will deliver long-term value.

Group results from continuing operations on an adjusted basis exclude amortisation of acquired intangibles and products, and other non-underlying items (see note 4 and 7 of the consolidated financial statements). Adjusted measures are presented as they allow a more effective year-on-year comparison and identification of core business trends by removing the impact of items occurring either outside the normal course of operations or as a result of intermittent activities such as business combinations and restructuring. The principles to identify adjusting items have been applied to the current and prior year comparative numbers on a consistent basis. Adjusted EBITDA includes the Group's share of EBITDA from its joint venture.

#### **OUR BUSINESS MODEL**

# **WE'RE THE TRUSTED** GLOBAL **PLATFORM**

Around the world, millions of patients can't access the medicines they need when they need them. New therapies must go through a complex and lengthy development process before they can be approved. Launching these medicines may then take years in some countries, and may never happen at all in others. Meanwhile, established medicines may be deprioritised, or long-standing supply chains disrupted.

Clinigen exists to enable quicker and broader access to these medicines around the world. Our global platform stretches across the pre & post-launch phases of a medicine's lifecycle, from phase II to commercial. Offering a critical service to pharma and biotech companies by simplifying their partnering strategy. And saving time and resource for healthcare professionals sourcing vital products.

Meaning Clinigen can provide access to a medicine throughout its life - from development to commercialisation and back - ensuring the right medicine gets to the right patient at the right time.

#### PRE-LAUNCH

Niche innovative solutions to accelerate development and access to new medicines

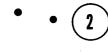
#### **CLINICAL SUPPLY**

Innovative logistics, packaging, distribution, comparator sourcing and biorepository solutions

## **SERVICES**

#### MANAGED ACCESS

Design and implementation of global Managed Access Programs providing access to innovative new medicines for unmet medical needs



#### **MARKET DRIVER**

Increased number of highly specialised complex medicines originated by biotech's

<sup>1.</sup> Pharma Intelligence: Pharma R&D Review 2020

<sup>2.</sup> EFPIA WAIT indicator - 2019

<sup>3.</sup> EY Global Corporate Divestment Study 2020

#### **POST-LAUNCH**

Global platform to enable broader access to critical medicines in unlicensed and licensed markets

#### PARTNERED

Partnering with pharma and biotech to provide access to their medicines in both licensed and unlicensed markets through an exclusive supply or licensing arrangement

# **PRODUCTS**

#### **ON-DEMAND**

Sourcing and supply of difficult-to-find unlicensed and short supply medicines in response to demand for access from healthcare professionals

#### OWNED

Medicines that have been acquired or developed by Clinigen with the goal to maximise access through unlicensed and licensed markets

More new therapies being approved, launch delays, reduced pharma footprints, portfolio rationalisation, and continued pressure on healthcare budgets POTENTIAL DELAYS
BEFORE NEW MEDICINES
ARE LAUNCHED?

**78**%

PHARMA EXECS LOOKING TO DIVEST ASSETS WITHIN 2 YEARS **OUR BUSINESS MODEL CONTINUED** 

# WE'RE OPENING ACCESS TO THE WORLD

The platform that Clinigen has built enables it to partner with pharmaceutical companies and provide access for healthcare professionals at multiple points across a medicine's lifecycle. This is what makes Clinigen unique and is what drives greater value for all our stakeholders. A key strategic goal for Clinigen is to maximise the number of medicines and relationships that sit across multiple parts of the platform. By doing this, Clinigen will become the lifecycle partner of choice for pharma companies and the go-to platform for healthcare professionals to access innovative and difficult-to-source medicines.

+24
PHARMA CLIENTS
UTILISED ONE PART
OF PLATFORM IN

**LAST 12 MONTHS** 

43 +6
PHARMA CLIENTS
UTILISED MULTIPLE
PARTS OF PLATFORM

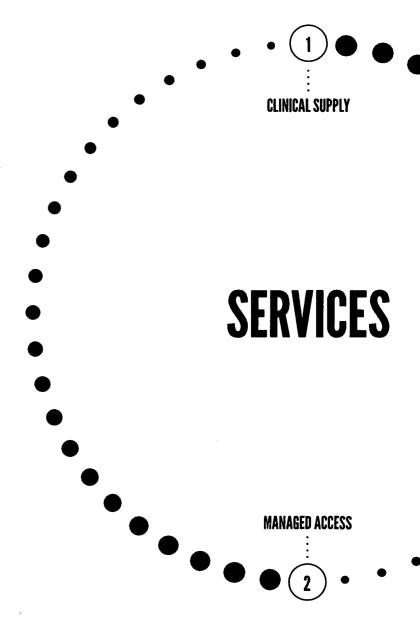
IN LAST 12 MONTHS

NEW CONTRACTS
SECURED THROUGH
INTER-COMPANY
REFERRALS

128 COUNTRIES

25,127
HEALTHCARE
PROFESSIONALS

PRE-LAUNCH

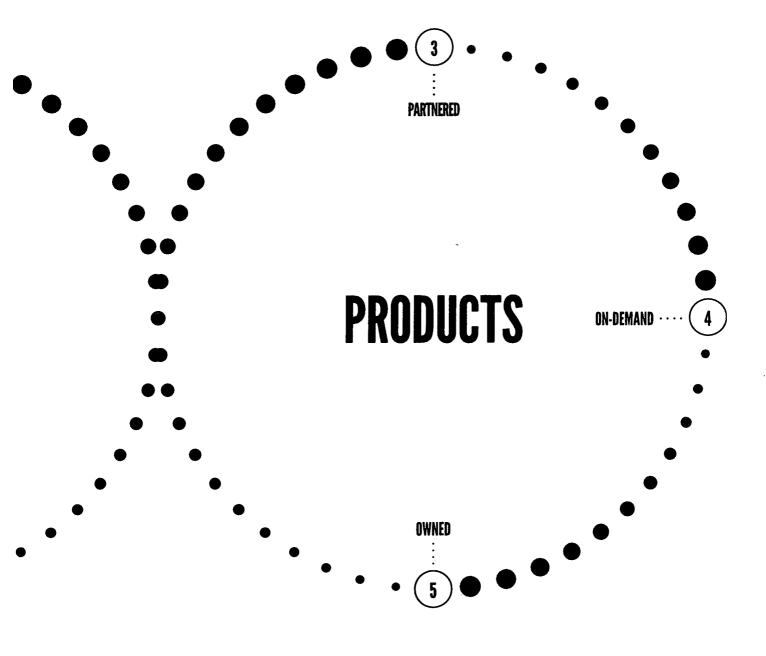


462

CLINICAL CLIENTS 161

MANAGED ACCESS PROGRAMS

#### **POST-LAUNCH**



185 PARTNERED PRODUCTS

900+

ACTIVE On-Demand Portfolio 20 owe pro

UWNED Product:

#### HOW WE'RE HELPING HEALTHCARE PROFESSIONALS

Clinigen work with healthcare professionals around the world, helping them to access critical medicines for their patients.

# WE'RE CONNECTING WITH HEALTHCARE PROFESSIONALS

#### LOVE YOUR PHARMACIST AWARDS

In 2021 Clinigen hosted the inaugural Love Your Pharmacist Awards. The awards were created to recognise and celebrate the significant role pharmacists play in enabling better access to medicines and improving people's lives. To learn more about the awards visit **www.loveyourpharmacist.com** 



#### CLINIGEN MAKE OUR ROLE AS CLINICAL PHARMACISTS SO MUCH EASIER AND ENABLE US TO PROVIDE BETTER HEALTHCARE.



# CLINIGEN HAVE THE CONNECTIONS WITH THE PHARMA COMPANIES AND ARE ABLE TO LOOK AT PATHWAYS TO GET THESE MEDICINES INTO AUSTRALIA FROM OTHER COUNTRIES.



#### COULD YOU TELL ME ABOUT YOUR ROLE?



#### CLINICAL PHARMACIST

Johannesburg, South Africa

My role is to get hold of medications which are not available in South Africa – either because they have run out of stock or because they are not registered. Most of the drugs I support are unapproved and I need to work with the infectious disease physician to try and import the medication from another country.



#### SENIOR PHARMACIST

Queensland, Australia

I am a senior pharmacist looking after the outpatient oncology patients providing services and education. Also, when physicians prescribe weird and wonderful medication that is not readily available in Australia, it falls on me to get hold of these medicines.

WHAT LOGISTICAL CHALLENGES DO YOU COME ACROSS IN TRYING TO ACCESS CRITICAL MEDICINES – AND HAS COVID-19 MADE THIS MORE CHALLENGING? Some of the local manufacturers have been running out of stock of key medicines we use. One of our most used medicines comes in two available brands but there have been challenges around the availability which means we have to swap from one brand to another, which is not ideal. Alongside this, due to COVID-19, there have been staff shortages at the port authorities which adds another challenge in terms of timelines to import a therapy.

There have been a number of medications that have been hard to access in Australia – even in some cases for medication that is registered in Australia. It can often be difficult and time consuming getting hold of the manufacturers ourselves to understand if we can import the medicine. During COVID-19 there have also been longer delays at customs which adds further challenges for the treating of patients on time.

WHY IS A COMPANY LIKE CLINIGEN IMPORTANT TO YOU IN YOUR ROLE AND HOW HAVE THEY HELPED ADDRESS THESE CHALLENGES?

Working with Clinigen has been a great help. One medicine in particular which is not yet registered in South Africa is a really important drug to treating multi-drug-resistant infections. It has been great being able to work with Clinigen to import that medicine and has meant access to a medicine we otherwise wouldn't have.

Clinigen have the connections with the pharma companies and are able to look at pathways to get these medicines into Australia from other countries. This has meant patients have got treatment that they otherwise would not have.

DO YOU HAVE ANY OTHER EXAMPLES OF WHERE CLINIGEN MADE A REAL DIFFERENCE TO YOU AND YOUR PATIENTS?

In transplant there are so many specialist medicines available in Europe that we don't have access to - it is really valuable to have access to these medicines. It makes our role as clinical pharmacists so much easier and enables us to provide better healthcare.

In one example we had a patient in her early 30s with breast cancer who had already gone through several lines of treatment. There was a new unapproved medicine we wanted to import into Australia, but we were not able to source. Clinigen were able to work directly with the pharma company to import the medication which made a huge difference for the mental health of the patient who now has hope about the future. For us as pharmacists, Clinigen make our lives significantly easier on a daily basis - they have reduced the amount of work and removed the complexities in trying to access medicines.

#### HOW WE'RE HELPING PHARMA CLIENTS

Clinigen's lifecycle platform simplifies our pharma clients' partnering strategy by enabling them to utilise multiple access solutions across a medicine's lifecycle.

Over the last 12 months Clinigen has been working with BeiGene – a global biopharmaceutical company with multiple medicines on the market in the United States and China and more reaching key stages of the development process.

BeiGene has a significant pipeline including three internally-developed molecules approved for different lifethreatening cancer types. The most advanced of the three molecules, zanubrutinib, a BTK inhibitor, has already been approved in major territories such as the USA and China and further approvals in Europe and other countries and regions are expected. Tislelizumab, an immunooncology drug and checkpoint inhibitor that is approved for several indications in China, delivered positive global phase 3 development studies: approvals in the USA, Europe and other territories are planned. And pamiparib, which is approved in China for the treatment of ovarian cancer.

There were three key priorities for BeiGene:

- Enable investigator-led research exploring treatment options for targeted indications, specific subgroups of patients or hypothesis generating work.
- Enabling compliant and controlled access to their oncology portfolio for treatment of unmet medical needs
- Fast and efficient delivery of their licensed medications post approval.



CLINIGEN IS A KEY PARTNER FOR US IN ENABLING ACCESS TO OUR MEDICINES ACROSS THE MEDICINE'S LIFECYCLE. WE ARE ABLE TO UTILISE THEIR PLATFORM AT VARIOUS STAGES FOR DIFFERING ACCESS CHALLENGES ACROSS MULTIPLE PRODUCTS — THIS IS EXTREMELY IMPORTANT FOR US AS IT SUPPORTS OUR MISSION OF PROVIDING ACCESS TO MORE PATIENTS, SIMPLIFIES OUR PARTNERING STRATEGY AND STREAMLINES OUR APPROACH.

WHERE ARE CLINIGEN AND BEIGENE WORKING TOGETHER:

#### **SERVICES**

#### CLINICAL

Investigator-led research can be critical in further understanding molecules and their appropriate application. Co-ordination and facilitation of requests from global sites can however be complex, resource intensive and often requires a nimble and responsive supply chain. Clinigen receiving and facilitating these requests on behalf of BeiGene helps to ensure compliant and timely responses and builds and maintains important relationships with key sites.

#### **MANAGED ACCESS**

BeiGene is committed to ensuring appropriate patients with unmet medical needs can access their molecules prior to commercial availability in a compliant manner. As a result BeiGene has initiated key programs: to enable access to zanubrutinib, tislelizumab and pamiparib where their physician deems it the most suitable treatment option over existing commercial therapies. Clinigen has worked with BeiGene to design, implement and deliver these programs to ensure no eligible patient request goes unanswered.

#### **PRODUCTS**

#### **PARTNERED**

Should zanubrutinib be approved in the EU, BeiGene will want to ensure smooth and efficient commercial roll-out in key markets as soon as possible. Whilst BeiGene is expanding its European footprint and medical functions to prepare, it also needs a distribution partner in the UK following Brexit. Clinigen will be that partner, facilitating UK commercial distribution following commercial launch.

# WE'RE SIMPLIFYING PARTNERING STRATEGIES

#### HOW WE'RE HELPING PATIENTS

At Clinigen, we are passionate about getting the right medicine to the right patient at the right time. We work to support inclusion of the right inputs and perspectives to foster successful development of Managed Access Programs. The patient voice is absolutely central to this.

# WE'RE CONNECTING WITH PATIENT GROUPS



A PATIENT ADVOCATE
FELLOWSHIP IN EARLY ACCESS
HAS THE POTENTIAL TO
STREAMLINE HOW PEOPLE GET
ACCESS TO LIFE-SAVING DRUGS.
IT CAN FEEL LIKE BEING LOST IN
A MAZE. EVERYONE IS TRYING
TO GET TO A SIMILAR PLACE
BUT KNOWING THE RIGHT WAY
TO GO AT THE SAME TIME IS
A CHALLENGE.

#### LINDSAY WEAVER

Former CEO, Metabolic Support UK and Co-Founder and CEO, Realise Advocacy

This year Clinigen launched the Patient Advocate Fellowship in early access, an initiative aimed at equipping patient groups and their leadership with the skills and experience they need to engage meaningfully within early access.

Patient groups are often stretched for time and resources, and so are not always in a position to get to engage deeply with the topic of early access. And yet, their timely input can make all the difference in developing a Managed Access Program that better serves both patients and company.

That's why Clinigen founded the innovative fellowship scheme to reduce barriers to entry for patient advocates in this specialist area. We worked with experienced patient advocates to shape a scheme that would be fit for purpose.

The 2021 scheme is now ongoing, offering leaders of patient groups opportunity to promote the interests of their community through tailored learning, networking and peer support relevant to early access.

#### STAKEHOLDER ENGAGEMENT

# WE'RE DRIVING SYNERGIES

Since its inception, the Group has been building out its infrastructure platform, refining its value proposition and driving the synergies between its 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.

#### **PATIENTS**

Clinigen's mission is 'Right Medicine, Right Patient, Right Time'. Patients are at the heart of everything we do and are a key reason why many of our employees choose to work for the Group.

"YEAR ON YEAR, CLINIGEN SEEKS TO WORK MORE CLOSELY WITH THE PATIENT COMMUNITY – TO UNDERSTAND ACTUAL NEEDS AND GAPS. WE RAISE AWARENESS OF THE VARIOUS CONDITIONS THAT OUR PRODUCTS ARE INDICATED FOR, WITH A FOCUS ON IMPROVING PATIENTS' QUALITY OF LIFE IN A NUMBER OF IMPORTANT THERAPY AREAS."

Commercial Director - Generics

#### WHY THEY ARE IMPORTANT TO THE GROUP

Patients are central to the service Clinigen provides to pharma companies and healthcare professionals. It is ultimately patients' needs and requirements that help to shape the type of services and products Clinigen provide.

#### WHY THE GROUP IS IMPORTANT TO THEM

Clinigen is in the business of enabling access to medicines. Through its Services and Products divisions, it makes new or different treatment options available for patients with unmet needs around the world. This makes all the difference for patients, whether it be enabling access to a life-saving or extending treatment, or introducing an option that could have a vast impact on a patient's quality of life.

#### **HOW WE ENGAGE**

We engage with the patient community through our global patient advocacy function within medical affairs. Across the Group, our aims have been to create a feedback loop with the community whereby actual patient needs can be heard, and have an impact upon Clinigen's business and priorities.

#### 2021 EXAMPLES

This year, Clinigen launched the Patient Advocate Fellowship in early access, an initiative aimed at equipping patient groups and their leadership with the skills and experience they need to engage within early access, improving it for all.

#### PHARMACEUTICAL AND BIOTECH CLIENTS

Pharmaceutical and biotech clients are broadening their relationship with Clinigen to gain ethical, compliant and valuable access solutions across the medicine lifecycle.

"PHARMACEUTICAL COMPANIES ARE LOOKING FOR SPECIALIST ACCESS PARTNERS TO WORK ALONGSIDE THEM DURING THE WHOLE PRODUCT LIFECYCLE. CLINIGEN'S ABILITY TO SUPPORT THEM FROM CLINICAL TO COMMERCIAL IS A KEY FACTOR IN WHY THEY PARTNER WITH US."

**VP Business Development** 

#### WHY THEY ARE IMPORTANT TO THE GROUP

Clinigen provide solutions to pharmaceutical and biotech companies at all stages of the medicine lifecycle. It is only through strong relationships with pharma companies that Clinigen can expedite and broaden access to medicines for patients around the world.

#### WHY THE GROUP IS IMPORTANT TO THEM

Clinigen's platform provides pharmaceutical and biotech companies with ethical, compliant and efficient solutions to medicine access challenges throughout the medicine lifecycle. These solutions drive value and simplify partnering strategies.

#### **HOW WE ENGAGE**

Clinigen engage pharmaceutical and biotech companies at multiple points throughout a medicine's lifecycle - from phase II to commercial. The solutions Clinigen provide vary depending on the company's internal capabilities and specific access needs.

#### 2021 EXAMPLES

Over the last 12 months Clinigen has provided solutions to more than 500 pharma and biotech companies. These companies range from large Top 20 pharma companies to small niche biotechs.

#### **HCP CUSTOMERS**

HCPs around the world rely on Clinigen to obtain ethical and compliant access to hard-to-find medicines.

"OUR TEAMS ARE SPEAKING TO HEALTHCARE PROFESSIONALS AROUND THE GLOBE ON A DAILY BASIS. IT IS VITAL WE BUILD STRONG RELATIONSHIPS AT A LOCAL LEVEL AND THAT WE HAVE THE KNOWLEDGE AND CAPABILITIES TO PROVIDE EFFICIENT SOLUTIONS TO THEIR ACCESS CHALLENGES."

**Customer Service Director** 

#### WHY THEY ARE IMPORTANT TO THE GROUP

Along with pharmaceutical and biotech companies, HCPs are the other main user of the service Clinigen provides. Effectively servicing the needs of HCPs across the world is critical to being able to achieve our mission.

#### WHY THE GROUP IS IMPORTANT TO THEM

Clinigen provides a platform that enables HCPs to access critical medicines in a simple, efficient and compliant manner. This saves time, minimises resource impact and enables HCPs to treat their patients as quickly as possible.

#### **HOW WE ENGAGE**

Clinigen's multi-channel platform, Clinigen Direct, enables Clinigen to engage with HCPs via phone, email and online. Clinigen also have field-based teams such as Medical Science Liaison that consult directly with treating physicians.

#### **2021 EXAMPLES**

This year Clinigen launched the 'Love Your Pharmacist Awards' to recognise the vital role pharmacists across the world play in enabling access to medicines.

More than 6,000 additional HCPs have registered on Cliniport during FY2021.

During FY2021 Clinigen have interacted with HCPs in more than 120 countries.

#### STAKEHOLDER ENGAGEMENT CONTINUED

#### **EMPLOYEES**

We employ over 1,000 people in 14 international locations and are committed to a policy of equal opportunities in the recruitment, engagement and retention of employees.

"WE ARE PROUD TO BE A TRULY INCLUSIVE PEOPLE-CENTRIC BUSINESS. OUR DIVERSE GLOBAL WORKFORCE BRING TO LIFE OUR CLINIGEN-WAY PRINCIPLES. WE ARE PASSIONATE ABOUT EMPLOYEE ENGAGEMENT, COLLABORATION, AND CAREER DEVELOPMENT TO MAKE CLINIGEN A GREAT PLACE TO WORK."

SVP Human Resources

#### WHY THEY ARE IMPORTANT TO THE GROUP

Our employees are vital to help us deliver on our strategic objectives and so it is critical to recruit, develop and retain the right people. It is only by having a happy, thriving and high performance team that we can continue to serve the needs of our customers.

#### WHY THE GROUP IS IMPORTANT TO THEM

Many of our employees are attracted to Clinigen due to the nature of the work enabling better access to medicines. In addition, Clinigen offers a diverse working culture that will offer opportunities for career development and personal growth.

#### **HOW WE ENGAGE**

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

#### 2021 EXAMPLES

110 employees completed the Clinigen Management Academy training program during the year.

All people managers across the Group completed mental health awareness training as part of our commitment to wellbeing.

Clinigen launched a global job grading framework to underpin our commitments to reward and recognition and development.

#### SHAREHOLDERS

The Board realises that effective communication with shareholders on growth forecasts, strategy and governance is an important part of its responsibilities.

"COMMUNICATING EFFECTIVELY AND REGULARLY WITH SHAREHOLDERS AND POTENTIAL INVESTORS ON PROGRESS AGAINST KEY METRICS, MILESTONES AND OUR FUTURE STRATEGIC DIRECTION IS KEY. IT IS ALSO VITAL THAT THEIR VIEWS ARE APPROPRIATELY REPRESENTED AT THE BOARD LEVEL."

**VP Investor Relations** 

#### WHY THEY ARE IMPORTANT TO THE GROUP

Shareholders play a vital 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.

#### WHY THE GROUP IS IMPORTANT TO THEM

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**

The Chairman, 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.

#### **2021 EXAMPLES**

The Chairman, CEO and CFO had a regular dialogue with institutional shareholders, engaging proactively with them and ensuring their views are communicated back to the Board.

Clinigen engaged with 113 institutional investors during the year, holding more than 150 meetings and attending three international investor conferences.

#### **COMPETENT AUTHORITIES**

Clinigen engages with Competent Authorities including regulators and government departments in order to operate within the appropriate regulatory and legal framework and expedite access to medicines.

"WORKING CLOSELY WITH COMPETENT AUTHORITIES AROUND THE GLOBE IS VITAL TO BE ABLE TO FULFIL OUR MISSION. WE MUST FULLY UNDERSTAND AND COMPLY WITH REGULATORY REQUIREMENTS TO ENSURE WE CAN PROVIDE ACCESS IN A COMPLIANT AND TIMELY MANNER."

VP Regulatory Affairs

#### WHY THEY ARE IMPORTANT TO THE GROUP

Competent Authorities ensure that every element of the service Clinigen provides is compliant and, most importantly, protects the patients we provide access for. Forming strong and transparent relationships with Competent Authorities is key to service the needs of our pharmaceutical clients and HCP customers.

#### WHY THE GROUP IS IMPORTANT TO THEM

Competent Authorities ensure that pharmaceutical companies, like Clinigen, operate in line with global guidelines and local regulations to ensure patient safety.

#### **HOW WE ENGAGE**

Clinigen engages with Competent Authorities via our regulatory and quality functions for a number of reasons, including: marketing authorisations, importing and exporting of unlicensed medicines, strategic guidance, and periodic inspections.

#### 2021 EXAMPLES

Over the year, Clinigen has been inspected seven times by Competent Authorities.

We have also been engaged with Competent Authorities around the globe, some examples include: gaining US Orphan Drug designation for Proleukin for ALS, decentralised procedures for developed products Glycopyrronium Bromide and Melatonin in Europe, approval for Erwinase emergency supply in France, UK, US and Canada, establishment of Exploitant status in France, record year of Compassionate Use submissions in Germany and Belgium, further submissions in other EU countries and registration of Foscavir bag presentation in the US.

#### **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 64.

#### MARKET OVERVIEW

Clinigen operates from phase II to commercial in a pharmaceutical market with an increasing number of niche and targeted therapies developed by smaller companies.

It has a unique business model that provides access to medicines and services across the medicine lifecycle. 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 two business operations. Some of the more common macro market trends and key market drivers for Clinigen are discussed in this Market Overview.

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

#### **SERVICES**

#### **MARKET DRIVERS**

- Increase requirement for bespoke and tailored solutions for smaller patient populations
- Focus on patient-centric solutions that help with recruitment and retention in clinical trials
- Increased role of patient advocacy groups and online resources leading to greater patient demand for early access
- Continued need for additional data to support approvals and pricing and reimbursement
- Requirement for digital solutions that support access

#### **PRODUCTS**

#### **MARKET DRIVERS**

- Pharma looking to reduce number of partners they have for their products
- Continued challenges globally in accessing unapproved and approved medicines due to shortages
- Increased need for pharma to find outsourced access solutions in tier two and three markets
- Continued budget challenges making price a larger factor in pharmacy buying decisions

#### **CLINIGEN DIFFERENTIATORS**

- Flexible and agile global supply chain and distribution network
- Ability to manage deep cold storage including cryogenic
- Patient-focused offerings such as direct-to-patient shipping
- Market-leading offering for early access solutions coupled with patient-focused initiatives (Patient Advocate Fellowship)
- Real World Data capture alongside early access that has been utilised to support market access

#### **CLINIGEN DIFFERENTIATORS**

- Ability to provide access in licensed and unlicensed markets across the globe
- Global sourcing network with ability to provide rapid solutions for hard to find medicines
- Established capabilities across the globe with local teams in the US, Europe, Asia, Africa and Japan
- Existing relationship with network of pharma manufacturers and wholesalers built up over 30 years leading to greater sourcing power

#### **GLOBAL MARKET TRENDS**

### CONTINUED GROWTH IN R&D AND APPROVALS<sup>1</sup>

There continues to be strong growth in the overall size of the R&D pipeline as well as the number of new medicines coming to the market.

The R&D pipeline is growing year-on-year with further growth in 2020 of 9.62%. This is up from 5.99% growth in 2019. The result of this is estimated to be around 1,556 more drugs in development (in total). This is a result of both more research on existing therapies as well as new therapies coming into the pipe. In fact, in 2020 there are reports of 4,730 new molecules being added into the pipeline which is a rise from 2019. It is also important to note that there was an increase at every phase of development from pre-clinical through to launched medicines.

Alongside this R&D growth there continue to be a high number of drug approvals. In 2020 there were 53 novel therapeutics approved which is up from 48 in 2019. This represents the second highest number of FDA approvals outside of 2018. Whilst the US is not the only indicator here we believe it is a key indicator of new medicines coming into the market that healthcare professionals will want to access. The US was the first approval market for 75% of 2020 FDA approvals.

R&D is a key driver for growth across clinical services, likely leading to an increase in logistics, distribution, labelling and sourcing opportunities. It is also likely to lead to a rise in managed access opportunities as these filter from phase two to phase three and beyond.

Year-on-year FDA drug approvals are a key indicator for managed access and partnering deals as healthcare professionals look to access and pharma need to roll out global launches.

#### **RISE OF SMALLER COMPANIES**

Smaller pharma companies with one or two drugs in their portfolios account for around 19% of the total pharma pipeline. Within this there has been a significant rise in the actual number of small companies conducting the research.

There are a reported 735 companies with just two drugs in the portfolio which represents a 10% increase from 2019. There are a reported 1,849 companies with a single drug in development which equates to over 50% of all companies with a drug in development.

Alongside this, of the 101 drugs that have been approved by the FDA in the last two years it is noted that a large proportion of these were developed by what could be defined as a 'smaller company' or one with a limited geographic footprint outside the USA.

The high number of new drugs in development and being approved that sit with smaller companies is a key driver for Clinigen.

These companies are often more focused on an outsource model at the clinical stages and are looking to companies like Clinigen to support them through the development process.

They also don't have the capacity or, in some cases, expertise to supply their drugs outside the US into unlicensed markets or indeed to commercialise these medicines themselves. They will be looking for a partner that can guide through the unlicensed to licensed process and ensure patients around the world can access their medicines.

#### FOCUS ON ONCOLOGY AND NICHE THERAPEUTICS

There remains a large focus on driving R&D in oncology with 36.7% of molecules in development being cancer candidates, increasing by 13.2% from 2019.

This is also the case with drug approvals, with 30% of approvals in the last two years being for cancer treatments.

Furthermore we see the biggest increase in the cellular therapy, chimeric antigen receptor, or CAR-T, category whose pipeline size has increased by 77.9%.

Outside of cancer there have been further increases in the development of genc therapies where R&D has expanded by 47.3%. There has also been an increase of drugs in development for rare and orphan indications, which is up 7% and covers a total of 608 rare diseases.

All of this focus is good for patients with unmet medical needs but presents challenges for pharma companies.

Firstly, these molecules are often complex to handle and patient mapping can be difficult, meaning development can be complex and costly.

Secondly, when they do get approvals the supply chains are complex and there are often other significant barriers to the market such as pricing and reimbursement.

Clinigen's model is set up to address these challenges. Our model is being developed to support these highly complex therapeutics, where there is a high unmet medical need from clinical through to commercialisation.

YEAR-ON-YEAR GROWTH IN NON-SOURCING CLINICAL WINS

+62

**NUMBER OF PHARMA CLIENTS** 

577

% of maps in oncology & rare disease

**50**%+

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

ONE THING THAT HAS BEEN HIGHLIGHTED DURING THE PAST 12-18 MONTHS IS THE IMPORTANCE OF OUR BUSINESS TO PATIENTS AROUND THE WORLD.

Clinigen CEO, Shaun Chilton, discusses the Group's performance in 2021 and addresses some common questions received from investors over the past year.

### **Q** TELL US ABOUT THE GROUP'S FINANCIAL RESULTS THIS YEAR

Clinigen this year has seen financial performance impacted by COVID-19, particularly in our Products division across On-Demand and Proleukin. This has been due to hospitals globally focusing their efforts on dealing with the pandemic, significantly reducing usual activities, which we provide solutions for, and patients understandably not being willing or able to get into hospitals.

However, despite the challenges brought about by the global pandemic, we demonstrated our ability to refine our services to make them relevant and helpful in this scenario. We have continued to demonstrate the strength of our platform with a record number of business wins across the Services division, the rollout of Erwinase and continued strong performance across the AAA region.

Due to the strength of the underlying business we anticipate EBITDA growth between five and ten percent in the next financial year. We also remain focused on reducing the net debt position.

# O COVID-19 HAS FORCED MASSIVE CHANGE ON THE WAY THE PHARMACEUTICAL INDUSTRY DOES BUSINESS. HOW HAS CLINIGEN RESPONDED?

COVID-19 has been a major global crisis, not just for those directly impacted but also for patients suffering from other diseases that have been deprioritised during the pandemic. Over the past 12-18 months our business has been able to assist many patients around the world and we have been proud to play a role at this very challenging time.

Clinigen has supported more than 50 COVID-19 related projects and has continued to provide access to critical medicines for hundreds of thousands of patients during the pandemic. We, like most businesses, have had to adapt to a more virtual way of working and our employees have been steadfast in the way they have continued to focus on doing what needs to be done to get the right medicine to the right patient at the right time.

Our direct-to-patient clinical support services have been utilised more widely during the pandemic as we see a shift to clinical trials being managed in a more decentralised way which could be a long-term trend we are well placed to support.

The Clinigen platform has been built to provide access to difficult to find medicines globally and provides tangible benefits to both pharmaceutical and biotechnology companies and healthcare professionals. We enable companies to provide access to their medicines in a way that maximises their value and minimises risks, protecting critical relationships with their customers. These customers depend upon us to save them valuable time and provide these medicines quickly and safely. These services will continue to be in high demand in the post-pandemic world.

### Q IS THE STRUCTURE OF THE BUSINESS NOW RIGHT TO DRIVE FUTURE GROWTH?

We recognise that in order to continue to deliver good growth, we need to focus the business on those areas we feel we make a difference and have competitive advantage - a major reason why during the past 12 months we have worked hard to simplify the business. Moving from three divisions to two was a natural step for us and helps us better position the business to stakeholders as well as realise synergies across the organisation. The divestment of the UK Specials and Aseptics business was also important to ensure that we are focused on those services and products we believe can deliver most value for our stakeholders.

We have also continued to strengthen our team, which is integral to strong future growth. We brought in a Chief Operating Officer, Sam Herbert, to ensure operationally we have the right capabilities and capacity for future growth. Our Board has also been strengthened and further internationalised over the period. Elmar Schnee has succeeded Peter Allen as Group Chairman, bringing strong experience from the international pharmaceutical industry. Sharon Curran and Ian Johnson also joined, adding significant listed UK healthcare experience.

Looking forward, in response to the growing demand for services such as our Managed Access Programs, we will seek to accelerate our focus on those areas of the Group where we have growing and sustainable competitive advantage and, as we do so, continue to drive revenue and cost synergies. Clinigen's most differentiated offerings are from the Services division and the Partnering segment of the Products division where our platform provides market-leading solutions from the clinical phase through the commercial lifecycle phases of a drug product. In addition, we are focused on streamlining and simplifying the Products division and optimising our core business, which we believe will strengthen our offering whilst creating greater shareholder value.

We also continue to focus on developing our people and building the right culture to ensure we have a thriving work force. And we will continue with our digital roll-out with key milestones approaching in FY2022 which we believe are central to Clinigen's future growth plans.

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

#### WHAT ARE THE MOST IMPORTANT DRIVERS OF GROWTH ACROSS THE BUSINESS?

Firstly, we are in a position where the markets we operate in are growing, which is clearly important. For example, there are more clinical trials being conducted year-on-year, more being spent on R&D, more innovative drugs being approved-all of which are real drivers in the first instance for the Services part of the business, an area where our pipeline remains strong, and where we are engaging with pharma companies as early as phase II research.

Secondly, a growing proportion of these pharma and biotech companies will need a partner to supply of their medicines into both unlicensed and licensed markets.

It is because of this that we recognise a key growth driver moving forward is partnering. Our ability to manage the licensed and unlicensed markets of a product through one platform is a key differentiator and makes us an attractive partner for a pharmaceutical or biotechnology company.

The ability to really drive the synergy (or handover) between the two divisions and realise long-term and more predictable revenue and profit - what we call 'Join The Dots' is a key driver of growth. In the short-term, licensing agreements such as Erwinase and Hunterase are good potential growth drivers and in the mediumterm, Proleukin with the successful launch of TIL therapies and also low dose use in additional indications.

