

## WE'RE 'JOINING-THE-DOTS' TO EXPAND AND EXTEND THE LIFECYCLE OF A MEDICINE, FROM CLINICAL TRIALS 1 UNLICENSED TO LICE ACROSS AN INCREASING NUMBER OF TERRITORIES.

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



#### CONTENTS

#### **OVERVIEW**

- Financial highlights
- 02 Investment case

#### STRATEGIC REPORT

- Chief Executive Officer's statement
- 08 Our business explained
- Relationships with key stakeholders 16
- 18 Market overview
- Q&A with Clinigen CEO, Shaun Chilton 20
- 24 Our track record and future growth guidance
- Strategy
- 28 Key performance indicators
- Strategy in action
- Operational review
- Clinical Services
- 38 Unlicensed Medicines
- Commercial Medicines
- 42 Financial review
- 46 Principal risks
- Corporate social responsibility

#### **GOVERNANCE REPORT**

- Board of Directors
- Chairman's introduction to governance
- Corporate governance statement
- Audit and Risk Committee report 60
- 62 Remuneration report
- Report of the Directors

#### **FINANCIAL STATEMENTS**

- Independent auditors' report
- 80 Consolidated income statement
- 80 Consolidated statement of comprehensive income
- Consolidated statement of financial position
- Consolidated statement of cash flows
- 83 Consolidated statement of changes in equity
- Notes forming part of the consolidated financial statements
- Independent auditors' report
- Company balance sheet
- Company statement of changes in equity
- Notes to the Company financial statements
- Company information

#### FINANCIAL HIGHLIGHTS

#### ADJUSTED GROSS PROFIT (£M)

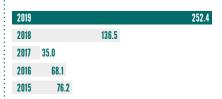
**182**3



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

2019					54.4
2018				45.4	
2017			41.3		
2016		33.4			
2015	25.6				

#### NET DEBT (£M)



#### ADJUSTED EBITDA (£M)

INN 8



#### **REVENUE (£M)**

**456.9** ~20%

2019			456.9
2018		381.2	
2017		302.3	
2016		339.9	
2015	184.4		

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



- 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 EBITDA includes the Group's share of EBITDA from its joint venture. Adjusted results include amortisation on software and internally developed IP. \*Year-on-year comparisons referred to as 'organic' are a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions. Business and product acquisitions in the current year are excluded from organic EBITDA, and for the acquisitions completing in the prior year, they are included on a pro forma basis as if they occurred on the first day of the prior year. Organic growth is presented to aid the reader's understanding of the underlying performance of the business. Operating cash flow is net cash flow from operating activities before income taxes and interest.
- Adjusted gross profit up 30% (+1% on an organic basis\*) to £182.3m (2018: £140.1m); with adjusted gross profit on an organic basis\* excl. Foscavir and UK Specials business +7%
- Adjusted EBITDA up 33% (+4% on an organic basis\*) to £100.8m (2018: £76.0m); with adjusted EBITDA growth on an organic basis\* excl. Foscavir and UK Specials business +23%
- Adjusted EPS up 20% to 54.4p (2018: 45.4p), continuing double digit EPS growth each year since IPO
- Reported EPS of 4.0p (2018: 22.9p)
- Profit before income tax of £12.3m (2018: £35.9m)
- Net debt as at 30 June 2019 of £252.4m, representing a strong cash flow performance and pro forma leverage of 1.99x
- Full year dividend increased 20% to 6.7p (2018: 5.6p)

**INVESTMENT CASE** 

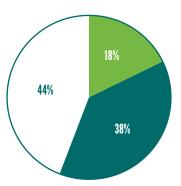
# THE TRUSTED GLOBAL LEADER IN ACCESS TO MEDICINES

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

#### UNIQUE AND DIVERSE BUSINESS MODEL

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

#### **BUSINESS OPERATIONS**



Clinical ServicesUnlicensed MedicinesCommercial Medicines

#### DISCIPLINED CORPORATE AND PRODUCT ACQUISITIONS

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

#### **CORPORATE ACQUISITIONS SINCE IPO IN 2012**

6

PRODUCT ACQUISITIONS SINCE IPO IN 2012

6

#### **GLOBAL CAPABILITY**

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

#### **EXPERIENCED MANAGEMENT TEAM**

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

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

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

#### INTERNATIONAL LOCATIONS

14

EXECUTIVE MANAGEMENT TEAM (TENURE)



2

0-2 years

2-4 years4-6 years>6 years

POSITION

#1

#### **COUNTRIES SUPPLIED IN LAST THREE YEARS**

129

#### BROAD CLIENT AND CUSTOMER BASE

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

#### SIGNIFICANT LONG-TERM GROWTH POTENTIAL

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

#### **HIGHLY CASH GENERATIVE**

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

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

**532** 

#### HCPS AS CUSTOMERS<sup>1</sup>

15,580

#### **ADJUSTED GROSS PROFIT BY REGION**

RoW



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



- 1. HCPs as customers indicates the number of registered users on Cliniport.
- Operating cash flow is net cash flow from operating activities before income taxes and interest.

#### CHIEF EXECUTIVE OFFICER'S STATEMENT

# EXECUTING ON STRATEGY AND DELIVERING ON PERFORMANCE

We have continued to execute on strategy with the recent acquisitions strengthening our offering and global capabilities as well as diversifying our portfolio of businesses and products. In financial terms, we have delivered strong growth in profits and we remain a highly cashgenerative company.