## THERE HAVE BEEN A NUMBER OF ACQUISITIONS IN RECENT YEARS. HOW HAVE THEY CONTRIBUTED TO THE GROUP?

The acquisitions we have made have all been focused on expanding and enhancing the offerings across the platform or bringing in products which we can maximise the value of through the platform. CSM and iQone are good recent examples of acquisitions that have enabled us to broaden our offering to pharma clients and ultimately led to us winning business on other parts of the platform which we would not otherwise have won.

From a product perspective, Proleukin is a product we believe we can maximise the value of given our ability to supply into clinical, unlicensed and commercial markets, something that may be key as it goes through development for new indications. Products like Proleukin continue to allow us to build out our technical capabilities as well expand geographically.

## HELP US UNDERSTAND THE SYNERGIES BETWEEN THE PRODUCTS AND SERVICES BUSINESSES?

There are a number of synergies we see across the two divisions. Firstly, with the number of pharmaceutical and biotech companies we now interact with across the two divisions, we have the ability to leverage these relationships and cross-sell across our offerings so Clinical Services leading to Managed Access Programs to product Partnering opportunities.

There are capability synergies even within a Division where offerings in one part of the business are being positioned through another part of the platform. A good example of this is where the Clinical packaging business supports work for Managed Access Programs.

There are customer synergies since often the physician or pharmacist coming to us for a managed access product is also an investigator in a clinical trial benefitting from our Clinical Services and at the hospital that needs a number of products not available in their country.

And there are also cost synergies for our clients where they are able to store medication in a single location that can then be utilised to supply out to unlicensed markets, commercial markets or clinical trials reducing the needs for multiple partners.

The operational elements underpinning the platform such as Logistics, Customer Services, Quality Assurance, Regulatory, Finance, Legal amongst others are deployed across the two divisions rather than having two separate operating platforms by division. This provides cost synergies as well as making it a more diverse and therefore attractive career for those involved.

A key measure of success here is how many pharmaceutical and biotech companies we work with across multiple parts of the business over a twelve month period. We have seen progress this year with that number increasing by six to forty-three in total and we will have continued focus in this area.

## HOW WOULD YOU VIEW THIS YEAR'S PROGRESS AGAINST YOUR STRATEGIC OBJECTIVES?

This year we have made good progress against our strategic objectives. Despite the challenges of working remotely for most of our people, we continue to invest a huge amount in them, for example we have had an additional 110 people that have completed our Management Academy, a module that not only impacts managers but the teams that they lead.

We also assess progress through Peakon, an anonymous employee feedback platform we have embedded in Clinigen. We continued to score well on employee engagement through the year with an engagement score of 7.5 which is above industry average.

Operationally we have achieved a huge amount, with the simplification of the business model, the successful implementation of our Brexit solution and the continued development of capabilities such as cold chain expansion. Of course, bringing in a Chief Operating Officer has been and will be key to ensuring operational excellence in the future.

We continue to grow the number of relationships we have with pharmaceutical companies across the Group and we continue to see growth in business wins in both Services and Products.

Digital is a key strategic objective and driver of future growth. There have been further roll outs of our digital platform - to expand and extend our relationships with Clients and Customers - as well as the implementation of a new global CRM platform to further drive 'Joining The Dots'.

Alongside this we have been able to roll out a new ESG framework and within that framework initiatives like the Early Access Fellowship which is key to both thought leadership and patient focus.

Looking forward, we will continue to pursue our goal to deliver solutions to long-term unmet and underserved needs for pharma and biotech companies and HCPs around facilitating access to medicines. To that end, we will seek to accelerate our focus on those areas of the Group where we have growing and sustainable competitive advantage and, as we do so, continue to drive revenue and cost synergies.



#### OUR VISION IS ALL ABOUT THE PLATFORM WE HAVE CREATED AND CONTINUE TO DEVELOP

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

Access to medicines is a long-term unmet need for both pharmaceutical and biotech companies and healthcare professionals. A significant proportion of the world's population still don't have access to the medicines they need.

The majority of research and development being done is by smaller companies who need to partner around the world as they don't have the capabilities to manage their medicines globally. Whilst we have focused on growing the amount of pharmaceutical clients that utilise multiple parts of the Clinigen platform there is clearly an opportunity to increase this number. In fact, increasing it by just 5% or 10% could have significant impact on the business.

Pressures on global supply chains and the presence of counterfeit and substandard medicines means pharmaceutical companies and healthcare professionals need a partner they can rely on and that can deliver a quality assured service global solution.

With a platform that now spans over 570 pharmaceutical and biotech clients and thousands of healthcare professionals that have utilised our platform over the past twelve months, we have the ability to embed ourselves between these two stakeholders and maximise the value of these relationships.

## WHAT DO YOU THINK ESG LOOKS LIKE FOR THE INDUSTRY AND HOW ARE YOU ADDRESSING THIS AT CLINIGEN?

The work we do at Clinigen is an important part of our pharmaceutical clients' ESG strategies. For example, helping to facilitate better access to medicines on a global basis is directly aligned with some of the UN sustainable development goals – something we ourselves have signed up to.

Whilst ESG is something we have had to get better at communicating about to our stakeholders, a lot of the key principles have always been core to the business and not necessarily new. Driving a diverse, responsible, thriving culture has been aligned to our values for some years it just has not necessarily been something we have communicated as well as we could.

Our new ESG model helps us better outline our approach to these principles and ensure we have continued and consistent focus on the right areas. For example, a key area of focus for us over the last twenty-four months has been employee engagement and we have worked hard to improve on this through management training and the employee engagement platform. Another area we are focused on is our impact on the environment and we are already taking steps to put together a more global picture so that we can put in place a sensible action plan. Certainly ESG is here to stay and given the global nature and size of the pharmaceutical industry we can make a hugely positive difference if we get it right.

## WHAT ARE THE MAJOR MILESTONES TO LOOK OUT FOR IN 2022? WHAT DOES SUCCESS LOOK LIKE?

FY2021 saw a record number of signings across the Services division, so we are very focused on turning this order book into completed projects. Doing this and doing it well is key in FY2022. Some of the projects secured could also be very large in their own right so we will be looking at how they progress in the first half of the year.

Alongside this, the continued global rollout of Erwinase will, of course, also be very important for the Products division and we will of course be providing updates through the year.

Clearly we are focused on business performance and continuing to reduce our debt levels - we know this will be critical to the market and we are confident we will do so.

#### WHAT IS YOUR FIVE-YEAR VISION FOR CLINIGEN?

A Clinigen is the 'go to' partner for managing niche hospital medicines globally.

Clinigen is the 'go to' digital marketplace for companies needing truly global access for their medicines and for Healthcare Professionals to quickly, easily and safely get the medicines they need.

Complementing the global digital platform, we will have distribution hubs in each major pharmaceutical region in the world.

The platform will continue to support hundreds of thousands of patients around the globe gain access to critical medicines every day.

#### **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

#### 202

Launches Hunterase in Japan and begins roll-out of Erwinase in licenced and unlicenced markets. COVID-19 headwinds impact demand for Proleukin and On-Demand. Divests UK Specials and Aseptic Compounding business As announced in the half year results, from 1 January 2021, the Group structure was simplified, moving from three divisions to two: Services and Products. This change better reflects the alignment of the Group's activities to its end customers: pharmaceutical clients and healthcare professionals.

CAGR GROWTH IN ADJUSTED NET REVENUE

36%

CAGR GROWTH IN ADJUSTED EBITDA

47%

STRATEGY

# WE'RE FOCUSED ON SIX STRATEGIC PILLARS

STRATEGIC OBJECTIVES

CULTIVATE A THRIVING
HIGH PERFORMANCE
CULTURE

2 DRIVE OPERATIONAL EXCELLENCE

LINK TO ESG MODEL







The Groups six strategic pillars are fundamental to everything we do at Clinigen. By linking our day-to-day activities as well as our long term priorities to these six pillars we able to ensure there is a clear and consistent pathway to growth for the business.

The pillars provide clarity for all our stakeholders on the key initiatives across the business, why we are doing them and how success will be measured. They are also linked to our Environmental, Social and Governance approach where key priorities and goals can sit within both the strategic pillars and the ESG framework (as outlined on page 32).

#### **2021 PROGRESS**

- >80% of employees have personal development plans
- 110 individuals completed Management Academy
- >95% of roles advertised internally
- >60 internal promotions during FY2021
- 10% increase on average training spend per employee
- Launched new e-learning program on career development for employees and managers
- Roll-out of job grading framework across Group
- Conducted talent and succession planning review across the Group
- New COO in place to drive operational change

- Successful implementation of Brexit solution
- Conducted global review of supply chain to enable optimisation of current partners and hubs
- Simplification of organisation from three divisions to two divisions to drive synergies
- Expansions of US, EU hubs' deep ultra-cold storage
- Disposal of UK Specials and Aseptic business to ensure operational focus
- Introduced process governance structure
- Introduced Internal Audit and Risk function
- Launch of serialisation in the US

#### LINK TO ESG MODEL



**ENVIRONMENTAL IMPACT** 



PRODUCTS & SERVICES



**OUR PEOPLE** 



**RESPONSIBLE BUSINESS** 

#### PERFORMANCE METRICS

IRMANCE EMPLOYEE ENGAGEMENT

**15** 

**COUNTRIES SHIPPED TO IN LAST 3 YEARS** 

**128**%

#### **2022 OBJECTIVES**

- Roll out of leadership academy for business leaders
- Next cohort for Management Academy
- Development of hybrid working practices
- Continued focus on talent and succession planning
- Embedding of job grading across group
- Launch of CALM wellness app for all employees
- Introduction of flexible benefits platform

- Utilise AI technology to monitor supply chain cost and service levels in real time
- Continue to develop synergies between Divisions and Businesses through development and integration to drive value for clients and customers

PARTNER WITH CLIENTS TO DELIVER SYNFRGISTIC VALUE

LEAD THE MARKET IN CUSTOMER EXPERIENCE

5 ENHANCE THE PORTFOLIO OF ASSETS, SERVICES AND TERRITORIES

REALISE COMPETITIVE ADVANTAGE THROUGH TECHNOLOGY



















- Increase in clients utilising more than one part of the platform
- 10 successful crossdivisional referrals to drive value for existing clients
- Increased total number of clients that have utilised Clinigen platform over last 12 months
- Initiation of Erwinase roll-out ahead of schedule
- Launch of Hunterase in Japan
- Held first 'Love Your Pharmacist' Awards' to the recognise work done by HCPs
- Customer workshops to inform direction of e-commerce platform
- Pivoted focus to provide multiple COVID-19 solutions for pharma clients and HCPs
- Highest number of Managed Access Programs added to portfolio than ever before
- Record number and value of business wins in Clinical packaging and logistics
- Strong growth in number of Partnered products being managed
- Roll-out of Patient Fellowship to change behaviours in early access
- Opening of Malaysia office to strengthen presence in Asia

NUMBER OF PRODUCTS UNDER AGREEMENT

- Implementation of new CRM platform to support BD activities
- Beta release of Clinigen Direct delivered
- First full Clinigen Direct service release
- Continued enhancements of ClinigenOne ERP platform

NUMBER OF CLIENTS UTILISING MORE THAN ONE PART OF LIFECYCLE PLATFORM

43

% REPEAT CUSTOMERS

80<sub>+\*</sub>

(MAP AND PARTNERED)

346

NUMBER OF HCP USERS IN CLINIPORT

25,127

 More than 80% customers order more than once

- Pipeline of 15 additional companies that are at proposal stage for utilising more than one part of the Clinigen platform
- Further focus on securing Partnering deals with existing Services clients
- Driving cross divisional referrals and Group client approaches
- Customer loyalty and satisfaction benchmarking
- Process excellence in OTIF
   Utilise MSL network to educate specialist prescribers
- Continued enhancement of client services team across Services division to deliver on existing and new business
- Expansion into China and Korea through business partnership or 'go alone' strategies
- Further roll-out of Developed products and SKUs
- Roll-out of Erwinase into additional licenced markets including the USA
- Further portfolio growth across Managed Access and Partnered
- Roll-out of Clinigen Direct into key markets
- Enhanced data platform and insight tools to provide deeper customer insights
- Transition Managed Access clients and HCPs onto Clinigen Direct
- Further CRM roll-out to global business

#### **ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE**

# WE'RE CREATING A MODEL FOR THE FUTURE

Clinigen is dedicated to solving an increasingly global healthcare problem – ensuring patients around the world have access to the critical medicines they need. Our mission to deliver the Right Medicine, to the Right Patient, at the Right Time is at the heart of everything we do. This mission gives Clinigen a clear purpose – to ultimately improve health outcomes and improve the lives of patients accessing our medicines whilst also delivering greater value and sustainability to our stakeholders.

Our business operates to the highest standards of governance and compliance. We recognise the value of having a clear purpose supported by a strong culture of ethics, quality and patient safety. We are responsible, transparent and focused on making a positive impact across our value chain, the environment and society.

As a global leader in ethical access to medicines there is an increasing expectation amongst our stakeholders that we contribute, measure and communicate the impact our strategy has on a range of sustainability issues.

This year Clinigen conducted a full review of how our strategy aligns to stakeholder values to ensure that our business model, objectives and growth plans are clearly aligned to the sustainability agenda.

#### **OUR JOURNEY SO FAR**

The Environmental, Social and Governance ('ESG') agenda over the past 12 months has significantly gathered pace. We have used this time to gather, understand and formulate our sustainability framework, approach and commitments.

This journey started by consulting with various internal and external stakeholders to understand what the key elements a successful ESG model would need to incorporate.

The Group then signed up to the United Nations Global Compact ('UNGC') and UN Sustainable Development Goals ('SDGs') and formalised our commitment to sustainability. Moving forward the Clinigen will more formally incorporate the Ten Principles of the UNGC into our strategies, policies and procedures in the future.

The Group then conducted its first materiality assessment – something that will now be carried out every year. The process helped identify the economic, social and environmental issues that matter most to our business and our stakeholders.

Conducting a thorough assessment in this way not only helps in identifying issues to be covered in our reporting and disclosures but also helps us to decide where to prioritise our resources. The assessment also feeds directly into our enterprise risk management framework and established risk governance framework.

The assessment identified 30 issues of material importance. The issues identified were placed on a matrix, their position relative to the degree of stakeholder importance and potential business impact. These results represent the material issues facing our business, with us focusing most on those categorised and having significant impact on our business and also significant importance to our stakeholders. The outcomes were used to help drive sustainability plans and targets and ultimately inform the ESG model we have built.

#### WHAT WE'VE DONE SO FAR

Consulted with 20+ investors to gauge views on approaches to ESG and importance

Consulted with the business and external firms

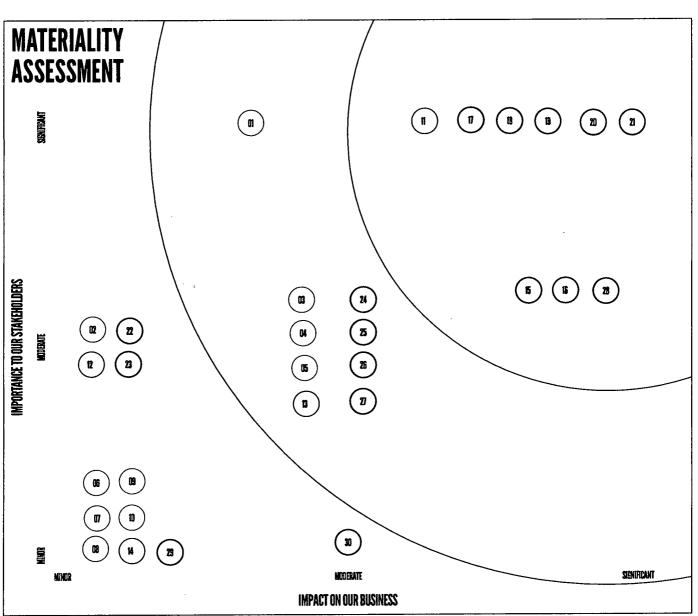
Signed up to UN Sustainable Development Goals and Valuable 500

Conducted materiality assessment to highlight areas of focus

Compiled key data points to be tracked

Created model to guide how we approach ESG within Clinique

Created website content for sustainability and approach



#### **ASSESSING MATERIALITY**

The ongoing review of our approach to ESG issues is in line with the principle of materiality, as described in the Global Reporting Initiative ('GRI') Standards, and with reference to the materiality considerations set out in the Sustainability Accounting Standards Board ('SASB') Standards.

We assess the strategic relevance of ESG factors via two lenses: their relative importance to external stakeholders, and their potential impact on our business success. This helps us to prioritise and govern our activity, ensuring that we are closely aligned with our stakeholders' expectations.

#### **OUR SUSTAINABILITY PILLARS**

#### **O ENVIRONMENT**

- 01. Fuel Fleet Management
- 02. Waste Management
- 03. Carbon Emissions
- 04. Energy Efficiency/ Usage
- 05. Climate Action Failure
- 06. Biodiversity Loss
- 07. Human Environmental Damage
- 08. Major Geographical Disasters
- 09. Natural Resource Crisis
- 10. Extreme Weather Events

#### PRODUCTS & SERVICES

- 11. Access to Medicines (Healthcare)
- 12. Affordability & Pricing
- 13. Product Lifecycle Management
- 14. Infectious Diseases

#### **OUR PEOPLE**

- Employee Recruitment, Development & Retention
- 16. Healthy, Safe & Happy Workforce

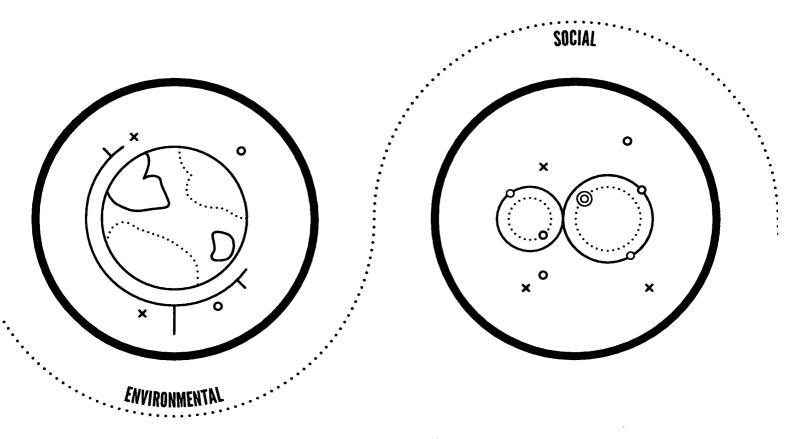
#### O RESPONSIBLE BUSINESS

- 17. Drug Safety
- 18. Counterfeit Drugs
- 19. Product Safety
- 20. Supply Chain Management
- 21. Data Privacy/Cyber Security
- 22. Patient Privacy & Electronic Health Records
- 23. Economic Contribution
- 24. Ethical Marketing
- 25. Taxation & Compliance
- 26. Human Rights
- 27. Gender Equality
- 28. Business Ethics Healthcare Fraud and Abuse
- Contributing to our Communities
- 30. Safety of Clinical Trial Participants

#### ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE CONTINUED

#### **OUR MODEL & COMMITMENTS**

Clinigen's sustainability model contains four key pillars that will be used to guide, embed and communicate our approach to the ESG framework. Through the model the Group is making 17 key commitments that align to seven of the UN Sustainable Development Goals (UN SDGs) where we can make most contribution. Through each pillar there are data points that will be captured and reported on through the sustainability framework.



#### **ENVIRONMENTAL IMPACT**

#### Minimise any negative impact we have on the environment.

- Minimising our impact on the environment
- Compliance with environmental laws and regulations
- Responsible consumption and production
- Combating climate change

SDGs

#### **PRODUCTS & SERVICES**

SD&s

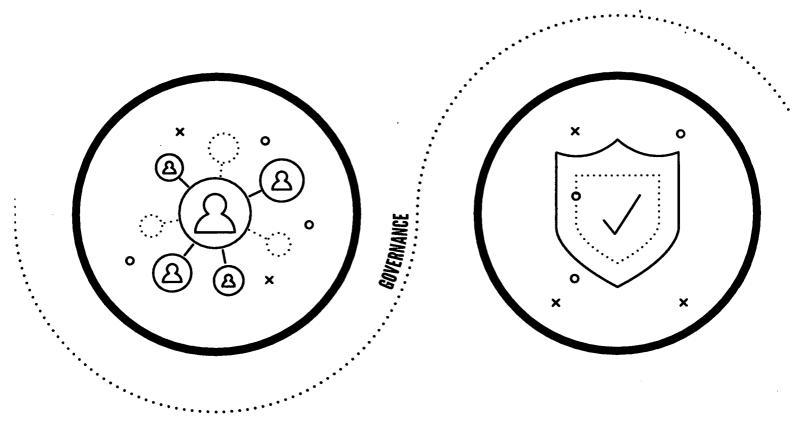
Enabling better health by maximising global access to important medicines.

- Broader access to approved medicines
- Quicker access to new medicines
- More access in developing countries
- Patient-focused solutions

4 KEY PILLARS

**17** KEY COMMITMENTS

UN SUSTAINABLE Development goals



### **OUR PEOPLE**

Making sure our people are happy and thriving will help us achieve our ambitions.

- Attract, retain and develop our people
- Promoting greater diversity, inclusions and quality
- Supporting our employees to be healthy
- Engaging with our workforce

### RESPONSIBLE BUSINESS

Conduct business in a responsible way and to the highest ethical standards.

- Safe production and supply of products and services
- Ethical supply chain
- Zero tolerance towards bribery, corruption and fraud
- Robust data governance and compliance
- Upholding external standards to protect human rights

9

### ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE CONTINUED

### **ENVIRONMENTAL IMPACT**

CO2e TONNES

**254**.6

2020: 681

Minimise any negative impact we have on the environment.

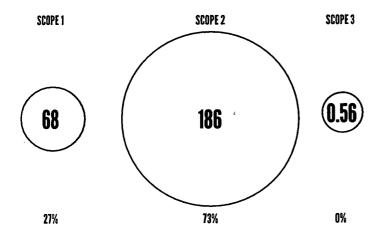
### **ENERGY AND CARBON REPORTING**

Clinigen have continued to capture UK emissions as required by the SECR regulations that came into play on 1 April 2019. 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 2021. 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 below.

There has been a total of 254.6 tonnes of CO2e emitted during FY2021 which compares to 681 tonnes for the prior financial year. However, this will largely be driven by the fact that a large proportion of the workforce has been home working. The intensity measure variable that the Group has used is total carbon dioxide equivalent emissions (tonnes) per £m of turnover. 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 have improved. The result for the year ending 30 June 2021 is an intensity ratio of 0.49 tonnes of CO₂e per £m of turnover (FY2020: 1.49 tonnes).

During FY2022 Clinigen have set ourselves the goal of capturing and reporting global emissions and wastage data which will be reported in FY2022 results. This data will be used to set global environmental objectives and initiatives. In FY2022 we will also be reporting utilising the TCFD disclosure. Clinigen have also completed a CDP disclosure as well as registered on EcoVardis, both of which giver greater transparency to all our stakeholders on the impact we have on the environment and the measures put in place to reduce that impact.

During the year Clinigen put in place a number of initiatives to reduce our impact on the environment such as converting to reusable plastic totes across some of our US hubs and in April 2021 we announced the launch of our Foscavir Infusion Bags in the USA. The launch of an IV bag presentation, which replaced glass vials, will result in lighter weight transportation and ultimately a reduced carbon footprint during transportation. We also continue to promote recycling and waste disposal throughout the Group through education and audit through our Environmental Management System.



YEAR ENDED 30 JUNE	SSOR	SCAPE 2	SCOPE 3	TUTAL
Tonnes of CO₂e	68	186.07	0.56	254.6
Percentage	26.69	73.09	0.22	100%

### **PRODUCTS & SERVICES**

1.400+

Enabling better health by maximising access to important medicines.

Clinigen exists to provide quicker and broader access to critical medicines around the world. In the last three years Clinigen have provided access to medicines into 128 countries around the globe, 66 of which were developing countries and a further 12 transitioning countries where there are challenges in gaining access to critical medicines.

Clinigen currently provide access to more than 1,400 medicines through our Managed Access, Partnered and On-Demand channels. We also support access of medicines into hundreds of pharma led and physician led clinical trials through the clinical services function, meaning the portfolio of medicines we provide enables access for patients in clinical studies, unlicensed markets and licensed markets.

Clinigen also work with closely with our pharma partners to provide solutions that enable them to fulfil their ESG goals of providing broader access to their medicines. In the last 12 months we have partnered with 577 pharma and biotech companies to facilitate better access to medicines.

Clinigen currently have more than 25,000 healthcare professionals registered as users on our online platform Cliniport, of which more than 6,000 where added in the past 12 months.

### PATIENT FOCUSED

It is vital that the solutions we provide put the patients' needs first and so throughout the year we have remained focused on patientcentric solutions and offerings.

We continue to provide Direct-to-Patient services through our clinical services and in 2021 we also joined the Decentralised Trials and Research Alliance ('DTRA'). The DTRA consists of an alliance of life sciences and healthcare companies that seeks to accelerate the broad adoption of patient-focused. decentralised clinical trials and research.

It is estimated that clinical trials may be set back by several years in the context of COVID-19, due to prospective patients' inability or reluctance to schedule visits at physical research locations. Decentralized approaches to conducting research facilitate participation by a more diverse patient population and could ease COVID-19-imposed difficulties for both patients and clinical investigators.

In FY2021 the Group also rolled out the Patient Advocate Fellowship in early access, an initiative aimed at equipping patient groups and their leadership with the skills and experience they need to engage meaningfully within early access (pages 16-17).

**COUNTRIES SUPPLIED** 





**DEVELOPING COUNTRIES\*** 





### **ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE CONTINUED**

### **OUR PEOPLE**

Making sure our people are happy and thriving will help us achieve our ambitions.

### PEOPLE DEVELOPMENT

During FY2021 the Group has continued to focus on the development of its talent and has seen a 10% increase on average training spend per employee. As part of that training a further 110 people complete the Clinigen Management Academy.

The Academy is a six month-long development program and is aimed at provider leadership and management skills to current and future team leaders. In FY2021 we opened the Academy up to more of the global locations and had graduates from more than six countries.

### **MANAGEMENT ACADEMY GRADUATES**

110

INTERNAL PROMOTIONS

60+

### MENTAL HEALTH AND WELL BEING

During FY2021 Clinigen ran mental health awareness training for managers so they are able to spot mental health issues within their team and guide them to appropriate resources. This has been particularly important given COVID-19 and the isolation some people feel from remote working conditions.

In FY2022 we intend to launch CALM across the Group which is a mental health and wellness app.

### **DIVERSITY**

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.

We have conducted an analysis around age groups employed across the Group and can report that our workforce is balanced and in line with general age/working population distribution. Clinigen currently have 17% aged 20-29, 32% aged 30-39, 25% aged 40-49, 18% aged 50-59 and 8% aged 60+.

### **BOARD GENDER DIVERSITY**

### SENIOR MANAGEMENT TEAM GENDER DIVERSITY

### **GROUP EMPLOYEES**

One route through which we help to ensure continued diversity is through the Management Academy where one-module is largely dedicated to unconscious bias to help managers learn how to make fair and equitable decisions when recruiting, hiring, promoting and giving opportunities to team members.

In FY2021 Clinigen joined Valuable 500, a global campaign to unlock the value of 1.3 billion people living with disabilities around the world. As part of that initiative we will:

- Review our Diversity and Inclusion policies to ensure we commit to driving an inclusive and accessible workplace for all
- Ensure our recruitment and selection processes are inclusive and accessible for all
- Provide frequent reporting to the Executive and Management Team on initiatives supporting a more inclusive workplace
- Deliver targeted training for our people managers to build a culture of inclusivity from the top down

### **GENDER RATIO AND PAY**

Out of the 1,069 employees, 58% are female and 42% male. 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. The Group also publishes a gender pay gap report each year. Based on the data we know that gender is not a factor in setting the rate of pay at Clinigen (in the UK). The report showed that our UK median gender pay gap is 9.5% below the national average of 15.3%. We have also conducted preliminary calculations into a global metric and can confirm it doesn't show any signs of gender being a factor in setting pay at Clinigen at a Group level.

From April 2019 – April 2020 62% of internal promotions were for female employees and in FY2021 59% of Management Academy participants were female.

### **CLINIGEN WAY**

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. They are: Make a difference; Show mutual respect; Nurture success; Put best interests first, Maintain integrity; and Measure progress. They reflect the Group's rich and varied historic businesses and the common purpose employees all share today.

### **EMPLOYEE ENGAGEMENT**

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 senior management team. The strategic objectives of the Group are communicated to employees through regular updates and, this year, that included at virtual all-staff conferences.

In the last 12 months we have continued to use Peakon feedback to drive 'You Spoke, We Listened' action planning, with a particular focus on career paths, support and development. The external platform ensures anonymity and empowers management to take prompt and informed action.

Clinigen continues to measure employee engagement and in FY2021 achieved a score of 7.5, which is the same as FY2020 and above industry standard.

### **EMPLOYEE ENGAGEMENT**

**7.**5

### ENVIRONMENTAL, SOCIAL AND CORPORATE GOVERNANCE CONTINUED

### **RESPONSIBLE BUSINESS**

Conduct business in a responsible way and to the highest ethical standards.

### **REGULATORY INSPECTIONS OF CLINIGEN**

7

AVERAGE CRITICAL FINDINGS
PER AUDIT OF CLINICEN

0.02

### PRODUCT RECALLS OF OWNED PRODUCTS

0

### PRODUCT QUALITY AND PATIENT SAFETY

Ensuring the quality of the medicines we deliver is of the utmost importance. The supply of our products and services is becoming ever more complex, and, with the significant regulatory changes taking place across the industry, the expectations of a specialist service provider in terms of technical and project management capabilities are increasingly demanding.

We use our Quality Policy and Quality Management System (QMS) to meet the requirements of our clients and customers in conformance with the Company's Quality Specifications and current legal and regulatory requirements.

Our quality system is underpinned by our holding manufacturer/ wholesaler/distributor licences around the world, including in the EU, UK, US and Asia-Pacific regions. All of our sites are audited regularly, by a combination of regulators and our pharmaceutical company clients we see this as a core part of doing business and are very proud of our ability to complete them successfully. In FY2021 there were 114 audits of Clinigen, with an average of 0.02 critical findings per audit. There were also zero product recalls of Clinigen 'Owned' products.

### SUPPLY CHAIN, QUALITY ASSURANCE, ETHICS

In 2021, we took steps to further strengthen our approach through the introduction of a new Supplier Code of Conduct. This new code will sit alongside the existing Quality Supplier Terms & Conditions (QTC) document which set out in detail our T&Cs in line with our QMS and compliance with key regulators such as the MHRA.

Clinigen works in a highly regulated industry, and the requirements for qualifying suppliers are well defined within legislation.

For example, EU Good Distribution Practice requires Clinigen to obtain their supplies of medicinal products only from persons who are themselves in possession of a wholesale distribution authorisation, or who are in possession of a manufacturing authorisation which covers the product in question and are required to verify that the supplier complies with the principles and guidelines of good distribution practices.

In FY2021 Clinigen performed 49 audits/inspections of it suppliers and partners.

The Group fully supports the aims of the Modern Slavery Act 2015 to eradicate human slavery and trafficking. We support the UN Guiding Principles on Business and Human Rights and are committed to upholding and respecting human rights both within our business and in that of our third parties.

In FY2021 Clinigen rolled out a new Human Rights Policy which was approved by the Board in April 2021. We also require all of our suppliers to confirm compliance with our Supplier Code of Conduct which equally sets out the Group's expectations regarding Human Rights.

We also developed a new 'Speak up' Policy which provides a formal route for employees to confidentially speak up about any concern they have at work that they feel is important.

### COMPLIANCE

In FY2021 a new Internal Audit and Risk function was established, with the appointment of a new Group Head of Internal Audit and Risk who is supported by an external firm to provide additional capacity and expertise.

The Internal Audit remit includes monitoring and assessing the robustness of our Ethics and Compliance activities, including the Anti-Bribery and Corruption ('ABAC') Policy and program, with periodic reporting to the Audit and Risk Committee.

During FY2022, further work will be completed to strengthen our approach to fraud prevention and detection. This includes conducting a Fraud Risk. Assessment and monitoring our Ethics and Compliance programs through the internal control framework and activities of Internal Audit.

### WHAT NEXT

The last 12 months have been a critical milestone in our ESG journey as we developed and rolled out a clear ESG framework.

During FY2022 we will be tracking 29 different data points that we believe are key indicators for progress against our ESG principles and objectives. This will give us a true benchmark as to where we sit across these measures, enabling clear goals and targets to be set in FY2023 and beyond.

We have set out a clear ownership structure (see below) to ensure ESG is fully embedded throughout the Group and progress communicated regularly to all stakeholders.

We are proud of what we have achieved in the last 12 months and look forward to developing further in our approach to ESG.

### FY2021: FRAMEWORK

Create framework for ESG and embed into business

### FY2022: MEASURE & REPORT

Measure key data points and communicate ESG principles and progress to key stakeholders

### FY2023: IMPROVE

Set realistic targets to drive up ESG rating. Build on data points where needed

### OWNERSHIP

BOARD OWNER

- Approves ESG strategy
- Overall responsibility for monitoring sustainability performance and approach

EXEC Sponsor

- Supports Board in communicating tone regarding sustainability approach
- Monitors and reports progress to Board through KPIs

STEERING COMMITTEE

- Responsible for operationalising sustainability framework
- Develops policies, targets and initiatives
- Captures progress against KPIs

OUR People

- Individual accountability for specific sustainability topics
- Engaged to drive Group-wide objectives
- Identify, manage and mitigate sustainability risks

ASSURANCE AND COMPLIANCE OVER ESG FRAMEWORK

- Individual accountability for specific sustainability topics
- Engaged to drive Group-wide objectives
- Identify, manage and mitigate sustainability risks

**ESG RATING BY MSCI IN 2021** 

A

SUSTAINALYTICS ESG RATING

**MEDIUM** 

### **KEY PERFORMANCE INDICATORS**

Our performance is measured against a number of KPIs.

**FINANCIAL** 

ADJUSTED NET REVENUE (£M)

**458.6** ^7%

ADJUSTED EBITDA (£M)

116.3 ~10%

Why we measure it: Adjusted net revenue is viewed by the Board as the preferred measure of top-line 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 from continuing operations increased by 7% (13% on an organic basis), driven by increased volume and profit mix in the Services division.

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 from continuing operations decreased by 10% (-5% on an organic basis) to £116.3m (2020: £129.8m) reflecting the impact of COVID-19 and a change in gross profit mix partially offset by good cost control.

**ADJUSTED BASIC EPS (PENCE)** 

**55.9**  $^{14}$ 

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 from continuing operations was down 14% as a result of the decline in adjusted EBITDA and increased amortisation and depreciation costs.

### NON-FINANCIAL

COMMUNITY OF REGISTERED USERS ON CLINIPORT

**25,127** ~35%

NUMBER OF PRODUCTS UNDER AGREEMENT (MAP & PARTNERED)

346

**^19**%

### STRATEGIC LINK: 6

Why we measure it: Measures the progress made in building a community of HCP customers.

**Performance:** There has been continued growth in the total HCP users registered on Cliniport. This will be partly driven by new products within the portfolio as well as regional customer development.

### STRATEGIC LINK: 5

Why we measure it: Measures the quantity of managed access and partnering agreements with pharma clients, demonstrating the business's potential for future growth.

**Performance:** There have been a 19% increase in products within managed access and partnered. This is driven by a net gain of thirty new Managed Access Programs and a net gain of 27 partnered products.

### NUMBER OF CLIENTS UTILISING MORE THAN ONE PART OF LIFECYCLE PLATFORM

43

Λf

### **KEY TO STRATEGIC OBJECTIVES**

- Cultivate a thriving high performance culture
- 2 Drive operational excellence
- 3 Partner with clients to deliver synergistic value
- 4 Lead the market in customer experience
- **5** Enhance portfolio of assets, services and territories
- Realise competitive advantage through technology

### STRATEGIC LINK: 3

Why we measure it: Measures how many clients utilise multiple parts of the lifecycle platform within a 12 month period-driving greater value and strengthening the relationship.

**Performance:** Increase of six partly driven by ten successful cross-divisional referrals.

**OPERATING REVIEW** 

### **SERVICES**

## WE'RE PROVIDING HIGH VALUE SERVICES

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

**Clinical:** Provision of innovative logistics, packaging, distribution and biorepository solutions alongside global sourcing and supply of comparator medicines, ancillaries and devices for use in clinical studies to both industry and investigator led researchers.

Managed Access: Design and implementation of global Managed Access Programs ('MAPs') – otherwise known as Compassionate Use, Named Patient, Early Access, or Expanded Access) to enable pre-approval access to innovative new medicines for the treatment of unmet medical needs.

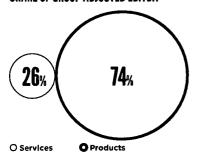
The high number of business wins and delivery against key projects contributed to a 15% increase in net revenue to £218.9m (2020: £190.0m). Due to the profit mix of these wins favouring lower-margin sourcing activity alongside slower than expected uptake on Managed Access Programs, gross profit was flat at £66.6m (2020: £66.9m) and EBITDA declined by 6% to £32.7m (2020: £34.9m). It should be noted that COVID-19 headwinds continued throughout H2 for the Services division with the impact of delayed or cancelled studies and lower uptake on Managed Access Programs due to reduced numbers of patients attending hospitals being felt.

The outlook for Services is positive with a continued strong pipeline and a good number of new high value projects to deliver revenues in FY2022. There are currently more than 350 opportunities across the pipeline with a combined value of more than £80m.

### **NET REVENUE YEAR ENDED 30 JUNE**

			EROWTH	
	2021 Sm	2028 £#	REPORTED	CREANIC
Clinical	191.3	162.2	18%	
Managed Access	27.6	27.8	(1)%	•
Divisional Total	218.9	190.0	15%	18%
Divisional EBITDA	32.7	34.9	(6)%	(2)%

### SHARE OF GROUP ADJUSTED EBITDA\*



NET REVENUE (£M)

2020: 190.0

**~15**%

ADJUSTED EBITDA (£M)

2020: 34.9

NUMBER OF CLIENTS

**COUNTRIES SHIPPED TO (FY2021)** 

**ADJUSTED NET REVENUE BY PORTFOLIO** 

**ADJUSTED NET REVENUE BY REGION** 

### CLINICAL

Net revenue in the Clinical business grew by 18% to £191.3m (2020: £162.2m), driven by new business wins across both sourcing and logistics offerings, despite a number of trials being cancelled or delayed due to COVID-19. There was a higher weighting of comparator sourcing revenue in these new business wins, which is at a lower margin.

Business wins across both existing and new clients continued with a 19% increase in the number of non-sourcing work orders signed, representing an increase of more than 50% in total lifetime value versus FY2020. It is expected that this will contribute to future growth and offer new opportunities for crossselling across both the Clinical and Managed Access businesses.

During the year the clinical sourcing and non-sourcing (legacy CSM) parts of Clinical were brought together under the same operational teams and branding. This will drive further improvement in service levels and overall competitiveness, ensure our clients have a single Clinigen experience, and enhance cross-selling opportunities. At the year-end there were more than 300 opportunities across the clinical pipeline (2020: 168).

In FY2021 Clinigen signed 34 COVID-19 related clinical projects, bringing the total to 45, including one for vaccine storage, which has allowed the Group to expand its deep freeze storage capacity across European and US facilities. This expansion is expected to position the Group well for future management of niche medicines such as cell and gene therapy.

The Clinical team has also formed a partnership with N-Side, an EU-based innovative software consulting company, to further optimise clinical solutions provided to pharma and biotech companies. The main benefits to pharma clients include waste reduction, risk management, and drug allocation optimisation. In turn, this will deliver better cost control and potentially reduce time-to-market. This is an offering that will be rolled out in FY2022.

### **MANAGED ACCESS**

Net revenue was flat at £27.6m (2020: £27.8m) with the impact of COVID-19 being offset by a record number of MAP wins with a 36% increase versus FY2020 with 25% coming from new clients.

As at 30 June 2021, there were 161 individual product MAPs (2020: 131), including products in the COVID-19 space. Collectively, the top ten MAPs contributed 32% of the Managed Access gross profit (2020: 38%).

There was also continued strong performance in the number of Managed Access Programs that have Real World Data ('RWD') collection, with 30% of new programs including RWD.

On Cliniport, the Group's proprietary online platform for Managed Access, the number of registered HCP users grew strongly to 25,127 (June 2020: 18,625).

The pipeline of Managed Access Programs remains healthy with 44 potential new programs in progress.

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

Throughout the year there continued to be a focus on driving innovation and thought leadership across Managed Access with the launch of the Early Access Fellowship, an initiative aimed at equipping patient groups and their leadership with the skills and experience they need to engage meaningfully within early access.

<sup>%</sup> of adjusted EBITDA is before central unallocated costs.

Results are from continuing operations and comparatives have been re-presented

**OPERATING REVIEW CONTINUED** 

### **PRODUCTS**

## WE'RE ENABLING CRITICAL ACCESS

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

The Products portfolio comprises three distinct strategies:

Owned: Medicines that have been acquired or developed by Clinigen. Clinigen acquires products with the goal to maintain access to those that rely on them and growing access into new markets and disease areas through a targeted product revitalisation strategy. Products developed inhouse were previously supplied in an 'on-demand' form, the Unlicensed to Licensed ('UL2L') strategy.

Partnered: Partner of choice for pharma and biotech to provide access to their medicines in both licensed and unlicensed markets at a country, regional or global level through an exclusive distribution or licensing arrangement.

**On-Demand:** Sourcing and supply of unlicensed and short supply medicines in response to demand for access from healthcare professionals.

There has been promising progress in key areas of the division with an increase in the number of products and net revenue in the Partnered portfolio. The impact of the pandemic has however been more pronounced in the Products division due to the reduced demand for non-COVID-19 products, particularly the global reduction in hospital-based oncology treatments. Net revenue from continuing operations reduced slightly to £248.3m (2020: £250.2m) while adjusted EBITDA fell by 14% to £90.6m (2020: £105.2m). The Owned and On-Demand parts of the division were acutely impacted by the pandemic with net revenue falling by 11% and 18% respectively. Partnered products performed in line with expectations with a high number of business wins.

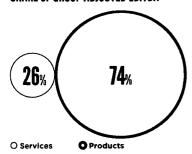
### **OWNED PRODUCTS**

Clinigen has a portfolio of 20 Owned products (7 acquired and 13 developed). Net revenue decreased by 11% to £106.4m (2020: £120.1m) reflecting the continued impact of COVID-19 on hospital admissions, the timing of shipments to key customers and the loss of Ethyol sales due to manufacturing disruption offset by solid growth from the developed products.

### **NET REVENUE YEAR ENDED 30 JUNE**

		2828 ·	ERBWTB	
	2821 SM		REPRITED	ORGANIC
Owned	106.4	120.1	(11)%	
Partnered	94.3	72.1	31%	
On-Demand	47.6	58.0	(18)%	
Divisional Total	248.3	250.2	(1)%	8%
Divisional EBITDA	90.6	105.2	(14)%	(10)%

### SHARE OF GROUP ADJUSTED EBITDA\*



NET REVENUE (£M)

248.3

2020: 250.1

ADJUSTED EBITDA (£M)

90.6

2020: 105.2 **14%** 

NUMBER OF CLIENTS

**72** 

**COUNTRIES SHIPPED TO (FY2021)** 

81

ADJUSTED NET REVENUE BY PORTFOLIO

**ADJUSTED NET REVENUE BY REGION** 

 % of adjusted EBITDA is before central unallocated costs.

Results are from continuing operations and comparatives have been re-presented.

As previously announced, Proleukin was negatively impacted by COVID-19 during the year with a significant reduction in US prescriptions for onlabel indications, resulting in a key order from a US wholesaler not being placed in Q4. Management believes it is prudent to expect this reduced level of demand for Proleukin to remain until revitalisation efforts into new indications alongside novel cell therapies are successful and normal hospital and cancer centre services have resumed.

Net revenue from Foscavir remained resilient despite the approval and launch of two generics. This is, however, expected to have a negative impact on FY2022 growth rates and beyond. During the year the bag formulation was launched in the US which is expected to slow decline and protect some market share along with existing GPO contracts.

Ethyol remained off the market in FY2021 due to manufacturing disruption and further clarity on when this can be resolved will be available in the next 12 months. Totect will be withdrawn from the market in H1 2022 due to the market being well-served, with the product carrying value having been fully impaired in FY2020.

Good progress was made with the Developed portfolio and internal expectations exceeded with net revenue increasing by 31% driven by key products Melatonin and Glycopyrronium Bromide, which also saw their first international launches. Melatonin capsules were launched, representing the first immediate release capsules in the UK market. Melatonin Oral Solution has been submitted for approval across ten other countries utilising the decentralised procedure ('DCP') with further launches across Europe expected in 12-18 months. The DCP procedure was also followed for Glycopyrronium Bromide, with submissions in 14 countries, with commercialisation into seven of these countries expected in H1 2022.

Further diversification of the portfolio is expected over time. Alongside the opportunity for acquisitions there are 10 assets in the development pipeline that could deliver a total of £40m+ in lifetime net revenues.

### **PARTNERED**

Net revenue increased 31% to £94.3m (2020: £72.1m). There has been positive progression with the total number of partnered products (both for licensed and unlicensed markets) rising to 185 (2020: 156). This is driven largely by strong growth in the number of exclusive products being supplied into unlicensed markets. Partnered is seen as a potential key growth driver in the future.

Growth across the AAA region remains strong where a further 16 local licensing deals were signed for both new and existing products during the year, one of the most significant of these was Hunterase (Idursulfasebeta) ICV in Japan which represented the first approval for Hunterase ICV in any country worldwide, providing an important treatment option for patients with the rare enzyme deficiency condition Hunter syndrome.

Onboarding of Erwinase continued with UK commercial launches rolled out and supply already being provided in more than 35 other countries where Erwinase is not currently commercially available. A Biologics Licence Application (BLA) has been submitted in the US by Porton Biopharma and licences have already been received in four European countries with six more expected in H1 FY2022 through the mutual recognition process. There will be further submissions in Europe and beyond during FY2022.

The pipeline across Partnered products remains healthy with more than 69 opportunities for both licensed and unlicensed products.

### ON-DEMAND

Net revenue from continuing operations fell by 18% to £47.6m (2020: £58.0m) as activity was materially impacted by COVID-19 with hospitals prioritising treating patients more directly affected by the pandemic.

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

At the end of the year Clinigen disposed of its non-core UK Specials manufacturing and Aseptic non-core UK Specials Manufacturing and Aseptic Compounding business. The Compounding Business sourced and manufactured specific unlicensed medicines referred to as 'specials' in a range of formulations for supply across the UK market and had been part of the On-Demand part of the business. The divested business contributed net revenue of £38.6m (2020: £37.6m) and adjusted EBITDA of £1.1m (2020: £1.2m).

The On-Demand portfolio remains strong with more than 900 active products available through Clinigen Direct.

FINANCIAL REVIEW

## STRONG OPERATING CASH CONVERSION

THE DIRECTORS ARE PLEASED WITH THE STRONG OPERATING CASH CONVERSION IN THE PERIOD OF 86%.

### RICHARD PALING

Interim Chief Financial Officer and Group Financial Controller 15 September 2021 REPORTED REVENUE (£M)

523.6

2020: 466.7

**~12**%

ADJUSTED GROSS PROFIT (£M)

198.0

2020: 210.0

**6**%

ADJUSTED NET REVENUE (£M)

458.6

2020: 428.6

**^7**%

ADJUSTED EBITDA (£M)

116.3

2020: 129.8

**~10**%

**ADJUSTED EPS (PENCE)** 

55.9

2020: 65.3

**~14**%

**REPORTED EPS (PENCE)** 

29.8

2020: 10.8

**^174**%

PROFIT BEFORE INCOME TAX (£M)

51.8

2020: 23.2

**~123**%

**FULL YEAR DIVIDEND (PENCE)** 

7.61

2020: 7.61

0%

NET DEBT (£M)

335.8

2020: 311.9

**~8**%

Given the significant headwinds experienced as a result of the COVID-19 pandemic, Clinigen has seen a reduction in profitability compared with the prior year. In spite of this, the business has demonstrated its ability to meet its challenges head on with a number of significant new wins, particularly within Services, and was successful in bringing forward the first sales of its new in-licensed product Erwinase.

Strong cash conversion remains a key objective and the Directors are pleased with the Group's operating cash conversion of 86% in spite of a significant investment in working capital from the earlier than expected onboarding of Erwinase. The strong operating cash flow in the period meant that net debt only rose by £28.5m to £316.9m (ex-IFRS 16) in spite of making the final deferred payment for CSM (£67.9m) in September 2020. Following this payment, Group free cash flows can be prioritised on organic growth and debt paydown, with the Board remaining committed to achieving a leverage ratio below 2.0x and which it expects to achieve within FY2023

Overall, net revenue from continuing operations increased by 7% (13% on an organic basis) to £458.6m (2020: £428.6m) whilst gross profit fell by 6% (-3% on an organic basis) to £198.0m (2020: £210.0m).

### SUMMARY ADJUSTED INCOME STATEMENT

	·		ERRATI	
YEAR ENDED SO ITHE ADJUSTED RESULTS'	2021 SM	2020 SM	LEPINTED	HEANIC
Gross revenue	523.6	466.7	12%	17%
Net revenue <sup>2</sup>	458.6	428.6	7%	13%
Gross profit	198.0	210.0	(6)%	(3)%
Administrative expenses	(81.8)	(80.8)	(1)%	
EBITDA from joint venture	0.1	0.6	(81)%	
EBITDA <sup>3</sup>	116.3	129.8	(10)%	(5)%
EBITDA <sup>3</sup> as % of net revenue	25%	30%	(490)bps	
Depreciation and amortisation	(15.7)	(10.4)		
EBIT	100.6	119.4	(16)%	
Finance cost	(8.3)	(11.3)	•••••••••••	••••••
Profit before tax	92.3	108.1	(15)%	
Basic EPS	55.9p	65.3p	(14)%	
Dividend per share	7.61p	7.61p	0%	

- 1. The summary adjusted income statement presents Group results from continuing operations on an adjusted basis excluding amortisation of acquired intangibles and products, and other non-underlying items (see notes 3 and 4 of the condensed financial statements). Adjusted measures are presented as they allow a more effective year-on-year comparison and identification of core business trends by removing the impact of items occurring either outside the normal course of operations or as a result of intermittent activities such as business combinations and restructuring. The principles to identify adjusting items have been applied to the current and prior year comparative numbers on a considerate basic.
- Adjusted net revenue excludes Managed Access pass through revenue which varies each period dependent on the mix of programs.
- 3. Adjusted EBITDA includes the Group's share of EBITDA from its joint venture.
  4. Organic growth is a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions and disposals. There were no acquisitions within the last 12 months of the reporting date and one disposal relating to the UK Compounding Business. Constant currency is derived by applying the prior year's actual exchange rate to this year's result. Organic growth is presented to aid the reader's understanding of the underlying performance of the business.

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 disposals, one off restructuring costs and impairment charges which are explained in note 7 of the consolidated financial statements.

### **PROFITABILITY**

As announced in the half year results, from 1 January 2021, the Group structure was simplified, moving from three divisions to two: Services and Products. This change better reflects the alignment of the Group's activities to its end customers: pharmaceutical clients and healthcare professionals.

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

### **ADJUSTED EBITDA BY BUSINESS FROM CONTINUING OPERATIONS**

			CROWTH	
YEAR ENDED SOUNIE	2021 SM	2020 112	LEPORTED	SINASSS
Services	32.7	34.9	(6)%	(2)%
Products	90.6	105.2	(14)%	(10)%
Central unallocated costs	(7.0)	(10.3)	32%	40%
	116.3	129.8	(10)%	(5)%

Adjusted EBITDA from continuing operations decreased by 10% (5% on an organic basis) to £116.3m (2020: £129.8m) reflecting the impact of COVID-19 and a change in gross profit mix within Services, partially offset by good cost control.

The Products divisional adjusted EBITDA reduced by 14% to £90.6m due to the reduction in demand for in-hospital critical medicines as a direct impact of COVID 19 along with headwinds from Foscavir generics launching during the year and Ethyol manufacturing disruption. This was offset by strong growth in partnered products which includes the onboarding and roll-out of Erwinase and better than expected growth in revenue from the developed portfolio.

Adjusted EBITDA in the Services division declined by 6% to £32.7m as a result of COVID-19 headwinds throughout the year with the impact of a delayed or cancelled studies and lower uptake on Managed Access Programs due to reduced patient numbers, partly offset by strong growth in clinical sourcing activity.

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

The table on the following page shows the reconciling items between the adjusted profit before tax of £92.3m (2020: £108.1m) and the statutory reported profit before tax from continuing operations of £51.8m (2020: £23.2m).

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 £0.1m (2020: £0.3m).

### FINANCIAL REVIEW CONTINUED

YEAR ENDED 30 JUNE	2821 £M	2020 £0
Adjusted profit before tax	92.3	108.1
Amortisation of acquired intangibles and products	(41.9)	(44.3)
Acquisition costs	(0.1)	(0.5)
Restructuring costs	(1.9)	(2.9)
Decrease/(increase) in the fair value of contingent consideration	5.9	(11.8)
Impairment of assets related to acquired products	(2.7)	(9.1)
Impairment of investment in joint venture	-	(5.9)
FX revaluation on contingent consideration	1.6	(2.0)
Unwind of discount on deferred and contingent consideration	(1.3)	(8.1)
Tax on joint venture in South Africa	(0.1)	(0.3)
Total adjustments	(40.5)	(84.9)
Reported profit before tax	51.8	23.2

Total amortisation from continuing operations was £51.1m (2020: £48.9m), of which £25.2m (2020: £29.3m) related to acquired intangibles, £16.7m (2020: £15.0m) related to acquired product licences, £8.3m (2020: £4.1m) related to software and £0.9m (2020: £0.5m) related to internally developed product licences.

Based on the latest forecast for the earn-out period, the fair value of the contingent consideration payable on the iQone acquisition has decreased by £5.9m. In the prior year an £11.8m charge was recognised as a result of an increase in the fair value of the contingent consideration payable on the CSM acquisition.

Restructuring costs relating to continuing operations were £1.9m (2020: £2.9m), in respect of redundancies as well as preparations for Brexit in the first half of the year.

There was a £1.6m foreign exchange credit (2020: £2.0m charge) from the revaluation of the contingent consideration on iQone (and CSM in the prior year) which is denominated in foreign currency.

### **CASH FLOW PERFORMANCE (£M)**

### FINANCE COST

The adjusted finance cost from continuing operations was £8.0m (2020: £11.3m) with the decrease due to a foreign exchange credit on the revaluation of the Group's borrowings. The average interest charge on gross debt, excluding the impact of IFRS 16, was 2.4% (2020: 2.6%). The reported finance cost from continuing operations was £9.4m (2020: £19.6m), after taking account of the non-cash £1.3m unwind of discount on the contingent consideration relating to acquisitions (2020: £8.1m).

### **TAXATION**

Taxation from continuing operations was £12.1m (2020: £9.0m), based primarily on the prevailing UK and overseas tax rates. This charge is calculated as £17.9m based on the adjusted profit before tax of £92.3m, offset by a credit of £5.8m in respect of the adjusted items. The Group's adjusted effective tax rate ('ETR') was 19.4% (2020: 19.8%).

### DIVESTMENT OF THE UK COMPOUNDING BUSINESS

On 30 June 2021 the Group completed the divestment of its non-core UK Specials Manufacturing and Aseptic Compounding business for an initial £5m with up to £2.75m deferred and contingent consideration. A loss on disposal of £8.3m is recognised within discontinued activities. Further information is provided in note 30 of the consolidated financial statements.

### FPS

Adjusted basic EPS from continuing operations, calculated excluding amortisation of acquired intangibles and products, and other non-underlying items, reduced by 14% to 55.9p (2020: 65.3p).Reported basic EPS from continuing operations increased by 178% to 29.8p (2020: 10.8p) primarily due to the reduction in non-underlying charges from contingent consideration payments and impairments recognised in the prior year.

### DIVIDEND

The Directors are proposing to maintain the final dividend at 5.46p per share (2020: 5.46p), resulting in a full year dividend of 7.61p per share (2020: 7.61p).

The final dividend will be paid, subject to shareholder approval, on 4 January 2022 to shareholders on the register on 3 December 2021.

### **CASH FLOW**

Adjusted operating cash flow for the year from continuing operations was £99.9m (2020: £93.9m), with the increase on prior year being in spite of a £15m increase in working capital from the onboarding of Erwinase. This represents an operating cash conversion from adjusted EBITDA of 86%.

Capital expenditure was £28.3m (2020: £22.7m), which includes £8.8m related to warehouse, IT and other infrastructure investments, £8.3m related to ongoing investment in the Group's digital strategy, and £11.2m on product development. Capital expenditure in FY2022 is expected to remain at a similar level with continued spend on digital, new product development and infrastructure improvements to increase capacity.

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

The other main cash outflows from continuing operations were tax paid of £15.6m (2020: £23.9m), interest paid of £10.6m (2020: £10.2m) and dividends paid of £10.1m (2020: £9.2m).

Total cash inflows from discontinued operations were £3.8m (2020: £0.2m).

### **USES OF CASH FLOW**

	EI .
Deferred consideration payments	69.7
Capex	28.9
Dividend	10.1
Restructuring costs	4.6
Total	113.3
Financed by:	
Free cash flow	83.0
Business disposal	3.1
Increase in net debt	27.2
Total	113.3

### TREASURY MANAGEMENT AND NET DEBT

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

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). As at 30 June 2021, interest cover was 10.0x and the net debt/adjusted EBITDA leverage was 2.8x. The Group has no history of default on its borrowings, including against its covenant terms. The leverage ratio is expected to fall below 2.0x target range during FY2023.

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. At 30 June 2021, the facility was denominated in £263m sterling (2020: £264m), €99m euros (2020: €90m), and US\$69m US dollars (2020: US\$108m).

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

A £26.2m (2020: £4.0m credit) charge was recognised during the year in respect of currency translation differences within other comprehensive income, arising from the impact of the strengthening of sterling on the translation of the Group's net investment in overseas entities.

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

### **CURRENT TRADING AND OUTLOOK**

In FY2022 we expect strong cash generation, driven by the strength of our underlying business and robust activity levels across the Group, and remain focused on debt paydown. We now expect EBITDA growth of 5% to 10% due to lower than anticipated sales of Erwinase in H1.

In Services, business wins secured in FY2021 are being integrated as expected, the pipeline is strong with a number of new high value projects already underway. As we refine our strategy our Services business is positioned to become a focal growth area for Clinigen in the future.

In Products, specific risks remain from COVID-19, as demand remains subdued for some products but has not worsened. There is continued momentum across the Developed portfolio and Partnering deals signed in FY2021 are contributing to growth alongside the anticipated further roll-out of Erwinase.

The long-term fundamentals of the business and its endmarkets remain strong despite the near-term uncertainty created by COVID-19, and we are confident that we will deliver long-term value.

### **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. If the current exchange rates are assumed to apply throughout FY2O22, the Group estimates it would have a 1% – 2% negative impact on adjusted EBITDA. Current spot exchange rates to sterling as at 15 September 2O21 are USD: 1.38, EUR: 1.17, ZAR: 19.77, and AUD: 1.89.

### 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 pay down and maintain net debt within a range of 1.0x to 2.0x EBITDA on an ordinary basis
- Make acquisitions in line with the Group's strategy with a disciplined approach to valuation

### PRINCIPAL RISKS FACING THE BUSINESS

Clinigen operates an embedded risk management framework, which is monitored and reviewed by the Board. There are a number of potential risks and uncertainties that could have a material impact on the Group's financial performance and position. These include risks relating to the political environment, competitive threat, supply chain disruption, legal and regulatory, IT systems and infrastructure, cyber and data security, foreign exchange, people, COVID-19, strategic acquisitions, and environment and climate change. These risks and the Group's mitigating actions are set out on pages 52 to 61.

### PRINCIPAL RISKS AND UNCERTAINTIES

# WE'RE IDENTIFYING, MANAGING AND MITIGATING RISKS TO DELIVER OUR MISSION

Operating in the current environment, it has never been more important to ensure that a rigorous and disciplined approach to risk management is embedded across our business. The success and sustainability of Clinigen is underpinned by our ability to identify, manage and mitigate those risks which may prevent us from delivering our mission and strategic plans.

### A MATURING APPROACH TO RISK MANAGEMENT

Our risk management approach aims to strike a balance between mitigating and monitoring our risks and maximising the potential opportunity and upside. We understand that risk will naturally arise from the operational and strategic decisions taken by the Group which need to be actively managed in pursuit of our mission.

The Board and Executive Management Team continue to recognise the importance of adopting a mature approach to risk management through the ongoing implementation of a framework based around the principles of the Committee of Sponsoring Organisations of the Treadway Commission ("COSO") Enterprise Risk Management - Integrated Framework and IIA's three lines model. In addition, the implementation of several recommendations made by KPMG in 2019 following a strategic review of the Group's governance, risk management and internal control framework, have strengthened our approach to risk management, helping to ensure we effectively identify, quantify, and then implement mitigations to reduce risks to an acceptable level.

In support of improving the rigour around risk and control, the Board has continued to invest in the Group's risk management capability, notably through the appointment of an experienced Group Head of Internal Audit and Risk and the appointment of BDO LLP to provide subject matter expertise and additional resource to the in-house Internal Audit function. This investment has enabled the Group to accelerate changes to how it undertakes risk management, through a Group-wide risk governance framework and clear accountabilities. This model will continue to evolve during the next 12 months, with the full implementation of Risk, Ethics Compliance & Sustainability ('RECS') Boards (group and divisional), the roll-out of new risk and control software (Rhiza) to support the facilitation and timely reporting of risk, and the full implementation of a control attestation process.

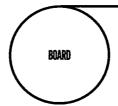
### **RISK GOVERNANCE MODEL**

The Board has overall responsibility for ensuring that there is an effective risk management framework embedded across the business. It is accountable for strategic risk management, including setting and articulating the Group's risk appetite, and ensuring a sound system of internal control and risk management is in place. The Audit and Risk Committee assists the Board by providing oversight and challenge of the effectiveness of risk management and mitigating controls. It annually provides an independent assessment and opinion on the effectiveness and efficiency of the Group's internal controls and risk management systems, obtaining assurance from Internal Audit and other independent assurance providers. The Audit and Risk Committee periodically reviews the Group's strategic risks and provides regular updates to the Board on actions taken to mitigate those risks to an acceptable level. Details of the Audit and Risk Committee's composition, responsibilities and activities can be found in the Audit and Risk Committee Report on pages 70 to 75.

Aligned to the Group's risk management approach, a three lines model (aligned to the Institute of Internal Auditor's guidance) has been adopted, with a set of controls, policies and procedures, and responsibilities designed to provide reasonable assurance. Operational management across the business operate as the first line. This ensures that day-to-day controls are implemented and monitored and that relevant systems are in place to identify, evaluate and mitigate operational risks inherent within our activities. The second line comprises several functions such as Quality, Legal, IT, Health & Safety (H&S) and the Process Governance team. These functions provide expertise, support, monitoring and challenge to the management of risk across the Group, supporting the first line. Internal Audit together with other independent assurance providers serve as the third line, providing independent assurance over the effectiveness of the Group's risk management, internal controls and governance.

All principal risks are assigned to a member of the Executive Management Team and this, combined with our three lines model, helps to ensure accountability throughout the business. In addition, targeted assurance over the Group's principal and operational risks is provided through the adoption of a risk-based internal audit strategy by the Internal Audit team.

### OUR FRAMEWORK FOR MANAGING RISK ROLES AND RESPONSIBILITIES



### Overall responsibility for risk management:

Risk appetite, strategy, policy and systems, approval of the strategic risk register



**Supporting the Board** with monitoring the application of the risk management framework, identifying and scrutinising areas of greater risk

**Assessing** the effectiveness and efficiency of the internal control and risk management systems

### REVIEWING

the Group's internal control, risk management systems and strategic risk register



**Defining** accountabilities and responsibilities for risk management

**Monitoring** the risk management governance framework and periodically assessing the strategic risk register and risk mitigation plans

### REVIEWING & UPDATING

the Group's strategic risk register and agreeing risk mitigation strategies



Identification of strategic and operational risks inherent at a group, divisional and regional level

Assessment of risk to quantify the inherent and residual probability and impact of the risks

Management and mitigation of risk through target remediation and risk mitigation strategies

Escalation & reporting those risks above appetite and/ or assessed as likely to have a significant impact on delivery of strategy



### FIRST LINE Business Operations/ Functions

Provision of products/ services to clients

Management controls, internal control measures

### SECONDLINE Quality, Legal, IT, H&S, Process Governance

Expertise, support, monitoring and challenge on riskrelated matters

### THIRDLINE Internal Audit

Independent and objective assurance and advice on all matters related to the achievement of the Group's objectives



Risk ownership and control ensuring day-to-day risk management controls are implemented and monitored, and that systems are in place to identify, evaluate and mitigate Group's strategic and operational risks

Monitoring and compliance regarding internal controls, processes and systems established to control and mitigate Group strategic and operational risks

Independent assurance over the Group's risk management, internal controls and governance frameworks

### PRINCIPAL RISKS AND UNCERTAINTIES CONTINUED



### **RISK APPETITE**

The UK Corporate Governance Code requires companies to determine their risk appetite. This is an expression of the amount and types of risk that the Group is willing to take in order to achieve its strategic and operational objectives. A risk that can seriously affect the performance, prospects or reputation of the company is deemed a principal risk. These are aligned to the Group's strategic pillars. The level of risk acceptable for principal and emerging risks is assessed on an annual basis by the Executive Management Team and subsequently by the Board, which defines risk appetite through the consideration of the potential impact of risk, likelihood of risk and ability to reduce risk through mitigation. This ensures alignment between our view of acceptable risk exposure and our ability to achieve our strategic pillars.

Clinigen faces a broad range of risks reflecting the highly regulated environment in which it operates. The risks arising from the business environment and operating model can be significant if not appropriately controlled and managed. Successful and sustainable financial performance for the group is achieved by managing these risks through intelligent decisionmaking, clear articulation of risk appetite, and through the adoption of a strong internal control framework.

### **EMERGING RISKS**

Emerging risks are those which, while not immediate, have the potential to materialise over a longer period of time, and could have significant impact on the Group. Emerging risks may be new risks not previously identified and/or fully understood, or changes to existing risks that are currently difficult to quantify.

Clinigen applies a consistent process to identify emerging risks, facilitated through our annual Long-Range Planning ('LRP') process. Emerging risks are identified within our divisional and functional business plans before being quantified and aggregated at a Group level. This process supports Clinigen in forming a longer-term view of emerging risk in respect of probability, impact and expected timeline of impact on the strategy.

In addition to the LRP process, the Group seeks to identify emerging risks at the earliest opportunity, with risk trend reports (such as the World Economic Forum's 'Global Risk Report') collated and analysed periodically by the Group Head of Internal Audit and Risk.

Emerging risks are monitored, managed, mitigated, and reported upon through the adopted risk management framework.

### RISK IN CONTROL

The Group faces risks across a broad range of risk categories, including strategic, operational, financial, technological, regulatory and people. To ensure these risks are appropriately controlled we invest time, resource and capability in ensuring an appropriate level of control is in place to mitigate the risks to an acceptable level. This commitment aligns with the Group's strategic pillar of 'operational excellence'. Assurance over the Group's systems of internal control is provided through the adoption of a targeted and risk-based approach by Internal Audit. In February 2021, the Committee approved a three year risk-based Internal Audit Strategy which will provide continued assurance coverage over our risks.

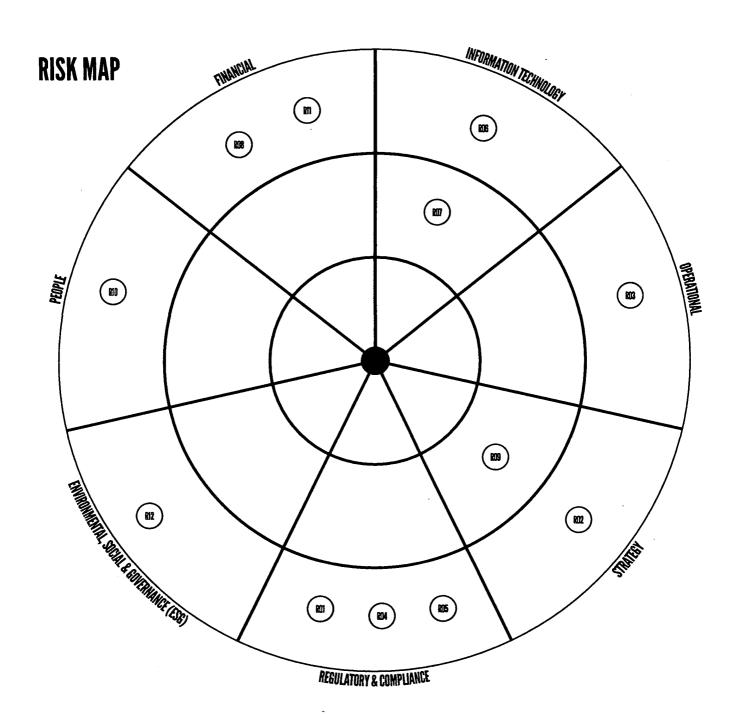
During the second half of this year, Internal Audit commenced a range of audits, including risk based reviews of Data Privacy, IT General Controls and Cyber Security. Each of these audits have provided direct assurance over controls established to mitigate specific strategic and operational risks. In addition, management assurance via the second line provides additional comfort over the strength of the Group's internal control systems, most notably in pharmaceutical compliance whereby the Group's Quality Assurance team monitors compliance against key regulatory requirements including Good Distribution Practice ('GDP') and Good Manufacturing Practice ('GMP').

### PRINCIPAL RISKS AND UNCERTAINTIES ASSESSMENT

The Group's principal risks, together with the management actions to mitigate the risk, are set out in detail on pages 56 to 61. They are not in any order of priority and do not comprise all risks associated with the Group. The principal risks are shown on the Group's risk map on page 55, plotted by risk category and residual risk level. Further risks not currently known or risks that have been considered to be less material may also have an adverse impact on the business. The principal risks and uncertainties were considered in assessing the long-term viability of the Company. The viability statement can be found on page 87.

The Board confirms that:

- It has carried out a robust assessment of the principal risks facing the Group, including emerging risks, and those that would threaten its business model, future performance, solvency or liquidity.
- The risk management framework has operated effectively for the year under review and up to the date of approval of the Annual Report and Financial Statements.



### **PRINCIPAL RISKS**

- **R01** Political
- **R02** Competitive Threat
- **R03** Supply Chain Disruption
- **R04** Serialisation and Counterfeit Products
- **R05** Legal and Regulatory
- **R06** IT Systems and Infrastructure
- **R07** Cyber and Data Security
- **R08** Foreign Exchange
- **R09** Strategic Acquisitions
- R10 People
- R11 Impact of COVID-19 on Group Trading and Demand
- R12 Environment and Climate Change

### **RISK LEVEL**

### HIGH

The residual risk is above an acceptable level of risk appetite. Requires immediate attention by management in order to bring about a reduction in exposure.

### MEDIUM

The residual risk is broadly within an acceptable level of risk appetite, however, risk mitigation plans are required to bring about a reduction in exposure.

### LOW

The residual risk is within an acceptable level of risk appetite. The risk has been assessed as being effectively managed by existing controls and normal operational procedures.

### PRINCIPAL RISKS AND UNCERTAINTIES CONTINUED

### RO1: Political risk

STRATEGIC PILLARS

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RISK APPETITE

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MOVEMENT VS PRIOR YEAR

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### WHAT IS THE RISK?

The Group's expanded global footprint has increased the exposure to adverse local political decisions, changes in regulation and economic events impacting the pharmaceutical industry, which may affect the ability to supply, local demand and/or pricing.

### WHAT IS THE IMPACT?

The longer-term effects of Covid-19 and Brexit continue to be difficult to predict but could include financial instability, slower economic growth or economic downturn (UK/globally), and/or continued impact on demand of products.

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### **HOW WE MANAGE AND MITISATE THE RISK**

- The Group mitigates this risk by having an increasingly broad product, service and geographical range, limiting the impact of events in any single territory.
- The Group monitors developments in key geographies and maintains 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 completed the actions necessary to ensure it can continue to trade in a post-Brexit environment.
- The Group's priority is to maintain continuity of supply of its products to its customers in the UK and EU. The Group manages supply of unlicensed medicines in the EU through its EU based subsidiary alongside an inventory management plan to ensure appropriate stocks are available across the continent.
- The Group has ensured that its products continue to be available in the EU by registering Marketing Authorisations within an EU registered subsidiary; and established a relationship with a third-party warehouse agent to act as our EU distribution hub.

### RO2: COMPETITIVE THREAT

STRATEGIC PILLARS

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**RISK APPETITE** 



**MOVEMENT VS PRIOR YEAR** 

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### WHAT IS THE RISK!

The Group faces a threat to its owned products from generic products and/or the development of alternative therapies by competitors.

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.

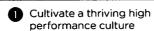
### WHAT IS THE IMPACT?

The Group's products are not typically protected by patents and thus competitor threat could significantly erode sales of our products, resulting in an adverse impact on the Group's financial performance.

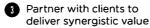
### HOW WE MANAGE AND MITIGATE THE RISK

- 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.
- The identification and ability to promote 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
- The Group closely monitors the competitive landscape in key markets to ensure a rapid and appropriate response to changes in competition.

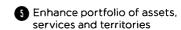
### **KEY TO STRATEGIC PILLARS**



2 Drive operational excellence



Lead the market in customer experience



Realise competitive advantage through technology

### RO3: SUPPLY CHAIN DISRUPTION

STRATEGIC PILLARS



RISK APPETITE

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MOVEMENT VS PRIOR YEAR

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### WHAT IS THE RISK?

The Group is unable to meet market demand for its products due to drug shortages and/or a major issue in the supply chain, for example, the manufacturing process at a Contract Manufacturing Organisation's (CMOs).

For several of our products, including Proleukin and Erwinase, the Group is often reliant on a single source supplier for manufacturing. A significant disruption in this process could impede our ability to supply and meet demand.

In addition, the loss or damage to product during transit could also cause significant disruption to supply due to lead times in the re-manufacturing process and/or ability to re-supply.

### WHAT IS THE IMPACT?

The Group's reputation could be undermined, and profits impacted if its products go into shortage of supply.

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An issue in the manufacturing process at one of our CMOs may result in significant business disruption and limit our ability to meet demand. Such a delay could also result in a loss of market share, particularly if a generic competitor entered the market.

The re-manufacturing process lead time could result in the Group being unable to fulfil orders and demand, resulting in loss of revenue and market share.

### BOW WE MANAGE AND MITIGATE THE RISK

- The Group has effective supply chain management, only working with trusted manufacturing and global distribution partners.
- The Group also seeks to maintain appropriate stock levels of its own products and related API to minimise the risk of shortage of supply.
- Business Interruption ('BI') insurance is procured to transfer an element of the financial risk exposure associated with potential loss of revenues in the event of significant disruption in the supply of product and services.
- Marine insurance is in place to limit our financial exposure and liability in the event of product being lost and/or damage during conveyance.
- Third party vendor management controls are in place to minimise the risk of disruption in the supply chain.

### RO4: SERIALISATION AND COUNTERFEIT PRODUCTS

STRATEGIC PILLARS



RISK APPETITE



MOVEMENT VS PRIOR YEAR

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### WHAT IS THE RISK?

The Group fails to meet its obligations to comply with increased regulation on the serialisation of licensed pharmaceutical products.

### WHAT IS THE IMPACT?

The Group's reputation could be undermined and profits impacted, if it fails to comply with serialisation regulatory requirements to mitigate the risk of counterfeit products in the supply chain.

### HOW WE MANAGE AND MITIGATE THE RISK

- During the year the Group went live in the US with a Verification Router Service ('VRS'), enabling wholesale distributors in the US to verify the product identifier before re-distributing saleable returned products. Clinigen is also now able to confirm that product identifiers are genuine, in the event of a suspected illegitimate product.
- In the US, the Group implemented a number of new policies, including a US Drug Supply Chain Security Act ('DSCSA') Policy and a US Suspect and Illegitimate Product Management Policy.
- Due to Brexit, products supplied to GB no longer comply with the EU Falsified Medicines Directive, and are not subject to verification and decommissioning at the point of supply. The MHRA confirmed that as part of their 2021-2023 roadmap, they will be delivering a phased implementation of the UKNI Medicines Verification System ('MVS'), to replace the EU system. The Group continues to monitor the impact of these changes and respond accordingly to ensure compliance.
- Robust supplier management practices are adopted by the group to ensure that supply chains are as short as possible and products are traceable to the manufacturer.
- The Group has implemented 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 Products operation and a supplier of licensed comparator products in its Clinical Services operation, Clinigen is fully compliant with serialisation regulation.









### PRINCIPAL RISKS AND UNCERTAINTIES CONTINUED

### RO5: LEGAL AND REGULATORY

### STRATEGIC PILLARS

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### RISK APPETITE



### MOVEMENT VS PRIOR YEAR



### WHAT IS THE RISK?

The Group fails to proactively identify and comply with global laws and pharmaceutical regulatory requirements across our value chain, including manufacturing, sales, supply, and marketing of our products and services.

### WHAT IS THE IMPACT?

The failure to comply with laws and regulatory requirements could result in fines, penalties, business disruption, reduced revenue, potential exclusion from government programs, and loss of trading licences.

### HOW WE MANAGE AND MITIGATE THE RISK

- The Group has a business and Group-wide compliance structure which is continually assessed to support compliance given the highly regulated industry that it operates within.
- Employees are regularly trained in key areas including policies relating to Clinigen's approach to GMP/GDP activities, including pharmacovigilance, manufacturing and distribution, as well as legal policies including whistleblowing, and anti-bribery and corruption. In addition, the employee code of conduct reinforces the Group's values of ethics, trust and quality.
- The continued integration of quality systems such as Electronic Quality Management System ('eQMS') and Learning Management System ('LMS') during the year has further strengthened our resource and capability to support cross-site activities. In addition, during the year the Quality Department restructured into three pillars: Shared Services and Process Governance, Products QA and Services QA, enabling greater alignment with Clinigen's divisions.
- Despite the pandemic, Clinigen has undergone numerous Competent Authority Inspections and client audits over the past year, with the majority resulting in an excellent result. Periodic internal audits and management reviews demonstrate that the quality management system is under control.
- Clinigen continues to monitor the regulatory landscape, with the main focus during the year being on the changes relating to Brexit. Clinigen has implemented new ways of working where required, to ensure continuity of supply to patients and clinical studies.
- In addition, the Group's three lines provides assurance over the internal control framework established to mitigate the risk of non-compliance. Targeted assurance is provided by Internal Audit and the Group's Quality Audit team.

### RO6: IT SYSTEMS AND INFRASTRUCTURE

### STRATEGIC PILLARS

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### RISK APPETITE.



### MOVEMENT VS PRIOR YEAR

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### WHAT IS THE RISK?

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.

### WHAT IS THE IMPACT?

The loss of a critical system and/or data could significantly impede our ability to trade and continue to supply our products and services in line with our standards and commitments to our customers and clients.

A significant loss of data could also result in a data privacy breach and ultimately reputational damage and/or financial penalties.

### HOW WE MANAGE AND MITIGATE THE RISK

- The Group's technology strategy is regularly reviewed to ensure that the systems it operates across the Group support its strategic direction.
- In 2021, the Group appointed a new VP IT who commenced a detailed review of the Group's existing IT infrastructure (including platform architecture and operating model), services, structure and IT controls. A refreshed IT strategy and roadmap was developed as a result of the
- Ongoing asset life-cycle management programs mitigate risks of hardware obsolescence whilst back-up procedures mitigate risk of data loss.
- The Group has continued to embed the ERP during the year, with further integration planned in 2021/22. The ERP is designed to make the business systems more efficient, scalable and reliable
- IT disaster recovery plans are developed and testing completed to ensure critical systems/ applications could be restored in the event of a disruption.

### **KEY TO STRATEGIC PILLARS**

- Cultivate a thriving high performance culture
- 2 Drive operational excellence
- Partner with clients to deliver synergistic value
- Lead the market in customer experience
- § Enhance portfolio of assets, services and territories
- Realise competitive advantage through technology

### **R07**: **CYBER AND** DATA SECURITY

STRATEGIC PILLARS



RISK APPETITE



MOVEMENT VS PRIOR YEAR



### WHAT IS THE RISK?

Increased levels of cybercrime represent a threat to the Group and may lead to business disruption or loss of data. The Group is exposed to the risk of external parties gaining access to Group systems and deliberately disrupting its business. This includes the risk of ransom demands, a material loss of revenue and profitability while systems are being restored, stolen information or fraudulent acts.

Cyber and data security remains a key and increasing risk as technology and third-party cloud-based services continue to be subject to the threat of increasingly complex cyber-attacks.

### WHAT IS THE IMPACT?

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.

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A data breach or attack resulting in operational disruption could reduce the effectiveness of our systems. This in turn could result in loss of revenue. loss of financial, customer or employee data, fines and/or reputational damage.

### HOW WE MANAGE AND MITIGATE THE RISK

- The Group has invested in the protection of its data and IT systems from the threat of cyberattack. Cyber security policies and procedures exist to minimise this risk, including preventative and detective controls.
- Our dedicated IT support teams and external service providers monitor and respond to new and expanding cyber risks and look to implement best practice in IT security management.
- Proactive and reactive security controls are implemented, including up-to-date anti-virus software across the estate, network/system monitoring and regular penetration testing to identify vulnerabilities.
- Incident response capability is in place to mitigate the impact of a cyber-attack on our day-to-day operations. This includes disaster recovery and business continuity plans to support the business in the event of a significant attack.
- Internal audit conducts periodic reviews of IT and security controls.
- The Group recently sought re-accreditation under Cyber Essentials + ('CE+') in order to validate the strength of its cyber controls.
- The Group also has in place Cyber Insurance, providing coverage and protection against a range of cyber-related security threats. This policy enables Clinigen to transfer an element of financial risk and liability.

### **R08**: **FOREIGN EXCHANGE**

STRATEGIC PILLARS

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**RISK APPETITE**  $\bullet$ 00

MOVEMENT VS PRIOR YEAR

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### WHAT IS THE RISK?

The Group has significant operations and activities outside the UK and has a high level of trading across a number of foreign currencies. It is therefore exposed to changes in foreign exchange rates.

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

### WHAT IS THE IMPACT?

Foreign currency movements may impact profits, balance sheet and cash flows. Ineffective hedging arrangements may not fully mitigate volatility or may increase it.

### HOW WE MANAGE AND MITIGATE THE RISK

- The Group reduces its exposure to currency fluctuation 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
- Hedging is in place for foreign exchange to help mitigate volatility and aid margin management.
- 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.



### PRINCIPAL RISKS AND UNCERTAINTIES CONTINUED

### R09: **STRATEGIC ACOUISITIONS**

STRATEGIC PILLARS



RISK APPETITE



### WHAT IS THE RISK?

The Group fails to integrate acquisitions efficiently, leading to disruption in operations and reduced returns on investment.

In addition, the Group could make acquisitions which do not support the business as intended or could fail to identify potential acquisitions to drive future growth aspirations.

### WHAT IS THE IMPACT?

Strategic acquisitions fail to provide the planned Return on Investment ('ROI').

Failure to enact the acquisition strategy could result in increased inefficiencies in operations, increased costs, and greater risk of non-compliance with laws and regulations.

Loss of market confidence in the Group's acquisition strategy.

### HOW WE MANAGE AND MITIGATE THE RISK

- 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.
- The Group's Program Management Board oversee all strategic acquisitions and undertake a rigorous approach to due diligence on all proposed acquisitions (and divestments).
- Financial modelling and stress testing is completed on all proposed acquisitions.

### R10: **PEOPLE**

### STRATEGIC PILLARS



RISK APPETITE



MOVEMENT VS PRIOR YEAR

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### WHAT IS THE RISK?

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 risk that a combination of key people in senior roles depart at short notice could impact the Group's ability to deliver on its strategy.

Failure to address and adapt to the challenges of wellbeing and mental health as a result of the pandemic may also increase the risk that we are unable to retain employees.

### WHAT IS THE IMPACT?

Loss of key individuals could result in operational disruption, while competition for employees could lead to higher-than-expected increases in the cost of recruitment, training and employee costs.

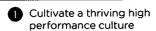
Loss of key personnel could have a reputational impact.

We fail to protect and offer a working environment/ culture that supports our people's health and wellbeing, resulting in increased attrition and turnover.

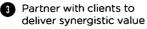
### **HOW WE MANAGE AND MITIGATE THE RISK**

- The Group has grown rapidly and now employs over 1,000 people in 14 countries. The Group ensures effective and regular internal communications in order to communicate and update on strategy and objectives.
- The Group has appropriate remuneration packages to help recruit and retain key employees. A new job grading framework was introduced in 2021, providing our people with a clear and transparent mechanism for progression, pay and reward. 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.
- Clear succession plans are in place for senior positions across the Group.
- Throughout the pandemic the health and wellbeing of our people has been paramount. Increased levels of communication and engagement have been in place throughout, whilst a range of initiatives, including mental health and wellbeing training, have equipped our managers to ensure the best support is offered to all our people.

### **KEY TO STRATEGIC PILLARS**



Drive operational excellence



Lead the market in customer experience 5 Enhance portfolio of assets, services and territories

Realise competitive advantage through technology

### R11: IMPACT OF COVID-19 ON GROUP TRADING AND DEMAND

### STRATEGIC PILLARS

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RISK APPETITE

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**MOVEMENT VS PRIOR YEAR** 

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### WHAT IS THE RISK?

COVID-19 continues to have a negative impact on demand as a result of a continued global reduction in hospital-based oncology treatments and delays to clinical trials. In particular, demand for Proleukin continues to be below forecast levels due to the pandemic.

### WHAT IS THE IMPACT?

Revenue and gross profit are not in line with forecast and expectations.

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Adjusted earnings before interest, tax, depreciation, and amortisation ('EBITDA') is below both internal and external expectations.

The Group is unable to achieve double-digit EBITDA growth in FY2022.

The Group is unable to generate sufficient levels of cash to reduce its debt level in line with internal and external expectations.

### HOW WE MANAGE AND MITIGATE THE RISK

- The Group believes it is prudent to expect a reduced level of demand for Proleukin to remain until revitalisation efforts into new indications alongside novel cell therapies are successful and normal Hospital and Cancer Centre Services have resumed.
- The Group continues to have ample liquidity and leverage meaningfully below the Group's banking covenant.
- No further deferred payments are required for previous acquisition CSM, nor for Proleukin unless sales exceed a pre-set milestone significantly above current levels and cash generation is focused on debt paydown.
- The Group will continue to support COVID-19 projects across the business. The Group is also gaining further share in its Service end-markets and has made faster-than-expected progress on the launch of Erwinase.
- The continued roll-out of ClinigenDirect, the Group's online platform to customers, will act as an enabler for greater access to our medicines and connectivity with HCPs and hospitals.

### R12: Environmental/ Climate Change

STRATEGIC PILLARS

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RISK APPETITE



MOVEMENT VS PRIDR YEAR

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### WHAT IS THE RISK?

The Group fails to plan and respond to the environmental and climate change agenda.

Future emission restrictions and the transition to a low carbon economy could impact operations and performance in the medium term.

### WHAT IS THE IMPACT?

The Group's impact upon the environment or the effects of climate change could expose it to regulatory breaches, significant disruption, reputational risk or a reduction in demand for its products and services.

The Group fails to discharge its responsibilities as a good corporate citizen, making it a less attractive place to work and invest in.

### HOW WE MANAGE AND MITIGATE THE RISK

- In 2021, the Group signed up to the UN Global Compact initiative and is also committed to making a voluntarily disclosure against the Taskforce for Climate-related Financial Disclosures ('TCFD') in next year's Annual Report and Accounts.
- The Group is committed to setting targets, implementing sustainability initiatives and reporting performance to its key stakeholders.
- A robust governance structure was implemented in 2021 to provide clear oversight and ownership of the Group's ESG/sustainability strategy and management of climate-related risks.
- Identification, mitigation and reporting on climate-related risks continues to be embedded into the Group's existing risk management process and is complementary to governance of the Group's ESG/sustainability strategy.
- The Group has developed a clearly articulated ESG strategy which outlines four key pillars and a range of sustainability-related initiatives aimed supporting our commitments as a good corporate citizen in relation to ESG. This strategy is also aligned to the UN Sustainable Development Goals ('SDGs').
- The Group also reports annually in line with the Streamlined Energy and Carbon Reporting (SECR) requirements and Section 172 of the Companies Act, under which Directors have a duty to act with regard to the company's impact on the environment.





### **BOARD OF DIRECTORS**

### **ELMAR SCHNEE**

Independent Non-Executive Chairman

### APPOINTED

Director in August 2021 and Chairman in September 2021

### COMMITTEES



### SKILLS AND EXPERIENCE

Elmar brings a wealth of experience from the international pharmaceutical industry, having held senior leadership and Board positions at a number of global pharmaceutical products and services companies.

Elmar most recently served on the Board of Jazz Pharmaceuticals. He also serves as a Non-Executive Director on listed Santhera AG and Calliditas AB and several private companies. Prior to this his global career spanned a range of senior roles at companies including Merck KGaA, as General Partner and member of the Executive Board, and Merck Serono as CEO.

### SHAUN CHILTON

Chief Executive Officer

### APPOINTED

Director in July 2013 and CEO in November 2016

### COMMITTEES

### SKILLS AND EXPERIENCE

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. Shaun was appointed CEO in November 2016 and has the responsibility for the Group achieving its KPIs and plays a central role in setting the Group strategy.

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).

### 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.

### SHARON CURRAN

Independent Non-Executive Director

### APPOINTED

April 2021

### COMMITTEES



### SKILLS AND EXPERIENCE

Sharon is an experienced Non-Executive Board Director as well as having proven top-level experience in leading high impact global marketing, commercialisation and growth strategies for world-class pharmaceutical corporations.

Sharon has held numerous senior operational and strategic roles at Eli Lilly, Abbott and most recently as VP, Global Marketing and Commercial Operations at AbbVie US, leading their global specialty franchise and development of commercial and launch capabilities. Sharon has an M.Sc. in Business Administration from Trinity College, Dublin and a B.Sc. in Biotechnology from Dublin City University. Sharon is a Chartered Director, accredited by the Institute of Directors, London.

### EXTERNAL APPOINTMENTS

Sharon is currently a Non-Executive Director for Circassia Group plc where she is Chair of the Remuneration Committee. She is also on the Board of MorphoSys AG (Audit and Risk Committee).

### **ALAN BOYD**

Non-Executive Director

### APPOINTED

November 2018

### COMMITTEES

### SKILLS AND EXPERIENCE

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.

### EXTERNAL APPOINTMENTS

Professor Boyd is currently CEO of Alan Boyd Consultants Limited, a private specialist biopharmaceutical consultancy company. He is also a Director of Celentyx Limited and Non-Exec Director of Transine Therapeutics Ltd.

### EXTERNAL APPOINTMENTS

In addition to Santhera and Calliditas, Elmar Schnee also serves as a director of Genkyotex SA (a subsidiary of Calliditas) alongside private companies Moleac Pte, Moleac RX Pte, Noorik AG, Damian Pharma AG, Kuste Biopharma, Mindmaze, Genpharm, GenKyoTex Suisse SA, ProCom RX Holding SA and MyDIO SA.

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

### IAN JOHNSON

Senior Independent Director

### APPOINTED

August 2021

### COMMITTEES

### SKILLS AND EXPERIENCE

Ian has extensive experience having spent his business career in life science. He also has listed company experience and was founder and CEO of Biotrace International PLC, which was a listed company until its sale to 3M in December 2006.

Prior to these appointments lan was a Non-Executive Director of Ergomed PLC and Executive Chairman of Bioquell PLC Non-Executive Chairman of Quantum Pharma PLC, Cyprotex PLC and Celsis Group Ltd. He has also served on the boards of various other public and private companies including AIM-listed companies Evans Analytical Group and AOI Medical Inc.

Ian studied at Cardiff University obtaining a B.Sc. and M.Sc. in Microbiology. He is a Chartered Biologist, a Fellow of the Royal Society of Biology and a member of the Institute of Directors.

### EXTERNAL APPOINTMENTS

In addition to his current role as Executive Chairman of Circassia Group PLC, Jan is also currently Non-Executive Chairman of Redcentric PLC.

### **ANNE HYLAND**

Independent Non-Executive Director

### APPOINTED

January 2018

### COMMITTEES



### SKILLS AND EXPERIENCE

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.

### IAN NICHOLSON

Independent Non-Executive Director

### APPOINTED

September 2012

### COMMITTEES



### SKILLS AND EXPERIENCE

Ian has over 25 years of international experience in management and transactions within the life sciences sector. He is currently an Operating Partner of London-based Advent Life Sciences LLP

lan previously spent eight years as CEO of the privately held antifungal drug development company F2G Limited and before that CEO of the oncology R&D company, Chroma Therapeutics Limited. Prior to that he was Senior Vice President, Business Development at UK biotechnology company Celltech Group plc.

Ian has worked extensively in licensing, M&A and market development in the UK, Europe and the US and holds a BSc (Hons.) from University College London and an MBA from Boston University. He holds Board positions at Clinigen Group plc and is Chairman of Bioventix plc.

### **AMANDA MILLER**

General Counsel and Company Secretary

### APPOINTED

June 2017

### SKILLS AND EXPERIENCE

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 pic 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

None

### EXTERNAL APPOINTMENTS

Anne is CFO of Kymab Ltd. a biopharmaceutical company acquired by Sanofi in April 2021 for an upfront payment of \$1.1 billion and upto \$350 million in deferred consideration. She is also a Non-Executive Director of Elementis plc, a global specialty chemicals company.

### **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.

### CHAIRMAN'S INTRODUCTION TO GOVERNANCE

### WE CONTINUE TO ENSURE ROBUST AND APPROPRIATE CORPORATE GOVERNANCE



WE WILL CONTINUE TO EVOLVE OUR CORPORATE GOVERNANCE ARRANGEMENTS TO ENSURE THAT THEY ARE ROBUST, APPROPRIATE AND SUPPORT OUR GROUP CULTURE AND PURPOSE.

### **ELMAR SCHNEE**

Independent Non-Executive Chairman 15 September 2021

### DEAR SHAREHOLDER

As I begin my first year as Chairman of Clinigen, I am pleased to introduce the governance section of the Annual Report for the year ended 30 June 2021. I would like to thank my predecessor Peter Allen for his important contribution and leadership since IPO in 2012 and wish him well for the future.

In the year under review the Board continued to evolve the Group's corporate governance arrangements to ensure that they are robust, appropriate and support the Group culture and the Company's purpose. The Board continues to believe that we must adhere to the principles of integrity, respect, transparency and openness and Board members are expected to lead by example.

As we set out in the pages that follow, the philosophy that underpins our Company purpose of 'Right Medicine, Right Patient, Right Time' also influences the Clinigen approach to governance. Although we are an AIM listed Company, and follow the AIM rules, we have also chosen to comply voluntarily with the UK Corporate Governance Code (the 'Code') which was drafted with larger, main market listed companies in mind. We feel that this more prescriptive and rigorous code is the best fit for our Company, where we strive to demonstrate best practice in all we do.

### COMPLIANCE WITH THE UK CORPORATE GOVERNANCE CODE

I am pleased to report that, throughout the year under review, the Company complied with all the principles of the UK Corporate Governance Code save for the requirement to undertake a Board evaluation process. Last year the Board took part in a full, externally facilitated, board evaluation exercise which proved very informative and the Board acted on a number of recommendations to ensure that the Board team was working effectively with the necessary rigour and challenge. This year the Board took the decision not to repeat the exercise due to the number of changes but will be undertaking an evaluation in 2022. Recently the Board membership has been through significant changes in personnel and we have now taken the decision to allow the new board members to settle into their roles before embarking on an evaluation exercise.

I am looking forward to leading the Board through the coming year and continuing to evolve and strengthen our governance arrangements.

### **CORPORATE GOVERNANCE STATEMENT**

As a company whose shares are traded on AIM, the Company is subject to the AIM Rules (the 'AIM Rules') for Companies. Pursuant to (amended) AIM Rule 26, 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 CLINIGEN APPROACH TO GOVERNANCE

The Board has elected to report against the UK Corporate Governance Code as we believe that it encompasses the best practice in UK governance. At its heart, the Code emphasises the value of good corporate governance to long-term sustainable success and this fits with our own corporate ethos. Although AIM listed companies are not required to comply with the Code (unlike those with a premium listing on the Main Market), the Board's election to follow it underpins our belief that effective corporate governance assists the delivery of the Group's corporate strategy, the management of risk and the generation of shareholder value. Good governance improves Board efficiency, boosts investor confidence, reduces cost of capital and helps protect our shareholders' long-term interests. Clinigen values corporate governance highly, not only in the boardroom but across the whole business of the Group.

Whilst the Clinigen Board follows both the Code and AIM Rules when ensuring that the highest standards of governance are met, we are also influenced by our corporate culture and our Company purpose. Our culture, which encompasses the values of excellence, teamwork, putting patients first, ethics and integrity is known internally as the 'Clinigen Way' as referenced in the ESG section on page 32. Our Company purpose of 'Right Medicine, Right Patient, Right Time' is set out in our Strategic Report on pages 8 to 11.

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.

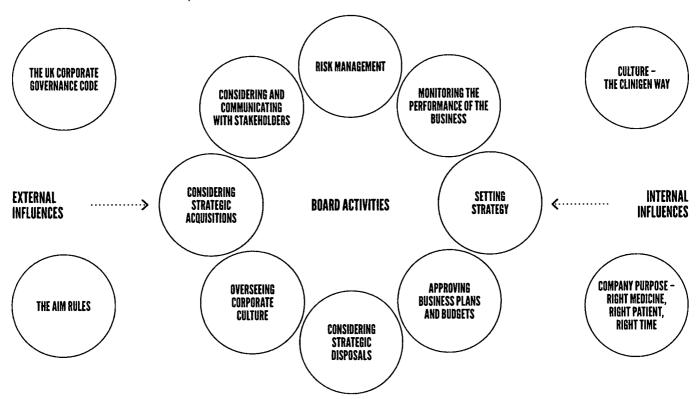
### **BOARD LEADERSHIP AND COMPANY PURPOSE**

Clinigen is led by an effective and entrepreneurial Board which establishes the vision and strategy for the Group and takes responsibility 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, and other stakeholders, 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 and the Executive Management Team.

The Board has a schedule of matters specifically reserved for its approval (which is reviewed annually) and follows an annual work schedule which is designed to ensure that all matters, which fall under its remit, are considered at the appropriate times of the year. Matters are delegated to the Board Committees, Executive Directors, Executive Management Team and senior management where appropriate and there is an effective feedback loop in place to ensure that the Board has continuous oversight on progress. 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.

### BOARD ACTIVITIES AND THE GOVERNANCE, CULTURE AND MISSION INFLUENCES



### CORPORATE GOVERNANCE STATEMENT CONTINUED

### MATTERS CONSIDERED BY THE BOARD IN 2021 INCLUDED:

TOPIC	DISCUSSION	CONSIDERATIONS	DELEGATION AND FEEDBACK
STRATEGY	<ul> <li>Strategy Review</li> <li>Acquisitions, disposals and earn-outs</li> </ul>	The generation and preservation of Company value.	<ul> <li>Day-to-day implementation of the strategy is delegated to the Executive Management team.</li> <li>The CEO provides a detailed report on progress at each Board meeting.</li> </ul>
CULTURE	<ul> <li>ESG/Sustainability</li> <li>Approval of a Human Rights Policy</li> <li>Approval of a Supplier Code of Conduct</li> <li>Review and approval of the Modern Slavery Act 2015 Statement for 2021/22, including a Modern Slavery Risk Assessment for 2021</li> <li>Agreeing the Clinigen 'Valuing Diversity' Commitment</li> </ul>	The necessity that our Directors, the wider workforce and those companies and individuals we work with exhibit behaviours and actions which fit with the Company's culture. The need to ensure that all who work for Clinigen commit to creating a workplace that maximises the potential of all people and where everyone is valued and feels empowered to contribute to our continued success.	<ul> <li>The Sustainability Steering Group is tasked with operationalising our sustainability framework. This group reports to the Board at regular intervals.</li> <li>The Group's HR and legal teams monitor developments in the field of human rights, modern slavery and employment law to assess any impact on the rights of the workforce, our customers or stakeholders.</li> <li>The procurement team ensures that the companies we work with comply with our Supplier Code of Conduct and report back to the senior leadership if there are any issues or discrepancies.</li> </ul>
FINANCE	- Approval of the financial statements and trading updates - Annual budget	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.	<ul> <li>The Audit Committee reviews the financial statements and relevant market announcements before making recommendations to the Board.</li> <li>The CEO and the CFO present the budget to the Board for scrutiny and challenge and report financial performance against budget at each Board meeting.</li> </ul>
RISK AND Internal Control	- External and Internal Audit plans	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.	<ul> <li>The Audit Committee scrutinises the plans, and the performance against plan, before making recommendations to the Board.</li> </ul>
GOVERNANCE	<ul> <li>Consideration of the Directors' duties under Section 172 of the Companies Act 2006</li> <li>Monitoring of developments within the sphere of corporate governance</li> </ul>	To ensure high standards of governance and adherence to applicable regulations throughout the Group.	<ul> <li>The General Counsel and Company Secretary is tasked with monitoring corporate governance developments and reports to the Board on any significant issues of relevance to the Group. She also provides training and information papers on governance topics at regular intervals.</li> </ul>

TOPIC	DISCUSSION	CONSIDERATIONS	DELEGATION AND FEEDBACK
SHAREHOLDER Engagement	<ul> <li>An investor relations report is a standing item on Board agendas</li> <li>Review of investor presentations</li> <li>Discussions on any meetings individual Directors have had with shareholders</li> </ul>	Recognising the need to ensure that investors are provided with timely and accurate information and that there is a process by which the views of the investors can be fed back to the Board.	<ul> <li>The CEO and the Investor Relations Director take responsibility for the investor relations program, ensuring that investors have opportunities to meet with the Board, where appropriate, and have their views relayed to the Board for consideration.</li> </ul>
WORKFORCE Engagement	<ul> <li>Regular review of the output from the Peakon employee engagement platform</li> <li>Presentation by the Workforce Engagement Director on his program of work for the year</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.	<ul> <li>The Workforce Engagement Director, along with the SVP HR, are tasked with ensuring that the views of the workforce are communicated to the Board and with ongoing communication to the workforce about how the Board has considered and acted on feedback.</li> <li>The Workforce Engagement Director ensures that the views of the workforce are taken into consideration during Board discussions.</li> </ul>
OTHER KEY STAKEHOLDER ENGAGEMENT	- Ongoing consideration of how any decision made by the Board will impact the Company's key stakeholders	The need to consider all stakeholders when making strategic decisions.	<ul> <li>The Executive Directors and Executive Management Team are required to demonstrate consideration of the Company's key stakeholders when putting proposals to the Board.</li> <li>The impact of the Company's activities on its key stakeholders are included in any review of the significant risks faced by the Company.</li> </ul>
AGM OUTCOMES	- Review of voting at the 2020 AGM	Recognising the need to take into account any significant numbers of votes against any of the resolutions at the Company's AGM.	<ul> <li>Monitoring of votes as they are cast by the General Counsel and Company Secretary who updates the Board regularly on any dissent.</li> <li>The votes cast in favour of each of the resolutions put to the 2020 AGM were well over 80% of total votes cast.</li> </ul>
WHISTLEBLOWING	- Approval of the Freedom to Speak Up Policy, including an anonymous email function available to all employees globally.	Recognition that employees and contractors must be able to access a means of reporting any concerns of illegality or wrongdoing at work. This system must provide anonymity for users if this is desired.	<ul> <li>The Audit and Risk Committee regularly reviews any reports which come up through the Freedom to Speak Up system and, where necessary, would escalate these up to the Board.</li> <li>The legal team monitors the system and would escalate any serious matters which come to light between regular Audit and Board meetings.</li> </ul>
CONFLICTS Of Interest	<ul> <li>Directors are required to declare any conflicts of interest on any matter to be discussed at the beginning of each Board meeting.</li> </ul>	The need for Directors to avoid situational conflicts of interest and recuse him/herself from any discussions where a conflict of interest might arise.	<ul> <li>Any conflicts or potential conflicts of interest are dealt with at the time they arise.</li> <li>The Board does not delegate this responsibility.</li> </ul>
RECORDING OF Any Matters Of Concern	<ul> <li>Any matters of concern expressed by any Board member will be included in the minutes of that meeting.</li> </ul>	The necessity to ensure that minutes accurately reflect the views of the Directors, including any that conflict with the general consensus.	<ul> <li>The General Counsel and Company Secretary produces accurate minutes.</li> <li>These are reviewed by all Board members before they are approved.</li> </ul>

### CORPORATE GOVERNANCE STATEMENT CONTINUED

### **BOARD COMMITTEES**

The Board has established a Nomination Committee, Audit and Risk Committee, and Remuneration Committee, each having separate duties and responsibilities. Reports from each of these committees can be found on pages 69 to 85.

### **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 2021 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 non-executive directors meet regularly without management present.

Moving forward the Audit Committee shall meet regularly with an external auditor (including once at the planning stage before the audit and once after the audit at the reporting stage) and, at least once a year, meet with the external auditor without management being present, to discuss the auditor's remit and any issues arising from the audit.

The Directors' attendance during the year ended 30 June 2021 was as follows:

	nan	AUDIT AND RISK Committee	REM WKERATION Committee	ESMANATION Committee
S Chilton	8	31	2 <sup>1</sup>	4 <sup>1</sup>
N Keher	8	31	2¹	41
P Allen	8	3	4	6
J Hartup²	3	3	3	3
l Nicholson	8	3	4	6
A Hyland	8	3	4	2 <sup>1</sup>
A Boyd	8	31	-	2 <sup>1</sup>
S Curran³	1	-	-	1

- 1. By invitation
- Stepped down from the Board on 26 November 2020
   Appointed to the Board on 27 April 2021

### **DIVISION OF RESPONSIBILITIES**

There is a clear division of responsibilities between the Chairman, the CEO of the Company and the Senior Independent Director. The Board includes an appropriate combination of Executive and Non-Executive directors, so that no one individual or small group dominates decision making.

The role of the Chairman is to lead and manage the Board, ensuring the Board's effectiveness in all aspects. He ensures the active engagement by all Board 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 Senior Independent Director ('SID') serves as a sounding board for the Chair and acts as an intermediary for other Directors. They hold annual meetings with non-executives, without the Chair present, to appraise the Chair's performance. They are also available to meet with fellow non-executives on other such occasions if this proves necessary. Role descriptions of the Chairman, CEO and SID are available on the Company's website www.clinigengroup.com.

The Workforce Engagement Director is the Non-Executive Director tasked with helping to ensure that the views and concerns of the workforce are brought to the Board and taken into account.

The Non-Executive Directors' responsibilities are to challenge, guide and contribute towards the Group's strategy, and to challenge the financial controls and systems around risk management to ensure that are suitably robust. They are tasked with appointing Executive Directors if and when vacancies arise and they are required to hold the incumbent executives and management to account. The Chairman ensures that the Non-Executive Directors meet at least once a year for discussion without management present. Non-Executive Directors are required to devote a minimum number of hours per annum to their roles on the Clinigen Board and this is set out in their letters of appointment. Directors are required to gain prior approval for any additional external appointments. 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. As required by the Code, half the members of the Board are deemed to be independent.

The Company Secretary, who is also the Group's General Counsel, supports the Board and advises on all governance matters and, along with the Chairman, ensures that the Board has the policies, processes, information and resources to function effectively. She schedules the Board meetings, ensuring that sufficient time is allowed to consider all the relevant agenda items. All Directors have access to the advice of the Company Secretary and her appointment is a matter for the Board.

### BOARD COMPOSITION, SUCCESSION AND EVALUATION

The Board believes that it has the right combination of skills and experience among its members and the members of the senior management team. Biographies are set out on pages 62 to 63.

### SUCCESSION PLANNING

The Board continually assesses its membership to ensure it has the necessary qualities required to operate within a robust governance structure which the Board believes fits the requirements of the Group. During the year the Board strengthened its membership with the appointment of Sharon Curran as an Independent Non-Executive Director, Sharon will take over as Chair of the Remuneration Committee when lan Nicholson steps down from the Board in November.

Peter Allen, independent Non-Executive Chairman ('Chairman'), who served the Company for nine years as Chairman of the Board, stepped down on 1 September 2021 and Ian Nicholson, who has also served for 9 years, will be standing down at the Company's AGM in November 2021. Elmar Schnee, who was appointed to the Board on 3 August 2021 was appointed Chairman on 1 September 2021. Ian Johnson was also appointed to the Board on 3 August 2021 and serves as the Company's Senior Non-Executive Director. Nick Keher stepped down from the Board on 24 August 2021.

Details of the process followed for both appointments and the work undertaken around succession planning within the Group is set out in the Nomination Committee report on page 69.

### 2021 BOARD EVALUATION

In June 2019, the Board conducted an externally facilitated evaluation and the recommendations of that report were set out in the 2020 annual report. The Board has not conducted an evaluation in the year under review and further details on the reasons for this are included in the Chairman's introduction to this report.

As required by the Code all Directors, apart from Ian Nicholson who is stepping down, will offer themselves for election or re-election at the AGM.

**BOARD COMPOSITION** 

**BOARD TENURE** 

**BOARD GENDER DIVERSITY** 

SENIOR MANAGEMENT TEAM GENDER DIVERSITY

### APPOINTMENT PROCESS



### NOMINATION COMMITTEE DISCUSSION

(both scheduled and ad hoc meetings including **Executive Directors where appropriate)** 

- CONSIDERATIONS Identification of a vacancy
  - The needs of the organisation, currently and in the future
  - The personal skills and qualifications required
  - The dynamics of the current Board

### **APPOINTMENT OF A HEADHUNTER**

- **CONSIDERATIONS** Market reputation
  - Reach
  - Understanding of the Clinigen culture and company purpose

SFARRO



### PRODUCTION OF A LONG LIST

CONSIDERATIONS - Skillset

- Experience
- Gender, ethnicity, and background diversity

### PRODUCTION OF A SHORT LIST

- CONSIDERATIONS Specific skills
  - Experience
  - Potential for overboarding

### **BOARD MEETINGS WITH THE SHORT-LISTED CANDIDATES**

**CONSIDERATIONS** - Cultural fit

- Ability to challenge

APPOINTMENT



### NOMINATION COMMITTEE RECOMMENDATION TO THE BOARD

CONSIDERATIONS - Due Diligence findings

### POST APPOINTMENT



### INDUCTION PROGRAMME

- **CONSIDERATIONS** Director's duties and responsibilities - Familiarisation with the business

  - Meetings with key employees

### NOMINATION COMMITTEE REPORT

The Chairman of the Nomination Committee is Elmar Schnee (previously Peter Allen), with Sharon Curran (and previously John Hartup) and Ian Nicholson being the other members of the Committee. The Committee meets at such times as the Chairman of the Committee requires. The Committee met six times during the year to discuss succession planning and Board composition.

### **SUCCESSION PLANNING**

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. When considering succession planning, the Committee is cognisant of the desirability to promote diversity of gender, social and ethnic backgrounds, and cognitive and personal skills. The terms of reference for the Committee can be found on the Company's website www.clingengroup.com.

### **BOARD CHANGES**

At the AGM in November 2020, John Hartup stepped down from the Board. John had been on the Board for over 8 years, and during that period had served as Senior Independent Director, Workforce Engagement Director and a member of the Audit and Risk, Remuneration and Nomination Committees.

During the year the Committee considered the appointment of a new Non-Executive Director and was assisted in its work by an external headhunter, RSA. Following a formal, rigorous and transparent procedure (set out below), the Committee was pleased to recommend the appointment of Sharon Curran to the Board. Sharon has significant experience in the pharmaceutical sector and the expertise she brings from the industry and other company boards fitted the criteria scoped out by the Committee. Sharon has also been identified as the successor to Ian Nicholson, as Chair of the Remuneration Committee, when Ian steps down from the Board in November.

There have been a number of changes to the Board since the year end. Elmar Schnee, joined the Board on 3 August 2021 as an independent Non-Executive Director and designated successor to Peter Allen as Chairman. Peter Allen then stepped down from the Board on 1 September 2021 having served 9 years as Chairman.

lan Johnson joined the Board on 3 August 2021. lan's appointment was suggested by one of the Group's major shareholders and the Board and Nomination Committee, having undertaken extensive due diligence, agreed that his appointment was appropriate. It was also agreed that lan himself was aligned with the Group's culture and would be provide the necessary rigour and challenge in the Board room. Given these factors and having only recently considered other candidates for a non-executive role, in the process to appoint Sharon Curran, the Board did not use the services of an external headhunter or consider a longlist of candidates. Ian was also been appointed Senior Independent Director, a role he took over from Anne Hyland who stepped into the position temporarily, following the departure of John Hartup. Nick Keher stepped down as a Director of the Company on 25 August 2021. He has agreed to remain in the business and will facilitate a smooth handover once his successor is found.

Ian Nicholson, who joined the Board in 2012, will be stepping down from the Board at the AGM. Ian has served on the Audit and Risk, Remuneration and Nomination Committees.

**AUDIT AND RISK COMMITTEE REPORT** 

### WE'RE CONNECTING RISK & CONTROL

THE GLOBAL PANDEMIC HAS
HEIGHTENED THE NEED TO
MAINTAIN A ROBUST SYSTEM
OF INTERNAL CONTROL AND RISK
MANAGEMENT TO ENSURE THE GROUP
CONTINUES TO REMAIN RESILIENT,
AGILE AND IN CONTROL

**ANNE HYLAND** 

Audit and Risk Committee Chair 15 September 2021 **COMMITTEE MEETINGS** 

3

ATTENDANCE

100%

### **COMMITTEE MEMBERSHIP**

	ABDIT AND RISK Committee
A Hyland	3
J Hartup¹	3
l Nicholson	3
S Curran²	-

1. Stepped down from the Committee on 26 November 2020

2. Appointed to the Committee on 27 April 2021

### **COMMITTEE HIGHLIGHTS**

- Assessment of the key estimates and judgements used in respect of the half and full-year results.
- Oversaw the establishment of a new Internal Audit function, including the appointment of a new Group Head of Internal Audit and Risk, and BDO LLP as a co-source partner following a competitive tendering exercise.
- Reviewed the enhanced process for identifying and managing risk and completed a full review of the principal risks and how they are mitigated.
- Supported the Board in reviewing and approving the Group's new ESG model, including how climate risk and opportunities will be assessed and reported in preparation for TCFD disclosure in next year's Annual Report.

#### STATEMENT FROM THE CHAIR OF THE AUDIT AND RISK COMMITTEE

I am pleased to present the Audit and Risk Committee's ('the Committee') report for the year ended 30 June 2021. This report sets out details of the activities undertaken by the Committee during the period, in order to discharge its responsibilities in relation to supporting the Board in its oversight and monitoring of the robustness and integrity of financial reporting, and in gaining assurance on the effectiveness of the risk management and internal control system in place at Clinigen.

The global pandemic has heightened the need to maintain a robust system of internal control and risk management to ensure that the Group remains resilient, agile and in control. As a Committee we have continued our work on the essential oversight of financial reporting, internal control and risk management systems, including overseeing the implementation of a new control attestation in relation to Internal Controls over Financial Reporting ('ICFR'), the introduction of an enhanced approach to risk management, and the commencement of assurance activities over key areas of risk such as cyber, data privacy and IT general controls.

Whilst the pandemic has impacted the Group's financial performance during the year, we have continued to operate with minimal disruption to our supply chain operations, adapting operational processes where required to enable employees to work safely whilst ensuring supply to our customers. I am pleased to report that throughout this challenging year, the Group's governance and internal controls over financial reporting have continued to operate as intended. In addition, the introduction of a new Internal Audit function in October 2020 has increased the Group's focus, capability and capacity over assurance.

Looking ahead, the Committee will continue to monitor the potential impact of the pandemic on the financial performance of the business whilst maintaining a strong focus on internal controls and the developing maturity of the Group's risk management approach. We will also monitor the development of plans in readiness for the changes required to meet the UK Government's proposals coming out of the 'Restoring Trust in Audit and Corporate Governance' consultation.

# THE PURPOSE AND FUNCTION OF THE AUDIT AND RISK COMMITTEE Purpose

The role of the Audit and Risk Committee is to monitor and review the integrity of financial information and to provide assurance to the Board that the Group's internal controls and risk management processes are appropriate and regularly reviewed. We also oversee the work of the external auditor, approve their remuneration and recommend their appointment. In addition to the disclosure requirements relating to audit committees under the Code, this report sets out areas of significance and particular focus for the Committee.

#### Membership, meetings and attendance

The membership of the Committee, together with appointment dates and attendance at meetings, are detailed on page 70. Sharon Curran joined the Committee on her appointment to the Board in April 2021. All Committee members are Non-Executive Directors.

The Board considers that all members of the Committee are independent and have competencies relevant to the sector in which the Company operates. Anne Hyland, as Chair, is a Chartered Accountant with over 25 years' financial, risk and commercial experience in listed companies. The Board has determined that the Group meets the Code requirements for the Committee to include at least one member with recent and relevant financial experience. The biographies of all Committee members are detailed on page 62 to 63.

Meetings are attended by the members of the Committee and others who attend by invitation, being principally the CEO, CFO, Group Financial Controller, General Counsel & Company Secretary, and the Group Head of Internal Audit and Risk. Other members of executive management may be invited to attend to provide insight or expertise in relation to specific matters. The PwC Engagement Leader and other representatives of the external auditor are also invited to attend Committee meetings to present their reports on the interim results and full-year audit. They also present their proposed audit plan to the Committee.

In addition, the Committee Chair meets with the Group Head of Internal Audit and Risk and the external audit Engagement Partner outside of the Committee meetings to obtain a full understand of the key agenda items, enabling these subjects to be discussed meaningfully at the meetings.

#### **AUDIT AND RISK COMMITTEE REPORT CONTINUED**

#### MAIN ACTIVITIES OF THE COMMITTEE

The Committee has met three times since the last Annual Report was issued. These meetings were scheduled meetings and are generally timed to coincide with the financial reporting timetable of the Company. The annual program of work ensures the Committee considers standing items of business alongside any exceptional matters that may arise during the year.

At each meeting, the Committee reviews the following items routinely:

- status of statutory audits and reporting;
  the internal audit progress report; and
- the strategic risk register.

The table below shows the full breadth of Committee activity during the year:

TOPIC	FY21 MAIN ACTIVITIES AND REY AREAS OF FOCUS					
PURPOSE AND FUNCTION OF THE COMMITTEE	<ul> <li>Reviewed the Committee's terms of reference</li> <li>Reviewed the effectiveness of the Committee</li> </ul>					
FINANCIAL REPORTING	<ul> <li>Reviewed and considered the half-year review memorandum prepared by the external auditor</li> <li>Reviewed the Group's preliminary statement, draft Annual Report for the year ended 30 June 2021 and management presentation to investors</li> <li>Reviewed the annual and half-yearly financial reports and related statements including clarity and completeness of disclosures and use of alternative performance measures</li> <li>Discussed the key findings of the external auditor on the interim and annual consolidated financial statements</li> <li>Reviewed the independence, objectivity, performance and effectiveness of the external auditor</li> <li>Reviewed the integrity and consistency of the key accounting judgements in determining half-year and full-year results</li> <li>Considered if the Annual Report and Accounts taken as a whole are fair, balanced and understandable</li> <li>Considered the audit memorandum prepared by the external auditor, including: <ul> <li>review of accounting treatment of non-underlying items</li> <li>assessment of acquired intangible assets and goodwill including impairment assessments undertaken</li> <li>commentary on the general control environment across the Group</li> </ul> </li> <li>Reviewed the Group's accounting for the divestment of the UK Specials Manufacturing and Aseptic Compounding business during the year</li> </ul>					
INTERNAL CONTROLS And Risk Management	<ul> <li>Oversaw plans by Internal Audit to implement a new control attestation process in support of the ICFR</li> <li>Reviewed and endorsed plans to enhance the Group's approach to enterprise risk management</li> <li>Reviewed the Group's stated principal risks and uncertainties</li> </ul>					
INTERNAL AUDIT	<ul> <li>Appointed a new Group Head of Internal Audit and Risk to build capacity and capability in respect of the internal control and risk management framework</li> <li>Appointed BDO LLP as Clinigen's co-source internal audit service provider following a competitive tendering exercise</li> <li>Considered and approved the Group Internal Audit Plan and Strategy</li> <li>Received and approved the Internal Audit Charter</li> <li>Received periodic progress reports on internal audit and risk management</li> </ul>					
EXTERNAL AUDIT	<ul> <li>Reviewed and approved the external auditors half-yearly plan</li> <li>Reviewed and approved the external auditors full-year external audit strategy</li> <li>Reviewed the findings from the external audit, including financial judgements and internal control observations</li> <li>Reviewed external auditor's performance and effectiveness throughout the financial year</li> <li>Reviewed external auditor's independence and associated non-audit fees</li> </ul>					

#### FINANCIAL AND NARRATIVE REPORTING

All significant matters that the Committee considered during the year were supported by relevant justification papers and were fully discussed so that due and appropriate consideration was given before any decision was approved.

#### FINANCIAL JUDGEMENTS

The Committee reviewed both the half-year and full-year reporting and carefully considered the key judgements applied in preparation of the consolidated financial statements including the annual impairment review of goodwill, impairment reviews for intangible assets, the revenue recognition estimates for sale of products wholesale, the Managed Access judgment of being a principal, estimates of contingent consideration payable for iQone, and the basis for the allocation of goodwill and intangibles in the calculation of loss on sales of the UK Compounding business. Further details of these judgments and estimates are detailed in note 2 of the financial statements.

The Committee gave particular attention to significant matters where judgement was involved, which were complex in nature, or where alternative performance measures ('APMs') were provided to enhance investors' understanding of the underlying performance. The Group uses various non-GAAP APMs within internal management reporting, the Half-Yearly Report and the Annual Report. The objective of these APMs is to isolate the impact of exceptional, one-off, or non-trading related items, to allow the Board and users of the accounts to understand better the underlying performance of the business. The Group also uses constant exchange rate growth percentages to eliminate the impact of exchange rate fluctuations and to show the underlying business growth. These matters were well supported by papers provided by management and were specifically reviewed and agreed by the external auditor in their reports to the Committee and in related discussions.

#### **GOING CONCERN AND VIABILITY STATEMENTS**

The Committee reviewed the Group's going concern and viability statements set out on page 87 of the Governance Report. In considering the viability statement the Committee paid particular attention to the robustness of the stress testing scenarios, the cash flows forecast by the Group and the committed bank facilities available. The Committee agreed that the process be amended this financial year to disclose the impact of COVID-19 on trading as a principal risk and to develop additional viability stress testing scenarios. The external auditor reviewed management's assessment and discussed this review with the Committee.

#### FAIR, BALANCED AND UNDERSTANDABLE STATEMENT

The Committee considered this Annual Report and Financial Statements 2021, taken as a whole, and concluded that the disclosures, as well as the processes and controls underlying its production, were appropriate and recommended to the Board that the Annual Report and Financial Statements 2021 is fair, balanced and understandable while providing the necessary information to assess the Company's position and performance, and strategy.

#### INTERNAL CONTROL FRAMEWORK AND RISK MANAGEMENT

The Board retains overall responsibility for the management of the Group's Internal Control Framework ('ICF') and risk management systems, and has delegated the ongoing monitoring and review of the effectiveness of the Group's internal controls to the Committee. During the year, the Group has continued to review and mature its approach to internal control and risk management, facilitated through the introduction of a new Internal Audit function.

The Group's internal control and risk management framework includes:

- a review of management's assessment over the effectiveness of the internal control framework;
- consideration of Internal Audit's reporting and assurance provided across Clinigen's risks and controls;
- a review of the going concern and viability statements together with the financial stress testing conducted to support these statements; and
- an ongoing review of baseline financial controls and management attestations on their effectiveness across the Group. During the year this has included the phased deployment of a 'control attestation' process to obtain management representations over the design and operating effectiveness of ICFR. This process will continue to evolve during the new financial year, extending out to include IT General Controls ('ITGC') and key operational compliance controls in preparation for addressing the potential requirements arising from the BEIS consultation on 'Restoring Trust in Audit and Corporate Governance'.

Further details in respect of the Group's risk management and internal control framework are provided on pages 52 to 61 of the Strategic Report, along with the principal risks, controls and mitigating actions and emerging risks. The Board's statements on the effectiveness of these processes are provided on page 56 of the Governance Report.

#### INTERNAL AUDIT FUNCTION

The Group established a new Internal Audit function during the year, appointing an in-house Group Head of Internal Audit and Risk in October 2020. Internal Audit's responsibilities include supporting management in assessing and mitigating risks to protect the business, delivering the audit plan and reporting on the effectiveness of the systems of internal control. Management continues to remain responsible for establishing and maintaining an appropriate system of risk identification and internal control, and for the prevention and detection of irregularities and fraud.

Internal Audit operates under a 'co-source' model, with additional resourcing and capacity provided by BDO LLP, who were appointed in December 2020 following a competitive tender process. The adoption of a co-source model enables the Group to access:

- a diverse range of subject matter experts to provide targeted support in those areas considered to be high risk and complex, such as data privacy, cyber security and contract compliance; and
- BDO's team of global internal auditors across those territories that we operate within.

A three-year plan to develop the Internal Audit function in line with projected business growth has been approved, including increasing the capacity and capability of the function.

#### **AUDIT AND RISK COMMITTEE REPORT CONTINUED**

#### **Internal Audit Plan**

Internal Audit operates a three-year risk-based assurance plan which seeks to provide balanced coverage of the Group's strategic and operational risks and activities. The plan is supported by a documented 'Audit Universe' which maps risks to the Group's divisions and areas of activity and provides coverage across areas considered to have a material financial, operational and compliance risk associated with them.

The plan was prepared following wide consultation with a range of key stakeholders. It consists of a rolling program of core assurance activities, categorised as either 'routine' (cyclical), 'risk' (specifically linked to a Group principal or operational risk); or 'request' (included following a specific request by management). An agile approach to assurance activity will be deployed to ensure new risks, new acquisitions and/or areas of major business change are considered for inclusion. The annual internal audit plan, which defines the specific assurance work to be delivered each calendar year, is developed from the three-year plan. In February 2021, the Committee approved an interim plan of assurance work through to 30 June 2021 alongside the full-year annual plan for the year to 30 June 2022.

The key areas addressed by Internal Audit through to the year-end 30 June 2021 included:

- consulting work to document the internal financial control framework and deploy a phased roll out of a Group-wide control attestation process,
- IT control environment,
- data privacy; and,
- cyber security.

Internal audit recommendations are communicated to Executive Sponsor(s) and the relevant Business Leaders. All observations and improvements to systems, processes and controls are agreed with the sponsor(s) prior to the finalisation of each report. Moving into the new financial year, the implementation of agreed actions will be monitored and reported monthly. The Group Head of Internal Audit and Risk presents the results and conclusions of all assurance reports to the Committee together with a progress report summarising the preceding periods assurance activity.

#### INDEPENDENCE AND EFFECTIVENESS OF INTERNAL AUDIT

The Committee considered the effectiveness of the Internal Audit function and confirmed that in its opinion, internal audit had operated effectively and provided an appropriate level of independent scrutiny of the operations of the Group during the financial year, recognising the function was only formed in October 2020. This assessment is based upon the following considerations:

- the Internal Audit Charter approved by the Committee in February 2021 clearly articulates the role, independence and authority of Internal Audit;
- the Internal Audit Plan and Strategy presented to the Committee was risk-based and appropriately linked to the Group's principal and strategic risks;
- Internal Audit has added value and additional assurance over the Group's risk exposures;
- the observations and recommendations raised by Internal Audit were clearly articulated and concise;
- effective judgement over the materiality and risk of key findings was applied:
- Internal audit has constructively challenged management and displayed independence in providing their conclusions and observations;
- the dual reporting lines for the Group Head of Internal Audit and Risk into the CFO and Chair of Audit and Risk Committee worked well and did not compromise independence; and
- the assurance activity delivered was based on a clearly defined plan supported by comprehensive terms of reference for each audit.

#### **EXTERNAL INDEPENDENT AUDITORS**

PricewaterhouseCoopers LLP ('PwC') were appointed as the Group's external auditor effective from June 2013 following a competitive tendering exercise. The Committee confirms that the statutory audit services for the financial year under review were conducted in compliance with the Competition and Markets Authority ('CMA') Order.

PwC agreed their audit plan with the Committee, which included their audit scope, key audit risk areas and materiality. The Committee discussed the audit plan with PwC and approved it, together with the fees proposed.

# INDEPENDENCE, EFFECTIVENESS AND OBJECTIVITY OF THE AUDIT PROCESS Independence and objectivity

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.

#### **Effectiveness**

The Committee reviewed the work of PwC during the year and concluded that they provide an effective audit, have constructive relationships with the relevant parties and that the External Audit Engagement Partner provided clear and strong leadership to the audit team. This assessment was based upon:

 the Committee's own assessment of the quality of the audit plan, the rigour of the audit findings and conclusions, the extent to which the External Audit Engagement Partner understands the business and constructively challenges management and the quality and clarity of the technical and governance review provided;

- feedback from the Group's Finance Leadership Team ('FLT') and those involved in the audit was sought on the quality of the external audit process and team covering the following aspects:
  - audit planning and strategy adopted;
  - audit execution and conclusion
  - timeliness and quality of communication and audit reporting;
  - efficiency of the audit process and procedures adopted;
  - provision of insights and understanding of the Group;
- a report prepared by PwC setting out its processes to ensure independence and its confirmation of compliance; and,
- the level of non-audit fees as a percentage of the audit fees paid to the external auditor.

The feedback from management was reported to the Committee at the meeting on 9 September 2021. Based on the review set out above, the Committee is satisfied with the external auditor's independence, effectiveness and objectivity.

#### **RE-APPOINTMENT OF EXTERNAL AUDITOR**

At the forthcoming Annual General Meeting ('AGM'), a resolution to re-appoint PwC as the external auditor and to authorise the Committee to set their remuneration will be proposed. In recommending the re-appointment of the external auditor at the AGM, the Committee also considers the time frame for the tendering of the audit financial year.

#### **NON-AUDIT ASSIGNMENTS**

The independence of the external auditor is an essential part of the audit framework and the assurance that it provides. In line with the Revised Ethical Standard issued by the FRC in December 2019, the Committee has adopted a policy, which sets out a framework for determining whether it is appropriate to engage the Group's auditor for non-audit services and pre-approving non-audit fees.

The overall objective is to ensure that the provision of non-audit services does not impair the external auditor's independence or objectivity. This includes, but is not limited to, assessing any threats to independence and objectivity resulting from the provision of such services; any safeguards in place to eliminate or reduce these threats to a level where they would not compromise the auditor's independence and objectivity; the nature of the non-audit services; and whether the skills and experience of the audit firm make it the most suitable supplier of the non-audit service.

A summary of audit and non-audit fees in relation to the year is provided in note 5 to the Group's consolidated financial statements.

#### **KEY AREAS OF COMMITTEE FOCUS IN FY2022**

During the year, the Committee has continued to keep under review the BEIS consultation on 'Restoring Trust in Audit and Corporate Governance' and thus the impact of likely regulatory reforms on the Group and role of the Committee.

Management have already started to consider the Group's readiness in certain areas, for example the potential adoption of a 'UK SOX' approach regarding internal controls coupled with the introduction of an annual attestation on the effectiveness of the ICFR. We will detail in next year's Committee report which recommendations we will adopt (subject to the UK Government publication of the final reforms) and what progress we have made in implementing them.

In addition to monitoring and keeping under review the Group's response to the reforms, the Committee's additional planned activities include:

- keeping under review the impact of COVID-19 on internal controls, risk management and financial reporting;
- receiving updates on the operationalisation of the Group's ESG framework; and,
- monitoring the development of the Group's approach to climate reporting as part of its commitment to report and disclose against the Task Force on Climate-Related Financial Disclosures ('TCFD') in 2022.

#### CONCLUSIONS

The Committee has had a 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 the internal control and risk management capability across the Group continues to mature as we continue to operate in an increasingly challenging external environment.

#### **ANNE HYLAND**

Audit and Risk Committee Chair 15 September 2021

#### REMUNERATION REPORT

# WE'RE PROVIDING ACCOUNTABILITY TO SHAREHOLDERS



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.

#### IAN NICHOLSON

Remuneration Committee Chair 15 September 2021 **COMMITTEE MEETINGS** 

4

ATTENDANCE

100%

#### **COMMITTEE MEMBERSHIP**

	REMUNERATION Committee
I Nicholson	4
P Allen	4
A Hyland¹	4
J Hartup²	3
S Curran³	-

- 1. Appointed to the Committee 23 July 2020
- 2 Stepped down from the Committee on 26 November 2020
- 3. Appointed to the Committee on 27 April 2021

#### **DEAR SHAREHOLDER**

On behalf of the Board, I am pleased to present you with the Remuneration Committee's ('the Committee') report for the year ended 30 June 2021.

The Committee was chaired by me throughout the year and my co-members were Peter Allen and Anne Hyland. Sharon Curran also joined the Committee on 27 April 2021. The Committee met four times formally in 2021.

As one of the larger listed companies on the AIM market, the Board and the Committee take governance seriously and this report is put to an 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, which 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 1,000 employees in 14 international locations. The governance of the remuneration policy is equally important to ensure it is appropriate for the size and profile of the Group.

#### PERFORMANCE HIGHLIGHTS

The Group's financial results:

- Adjusted net revenue of £458.6m, up 7%
- Adjusted EBITDA of £116.3m, down 10%
- Adjusted EPS down 14% to 55.9p

Headwinds felt by COVID-19 have continued to impact multiple parts of the business in FY2021. The Products division has been most significantly impacted with net revenue falling in both the Owned and On-Demand categories by 11% and 18% respectively, leading to a fall in divisional EBITDA. In Services, the high number of business wins and delivery against key projects has led to a 15% increase in net revenue, but due to the profit mix of these wins and slower than expected uptake on Managed Access Programs EBITDA has fallen by 6%.

#### **REMUNERATION FOR FY2021**

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 increased to £330,000.

Reflecting the performance in 2021 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 strategic objectives (30%). In view of performance, the Committee has determined that:

- Adjusted EBITDA of £116.3m was below the threshold level of £125.6m, resulting in 0% out of 70% payout for this element
- The strategic objectives for both Shaun Chilton and Nick Keher were set on an individual basis and are linked to the corporate, financial, 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 partially met
- Despite partial achievement of non-financial objectives the Committee has used its discretion and accordingly Shaun Chilton and Nick Keher will not receive bonus

#### LTIP

Shaun Chilton was granted LTIP awards in October 2018. This award will vest in October 2021, shortly after the reporting of the results for the 2021 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 30 October 2021 -TSR based on performance to 30 August 2021 was 29% 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 2021 period was 175.8p which is above the maximum target of 165.3p and therefore 40% out of 40% will yest

- 20% was subject to strategic 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 2021. 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 2017 LTIP and November 2017 LTIP would vest at 60% for Shaun Chilton. The final TSR performance was below the Index and therefore, we can confirm that the October 2017 LTIP and November 2017 LTIP both vested at 60% in October and November 2020.

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

#### **MANAGEMENT CHANGES**

On 25 August 2021 we announced that Nick Keher stepped down as a Director.

Nick remains an employee and will leave the Group on 27 February 2022. Nick will receive his base salary and contractual benefits during his notice period until his termination date.

Upon leaving Clinigen, he shall be treated as a good leaver for LTIP awards granted in 2019 and 2020, as per the plan rules, meaning that these awards would be permitted to vest on a pro-rata basis to the termination date, at the normal vesting date, subject to the standard performance conditions. For the strategic objectives component of each award Nick will receive half (50%) of the maximum 20% target. He will receive a termination payment of £181,500 as well as payment in lieu of his accrued annual leave. The Committee believe that the terms agreed in respect of Nick Keher's departure are fair and in line with good practice, his terms of employment and his contribution to the business.

The Company will provide reasonable outplacement support with such costs being paid directly to the relevant advisors.

#### **IMPLEMENTATION OF POLICY IN FY2022**

Following the review in September 2021, Shaun Chilton's annual base salary remained unchanged at £600,000 (no change since 1 November 2017).

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% of salary for Shaun Chilton and will be based on stretching EBITDA targets with the balance based on strategic goals
- The Committee intends to grant Shaun Chilton 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 strategic objectives. The Committee considered the level of award in light of market practices

#### REMUNERATION REPORT CONTINUED

#### 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 over time, 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

#### 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 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 us 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.

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 24 November 2021.

#### 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, Executive Directors 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:

strategic priorities in place

TOPIC	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.	The Remuneration Committee sets base salaries taking into account a range of factors including: - The individual's skills, performance and experience - Internal relativities and wider workforce salary levels - External benchmark data - The size and responsibility of the role - The complexity of the business and geographical scope - Economic indicators	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.	Vesting of the award is based on a combination of the following performance measures:  - Cumulative Group adjusted EPS compared to targets  - Cumulative Group TSR compared to FTSE SmallCap Index (ex Investment Trusts); FTSE 250 Index (ex Investment Trusts) for awards granted from 1 July 2019  - Strategic objectives  The split between measures, for each grant, is set annually by the Remuneration Committee. In 2021, 40% of the award was based on EPS, 40% on TSR and 20% on strategic objectives. The strategic 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.

#### REMUNERATION REPORT CONTINUED

TOPIC	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:

	BATE OF CONTRACT	CHEXPIRED TERM (MONTES) ON ROLLING CONTRACT	NATICE PERIOD (NONTRS)
S Chilton	3 January 2012	Rolling	12
l Nicholson	1 September 2012	Rolling	3
A Hyland	1 January 2018	Rolling	3
A Boyd	15 November 2018	Rolling	3
S Curran	27 April 2021	Rolling	3
E Schnee	3 August 2021	Rolling	3
l Johnson	3 August 2021	Rolling	3

#### REMUNERATION GOVERNANCE

The Remuneration Committee consists of four independent Non-Executive Directors. In 2021 Sharon Curran joined the Committee and, John Hartup left the Committee when he stepped down from the Board in November. Since the year-end Peter Allen left the Committee when he stepped down from the Board in September 2021 and Elmar Schnee joined the Committee in September 2021. The table below provides each member's attendance record at Committee meetings during the year. The Committee members' biographies are set out on pages 62 to 63.

COMMITTEE MEMBER	POSITION	APPAINTED (RESIGNED)	ATTEKBARCE
l Nicholson	Committee Chair	September 2012	4/4
P Allen	Non-Executive Director	(September 2021)	4/4
A Hyland	Non-Executive Director	January 2018	4/4
J Hartup	Non-Executive Director	(November 2020)	3/4
S Curran	Non-Executive Director	April 2021	-
E Schnee	Non-Executive Chairman	September 2021	_

The key areas of focus for the Remuneration Committee during 2021 included:

- Approved the Remuneration Report
- Reviewed and approved UK and international sharesave plans
- Reviewed performance conditions and targets for 2021 bonus and LTIP
- Reviewed 2020 strategic objectives and set 2021 strategic 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 2022 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
- Determine the remuneration package for a new CFO appointment

FIT advised on market trends, corporate governance, Remuneration Report disclosures and on Directors' remuneration arrangements in 2021/22. 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 2021 and 2020:

_	2921			2928						
6813	SALARY/FEES	883.02	LTIP	OTREP	TBTAL	SALARY/FEES	20312	LTIP	OTHER!	TOTAL
S Chilton	600	_	293	62	955	600	450	377	62	1,489
N Keher	315	-	-	33	348	300	225	-	31	556
P Allen	140	_	_	3	143	140	_	-	3	143
J Hartup	29	-	-	-	29	70	-	-	-	70
I Nicholson	70 ·	-	_	_	70	70	-	_	_	70
A Hyland	70	_	_	_	70	70	-	-	_	70
A Boyd	60	-	-	-	60	60	-	-	_	60
S Curran	10	_	-	_	10		_	-	_	-

<sup>1.</sup> The 2021 LTIP figure relates to the October 2018 award which is due to vest in October 2021. This award is subject to a TSR performance period ending on 30 October 2021. 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 2021. 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 2021 to 30 August 2021. The actual vesting value will be updated in next year's report to reflect the share price on vesting date. The 2020 LTIP value relates to the October 2017 award and the November 2017 award that vested on 5 October 2020 and 16 November 2020 respectively. The 2021 LTIP figure includes an adjustment of £78,000 reflecting the lower actual share price at vesting.

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 (2020: two) were members of the defined contribution pension scheme during the year.

#### REMUNERATION REPORT CONTINUED

As mentioned on page 77, 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 increased to £330,000 with effect from 1 January 2021.

The amount payable to the highest paid Director in respect of emoluments was £955,000 (2020: £1,489,000), comprising basic salary of £600,000 (2020: £1,050,000), long-term share-based incentives vesting of £293,000 (2020: £377,000) and other benefits of £62,000 (2020: £62,000).

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

#### **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 strategic objectives. Adjusted Group EBITDA targets unlock up to 70% of maximum bonus potential, whilst strategic objectives unlock up to 30%.

The bonus calculations in relation to adjusted Group EBITDA for 2021 are set out below:

TURESHOLD LEVEL OF ADJUSTED GROUP ERITDA Sm	TARGET LEVEL OF ARIUSTED EROUP EDITAA En	MAXIMUM LEVEL OF ARIOSTED ERRUP ERITDA EM	ACTUAL LEVEL OF ADJUSTED CHEER ACTUAL LAWTER M 2	BSNUS EARNED (% OF MAXIMUM)
125.6	139.5	153.5	116.3	0%
40% payable	100% payable	130% payable		

The strategic 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.

Despite partial achievement of non-financial objectives the Committee has used its discretion and accordingly Shaun Chilton and Nick Keher will not receive bonus.

The annual bonuses awarded for the 2021 financial year were as follows:

COLO	BEHUS PAYABIE (% UF SALARY	TOTAL BRNOS AWARDED IN SEPTEMBER 2021 (RELATING TO 2021 FINANCIAL YEAR)	CASH BONUS TO BE PAID IN SEPTEMBER 2021 (BELATINS TO 2021 FINANCIAL YEAR)	OFFERRED BRAUS TO BE PAID IN SEPTEMBER 2022 (RELATING TO 2021 FIRANCIAL YEAR)
S Chilton	0%	-	-	_
N Keher	0%	-	-	-

For the 2021 financial year, the annual bonus awarded to Shaun Chilton and Nick Keher was 0% of their base salary.

#### LTIP AWARDS VESTING IN THE YEAR

#### 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 strategic objectives (20%).

MEASURE	TERESEOLO VESTING	MAXIMUM VESTILLE	OTTCOME	VESTINE (% OF MAXIMUM)
Relative TSR	Equal to the FTSE SmallCap Index (ex Investment Trusts)	Index plus 15% outperformance or higher	Index minus 18%	0%
EPS growth	5% p.a.	10% p.a.	13% p.a.	40%
Strategic objectives	- Broaden service capability - Utilise international platfor - Drive performance of porti	m and client relationships to		20%
				60%

A total performance score of 60% was achieved by Shaun Chilton, made up of 40% EPS and 20% strategic objectives.

#### October 2018 awards

Nil cost share options were granted to Shaun Chilton in October 2018 and these will vest in October 2021. These awards are subject to a performance condition of TSR (40%) for the period from 1 November 2018 to 31 October 2021, cumulative EPS (40%) for the three financial years ending 30 June 2021, and strategic objectives (20%).

MEASURE	THRESHOLD VESTING	MAXIMOM VESTINS	CHTCOME	VESTING (% OF MAXIMUM)
Relative TSR	Equal to the FTSE SmallCap Index (ex Investment Trusts)	Index plus 15% outperformance or higher	Index minus 29%	0%
EPS growth	5% p.a.	10% p.a.	18% p.a.	40%
Strategic objectives	<ul> <li>expanding portfolio of acq</li> <li>expanding community of k</li> <li>further upgrades to Compa</li> </ul>	ey opinion leaders and cust		20%
				Estimated 60%

It is expected that 60% of awards will vest on 30 October 2021.

#### LTIP AWARDS GRANTED IN THE YEAR

Awards were granted to Shaun Chilton and Nick Keher in October 2020, with vesting of the awards subject to the performance conditions, as set out below, in October 2023. 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 strategic objectives. The strategic objectives component can only vest if a minimum EPS target is achieved.

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

	NUMBER OF AWARDS AND OUT OF DASS					
	ERANTED	FACE VALUE	SALARY	VESTING DATE		
Shaun Chilton	127,442	£750,000	125%	30 October 2023		
Nick Keher	63,721	£375,000	125%	30 October 2023		

<sup>1.</sup> Valued using the share price on grant.

The performance conditions applying to these awards are as follows:

#### **TSR**

TSB ARAINST THE FTSE 250 INDEX (EX INVESTMENT TRBSTS) OVER THE PERFORMANCE PERIOD (WHICH IS THE THERE-TEAR PERIOD FOLLOWING THE GRANT DATE)	PERCENTAGE OF AWARD THAT VESTS
Less than the Index	0%
Equal to the Index	25%
Between the Index but less than 15% outperformance of the Index on a cumulative basis over the TSR performance period	Calculated on a straight-line basis between 25% and 100%
Equal to or greater than 15% outperformance of the Index on a cumulative basis over the TSR performance period	100%

#### EPS

	APPARTURE OF SUIT ON THE VICTOR
CUMULATIVE EPS OVER THE PERFORMANCE PERIOD (WEICH ARE THE TRREE FINANCIAL YEARS COMMENCING WITH THE FYZHZI FINANCIAL YEAR)	PERCENTAGE OF AWARD THAT VESTS
Less than 217.1p	O%
Equal to 217.1p	25%
	Calculated on a straight-line basis
Between 217.1p and 238.8p	between 25% and 100%
Equal to or greater than 238.8p	100%

#### Strategic objectives

The element of the award relating to strategic objectives shall only vest if the strategic objectives have been achieved and the minimum EPS threshold, shown above, is achieved. The strategic objectives are based on: expanding our portfolio of specialist oncology products, improving access to critical medicines through enhancing the service offering, evolving Clinigen's global footprint by expanding our client base across the range of Services and Products.

#### 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:

	BATE OF GRANT	30 10 ME 2R20	ERANTED	EXESCISEO	LAPSED	30 JERE 2021
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 - vested	34,904	-	-	13,961	20,943
	LTIP - 6 November 2017 - vested	43,630	-	-	17,452	26,178
	LTIP - 31 October 2018	106,007	_	-	-	106,007
***************************************	LTIP - 28 October 2019	95,238	_	-	-	95,238
•••••	LTIP - 22 October 2020	_	127,442	-	-	127,442
N Keher	LTIP - 29 March 2019	96,256	_	_	_	96,256
***************************************	LTIP - 28 October 2019	38,095	_	_	-	38,095
	LTIP - 22 October 2020	-	63,721	_	_	63,721
	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 2021 are as follows:

	NUMBER OF SPARES Owned attribut	NUMBER OF SHARE OPTIONS WITH PERFORMANCE CONDITIONS	NUMBER OF SHARE OPTIONS WITHOUT PERFORMANCE CONDITIONS	NUMBER OF VESTED BUT UNEXERCISED OPTIONS
S Chilton	330,044	328,687	-	285,277
P Allen	52,232	-	-	-
N Keher	10,100	198,072	2,538	-
l Nicholson	12,000	-	-	<del>-</del>
A Hyland	11,858	-	_	-
E Schnee	10,000	_	_	_
Lohnson	-	_	-	-
A Boyd	7,000	-	-	-
S Curran	-	-	-	-
Total	433,234	526,759	2,538	285,277

There has been change in the interests set out above between 30 June 2021 and 15 September 2021 as follows: Peter Allen acquired 5,000 ordinary shares, Ian Nicholson acquired 2,000 ordinary shares, Anne Hyland acquired 7,716 ordinary shares, and Alan Boyd acquired 7,000 ordinary shares. Elmar Schnee acquired 10,000 ordinary shares before he was appointed as a Director.

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 nine years since IPO on 24 September 2012 until 28 August 2021, the Group's TSR, defined as share price growth including reinvested dividends, has outperformed the FTSE All-Share Index by 225%, the FTSE 350 Pharma and Bio Index by 148% and the FTSE SmallCap Index (ex Investment Trusts) by 98%.

#### **CEO REMUNERATION**

The total remuneration for the CEO during each of the last five 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 2017	FINANCIAL YEAR 2018	FINANCIAL YEAR 2019	FINANCIAL YEAR 2020	FINANCIAL YEAR 2021	PERCENTACE CHANGE	PERCENTAGE CHANGE FOR ALL EMPLOYEES
Total remuneration (£000)	1,266	1,202	2,558	1,489	955	(36)%	(3)%
Annual bonus (% of maximum)	100%	58%	75%	75%	0%	(100)%	(57)%
LTIP vesting (% of maximum)	100%	95%	100%	60%	50%	(17)%	0%

#### **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 3 DICUNE	1921 £M	8545 80	CHANGE %
Total employee pay	55.6	53.4	15%
Dividends	10.1	9.2	0%
Adjusted profit before tax	92.3	108.1	(14%)

#### **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 page 39.

#### IMPLEMENTATION OF REMUNERATION POLICY IN 2022

Along with the salary review timetable for the Company as a whole, the Executive Directors' salaries for 2022 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 pension contribution is 10% of salary. He will receive standard benefits in line with those provided to the workforce.

The annual bonus opportunity for Shaun Chilton is 100% of salary, with 70% based on EBITDA and 30% on strategic 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 which 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 strategic objectives.

Following his appointment as Chairman, Elmar Schnee receives an annual fee of £170,000 per annum.

Following his appointment as Senior Independent Director, Ian Johnson receives an annual fee of £65,000 per annum.

No changes are proposed to the Non-Executive Directors' fees for FY2022.

#### IAN NICHOLSON

Remuneration Committee Chair 15 September 2021

#### REPORT OF THE DIRECTORS FOR THE YEAR ENDED 30 JUNE 2021

The Directors present their report together with the Strategic Report and the audited consolidated financial statements for the year ended 30 June 2021.

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

#### PRINCIPAL ACTIVITIES

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

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

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

Clinigen partner with more than 500 pharma clients and enable access for more than 22,000 healthcare professionals across more than 120 countries.

#### STRATEGIC REPORT

As permitted by legislation, some of the matters required to be included in the Report of the Directors have instead been included in the Strategic Report on pages 4 to 47, as the Board considers them to be of strategic importance. Specifically, these are Risk Management on pages 52 to 61, Business Review and Future Developments on pages 44 to 47, and Environmental, Social and Corporate Governance on pages 32 to 41. 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 MAP and Partnered products under management, the number pharma clients utilising more than one part of the platform 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. This policy will also be applied for 2022.

#### **MAJOR SHAREHOLDERS**

As at 30 June 2021, the following shareholders held an interest of 3% or more of the Company's issued share capital:

	M BF TOTAL YOTHE RETUS
Janus Henderson Investors	6.6%
Slater Investments	6.3%
Rathbones	5.6%
Octopus	5.5%
AXA Investment Managers	4.2%
Invesco	3.8%
NFU Mutual	3.1%
Allianz Global Investors	3.0%

As at 31 August 2021, the following shareholders held an interest of 3% or more of the Company's issued share capital:

	SHIFEY LATET TO X Stedin
Slater Investments	6.8%
Janus Henderson Investors	6.3%
Rathbones	5.7%
Octopus	5.6%
AXA Investment Managers	4.5%
Invesco	3.7%
NFU Mutual	3.3%
Allianz Global Investors	3.0%

On 10 September it was announced that Elliot Management Investment had acquired a 5.2% interest in the Company. There were no other changes to the list of major shareholders between 31 August and the date of this report.

#### DIVIDEND

The Directors propose to maintain the final dividend at 5.46p per share, subject to approval at the AGM on 26 November 2021. The dividend will be payable on 4 January 2022 to all shareholders on the register on 3 December 2021. 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 (2020: 7.61p 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:

(Resigned 24 August 2021)
(Resigned 1 September 2021)
(Appointed 27 April 2021)
(Resigned 26 November 2020)
(Appointed 3 August 2021)
(Appointed 3 August 2021)

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 international accounting standards in conformity with the requirements of the Companies Act 2006 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 international accounting standards in conformity with the requirements of the Companies Act 2006 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 international accounting standards in conformity with the requirements of the Companies Act 2006, 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 strategic plan is subjected to sensitivity analysis. Appropriate stress testing of certain key performance, solvency and liquidity assumptions underlying the plan has been conducted taking account of the principal risks and uncertainties faced and possible severe but plausible combinations of those risks and uncertainties. These include the shortage of supply for a key product, additional working capital requirements and lower profitability levels. The impact of these sensitivities is reviewed individually and in aggregate on the plan and does not indicate a viability concern.

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.

#### REPORT OF THE DIRECTORS FOR THE YEAR ENDED 30 JUNE 2021

#### 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 is not impacting on the Group's ability to continue as a going concern. At 30 June 2021, the Group had £83m of cash balances along with a further £32m of undrawn borrowing facility 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 12 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 of the consolidated financial statements.

#### **EMPLOYEES AND OTHER STAKEHOLDERS**

The policies relating to employees are discussed in the Environmental, Social and Corporate Governance section of the Strategic Report. See pages 18 to 21 for disclosure of 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
- 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's 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 24 November 2021, 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, PricewaterhouseCoopers, have expressed their willingness to continue in office and a resolution to re-appoint them will be proposed at the forthcoming AGM.

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

#### **SHAUN CHILTON**

Group Chief Executive Officer 15 September 2021

- DocuSigned by:

Shawa Chillon

Signer Name: Shaun Chilton
Signing Reason: I approve this document
Signing Time: 11-Nov-2021 j 6:39:22 PM GMT

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## INDEPENDENT AUDITORS' REPORT

TO THE MEMBERS OF CLINIGEN GROUP PLC

## REPORT ON THE AUDIT OF THE FINANCIAL STATEMENTS

In our opinion:

- Clinigen Group plc's group financial statements and parent company financial statements (the "financial statements") give a true and fair view of the state of the group's and of the parent company's affairs as at 30 June 2021 and of the group's profit and the group's cash flows for the year then ended;
- the group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006;
- the parent company financial statements 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
- the financial statements 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 2021 (the "Annual Report"), which comprise: the consolidated statement of financial position and the company balance sheet as at 30 June 2021; the consolidated income statement, the consolidated statement of comprehensive income, the consolidated statement of cash flows and the consolidated statement of changes in equity; 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

#### Overview

#### **Audit scope**

- Following our assessment of the risks of material misstatement of the Group Financial Statements we identified five components (2020: five components) where we performed a full scope audit of their complete financial information, either due to their size or risk characteristics. These components are located in the UK and United States of America and include Clinigen Group plc, Clinigen Healthcare Limited, Clinigen Inc., Colonis Pharma Limited and Quantum Pharmaceuticals Limited.
- Of the five full scope components identified above, all except Quantum Pharmaceuticals Limited are significant components of the Group.
- We also identified a further six components (2020: two) where we performed targeted specified procedures based on risk and
  materiality on the financial information. These components are located in: Belgium, United States of America, Germany, Japan,
  New Zealand and UK. This was supplemented by analytical procedures on the components that are not in scope.
- In addition the group audit team in the UK audited the consolidation and accounting areas that are centralised, including goodwill and intangible asset impairment assessments, share based payments, corporate taxation and discontinued operations
- This scope of work provided coverage of 68% (2020: 69%) of revenue, 96% (2020: 71%) of underlying profit before taxation (excluding consolidation adjustments), 77% (2020: 81%) of total assets and 90% (2020: 93%) of total liabilities.
- All audit procedures have been performed by the group audit team in the UK, except for specified procedures at Clinigen CSM Europe S.A. which have been performed by PwC Belgium, as component auditors. In addition, KPMG in Greece has assisted with certain procedures over capitalisation of intangible assets within Colonis Pharma Limited. The group engagement team has issued instructions to the component teams and overseen the work performed by them through meetings and a review of their deliverables.

#### **Key audit matters**

- Assessment of the carrying value of acquired intangible assets and goodwill (group)
- Coronavirus pandemic (COVID-19) (group and parent)
- Assessment of the carrying value of acquired intangible assets (parent)

#### Materiality

- Overall group materiality: £2,600,000 (2020: £3,000,000) based on 5% of underlying profit before taxation, less amortisation of acquired intangibles.
- Overall parent company materiality: £2,800,000 (2020: £2,300,000) based on 0.5% of net assets.
- Performance materiality: £1,950,000 (group) and £2,100,000 (parent company).

# INDEPENDENT AUDITORS' REPORT CONTINUED TO THE MEMBERS OF CLINIGEN GROUP PLC

#### 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.

#### 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.

CSM contingent consideration, which was a key audit matter last year, is no longer included because of the consideration being settled in the current year and therefore no longer a significant risk or judgement. Otherwise, the key audit matters below are consistent with last year.

#### KEY AUDIT MATTER

## Assessment of the carrying value of acquired intangibles and goodwill (group)

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.

#### ROW BUR AUDIT APBRESSED THE KEY AUDIT MATTER

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. We considered other evidence gathered in the audit to determine if any other trigger events had occurred, and agreed with the directors' assessment that no impairment was identified for acquired intangible assets, with the exception of Imukin, nor any impairment charge for goodwill was required to be recognised.

#### KEY AUDIT MATTER

## Coronavirus pandemic (COVID-19) (group and parent company)

Refer to page 70 (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. COVID-19 has also impacted the Group, especially within the Products segment as a result of lower number of non-Covid-19 hospitalisations and related treatment. As at the year end date and the date of signing the financial statements, whilst there continues to be some uncertainty over the future impact of COVID-19, management's assessment is that the impact on Clinigen is not expected to be significant in the medium and longer term, on the basis of its performance through the pandemic to date. 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.

## Assessment of the carrying value of acquired intangible assets (parent)

Refer to the critical accounting estimates and judgements in note 2 and note 4 (intangible assets) to the parent company 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.

#### HRW OUR AUDIT ADDRESSED THE KEY AUDIT MATTER

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 a number of more significant 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 below. In respect of impairment, refer to separate key audit matters relating to 'Assessment of the carrying value of acquired intangibles and goodwill' for the Group and 'Assessment of the carrying value of acquired intangible assets' for the parent company.

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 for acquired intangible assets was identified.

#### 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 and the parent company, the accounting processes and controls, and the industry in which they operate.

Clinigen is dedicated to providing healthcare professionals (HCPs) and their patients with greater access to medicines around the world, and in the process increasing the value of a pharmaceutical product by extending and expanding its lifecycle. The Group consists of two segments, Services and Products and operates worldwide.

Following our assessment of the risks of material misstatement of the Group Financial Statements we identified five components (2020: five components) where we performed a full scope audit of their complete financial information, either due to their size or risk characteristics. These components are located in the UK and United States of America.

We also identified a further six components (2020: two) where we performed targeted specified procedures based on risk and materiality on the financial information. These components are located in: Belgium, United States of America, Germany, Japan, New Zealand and UK. This is supplemented by analytical procedures on the components that are not in scope.

The coverage for both the current and prior year is sufficient and in compliance with the applicable auditing standards.

# INDEPENDENT AUDITORS' REPORT CONTINUED TO THE MEMBERS OF CLINIGEN GROUP PLC

#### 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:

,	FINANCIAL STATEMENTS - GROUP	FINANCIAL STATEMENTS - PARENT COMPANY
Overall materiality	£2,600,000 (2020: £3,000,000).	£2,800,000 (2020: £2,300,000).
How we determined it	5% of underlying profit before taxation, less amortisation of acquired intangibles	0.5% of net assets
Rationale for benchmark applied	We believe that underlying profit before taxation, less amortisation of acquired intangibles provides a consistent basis for determining materiality as it eliminates the impact of non-underlying items which fluctuate year on year and can have a disproportionate impact on the consolidated income statement.	We believe that net assets are an appropriate basis for determining materiality as the parent company is not a profit orientated entity.

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 £400,000 and £2,300,000.

We use performance materiality to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds overall materiality. Specifically, we use performance materiality in determining the scope of our audit and the nature and extent of our testing of account balances, classes of transactions and disclosures, for example in determining sample sizes. Our performance materiality was 75% of overall materiality, amounting to £1,950,000 for the group financial statements and £2,100,000 for the parent company financial statements.

In determining the performance materiality, we considered a number of factors - the history of misstatements, risk assessment and aggregation risk and the effectiveness of controls - and concluded that an amount at the upper end of our normal range was appropriate.

We agreed with those charged with governance that we would report to them misstatements identified during our audit above £130,000 (group audit) (2020: £150,000) and £140,000 (parent company audit) (2020: £115,000) as well as misstatements below those amounts that, in our view, warranted reporting for qualitative reasons.

#### Conclusions relating to going concern

Our evaluation of the directors' assessment of the group's and the parent company's ability to continue to adopt the going concern basis of accounting included:

- 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; and
- Verified debt covenant compliance through the financial year and for the forecast period to 31 December 2022.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's and the parent company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

However, because not all future events or conditions can be predicted, this conclusion is not a guarantee as to the group's and the parent company's ability to continue as a going concern.

In relation to the directors' reporting on how they have applied the UK Corporate Governance Code, we have nothing material to add or draw attention to in relation to the directors' statement in the financial statements about whether the directors considered it appropriate to adopt the going concern basis of accounting.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

#### 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 our work undertaken in the course of the audit, the Companies Act 2006 requires us also to report certain opinions and matters as described below.

#### 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 2021 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements.

In light of the knowledge and understanding of the group and parent company and their environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic report and Report of the Directors.

#### Corporate governance statement

ISAs (UK) require us to review the directors' statements in relation to going concern, longer-term viability and that part of the corporate governance statement relating to the parent company's compliance with the provisions of the UK Corporate Governance Code, which the Listing Rules of the Financial Conduct Authority specify for review by auditors of premium listed companies. Our additional responsibilities with respect to the corporate governance statement as other information are described in the Reporting on other information section of this report.

Based on the work undertaken as part of our audit, we have concluded that each of the following elements of the corporate governance statement is materially consistent with the financial statements and our knowledge obtained during the audit, and we have nothing material to add or draw attention to in relation to:

- The directors' confirmation that they have carried out a robust assessment of the emerging and principal risks;
- The disclosures in the Annual Report that describe those principal risks, what procedures are in place to identify emerging risks and an explanation of how these are being managed or mitigated;
- The directors' statement in the financial statements about whether they considered it appropriate to adopt the going concern basis of accounting in preparing them, and their identification of any material uncertainties to the group's and parent company's ability to continue to do so over a period of at least twelve months from the date of approval of the financial statements;
- The directors' explanation as to their assessment of the group's and parent company's prospects, the period this assessment covers and why the period is appropriate; and
- The directors' 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 its assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions.

Our review of the directors' statement regarding the longer-term viability of the group was substantially less in scope than an audit and only consisted of making inquiries and considering the directors' process supporting their statement; checking that the statement is in alignment with the relevant provisions of the UK Corporate Governance Code; and considering whether the statement is consistent with the financial statements and our knowledge and understanding of the group and parent company and their environment obtained in the course of the audit.

In addition, based on the work undertaken as part of our audit, we have concluded that each of the following elements of the corporate governance statement is materially consistent with the financial statements and our knowledge obtained during the audit:

- The directors' statement that they consider the Annual Report, taken as a whole, is fair, balanced and understandable, and provides the information necessary for the members to assess the group's and parent company's position, performance, business model and strategy;
- The section of the Annual Report that describes the review of effectiveness of risk management and internal control systems; and
- The section of the Annual Report describing the work of the audit committee.

We have nothing to report in respect of our responsibility to report when the Directors' statement relating to the parent company's compliance with the Code does not properly disclose a departure from a relevant provision of the Code specified under the Listing Rules for review by the auditors.

# 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 group's and 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 group or 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.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below.

Based on our understanding of the group and industry, we identified that the principal risks of non-compliance with laws and regulations related to Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and equivalent bodies in overseas territories, and we considered the extent to which non-compliance might have a material effect on the financial statements. We also considered those laws and regulations that have a direct impact on the financial statements such as the Companies Act 2006. We evaluated management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls), and determined that the principal risks were related to fraudulent journal entries (for example journal entries to increase revenue and profit) and bias in relation to judgements and estimates, particularly in the areas of goodwill and intangible assets impairment assessment. The group engagement team shared this risk assessment with the component auditors so that they could include appropriate audit procedures in response to such risks in their work. Audit procedures performed by the group engagement team and/or component auditors included:

- Understanding and evaluating the key elements of the group's internal control related to estimates;
- Validating the support behind the assumptions and judgements made by management including challenging against possible alternatives, for example in relation to goodwill and intangible asset impairment assessment;
- Identifying and substantively testing higher risk journal entries, in particular any that increased profit, that had unusual account combinations or were posted by senior management;
- Discussions with and corroborating key assertions made by finance management with internal audit, the group's legal counsel
  and senior group and divisional management including views on accounting judgements and estimates, and considering
  known or suspected instances of non-compliance with laws and regulation and fraud;
- Reading the minutes of the Board meetings to identify any inconsistencies with other information provided by management;
- Reviewing internal audit reports in so far as they related to the financial statements;
- Reviewing legal expense accounts to identify significant legal spend which may be indicative of serious breaches of laws and
- Reviewing component teams' key working papers, as required by ISA (UK), for in-scope components with a particular focus
  on the areas involving judgement and estimates.

There are inherent limitations in the audit procedures described above. We are less likely to become aware of instances of non-compliance with laws and regulations that are not closely related to events and transactions reflected in the financial statements. Also, the risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error, as fraud may involve deliberate concealment by, for example, forgery or intentional misrepresentations, or through collusion.

Our audit testing might include testing complete populations of certain transactions and balances, possibly using data auditing techniques. However, it typically involves selecting a limited number of items for testing, rather than testing complete populations. We will often seek to target particular items for testing based on their size or risk characteristics. In other cases, we will use audit sampling to enable us to draw a conclusion about the population from which the sample is selected.

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 obtained 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 parent company financial statements are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

#### PAUL NORBURY BSC FCA (SENIOR STATUTORY AUDITOR)

for and on behalf of PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors East Midlands 15 September 2021

## CONSOLIDATED INCOME STATEMENT

FOR THE YEAR ENDED 30 JUNE 2021

			2121	-	202	RE-PRESENTED (NOTE 30)	
(MEM)	KOTE	CHBERTAINS	NON-ORDERLYING (NOTE 7)	TETAL	ONSERTAINE	NON-ENDERLYING (HOTE 7)	TOTAL
Revenue	4	523.6	-	523.6	466.7	-	466.7
Cost of sales		(325.6)	(0.1)	(325.7)	(256.7)	(4.9)	(261.6)
Gross profit	4	198.0	(0.1)	197.9	210.0	(4.9)	205.1
Administrative expenses		(97.5)	(38.9)	(136.4)	(91.2)	(71.4)	(162.6)
Profit from operations	4	100.5	(39.0)	61.5	118.8	(76.3)	42.5
Finance costs	8	(8.3)	(1.4)	(9.7)	(11.3)	(8.3)	(19.6)
Share of profit of joint venture	15	-	_	-	0.3	-	0.3
Profit before income tax		92.2	(40.4)	51.8	107.8	(84.6)	23.2
Income tax expense	9	(17.8)	5.7	(12.1)	(21.1)	12.1	(9.0)
Profit for the year from continuing operations		74.4	(34.7)	39.7	86.7	(72.5)	14.2
Loss for the year from discontinued operations	30	0.2	(9.6)	(9.4)	0.3	(0.8)	(0.5)
Profit attributable to owners of the Company		74.6	(44.3)	30.3	87.0	(73.3)	13.7
Earnings per share (p)							
Basic	10			22.8			10.3
Diluted	10			22.3			10.2
Earnings per share from continuing operations (p)							
Basic	10			29.8			10.8
Diluted	10			29.2			10.6

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 30 JUNE 2021

		2021		2020			
(II SII)	UNDERLYING	(KOTE Y) Hon-Gnderlying	TOTAL	ONDERTAING	NON-ONDERLYINS (NOTE 7)	TOTAL	
Profit attributable to owners of the Company	74.6	(44.3)	30.3	87.0	(73.3)	13.7	
Other comprehensive income/(expense)	•••••••••••••••••••••••••••••••••••••••						
Items that may be subsequently reclassified to profit or loss							
Cash flow hedges	0.1	-	0.1	0.2	_	0.2	
Currency translation differences	(26.2)	-	(26.2)	4.0	_	4.0	
Net investment hedge	4.7	-	4.7	(1.3)	-	(1.3)	
Income tax relating to components of other comprehensive income	(0.9)	-	(0.9)	_	-	-	
Total other comprehensive (expense)/income for the year	(22.3)	-	(22.3)	2.9	_	2.9	
Total comprehensive income attributable to owners of the Company	52.3	(44.3)	8.0	89.9	(73.3)	16.6	
Total comprehensive income/(expense) arising from:							
Continuing operations	52.1	(34.7)	17.4	89.6	(72.5)	17.1	
Discontinued operations	0.2	(9.6)	(9.4)	0.3	(0.8)	(0.5)	

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

(UEW)	NOTE	2021	2020
Assets			
Non-current assets			
Intangible assets	12	718.3	788.3
Property, plant and equipment	13	13.6	13.4
Right-of-use assets	14	19.1	20.4
Investment in joint ventures and associates	15	-	_
Other financial assets	30	1.1	_
Deferred tax assets	22	10.8	7.2
Total non-current assets		762.9	829.3
Current assets			
Inventories	16	56.6	43.5
Trade and other receivables	17	163.2	125.9
Derivative financial instruments	21	-	0.2
Cash and cash equivalents	18	82.9	143.1
Total current assets		302.7	312.7
Total assets		1,065.6	1,142.0
Liabilities			
Non-current liabilities			
Trade and other payables	19	1.7	8.9
Borrowings and lease liabilities	20	413.9	450.7
Deferred tax liabilities	22	30.2	33.6
Total non-current liabilities		445.8	493.2
Current liabilities			
Trade and other payables	19	162.0	194.9
Corporation tax liabilities		6.0	3.7
Borrowings and lease liabilities	20	4.8	4.3
Derivative financial instruments	21	-	0.3
Total current liabilities		172.8	203.2
Total liabilities		618.6	696.4
Net assets		447.0	445.6
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)
Foreign exchange reserve	24	(4.7)	17.7
Retained earnings	24	123.2	99.5
Total equity		447.0	445.6

The notes on pages 101 to 131 form an integral part of the consolidated financial statements.

The financial statements on pages 96 to 131 were approved and authorised for issue by the Board of Directors on 15 September 2021 and were signed on its behalf by:

-DocuSigned by: Shawn Chilton

Signer Name: Shaun Chilton Signing Reason: I approve this document Signing Time: 11-Nov-2021 | 6:40:40 PM GMT E81ADF360DDE4FFBA6FCF15D1DD90986
SHAUN CHILTON

Director

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# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2021

(IXEM)	HOTE	2021	2020
Operating activities			
Profit for the year before tax		51.8	23.2
Share of profit of joint venture		-	(0.3)
Net finance costs	8	9.7	19.6
Profit from operations		61.5	42.5
Adjustments for:			
Amortisation of intangible fixed assets		51.1	48.9
Impairment of intangible fixed assets	•	2.6	4.2
Depreciation of property, plant and equipment		6.5	5.8
Impairment of investment in joint venture	15	-	5.9
Movement in fair value of derivative financial instruments	-	-	0.1
(Decrease)/increase in fair value of contingent consideration	7	(5.9)	11.8
Payment of increased fair value of contingent consideration	29	(33.2)	-
Currency revaluation on contingent consideration	7	(1.6)	2.0
Equity-settled share-based payment expense	6	3.7	3.5
		84.7	124.7
Increase in inventories		(15.2)	(8.3)
Increase in trade and other receivables		(47.9)	(17.0)
Increase/(decrease) in trade and other payables		45.1	(5.5)
Cash generated from operations		66.7	93.9
Income taxes paid		(15.6)	(23.9)
Interest paid		(10.6)	(10.2)
Net cash flows from operating activities – continuing operations		40.5	59.8
Net cash flows from operating activities – discontinued operations	30	4.7	0.8
Net cash flows from operating activities		45.2	60.6
Investing activities			
Purchase of intangible fixed assets (excluding products)	12	(23.2)	(19.9)
Purchase of property, plant and equipment	13	(5.1)	(2.8)
Purchase of specialty pharmaceutical products	12	_	(58.4)
Contingent consideration on purchase of subsidiaries	29	(34.7)	_
Proceeds from sale of business, net of cash disposed	30	3.1	
Net cash flows used in investing activities - continuing operations		(59.9)	(81.1)
Net cash flows used in investing activities - discontinued operations	30	(0.6)	(0.3)
Net cash flows used in investing activities		(60.5)	(81.4)
Financing activities		(00.3)	(01.4)
Proceeds from increase in Ioan	20	7.6	107.6
Loan repayments	20	(30.9)	(17.1)
Principal element of lease payments	20	(3.4)	(3.1)
Step acquisition of Clinigen Ireland Ltd	29	(1.8)	(3.1)
Dividends paid	11	(10.1)	(9.2)
Net cash flows (used in)/from financing activities – continuing operations	70	(38.6)	78.2
Net cash flows used in financing activities - discontinued operations	30	(0.3)	(0.3)
Net cash flows (used in)/from financing activities		(38.9)	77.9
Net (decrease)/increase in cash and cash equivalents		(54.2)	57.1
Cash and cash equivalents at 1 July	18	143.1	83.5
Foreign exchange (losses)/gains		(6.0)	2.5
Cash and cash equivalents at 30 June	18	82.9	143.1

#### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2021

(HEM)	SWARE CAPITAL (Note 23)	MEMBER PERME THURSDA	WERRED DESERVE	MEDCING RESERVE	FOREICH EXCHANGE Reserve	RETAINED EARNINGS	TOTAL EQUITY
At 1 July 2020	0.1	240.2	88.2	(0.1)	17.7	99.5	445.6
Profit for the year	-	-	-	-	-	30.3	30.3
Currency translation differences	_	-	-	-	(26.2)	-	(26.2)
Net investment hedge, net of tax	-	-	-	-	3.8	-	3.8
Cash flow hedges	•	***************************************	***************************************				
- Effective portion of fair value movements	-	-	-	0.6	-	-	0.6
- Transfers to the income statement (revenue)	-	-	-	(0.5)	-	-	(0.5)
Total comprehensive income	-	-	-	0.1	(22.4)	30.3	8.0
Employee share schemes (note 27)	-	-	-	-	-	3.7	3.7
Step-acquisition of Clinigen Ireland Ltd	-	-	_	-	-	(0.2)	(0.2)
Dividends paid (note 11)	-	-	-	-	-	(10.1)	(10.1)
Total transactions with owners of the Company, recognised directly in equity	-	-	_	-	_	(6.6)	(6.6)
At 30 June 2021	0.1	240.2	88.2	-	(4.7)	123.2	447.0
	SHARE CAPITAL (HUTE 23)	SHARE PREMIUM Account		GENETIKO RESERVE	FOREIEN EXCHANGE RESERVE	RETAINED EARNINGS	YOTALEQUITY
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	_	-	_	-	4.0	_	4.0
Net investment hedge, net of tax	-	_	_	_	(1.3)	-	(1.3)
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
Employee share schemes (note 27)	-	_	-	_	-	3.5	3.5
Step-acquisition of Clinigen Ireland Ltd	-	-	-	-	-	(1.6)	(1.6)
Deferred taxation on employee share schemes	_	-	-	_	-	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

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2021

#### 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 have been prepared under the historical cost convention, modified to include revaluation to fair value of certain financial instruments, in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006.

On 31 December 2020 EU-adopted IFRS was brought into UK law and became UK-adopted international accounting standards, with future changes to IFRS being subject to endorsement by the UK Endorsement Board ('UKEB'). The Consolidated Financial Statements will transition to UK-adopted international accounting standards for financial periods beginning 1 July 2021.

The preparation of these financial statements 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 presentation 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 is not impacting on the Group's ability to continue as a going concern. At 30 June 2021, the Group had £83m of cash balances along with a further £32m of undrawn borrowing facility 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 3

There was an amendment to IFRS 3 'Business Combinations' relating to the definition of a business, with an effective date of 1 January 2020, which the Group adopted from 1 July 2020.

The change in definition of a business within IFRS 3 introduces an optional concentration test to perform a simplified assessment of whether an acquired set of activities and assets is or is not a business on a transaction-by-transaction basis. This change is expected to result in more consistency in accounting in the pharmaceutical industry for substantially similar transactions that, under the previous definition, may have been accounted for in different ways despite limited differences in substance.

There were no other new standards, interpretations or amendments to standards that are effective for the financial year beginning 1 July 2020 that have a material impact on the Group's consolidated financial statements.

#### (b) New standards, interpretations and amendments not yet adopted

At the date of signing these financial statements, the following amendments were in issue but not yet adopted by the Group:

- Amendments to IAS 1 'Presentation of Financial Instruments', effective for periods beginning on or after 1 January 2021 not endorsed by the UKEB.
- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4, IFRS 16 in relation to interest rate benchmark reform phase 2, effective for periods beginning on or after 1 January 2021 – endorsed by the UKEB on 5 January 2021.
- Amendments to IAS 12 'Income Taxes' in relation to the recognition of deferred tax balances on transactions that, on initial recognition, give rise to equal amounts of taxable and deductible temporary differences such as leases, effective for periods beginning on or after 1 January 2023 - not yet endorsed by the UKEB.

These amendments and interpretations are not expected to have a significant impact on the Group's net results.

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2021

#### 1. ACCOUNTING POLICIES CONTINUED

#### **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 associates. Joint ventures and associates 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 Parent 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 statement of financial position presented are translated at the closing exchange rate on the date of that statement;
- b) Income and expenses for each income statement and statement of comprehensive income are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- 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. Further information on the segments the segmental disclosures in note 4 have been amended with the restatement of comparatives.

#### **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 and market vesting conditions are factored into the fair value of the options granted. As long as all other 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.

#### **Discontinued operations**

A discontinued operation is a component of the Group's business that represents a separate geographic area of operation or a separate major line of business. Classification as a discontinued operation occurs upon disposal or earlier if the operation meets the criteria to be classified as held-for-sale. Discontinued operations are presented in the Group income statement as a separate line and are shown net of tax

When an operation is classified as a discontinued operation, comparatives in the Group income statement and the Group statement of comprehensive income are re-presented as if the operation had been discontinued from the start of the comparator year.

#### 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 10 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.

### NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

#### FOR THE YEAR ENDED 30 JUNE 2021

#### 1. ACCOUNTING POLICIES CONTINUED

#### **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 5 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 seven 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 is 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 20%
- Fixtures, fittings and equipment 20% to 33%

#### 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;
- the exercise price of a purchase option if the Group is reasonably certain to exercise that option; and
- payments of penalties for termination of the lease, if the lease term reflects the Group exercising that option.

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.

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; and
- restoration costs.

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. The first in, first out or an average method of valuation is used. 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 as well as any associated income tax expense or credit is recognised in other comprehensive income and accumulated in the foreign exchange reserve.

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2021

#### 1. ACCOUNTING POLICIES CONTINUED

#### 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 macro-economic 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 pavables

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 in equity, respectively.

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; and
- 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 and the deferred 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. 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.

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 Managed Access Programs 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 is 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 over time as contracted milestones are achieved.

Monthly management fees are recognised as revenue over time as contractual services are 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.

#### Royalties

Royalty income is earned on product distribution agreements based upon a percentage of sales made by the distribution partner. As these sales-based royalties are on the licensing of the right to use the Group's intellectual property, revenue is only recognised at a point in time once the relevant product sales occur.

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.

#### 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 and sensitivities is included in note 12.

## 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 on the future performance of the product as well as the choice of discount rate and terminal future growth rate.

#### 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 £10.0m (2020: £8.3m). A 1% change in the estimated returns rate would result in a £1.0m (2020: £0.8m) additional adjustment to revenue.

## 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.

#### **Contingent consideration**

Contingent consideration payable and receivable is initially measured at the net present value of the expected future cash flows, discounted using an appropriate discount rate, to be paid or received 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. At 30 June 2021, the Group has a contingent consideration liability of £1.7m in relation to the iQone acquisition. Further information on the estimated fair value of the liability and the sensitivity of the estimate is provided in note 29.

## Allocation of acquired intangibles on disposal

On 30 June 2021 the Group disposed of its UK Specials Manufacturing and Aseptic Compounding business which had been acquired in 2017 as part of Quantum Pharma plc. On the acquisition of Quantum Pharma plc, the Group recognised certain goodwill and other separately identified intangibles which were assessed by an independent valuation expert. Following the disposal, management is required to make a judgement on the allocation of these intangibles between the part of the originally acquired business being disposed and the part remaining. The value of the Quantum brand has been treated as fully allocated to the disposal while the value of the goodwill and customer relationships has been allocated based on the value attributable to each business. This has been estimated using the relative adjusted EBITDA of the disposed and remaining businesses.

## 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 overleaf and reconciliation to the IFRS measure are included in note 4.

ALTERNATIVE PERFORMANCE MEASURE	RELATED IFRS MEASURE	BETRITION	B2E/EELEVANGE
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.
Adjusted EBITDA	Profit from operations	Consolidated earnings before interest, tax, depreciation, amortisation and adjusting items:  - Restructuring and acquisition costs - Adjustments to contingent consideration arising from earn-outs on acquisitions	Provides management with an approximation of cash generation from operational activities after removing the 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
		- Exceptional impairments - Including share of joint venture EBITDA	revolving credit facility.
			A reconciliation to profit from operations is included in note 4.
Adjusted profit before tax	Profit before tax	Profit before tax excluding adjusting items:  - As detailed above for adjusted EBITDA  - Amortisation of acquisition-related intangible assets  - Unwind of discount on contingent consideration  - Joint venture tax charge	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	Profit after tax excluding adjusting items:	
		<ul> <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.	Provides management with the level of leverage in the business and is used in the covenant calculations for the revolving credit facility.
		All amounts are closing balances as at the relevant balance sheet date.	
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. Adjusted operating cash flow excludes the element of CSM acquisition consideration recognised in operating cash flow.	Provides management with a view of the level of EBITDA converted into cash.

## 3. ALTERNATIVE PERFORMANCE MEASURES CONTINUED

ALTERNATIVE PERFORMANCE MEASURE	RELATED IFRS MEASURE	BEFIXITION	8SE/BELEFANCE
Free cash flow	Cash flow from operating activities	Free cash flow is the cash generated from operating activities excluding the cash impact of adjusting items:	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
		<ul> <li>Acquisition costs and related restructuring costs</li> <li>Acquisition-related income from</li> </ul>	are not reflective of the routine business operations.
		settlement of contingent legal claims outstanding at acquisition	A reconciliation to adjusted EBITDA is included on page 50.

## 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 Chief Operating Decision Maker ('CODM') during the reporting year. The CODM has been identified as the Executive Directors. During the year the organisational structure of the business has changed to the two reported businesses of Products and Services and the internal reporting to the CODM has changed to this basis.

#### **Operating segment results**

Net revenue and adjusted EBITDA 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 Managed Access Programs changes. Segmental adjusted EBITDA provides a measure of profitability with an approximation of cash generation.

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

	2121			2020 (NE-PRESENTER) (NOTE 30)		
(IBSM)	REPROTED REVENUE	NET REVENUE	ABJUSTED EBITBA	REPORTED REVENUE	MET REVENUE	ABJUSTED EBITDA
Commercial Medicines	183.1	183.1	80.5	156.7	156.7	85.5
Unlicensed Medicines	157.8	92.8	20.8	159.4	121.3	32.0
Clinical Services	191.3	191.3	22.0	162.2	162.2	22.6
Central unallocated costs and eliminations	(8.6)	(8.6)	(7.0)	(11.6)	(11.6)	(10.3)
Segmental result - continuing operations	523.6	458.6	116.3	466.7	428.6	129.8
Segmental result - discontinued operations	38.6	38.6	1.1	37.6	37.6	1.2
Segmental result	562.2	497.2	117.4	504.3	466.2	131.0

	2021			2020		
(M2HI)	REPORTED REVENUE K	NET REVENUE	ABIOSTEO EBITOA	REPORTED REVENUE	MET REVEXUE	ARIUSTED EBITDA
Products	248.3	248.3	90.6	250.2	250.2	105.2
Services	283.9	218.9	32.7	228.1	190.0	34.9
Central unallocated costs and eliminations	(8.6)	(8.6)	(7.0)	(11.6)	(11.6)	(10.3)
Segmental result - continuing operations	523.6	458.6	116.3	466.7	428.6	129.8
Segmental result - discontinued operations	38.6	38.6	1.1	37.6	37.6	1.2
Segmental result	562.2	497.2	117.4	504.3	466.2	131.0

Net revenue is presented after excluding pass through revenue of £65.0m (2020: £38.1m) from the Managed Access business within Services.

	2021			202	O (RE-PRESENTED) (NOTE 30	)
(INEM)	ENDERLYING	HAN-UNDERLYING (AUTE 7)	TOTAL	ONDERLY(NC	NON-ONDERLYING (NOTE 7)	TOTAL
Reconciliation to reported profit					•	
Gross profit	198.0	(0.1)	197.9	210.0	(4.9)	205.1
Administrative expenses excluding amortisation and depreciation	(81.8)	5.6	(76.2)	(80.8)	(22.9)	(103.7)
EBITDA	116.2	5.5	121.7	129.2	(27.8)	101.4
Analysed as:	***************************************					
Adjusted EBITDA including joint venture result	116.3	5.5	121.8	129.8	(27.8)	102.0
Joint venture EBITDA	(0.1)	_	(0.1)	(0.6)	_	(0.6)
EBITDA excluding joint venture result	116.2	5.5	121.7	129.2	(27.8)	101.4
Amortisation and impairment	(9.2)	(44.5)	(53.7)	(4.6)	(48.5)	(53.1)
Depreciation	(6.5)	-	(6.5)	(5.8)	-	(5.8)
Profit from operations	100.5	(39.0)	61.5	118.8	(76.3)	42.5
Finance costs	(8.3)	(1.4)	(9.7)	(11.3)	(8.3)	(19.6)
Share of profit of joint venture	-	-	-	0.3	-	0.3
Profit before income tax	92.2	(40.4)	51.8	107.8	(84.6)	23.2
Analysed as:						
Adjusted profit before tax excluding share of joint venture tax	92.3	(40.5)	51.8	108.1	(84.9)	23.2
Joint venture tax	(0.1)	0.1	-	(0.3)	0.3	-
Profit before tax including share of joint venture tax	92.2	(40.4)	51.8	107.8	(84.6)	23.2
Income tax	(17.8)	5.7	(12.1)	(21.1)	12.1	(9.0)
Profit for the year from continuing operations	74.4	(34.7)	39.7	87.0	(72.5)	14.2
Loss for the year from discontinued operations	0.2	(9.6)	(9.4)	0.3	(0.8)	(0.5)
Profit attributable to owners of the Company	74.6	(44.3)	30.3	87.0	(73.3)	13.7

## NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

FOR THE YEAR ENDED 30 JUNE 2021

## 4. SEGMENT INFORMATION CONTINUED

(IESM)	2821	2020
Disaggregation of revenue from continuing operations:		
Products		
Owned	106.4	120.1
Partnered	94.3	72.1
On-Demand	47.6	58.0
	248.3	250.2
Services		
Clinical	191.3	162.2
Managed Access	92.6	65.9
	283.9	228.1
Inter-segment eliminations	(8.6)	(11.6)
Total revenue from external customers	523.6	466.7

All revenue arises from contracts with customers and is recognised at a point in time or over time in accordance with the Group accounting policies.

**Geographical analysis** 

(IEEM)	2921	2020 RE-PRESENTED (NOTE 30)
Revenue from continuing operations arises from the location of the customers as follows:		
N	97.2	106.5
Europe	167.3	135.8
USA	129.8	121.4
South Africa	33.3	32.2
Australia	24.7	24.8
Rest of World	71.3	46.0
Total	523.6	466.7

Assets and liabilities are reported to the Executive Directors at a Group level and are not reported on a segmental basis.

## **5. EXPENSES - CONTINUING OPERATIONS**

## 5.1 Expenses

Profit from operations is stated after charging:

(MEMI)	2021	2020 Re-presented (Note 30)
Cost of inventories recognised as an expense in cost of sales	286.9	216.5
Employee benefit expense (net of capitalised costs of £0.9m (2020: £1.6m))	54.7	51.8
Amortisation and depreciation	57.6	54.7
Impairment of intangible assets	2.6	4.2
Impairment of investment in joint venture	-	5.9
Foreign exchange gains	0.3	0.9

#### 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:

(IIISM)	2021	2828
Fees payable to the Company's auditor for the audit of the Parent Company and consolidated financial		
statements	0.4	0.3
Fees payable to the Company's auditors for other services:	***************************************	
- The audit of the Company's subsidiaries	0.3	0.4
- Audit-related assurance services	0.2	0.1
- Tax advisory and compliance services	0.2	0.5

No new impermissible non-audit services were provided to the Group by the Parent Company's auditor after 15 December 2020.

## 6. EMPLOYEES - CONTINUING OPERATIONS

#### 6.1 Employee benefit expense

(IHEM)	2321	2020 RE-PRESENTED (NOTE 30)
Wages and salaries	46.2	44.4
Share-based payment expense (note 27)	3.7	3.5
Social security costs	4.0	3.8
Other pension costs	1.7	1.7
Gross expense	55.6	53.4
Capitalised labour	(0.9)	(1.6)
Net expense	54.7	51.8

#### 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	1921	2020 RE-Presented (Note 30)
Directors	2	2
Staff	1,011	959
Total	1,013	961

## 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 82 to 91.

#### 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.

(IVEN)	2921	2929
Directors' remuneration included in staff costs:		
Wages and salaries	1.4	2.1
Share-based payment expense	0.7	0.8
Total	2.1	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.

	2821	2020 RE-PRESENTED (NOTE 30)
(IFSII)		
Cost of sales	0.1	4.9
a) Impairment of Totect and Foscavir inventories		
Administrative expenses		
b) Acquisition costs		0.3
c) Restructuring costs (relating principally to acquisitions)	1.9	2.9
d) (Decrease)/increase in the fair value of contingent consideration (note 29)	(5.9)	11.8
e) Impairment of IP related to Imukin (2020: Totect) (note 12)	2.6	4.2
f) Impairment of investment in joint venture (note 15)	-	5.9
g) Foreign exchange revaluation on deferred and contingent consideration	(1.6)	2.0
h) Amortisation of intangible fixed assets acquired through business combinations and acquired products	41.9	44.3
	38.9	71.4
Finance costs		
i) Unwind of discount on deferred and contingent consideration	1.3	8.1
b) Acquisition costs	0.1	0.2
	1.4	8.3
Taxation		
j) Credit in respect of tax on non-underlying expenses	(9.9)	(12.1)
k) Deferred tax charge from change in future UK tax rate	4.2	
	(5.7)	(12.1)
Total non-underlying items	34.7	72.5

- a) In the prior year, impairment charges were recognised against Totect short-dated stock and excess Foscavir active pharmaceutical ingredient totalling £4.9m. The £0.1m charge in the current year relates to the write down of the remaining stock held.
- b) Acquisition costs in the prior year related 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 Brexit.
- d) The increase in the fair value of contingent consideration in the prior year related to the final earn-out calculation for the CSM acquisition. The reduction in the fair value of contingent consideration in the current year relates to a change in estimate for the iQone acquisition.
- e) An impairment charge has been recognised against the book value of Imukin due to lower than anticipated sales of the product. In the prior year, the book value of Totect was impaired to £nil.
- f) In the prior year, 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 took the decision to fully impair the investment.
- g) 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.
- h) The amortisation of intangible assets acquired as part of business combinations (namely brand, trademarks and licences, customer relationships, and contracts) and acquired products is included in non-underlying due to its significance and to provide the reader with a consistent view of the underlying costs of the operating Group.
- The non-cash unwind of the discount applied to the deferred and contingent consideration on the acquisitions of Proleukin, CSM, and iQone.
- j) The tax credit in respect of non-underlying items reflects the tax benefit on the costs incurred.
- k) Due to the change in the UK tax rate from 19% to 25% from 1 April 2023, an increase in the deferred tax liability on acquired intangibles of £4.2m has been recognised (see note 9).

## **8. FINANCE COSTS**

(IEEM)	2921	2028 RE-PRESENTED (HOTE 30)
Bank interest expense	9.5	9.6
Borrowing costs	0.3	0.1
Foreign exchange credit on borrowings	(3.0)	_
Amortisation of facility issue costs	0.9	1.1
Unwind of discount on lease liabilities	0.6	0.5
Underlying finance costs	8.3	11.3
Unwind of discount on deferred and contingent consideration on acquisitions	1.3	8.1
Acquisition costs	0.1	0.2
Total finance costs	9.7	19.6

## 9. INCOME TAX EXPENSE

2021	2028 Re-presented (Mote 10)
8.1	12.7
8.6	6.7
0.8	0.6
17.5	20.0
(6.9)	(13.4)
(2.7)	0.1
4.2	2.3
(5.4)	(11.0)
12.1	9.0
	8.1 8.6 0.8 17.5 (6.9) (2.7)

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:

(BEB)	2121	2820 RE-PRESENTED (NOTE 30)
Profit before income tax	51.8	23.2
Expected tax charge based on corporation tax rate of 19.0%	9.8	4.4
Expenses not deductible for tax purposes	0.9	2.7
Income not taxable	(2.1)	-
Tax relief for employee share schemes	(0.1)	(0.9)
Adjustments to tax charge in respect of prior years	(1.9)	0.7
Foreign tax credit	-	(0.2)
Recognition/utilisation of previously unrecognised tax losses	(0.5)	(0.5)
De-recognition of previously recognised tax losses	0.4	-
Change in deferred tax rate	4.2	2.3
Higher rates of taxes on overseas earnings	1.4	0.5
Total income tax expense	12.1	9.0

During the year it was announced that the UK corporation tax rate would increase from 19% to 25% effective from 1 April 2023. This change was included in the Finance Bill 2021 which has been substantively enacted and therefore UK deferred tax assets and liabilities for which the underlying timing difference is expected to unwind after 1 April 2023 have been re-measured accordingly resulting in the recognition of an additional deferred tax charge from continuing operations of £4.2m.

Further information on deferred tax movements and balances is provided in note 22.

## 9. INCOME TAX EXPENSE CONTINUED

Amounts recognised directly in equity

The income tax (charged)/credited directly to equity during the year is as follows:

(IVEW)	2021	2020
Unexercised share options and losses recognised directly in equity	-	0.1
Net investment hedge	(0.9)	-
	(0.9)	0.1

## 10. EARNINGS PER SHARE

	2821	2020 Re-presented (Note 30)
Profit/(loss) after tax (£m)		
Profit after tax used in calculating reported EPS	30.3	13.7
Profit after tax used in calculating reported EPS - continuing operations	39.6	14.3
Loss after tax used in calculating reported EPS - discontinued operations	(9.3)	(0.6)
Underlying profit after tax used in calculating adjusted EPS	74.4	86.7
Number of shares (million)		
Weighted average number of shares	133.0	132.7
Dilution effect of share options	2.9	2.0
Weighted average number of shares used for diluted EPS	135.9	134.7
Reported EPS (pence)		
Basic	22.8p	10.3p
Diluted	22.3p	10.2p
Basic - continuing operations	29.8p	10.8p
Diluted - continuing operations	29.2p	10.6p
Basic - discontinued operations	(7.0)p	(0.5)p
Diluted - discontinued operations	(6.9)p	(0.4)p
Adjusted EPS (pence)		
Basic	55.9p	65.3p
Diluted	54.7p	64.4p

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 2,886,474 (2020: 1,996,046).

## 11. DIVIDENDS

(#2#)	2021	2828
Final dividend in respect of the year ended 30 June 2020 of 5.46p (2020: 4.75p) per ordinary share	7.2	6.3
Interim dividend of 2.15p (2020: 2.15p) per ordinary share paid during the year	2.9	2.9
•	10.1	9.2

The Board proposes to pay a final dividend of 5.46p per ordinary share, subject to shareholder approval, on 4 January 2022, to shareholders on the register on 3 December 2021.

#### 12. INTANGIBLE ASSETS

	ACQUIRED INTANCIBLES							
(INEM)	ARAND	CONTRACTS	CESTEMER RELATIONSHIPS	ACQUIRED On a rhangeart Cedescu	DEVELOPED Trademarks and Licences	COMPUTER SOFTWARE	EUTOMITT	TOTAL
Cost								
At 1 July 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
Additions	-	-	-	7.2	3.9	12.1	-	23.2
Disposal of business	(9.3)	-	(1.3)	-	-	(0.3)	(4.4)	(15.3)
Other disposals	· <b>-</b>	-	-	-	-	(0.3)	-	(0.3)
Exchange differences	(0.3)	(0.1)	(4.9)	(16.4)	(0.1)	(0.3)	(9.3)	(31.4)
At 30 June 2021	58.7	28.4	131.4	282.5	14.1	46.5	370.7	932.3
Accumulated amortisation				· · · · · · · · · · · · · · · · · · ·				
At 1 July 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
Charge for the year	4.5	1,0	17.1	20.2	0.9	8.6	-	52.3
Impairment	-	-	-	2.6	-	-	-	2.6
Disposal of business	(3.4)	-	(0.8)	-	-	(0.1)	-	(4.3)
Other disposals	_	-	-	-	-	(0.3)	-	(0.3)
Exchange differences	(0.1)	(0.1)	(2.5)	(1.4)	-	-	-	(4.1)
At 30 June 2021	19.0	23.5	77.0	78.3	1.9	14.3	-	214.0
Net book value								
At 30 June 2021	39.7	4.9	54.4	204.2	12.2	32.2	370.7	718.3
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

#### Brand

The brands represent the Idis, Link, Equity, Homemed 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
- Link 15 years 4 months
- Equity 10 years 4 months
- Homemed 5 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.

## NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED

FOR THE YEAR ENDED 30 JUNE 2021

## 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 3 and 15 years.

#### **Trademarks and licences**

A total of 623 (2020: 649) trademarks and licences are held. £7.2m (2020: £4.5m) of internally developed trademarks and licences are assets in the course of development at the year end.

Trademarks and licences are reviewed for impairment triggers on an annual basis, and where they are identified a full impairment review is carried out as required by IAS 36. The recoverable amount of each asset under review has been determined based on value-in-use calculations. These calculations use pre-tax cash flow projections over a period of ten years and a pre-tax discount rate of 10.0% (2020: 10.5%), equivalent to the Group's weighted average cost of capital. As a result of these reviews, the decision was taken to impair the book value of trademarks and licences related to Imukin by £2.6m. In the prior year an impairment of £4.2m was recognised against the book value of Totect. These impairment losses were recognised within non-underlying administrative expenses (see note 7).

#### **Computer software**

Having implemented its Oracle ERP system, the Group is now building on this infrastructure to enable a more streamlined and high quality digital platform enabling better engagement with customers, the costs for which are being recognised as incurred. Amortisation started when the first major phase of the new system was brought into use.

#### Goodwil

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 cash-generating units ('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.

(#2#)	2121	2020
Products	133.0	137.8
Services	237.7	246.6
	370.7	384.4

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 five years and a pre-tax discount rate of 10.0% (2020: 10.5%), equivalent to the Group's weighted average cost of capital.

For each CGU, a terminal growth rate of 2.0% (2020: 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.

	2021	2028
Products	1%	3%
Services	6%	7%

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.

	21	2021 2020		20	
	· RATE CEO	· RATE REQUIRED TO ELIMINATE HEADROOM IN IMPAIRMENT ASSESSMENT			
	TAR THREEZIG	TERMINAL SERVED RATE	DISCRUET RATE	TERMINAL GROWTH RATE	
Products	23.5%	(59.1)%	17.8%	(15.2)%	
Services	16.2%	(10.5)%	16.3%	(9.8)%	

13	PROPERTY	PI ANT	AND	<b>EQUIPMENT</b>
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(M2HI)	LAND AND SPILINIES	LEASEHPLO IMPROVEMENTS	PLANT AND Machinery	FIXTURES, FITTINGS AND EQUIPMENT	TOTAL
Cost					
At 1 July 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
Additions	-	1.8	0.7	3.1	5.6
Disposal of business	(1.5)	-	(0.9)	(1.2)	(3.6)
Other disposals	-	(0.1)	-	(0.3)	(0.4)
Exchange differences	(0.3)	(0.4)	(0.1)	(0.3)	(1.1)
At 30 June 2021	2.9	7.1	1.2	9.7	20.9
Accumulated depreciation					
At 1 July 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
Exchange differences	_	(0.1)	(0.1)	(1.1)	(1.3)
At 30 June 2020	0.4	2.2	0.6	3.8	7.0
Charge for the year	0.2	0.7	0.3	1.6	2.8
Disposal of business	(0.2)	-	(0.4)	(1.0)	(1.6)
Other disposals	_	(0.1)	-	(0.3)	(0.4)
Exchange differences	· -	(0.2)	(0.1)	(0.2)	(0.5)
At 30 June 2021	0.4	2.6	0.4	3.9	7.3
Net book value					
At 30 June 2021	2.5	4.5	0.8	5.8	13.6
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

## 14. RIGHT-OF-USE ASSETS

(WEW)	Canadad Canadad	PLANT AND MAGNINERY	FIXTURES, FITTINGS AND EQUIPMENT	TOTAL
Cost				
At 1 July 2020	22.3	0.8	0.5	23.6
Additions	4.6	3.1	_	7.7
Disposal of business	(4.6)	(0.1)	-	(4.7)
Other disposals	(0.3)	-	-	(0.3)
Exchange differences	(0.6)	-	(0.1)	(0.7)
At 30 June 2021	21.4	3.8	0.4	25.6
Accumulated depreciation			•	
At 1 July 2020	2.8	0.3	0.1	3.2
Charge for the year	3.8	0.4	0.1	4.3
Disposal of business	(0.6)	(0.1)	-	(0.7)
Other disposals	(0.2)	-	-	(0.2)
Exchange differences	-	(0.1)	-	(0.1)
At 30 June 2021	5.8	0.5	0.2	6.5
Net book value			<del> </del>	
At 30 June 2021	15.6	3.3	0.2	19.1
At 30 June 2020	19.5	0.5	0.4	20.4

## 15. INVESTMENT IN JOINT VENTURES AND ASSOCIATES

(UEM)	2021	2828 `
At 1 July	-	6.5
Share of profit	-	0.3
Impairment	-	(5.9)
Cumulative currency losses	-	(0.9)
At 30 June	-	-

In the prior 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 was impaired by £5.9m to £nil.

The registered office is also the principal place of business.

RANE	YEAR EKD	CREATING OF CACCALD REALITY AND DESISTENCED OFFICE	MEASUREMENT METERO	RWKERSHIP
Novagen Pharma Pty Limited	31 March	100 Sovereign Drive, Route 21 Corporate Park, Nellmapius Drive, Irene 0157, Pretoria	Equity	45%
Novagen BBBEE Invest Co Pty Limited	31 March	100 Sovereign Drive, Route 21 Corporate Park, Nellmapius Drive, Irene 0157, Pretoria	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.

(DEN)	2021	2020
Summarised statement of financial position	***************************************	••••
Non-current assets	1.8	1.9
Cash and cash equivalents	0.7	0.9
Other current assets	2.8	2.3
Current liabilities	(1.3)	(1.4)
Net assets	4.0	3.7
Summarised income statement		
Revenue	5.4	8.5
Profit after tax	-	0.6
Reconciliation of the summarised financial information to the carrying amounts in the joint ventures and associates		
Opening net assets	3.7	3.7
Profit for the year	-	0.6
Cumulative currency losses	-	(0.6)
Closing net assets	3.7	3.7
Interest in joint ventures and associates	1.9	1.9
Goodwill	(1.9)	(1.9)
Accumulated impairment	_	_
Carrying value	-	_

## **16. INVENTORIES**

(II SII)	2021	2020
Raw materials and consumables	18.2	15.6
Work in progress	0.5	0.1
Finished goods and goods for resale	37.9	27.8
	56.6	43.5

The cost of inventories recognised as an expense and included in cost of sales amounted to £286.9m (2020: £216.5m from continuing operations).

During the year, due to the performance of the product, the decision was taken to discontinue Totect and as a result there was a one-off write down of stock valued at £0.1m (see note 7).

#### 17. TRADE AND OTHER RECEIVABLES

(IHSH)	2921	2020
Trade receivables	123.3	98.0
Less: provision for impairment of trade receivables	(0.8)	(1.0)
Trade receivables - net	122.5	97.0
Prepayments and accrued income	19.0	16.2
Payments made on account	9.1	1.1
Other receivables	12.6	11.6
Total trade and other receivables	163.2	125.9

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 macro-economic 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:

(W2N)	2021	2828
At 1 July	1.0	1.6
Disposal of business	(0.1)	-
Utilised in respect of debts written off	(0.2)	-
Released to the income statement	-	(0.9)
Charged to the income statement	0.1	0.3
At 30 June	0.8	1.0

The ageing analysis of the gross trade receivables balances and loss allowances is as follows:

	E1823	EROSS		
(B2KI)	2921	2020	2021	2928
Not past due	89.1	63.8	-	-
Up to 3 months past due	23.6	27.4	0.1	-
3 to 6 months past due	8.5	4.3	0.2	_
More than 6 months past due	2.1	2.5	0.5	1.0
	123.3	98.0	0.8	1.0

## 18. CASH AND CASH EQUIVALENTS

(B2N)	2821	2828
Cash at bank and in hand	82.9	143.1

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 long-term credit ratings were RBS: BBB, HSBC: A-, and ABSA: AA.

## 19. TRADE AND OTHER PAYABLES

2021	2821		
CERRENT	NEW-CHERENT	CURRENT	NON-CORRENT
74.1	-	61.9	_
-	-	0.3	-
4.6	-	5.7	-
1.3	-	0.9	_
82.0	-	51.9	2.0
-	-	1.6	-
-	1.7	72.6	6.9
162.0	1.7	194.9	8.9
	74.1 - 4.6 1.3 82.0	74.1 4.6 - 1.3 - 82.0 1.7	CRMENT         NIL-CRIENT         CREATED           74.1         -         61.9           -         -         0.3           4.6         -         5.7           1.3         -         0.9           82.0         -         51.9           -         -         1.6           -         1.7         72.6

The contingent consideration of £1.7m relates to the iQone acquisition and is payable in the year ending 30 June 2024 contingent on the adjusted EBITDA generated by iQone in the 12 months to 31 December 2023. The undiscounted fair value of the contingent consideration is €2.1m.

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:

(#3#)	2821	2020
Pank harrowings	395.9	431.3
Lease guarantee provided to divested business	0.9	-
Lease liabilities	21.9	23.7
Total borrowings and lease liabilities	418.7	455.0

The Group's multi-currency debt facility is £430m comprising an unsecured £180m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £250m. There has been no change to the facility during the year. At 30 June 2021, the drawn down facility was denominated in £263m sterling (2020: £264m), €99m euros (2020: €90m), and US\$69m US dollars (2020: US\$108m).

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). As at 30 June 2021, interest cover was 10.0x (2020: 13.3x) and the net debt/adjusted EBITDA leverage was 2.8x (2020: 2.3x). The Group has no history of default on its borrowings, including against its covenant terms.

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 2.5% (2020: 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:

	2121			2028		
(0.2 H)	ENSS SIRRIYWES	ONAMORTISED Issue costs	NET BURROWNES	ELOSS BERREWIKES	UNAMBETISED ETERS BUZZE	HET BORROWINGS
Within 1 year	4.8	-	4.8	4.3	_	4.3
In more than 1 year but less than 2 years	4.1	-	4.1	4.2	_	4.2
In more than 2 years but less than 5 years	411.4	(1.6)	409.8	449.0	(2.5)	446.5
	420.3	(1.6)	418.7	457.5	(2.5)	455.0

#### 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

(M2H)	TERM LOAN	REF	FINANCIAL SPARANTEE	LEASE LIABILITIES	BRAMANTISEO (358E 27201	TOTAL BOOKSWIKES	CASH AND CASH EQUIVALENTS	NET DEST
At 1 July 2020	183.0	250.8	-	23.7	(2.5)	455.0	(143.1)	311.9
Cash flow before borrowings	-	-	-	-	-	-	29.0	29.0
Disposal of business	-	-	0.9	(4.8)	-	(3.9)	1.9	(2.0)
Lease liability additions	-	-	-	7.8	_	7.8	-	7.8
Lease liability disposals	-	-	-	(0.2)	-	(0.2)	-	(0.2)
Proceeds from increase in loan	-	7.6	-	-	-	7.6	(7.6)	-
Repayments of borrowings	_	(30.9)	-	(3.7)	_	(34.6)	34.6	-
Amortisation of facility issue costs	-	_	-	-	0.9	0.9	-	0.9
Exchange differences	(6.4)	(6.6)	-	(0.9)	-	(13.9)	2.3	(11.6)
At 30 June 2021	176.6	220.9	0.9	21.9	(1.6)	418.7	(82.9)	335.8

Total borrowings represent liabilities arising from financing activities.

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; and
- 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; and
- derivative financial instruments.

The Group does not issue or use derivative financial instruments of a speculative nature.

A summary of the financial instruments held by category is provided below:

(HEM)	2921	2020
Financial assets measured at amortised cost		
Cash and cash equivalents	82.9	143.1
Trade and other receivables	150.2	101.4
Derivatives used for hedging	•	
Derivative financial instruments	-	0.2
Total financial assets	233.1	244.7
Financial liabilities measured at amortised cost		
Trade and other payables	159.1	198.1
Borrowings and lease liabilities	420.3	457.5
Derivatives used for hedging		
Derivative financial instruments	-	0.3
Total financial liabilities	579.4	655.9

## 21. FINANCIAL INSTRUMENTS - RISK MANAGEMENT CONTINUED

#### Risk management

A description of the Group's treasury policy and controls is included in the Financial Review on page 51.

#### 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 Group 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.

(INEW)	2821	2020
Financial assets - maximum exposure		
Cash and cash equivalents	82.9	143.1
Trade and other receivables	150,2	101.4
Derivative financial instruments	-	0.2
Total financial assets	233.1	244.7

#### 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 49% (2020: 44%) 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.

	2021	2021 28		20	
(M2 M)	ASSETS	LIABILITIES	ASSETS	LIABILITIES	
Forward foreign exchange contracts - cash flow hedges	-	-	0.2	0.3	

The notional principal amounts of the outstanding forward foreign exchange contracts at 30 June 2021 were US\$3m (2020: US\$5m and  $\epsilon$ 6m) with maturity in July 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\$1.35:£1 and  $\epsilon$ 1.15:£1.

In FY2019 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 2021, 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 £5.3m (2020: £10.5m) 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:

(INEM)	LESS TRAB 3 mentrs	BETWEEN 3 mbhtes and 1 year	BETWEEN I AND 2 YEARS	BETWEEN 2 AND 5 YEARS
At 30 June 2021				
Trade and other payables	157.0	0.4	_	1.9
Lease liabilities	1.3	3.5	4.1	10.8
Borrowings	-	-	-	395.9
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

#### Valuation hierarchy

The table below shows the financial instruments carried at fair value by valuation method:

(UEB)	2021 Level 1	2821 Level 2	2821 LEVEL 3	<b>2020</b> Level 1	2020 Level 2	2020 LEVEL 3
Assets/(liabilities)						
Derivative financial instruments – forward foreign exchange contracts		_	-	_	(0.1)	- -
Contingent consideration	-	-	(1.7)	_	-	(79.5)

The Level 2 forward foreign exchange valuations are derived from mark-to-market valuations as at 30 June 2021. Fair value gains of £0.6m (2020: £2.3m) 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 iQone (and CSM in the prior year) acquisition. The amounts payable have been calculated based on the latest forecast of earnings during the respective earn-out periods.

#### 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; and
- 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 less cash and cash equivalents (as detailed in note 20).

## 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 jurisdictions as follows:

(IVEN)	2921	2020
Deferred tax assets	10.8	7.2
Deferred tax liabilities:		
Deferred tax liabilities to be settled after more than 12 months	(25.2)	27.6
Deferred tax liabilities within 12 months	(5.0)	6.0
	(30.2)	33.6

The movement on the deferred income tax account is as shown below:

(M2 HI)	BALANEE AT 1 JULY 2020	DECORNISED IN Lucane Statement	DISPOSAL OF Business	FRREIGN EXCRAIGE ADJUSTMENTS	BALANCE AT 30 JUNE 2021	DEFERRED TAX ASSETS	BEFERRED TAX Liabilities	NET GEFERRED TAX LIABILITIES
Intangible assets	(34.8)	1.6	1.5	0.8	(30.9)	_	(30.9)	(30.9)
Property, plant and equipment	1.0	-	-	-	1.0	1.0	-	1.0
Inventories	6.1	1.1	-	(0.5)	6.7	6.7	-	6.7
Leases	0.6	-	(0.1)	-	0.5	0.5	-	0.5
Share-based payments	1.9	0.1	_	-	2.0	2.0	_	2.0
R&D tax credits	(1.7)	-	-	-	(1.7)	-	(1.7)	(1.7)
Losses	0.5	0.2	-	-	0.7	0.7	-	0.7
US chargebacks accrual		2.4	-	(0.1)	2.3	2.3	-	2.3
Jurisdictional offset	-	-	-	_	-	(2.4)	2.4	-
	(26.4)	5.4	1.4	0.2	(19.4)	10.8	(30.2)	(19.4)

(M2NI)	BALAKEE AT 1 JULY 2019	RECORNISED IN Income Statement	RECOGNISED IN EQUITY	STREETS EXERGISE STREETS GREAT	BALAKCE AT 30 JUNE 2020	DEFERRED TAX ASSETS	DEFERRED TAX LIABILITIES	NET BEFERRED TAX LIABILITIES
Intangible assets	(39.6)	4.9	_	(0.1)	(34.8)	-	(34.8)	(34.8)
Property, plant and equipment	1.1	(0.1)	_	_	1.0	1.0	-	1.0
Inventories	0.3	5.8	-	-	6.1	6.1	-	6.1
Leases	-	(0.1)		-	0.6	0.6	_	0.6
Share-based payments	1.1	0.7	0.1	-	1.9	1.9	-	1.9
R&D tax credits	(1.5)	(0.2)		_	(1.7)	_	(1.7)	(1.7)
Losses	0.3	0.2	-	_	0.5	0.5	-	0.5
Jurisdictional offset	-	_	······	-	_	(2.9)	2.9	-
	(38.3)	11.2	0.8	(0.1)	(26.4)	7.2	(33.6)	(26.4)

Deferred tax assets are recognised for tax losses carried forward to the extent that the realisation of the related tax benefit through future taxable profits is probable. 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.

The Group has de-recognised a deferred tax asset of £0.4m in respect of previously recognised tax losses of £2.4m in Clinigen Inc., a subsidiary registered in the US, as it has now been determined these losses may not be utilised before their expiry in 2030.

A deferred tax asset of £0.2m has been recognised in respect of previously unrecognised tax losses of £1.0m in Clinigen Healthcare Switzerland Sarl, a subsidiary registered in Switzerland, as it has now been determined that these can be utilised against future taxable income. A deferred income tax asset of £0.2m has not been recognised in respect of £1.3m of losses on the basis these may not be utilised before their expiry in 2024.

Similarly, a deferred tax asset of £0.5m has been recognised in respect of previously unrecognised tax losses of £1.8m in Clinigen KK, a subsidiary company registered in Japan, as it has been determined that these can now be utilised against future taxable income. These losses are not subject to expiry.

A deferred tax asset is 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.

A deferred tax asset is recognised by Clinigen Inc. in relation to the accrual made for chargebacks arising on wholesaler discounted sales in the US on the basis Clinigen Inc. (the company that made the sales) will generate sufficient taxable profits against which the temporary difference will reverse.

At 30 June 2021 the undistributed earnings of non-UK subsidiaries were £58.1m (2020: £37.0m). No deferred tax liabilities have been recognised in respect of these unremitted earnings because the Group is in a position to control the timing of any dividends from subsidiaries and it is probable that the repatriation of the accumulated earnings of foreign subsidiaries is not expected to take place in the foreseeable future.

## 23. SHARE CAPITAL

	NUMBER OF SHARE	(1883)	
USSGED AND FOLLY PAID	ORDINARY SHARES OF C.		
At 1 July 2019		132,479	
Issue of new shares		420	
At 30 June 2020		132,899	
Issue of new shares		130	
At 30 June 2021		133,029	
(BEB)	2821	2020	
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:

BESERVE	DESCRIPTION AND PROPOSE				
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 re-translating 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 2021 is £11.5m (2020: £8.7m) relating to unexercised share options which is not distributable.

## **25. CAPITAL COMMITMENTS**

At 30 June 2021, the Group had capital commitments of £0.4m (2020: £nil).

## **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 £1.8m (2020: £1.7m from continuing operations).

## 27. EMPLOYEE SHARE SCHEMES

An equity-settled share-based payment charge of £3.7m (2020: £3.5m) has been recognised in the year.

The Company operated the following schemes which are all equity-settled:

PLAN	TAX AUTEURITY STATUS	EMPLOYEES	CRANTIUR, PESTIUR COURTIONS AND EXERCISE OF SHARE OPTIONS
Clinigen Group Long-Term Incentive Plan	Unapproved	All employees	Subject to performance criteria comparing total shareholder return 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	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 Long Term Incentive Plan 2015	Unapproved	All employees	Subject to performance criteria comparing total shareholder return versus the relevant index (FTSE SmallCap Index (excluding investment companies) for grants in FY2016 to FY2019 and the FTSE 250 for grants in FY2020) 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 strategic objectives.
			If the individual leaves earlier than the earliest vesting date, entitlement is at the discretion of the Remuneration Committee.
Clinigen Group All Staff Long Term Incentive Plan	Unapproved	All employees	Subject to performance criteria comparing total shareholder return 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:

		2121		
	WEIGHTED AVERAGE Exercise Pride (P)	MEMBER	WEIGHTED AVERAGE EXERCISE PRICE (P)	MAMBEU
As at 1 July	0.82	2,531,033	0.93	2,279,105
Granted during year	0.92	1,447,276	0.97	887,285
Forfeited during the year	1.08	(604,532)	1.30	(415,241)
Exercised during year	2.29	(137,051)	1.24	(220,116)
As at 30 June	0.70	3,236,726	0.82	2,531,033
Vested and exercisable at 30 June	0.27	407,624	1.12	386,714

The weighted average share price (at the date of exercise) of options exercised during the year was £7.04 (2020: £7.87).

The exercise price of options outstanding at 30 June 2021 ranged between £nil and £9.25 and their weighted average remaining contractual life was 1 year 3 months.

The weighted average fair value of each option granted during the year was £3.99 (2020: £5.12).

The following information is relevant in the determination of the fair value of options granted during the year under the equity-settled 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.

	2021	2020
Weighted average share price at grant date (£) -	5.88	7.68
Exercise price (£)	nil to 7.09	nil to 9.25
Weighted average contractual life (in years)	3.0	2.8
Expected volatility (%)	44	30
Expected dividend yield (%)	N/A	N/A
Risk-free interest rate (%)	0	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.

#### **Subsidiary undertakings**

A full list of the Parent Company's subsidiary undertakings is given in note 14 to the Company financial statements. There are no significant non-controlling interests.

#### 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 £0.3m (2020: £0.5m) to Novagen, and recharged costs of £0.5m (2020: £0.4m) for goods and services provided. At 30 June 2021, the Group had no amounts receivable owing from Novagen (2020: £nil).

From time to time, the Group receives services from Alan Boyd Consultants Limited, a company owned and managed by Alan Boyd, one of the Group's Non-Executive Directors. During the year the Group received services amounting to £0.1m (2020: £0.2m).

There were no other transactions with related parties during the year.

## 29. BUSINESS COMBINATIONS

There were no business combinations in the year ended 30 June 2021 (2020: none).

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

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

The contingent consideration liability for the iQone acquisition has been revised down by £5.9m to £1.7m following a revision in the estimate of the likely payment. The liability has been discounted at a rate of 10%. A 100bps change in the discount rate would increase/decrease the fair value by £0.1m, and a 10% change in the expected value of the EBITDA in the earn out period would increase/decrease the fair value by £0.5m.

The contingent consideration liability outstanding at 30 June 2021 was £1.7m (2020: £6.9m). The movement in the year of £5.2m comprised a £5.9m change in estimate of the amount payable and a £0.4m exchange difference recognised through non-underlying administrative expenses offset by a £1.1m unwind of discount recognised through non-underlying finance costs.

## **30. DISPOSALS AND DISCONTINUED OPERATIONS**

On 30 June 2021, the Group completed the divestment of its non-core UK Specials Manufacturing and Aseptic Compounding business, and the results and cash flows of this business are accordingly classified as discontinued. As a result of this classification, the comparatives in the statement of comprehensive income and statement of cash flows, as well as the supporting notes, have been re-presented to separate the results for discontinued operations in accordance with the requirements of IFRS 5.

#### **Results for discontinued operations**

(III EM)	2821	2828
Revenue	38.6	37.6
Adjusted EBITDA	1.1	1.2
Restructuring (costs)/credit	(0.1)	0.1
Amortisation and depreciation	(1.8)	(1.8)
Finance costs	(0.1)	(0.1)
Loss before tax	(0.9)	(0.6)
Income tax (expense)/credit	(0.1)	0.1
Loss after tax	(1.0)	(0.5)
Loss on disposal of discontinued operations	(8.3)	_
Loss for the year from discontinued operations	(9.3)	(0.5)

The amortisation and depreciation charge includes amortisation of acquired intangibles of £1.1m (2020: £1.1m).

#### **Cash flows for discontinued operations**

(INEM)	2021	2020
Cash flows from operating activities	4.7	0.8
Cash flows used in investing activities	(0.6)	(0.3)
Cash flows used in financing activities	(0.3)	(0.3)
Net cash flow from discontinued operations	3.8	0.2

**Loss on disposal**The Group recognised a total loss on disposal of £8.3m which is analysed as follows:

(W2W)	
Net assets disposed of (book value at date of disposal):	
Goodwill	4.4
Other intangible assets	6.6
Property, plant and equipment	. 2.0
Right-of-use assets	4.0
Deferred tax assets	0.1
Inventories	2.8
Trade and other receivables	16.1
Cash and cash equivalents	1.9
Trade and other payables	(18.7)
Corporation tax liabilities	(0.1)
Deferred tax liabilities	(1.5)
Lease liabilities	(4.8)
Net assets disposed of	12.8
Consideration received:	
Cash proceeds	5.0
Deferred consideration	1.1
Transaction costs	(0.7)
Recognition of guarantee on lease liability	(0.9)
Total net consideration	4.5
Loss on disposal	8.3

## **COMPANY BALANCE SHEET**

AS AT 30 JUNE 2021

(III)	ROTE	2021	2028
Assets			
Non-current assets			
Intangible assets	4	63.0	61.3
Tangible assets	5	0.7	1.1
Investments	6	739.0	744.9
Deferred tax assets	11	2.0	1.9
Total non-current assets		804.7	809.2
Current assets			
Debtors	7	429.6	341.7
Corporation taxes recoverable		-	1.3
Cash and cash equivalents		5.4	50.4
Total current assets		435.0	393.4
Total assets		1,239.7	1,202.6
Current liabilities			
Creditors: amounts falling due within one year	8	278.0	176.3
Loans and borrowings	10	0.2	0.3
Total current liabilities		278.2	176.6
Net current assets		156.8	216.8
Total assets less current liabilities		961.5	1,026.0
Non-current liabilities			
Creditors: amounts falling due after more than one year	9	1.7	6.9
Loans and borrowings	10	396.0	431.6
Total non-current liabilities		397.7	438.5
Net assets		563.8	587.5
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
At 1 July		259.0	283.9
Loss for the year attributable to the owners		(17.3)	(19.4)
Other changes in retained earnings		(6.4)	(5.5)
Retained earnings		235.3	259.0
Total equity		563.8	587.5

The financial statements on pages 132 to 141 were approved by the Board of Directors on 15 September 2021 and were signed on its behalf by:

-DocuSigned by:

Shaun Chilton

Signer Name: Shaun Chitton
Signing Reason: I approve this document
Signing Time: 11-Nov-2021 | 6:41:15 PM GMT
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**SHAUN CHILTON** 

Director

# COMPANY STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2021

(MSM)	SHARE CAPITAL (NOTE 12)	SHARE PREMIUM Account	MERSED RESERVE	HEORING BEZERAE	RETAINED EARNINGS	TOTAL EQUITY
At 1 July 2020	0.1	240.2	88.2	-	259.0	587.5
Loss for the year	_	-	-	-	(17.3)	(17.3)
Employee share schemes	-	-	-	-	3.7	3.7
Dividends paid	-	_	_	-	(10.1)	(10.1)
Total transactions with owners of the Company, recognised directly in equity	_	-	-	-	(6.4)	(6.4)
At 30 June 2021	0.1	240.2	88.2	_	235.3	563.8
(M2NI)	SHARE CAPITAL (KBTE 12)	SHARE PREMIUM Account	MERGER RESERVE	HEORING RESERVE	RETAINED EARNINGS	TOYALEQUITY
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)

(M2NI)	SMARE CAPITAL (HBTE 12)	SHARE PREMIUM Account	MERGER RESERVE	HEORING RESERVE	RETAINED CARNINGS	TBYALERDITY
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
Employee share schemes		-	-	_	3.5	3.5
Deferred taxation on share-based payment scheme	-	-	-	-	0.1	0.1
Dividends paid	-	-	-	-	(9.2)	(9.2)
Total transactions with 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

The following describes the nature and purpose of each reserve within equity:

RESERVE	DESCRIPTION AND PREPASE		
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.		

## NOTES TO THE COMPANY FINANCIAL STATEMENTS

FOR THE YEAR ENDED 30 JUNE 2021

## 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 have been prepared on the going concern basis under the historical cost convention and in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 "Reduced Disclosure Framework", and applicable law). In preparing these financial statements, the Company applies the recognition, measurement and disclosure requirements of International Financial Reporting Standards in conformity with the requirements of the 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.

#### **Exemptions**

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 is included within the consolidated financial statements of Clinigen Group plc.

#### Critical accounting estimates and judgements

The judgements and accounting estimates with a significant risk of material adjustment in the next financial year relate to the carrying value of intangible assets and contingent consideration. These are discussed in detail within note 2 of the consolidated financial statements.

## 2. STAFF COSTS

(REM)	2021	2828
Staff costs (including Directors) comprise:		
Wages and salaries	8.2	5.1
Social security costs	0.7	0.6
Share-based payment expense	3.7	3.5
Other pension costs	0.1	0.1
Gross staff costs	12.7	9.3
Capitalised labour	(0.1)	(1.2)
Net staff costs	12.6	8.1

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:

KANDED	والمراجع معرضه والمراجع والمحاربة والمحاربة	Marylan Array Can	2021	2020
Directors			2	2
Staff			35	23
			37	25

#### 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.

(IEEM)			2021	2020
Directors' remuneration included in staff costs:	•			
Wages and salaries			1.4	2.1
Share-based payment expense	+	•	0.7	0.8
			2.1	2.9

Total emoluments of Directors (including pension contributions) amounted to £2.1m (2020: £2.9m). Information relating to Directors' emoluments, share options and pension entitlements is set out in the Remuneration Report on pages 76 to 85.

## 3. DIVIDENDS

(INEW)	2921	2020
Final dividend in respect of the year ended 30 June 2020 of 5.46p (2020: 4.75p) per ordinary share	7.2	6.3
Interim dividend of 2.15p (2020: 2.15p) per ordinary share paid during the year	2.9	2.9
	10.1	9.2

The Board proposes to pay a final dividend of 5.46p per ordinary share, subject to shareholder approval, on 4 January 2022, to shareholders on the register on 3 December 2021.

## 4. INTANGIBLE FIXED ASSETS

	TRADEWARKS		
(HEH)	ANDLICENCES	COMPOTER SAFTWARE	TOTAL
Cost			
At 1 July 2020	· 63.5	25.6	89.1
Additions	2.5	9.3	11.8
At 30 June 2021	66.0	34.9	100.9
Accumulated amortisation			
At 1 July 2020 -	- 25.7 <sup>-</sup>	2.1	27.8
Charge for the year	4.8	5.3	10.1
At 30 June 2021	30.5	7.4	37.9
Net book value			
At 30 June 2021	35.5	27.5	63.0
At 30 June 2020	37.8	23.5	61.3

## NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED

FOR THE YEAR ENDED 30 JUNE 2021

## 5. TANGIBLE FIXED ASSETS

(WEW)	BIGET-OF-OSE ASSETS	LEASEHOLD IMPROVENENTS	FURNITURE, FITTINGS And equipment	TOTAL
Cost				
At 1 July 2020	0.9	0.6	0.7	2.2
Additions	-	-	0.1	0.1
At 30 June 2021	0.9	0.6	0.8	2.3
Accumulated depreciation				
At 1 July 2020	0.3	0.4	0.4	1.1
Charge for the year	0.3	-	0.2	0.5
At 30 June 2021	0.6	0.4	0.6	1.6
Net book value				
At 30 June 2021	0.3	0.2	0.2	0.7
At 30 June 2020	0.6	0.2	0.3	1.1

The right-of-use assets relates to property leased by the Company for office and warehouse use.

## **6. INVESTMENTS**

(NEB)	2021	2828
Cost or valuation		
At 1 July	744.9	744.9
Impairment	(5.9)	-
At 30 June	739.0	744.9

As a result of the change in future forecasts of the iQone business which resulted in a reduction in the recognised contingent consideration liability, a comparable impairment of £5.9m has been recognised against the book value of the investment that the Company holds in Clinigen Healthcare Holding (Switzerland) SA which is the parent company of the iQone group of entities.

The Company directly holds interests in the whole of the issued share capital of the following undertakings.

NAME	COUNTRY OF INCORPORATION	MATURE 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 (Switzerland) SA	Switzerland	Holding company

All shareholdings in subsidiaries are owned 100% (2020: 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

(IREU)	2021	2020
Trade receivables	0.4	-
Amounts owed by Group undertakings	427.7	340.9
Prepayments and other debtors	1.5	0.8
	429.6	341.7

Amounts owed by Group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

## 8. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

(IKEM)	2021	2020
Trade creditors	2.3	1.5
Amounts owed to Group undertakings	269.6	97.7
Tax and social security	2.6	1.8
Other creditors	0.2	0.1
Accruals and deferred income	3.3	2.6
Contingent consideration	-	72.6
	278.0	176.3

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

(NEN)	- 12021	2020
Contingent consideration	1.7	6.9

The contingent consideration is payable in the year ending 30 June 2024 based on the adjusted EBITDA generated by the Group within the four EU markets of France, Germany, İtaly and Spain in the 12 months to 31 December 2023.

## **10. BORROWINGS AND LEASE LIABILITIES**

The book value of loans and borrowings are as follows:

		2021			2020	
(IREM)	CORRENT	MBN-CURRENT	TBTAL	CORRENT	NON-CORRENT	FOTAL
Bank borrowings	-	395.9	395.9	-	431.3	431.3
Lease liabilities	0.2	0.1	0.3	0.3	0.3	0.6
	0.2	396.0	396.2	0.3	431.6	431.9

The Group's multi-currency debt facility is £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 2021, the facility was denominated in £263m sterling (2020: £264m), €99m euros (2020: €90m), and US\$69m US dollars (2020: US\$108m).

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). As at 30 June 2021, interest cover was 10.0x and the net debt/adjusted EBITDA leverage was 2.8x. The Group has no history of default on its borrowings, including against its covenant terms.

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 2.5% plus LIBOR.

## 11. DEFERRED TAX

The movement on the deferred tax account is as shown below:

DEFERRED TAX ASSETS (III SM)	LASSES	ONEXERCISED SHARE OPTIONS	TOTAL
At 1 July 2019	0.3	1.1	1.4
(Charge)/credit to the income statement	(0.3)	0.7	0.4
Charge recognised in equity	-	0.1	0.1
At 30 June 2020	-	1.9	1.9
Credit to the income statement	_	0.1	0.1
At 30 June 2021	-	2.0	2.0

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2021

## 12. CALLED UP SHARE CAPITAL

	NUMBER OF SHARES ("ARDS)	
ISSUED AND FULLY PAID	ORDINARY SHARES OF O.	IP EACH
At 1 July 2019	132,4	479
Issue of new shares		420
At 30 June 2020	132,8	399
Issue of new shares		130
At 30 June 2021	133,0	)29
(BZB)	2821	2020
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)

(ik SM)	2021 LEVIL 1	2021 LEVEL 2	2021 LEVEL 3	2020 LEVEL 1	2020 LEVEL 2	2020 LEVEL 3
Assets/(liabilities)						
Contingent consideration	-	-	(1.7)	-	-	(72.6)

The Level 3 contingent consideration liability is the discounted amount payable in respect of the iQone (and CSM in the prior year) acquisition. The amounts payable have been calculated based on the latest forecast of earnings during the earn-out period.

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:

(M2NI)	FAIR VALUE 2021	CARRYING AMBENT 2021	FAIR VALUE 2028	CARRYING AMBURT 2020
Loans and receivables				
Cash and cash equivalents	5.4	5.4	50.4	50.4
Debtors excluding prepayments and taxes (note 7)	428.1	428.1	341.0	341.0
Total loans and receivables	433.5	433.5	391.4	391.4
Total financial assets	433.5	433.5	391.4	391.4
Financial liabilities measured at amortised cost				
Borrowings and lease liabilities	(396.2)	(396.2)	(431.9)	(431.9)
Creditors: amounts falling due within one year (note 8)	(275.4)	(275.4)	(174.5)	(174.5)
Creditors: amounts falling due after more than one year (note 9)	(0.7)	(0.7)	(6.9)	(6.9)
Total financial liabilities measured at amortised cost	(673.3)	(673.3)	(613.3)	(613.3)
Total financial liabilities	(673.3)	(673.3)	(613.3)	(613.3)
Total financial instruments	(239.8)	(239.8)	(221.9)	(221.9)

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.

## 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:

HAME	NATURE OF BASINESS	COUNTRY OF INCORPORATION
Clinigen Holdings Limited*	Holding company	UK¹
Clinigen International Holdings Limited*	Holding company	UK¹
Clinigen Healthcare Limited*	Supply of pharmaceutical products and services	UK1
Clinigen, Inc.	Supply of pharmaceutical products and services	US¹
Clinigen SP Limited*	Supply of pharmaceutical products	UK,
Clinigen Healthcare B.V.	Holding company	Netherlands
Clinigen Clinical Trials Limited	Holding company	UK¹
Clinigen Pharma Limited*	Holding company	UK¹
Clinigen GAP Limited	Dormant	UK¹
Clinigen CTS Limited	Dormant	UK¹
Clinigen Consulting Limited	Dormant	UK'
Keats Healthcare Limited	Dormant	UK¹
Clinigen GAP, Inc.	Dormant	US²
Idis Group Holdings Limited*	Holding company	UK'
Idis Group Limited*	Holding company	UK'
Idis Limited*	Dormant	UK'
Idis MA Limited	Dormant	UK¹
Idis GA Limited	Dormant	UK¹
ldis Pharma Limited	Dormant	UK¹
ldis Pharma Private Limited	Dormant	India
Clinigen Asia Pte. Limited	Holding company	Singapore
Link Healthcare Singapore Pte. Limited	Supply and distribution of pharmaceutical products	Singapore
Link Healthcare KK	Supply and distribution of pharmaceutical products	Japan
Clinigen KK	Supply and distribution of pharmaceutical products	Japan
International Medical Management Corporation KK	Supply and distribution of pharmaceutical products	Japan
Link Healthcare Sdn Bhd	Supply and distribution of pharmaceutical products	Malaysia
Link Healthcare Hong Kong Limited	Supply and distribution of pharmaceutical products	Hong Kong
Link Medical Products (Pty) Limited	Supply and distribution of pharmaceutical products	Australia
Link 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 medical devices	South Africa
Equity Pharmaceuticals (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
Equity Medical Technologies (Pty) Limited	Supply and distribution of medical devices	South Africa
Equipharm Specialized Distribution (Pty) Limited	Distribution of medical products and devices	South Africa
Clinigen Kenya Limited	Supply and distribution of pharmaceutical products	Kenya
Link Healthcare (Pty) Limited	Holding company	Australia
Link Holding 1 (Pty) Limited	Holding company	Australia
Link Holding 2 (Pty) Limited	Holding company	Australia
PMIP (Pty) Limited	Dormant	Australia
***************************************	······································	

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2021

## 14. RELATED PARTY TRANSACTIONS CONTINUED

NAME	NATURE OF BUSINESS	COUNTRY OF INCORPORATION
Plurilinx (Pty) Limited	Dormant	South Africa
Chloromix (Pty) Limited	Holding company	South Africa
Quantum Pharma Holdings Limited*	Holding company	UK²
Quantum Pharma 2014 Limited*	Holding company	UK²
Quantum Pharma Group Limited*	Holding company	UK²
UL Medicines Limited*	Supply and distribution of pharmaceutical products	UK²
Colonis Pharma Limited*	Development of pharmaceutical and related products	UK²
Protomed Limited	In liquidation	UK³
Lamda Pharma Limited*	Holding company	UK²
Lamda (UK) Limited*	Supply of pharmaceutical products	UK²
Lamda Laboratories SA	Development and supply of pharmaceutical products	Greece
Lamda Pharma SA	Development and supply of pharmaceutical products	Greece
Clinigen Ireland Limited	Manufacture and supply of pharmaceutical products	Ireland
Quantum Specials Trustee Limited	Corporate trustee	UK²
NuPharm Group Limited	Dormant	UK²
NuPharm Laboratories Limited	In liquidation	UK³
Clinigen Clinical Supplies Management Parent, Inc.	Holding company	US¹
Clinigen Clinical Supplies Management, Inc.	Provision of clinical packaging, labelling, warehousing, and distribution services	US'
Clinigen Clinical Supplies Management Holdings LLC	Provision of clinical packaging, labelling, warehousing, and distribution services	US¹
Clinigen Clinical Supplies Management SA	Provision of clinical packaging, labelling, warehousing, and distribution services	Belgium
Clinigen Clinical Supplies Management GmbH	Provision of clinical packaging, labelling, warehousing, and distribution services	Germany <sup>1</sup>
Clinigen Biological Sample Management, Inc.	Provision of clinical packaging, labelling, warehousing, and distribution services	US³
Clinigen Clinical Supplies Management Belgium SRL	Holding company	Belgium
Clinigen Healthcare Holding (Switzerland) SA	Provision of medical information services	Switzerland
Clinigen Healthcare Switzerland Sàrl	Provision of medical information services	Switzerland
Qone Healthcare France Sàrl	Provision of medical information services	France
Clinigen Healthcare France S.A.S	Provision of pharmaceutical services	France
Clinigen Healthcare Germany GmbH	Provision of medical information services	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.

COUNTRY OF INCORPORATION	REGISTERED AFFICE	
UK'	Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WW	
UK²	25 Bedford Square, Bloomsbury, London, WC1B 3HW	
UK³	Bulman House, Regent Centre, Gosforth, Newcastle Upon Tyne, NE3 3LS	
US¹	Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808	
US²	Registered Office Service Company, 203 NE Front Street, Suite 101, Milford, Delaware 19963	
US³	180 Gordon Dr Suite 109, Exton, Pennsylvania 19341	
Singapore	9 Raffles Place, #27-00, Republic Plaza, Singapore, 048619	
Japan	1-16-3, Nihonbashi, Chuo-Ku, Tokyo, 103-0027	
Malaysia	Upper Penthouse, Wisma RKT, No 2, Jalan Raja Abdullah, Off Jalan Sultan Ismail, 50300 Kula 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, RSM House, Level 2, 62 Highbrook Drive, East Tamaki, Auckland, 2013	
South Africa	100 Sovereign Drive, Route 21 Corporate Park, Nellmapius Drive, Irene 0157, Pretoria	
Netherlands	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	
Germany¹	Am Kronberger Hang 3, 75824 Schwalbach a. Ts.	
Germany²	Stefan-George-Ring 2, 81929 Munich	
ltaly	Viale Abruzzi, 94, 20131 Milan	
Spain	Calle Rafael Calvo, 18 28010, Madrid	
Switzerland	Modulis Business Park, Route de Suisse 162, 1290 Versoix	
Ireland	Mayfield Business Park, Lismore, County Waterford	
Greece	59, Ioannou Metaxa str., 19441 Koropi	
Kenya	Sameer Business Park, Mombasa Road, PO Box 10032 - 00100 - G.P.O Nairobi	
India	302, 3rd Floor, A-Wing, Rutu Business Park, Thane West, Mumbai 400606	

All shareholdings in subsidiaries are owned 100% (2020: 100%) through the subsidiaries' ordinary share capital.

## **15. CAPITAL COMMITMENTS**

At 30 June 2021, the Company had capital commitments of £0.1m (2020: £nil).

## **COMPANY INFORMATION**

Clinigen Group plc is a public company limited by shares, incorporated and registered in the UK with company number 6771928.

#### Directors

S Chilton (Group Chief Executive Officer)
E Schnee (Independent Non-Executive Chairman)
I Johnson (Senior Independent Non-Executive)
I Nicholson (Independent Non-Executive)
S Curran (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

Numis Securities Limited The London Stock Exchange Building 10 Paternoster Square London EC4M 7LT

#### **Joint brokers**

Numis Securities Limited
The London Stock Exchange Building
10 Paternoster Square
London
EC4M 7LT

RBC Capital Markets LLC Thames Court One Queenhithe London EC4V 3DQ

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