"THE STRONG GROWTH WAS DRIVEN PRIMARILY BY THE ACQUISITIONS, WITH EACH CONTRIBUTING TOWARDS THE GROUP'S PERFORMANCE. TWO OF THE LARGEST ACQUISITIONS, CSM AND THE US RIGHTS TO PROLEUKIN, HAVE EXCEEDED EXPECTATIONS."

De Capo

SHAUN CHILTON
Group Chief Executive Officer
18 September 2019

"HAVING MADE EACH OF THE ACQUISITIONS, INTEGRATION AND IDENTIFYING FURTHER COMMERCIAL OPPORTUNITIES REMAINS THE PRIORITY."

**ADJUSTED EPS (PENCE)** 

54.4

**^20**%

OPERATING CASH FLOW (£M)

**89.8** 

**~40**%

#### **OVERVIEW**

Clinigen is dedicated to providing HCPs and their patients with greater access to medicines around the world, and in the process increasing the value of a pharmaceutical product across its lifecycle. Clinigen achieves this through operating as a pharmaceutical and services group with a unique combination of businesses; Clinical Services, Unlicensed Medicines and Commercial Medicines - each focused on enabling ethical access to critically important hospital medicines - with each division working synergistically to facilitate access to medicines at key points of a product's lifecycle. Our mission is 'Right Medicine, Right Patient, Right Time'.

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

In strategic terms, we have had a transformational year. Four acquisitions were completed and largely integrated, and we saw good organic growth from a number of the core businesses which was offset by expected headwinds to Foscavir and the UK Specials business. One of the key performance indicators ('KPIs') that shows our progress in the year and the continuing development of the Cliniaen platform is the breadth and depth of our relationships with pharmaceutical companies. We have seen good progression here: five of the top 50 pharmaceutical companies have now worked with all three Clinigen business operations and 18 of the top 50 have worked with two or more of our business operations. As digital capability is key to our future success, it is also worth highlighting that we have also expanded the number of registered online users with whom we interact, to 15.580 (2018: 11.267) and launched Clinigen Direct a new digital service for HCPs to source hard to access medicines.

The Group made two corporate acquisitions, CSM and iQone, and two product acquisitions, Proleukin and Imukin during the year. CSM and iQone provide additional specialist services and international infrastructure in the US and EU. The largest product acquisition, Proleukin, is set to be highly earnings enhancing in the coming financial year with additional long-term revitalisation

potential. Integration of these acquisitions is either complete or well under way, and the Group is already seeing the benefits.

#### FINANCIAL PERFORMANCE

Once again, we have achieved double-digit growth in each of our three key financial performance metrics. Adjusted gross profit (the best measure of Clinigen's top-line performance) increased by 30%; adjusted EBITDA increased by 33%; and adjusted EPS, which takes account of the additional debt costs and share dilution from the acquisitions, increased by 20%.

The strong growth was driven primarily by the acquisitions, with each contributing towards the Group's performance. Two of the largest acquisitions. CSM and the US rights to Proleukin, have exceeded expectations. There was good organic growth in Clinical Services from Clinical Trial Services ('CTS'); in Unlicensed Medicines, from Managed Access and from the African and Asia Pacific regions in Global Access; in Commercial Medicines, we saw good growth from the developed product portfolio in the UK. These performances offset pressure both on Foscavir, from an alternative therapy, and on the UK Specials business within Unlicensed Medicines.

In addition, the Group has also achieved a strong cash flow performance, a fundamental KPI for the business, with operating cash flow up 40% to £89.8m.

Further details on our financial performance are covered by the Group Chief Financial Officer on pages 42 to 45.

#### ACQUISITIONS AND PROGRESS AGAINST STRATEGIC OBJECTIVES

During the year, the Group made two corporate acquisitions, CSM and iQone, and two product acquisitions, Proleukin and Imukin. Each of these acquisitions are in line with the Group's vision to be the trusted global leader in the access to critically important hospital medicines and are strategically important in building out the Clinigen platform.

In October 2018, the Group acquired CSM, a specialist provider of packaging, labelling, warehousing and distribution services with infrastructure in the US, Belgium and Germany. CSM has been largely integrated with the CTS business and has been brought under one business operation, Clinical Services ('CS') with one leadership structure. The acquisition of CSM has expanded our capabilities, diversified the global client base, adds important continental EU infrastructure, and reinforces the links between the Group's three business operations.

#### CHIEF EXECUTIVE OFFICER'S STATEMENT CONTINUED

"THE AGREEMENT WITH GC PHARMA IN JAPAN DEMONSTRATES OUR ABILITY TO PARTNER WITH PHARMACEUTICAL COMPANIES OUTSIDE THEIR HOME GEOGRAPHIES TO COMMERCIALISE THEIR PRODUCTS."

The other corporate acquisition, also made in October 2018, was the acquisition of iQone, a Swiss-based specialty pharmaceutical business. This acquisition will enhance Clinigen in a number of ways: supporting Clinigen's Commercial Medicines business in key EU markets: extending and enhancing the services provided by the Managed Access business within Unlicensed Medicines by providing EU medical scientific liaison ('MSL') support which is increasingly requested by clients; and enhancing the Group's proposition as a commercial licensing and/or divestment partner for pharmaceutical companies. See pages 30 to 31 which provides a case study on how both CSM and iQone contribute towards building out the Group's infrastructure platform.

Of the two product acquisitions in the year, the more substantial was the completion of the US rights to Proleukin in April 2019 following the acquisition of the rest of world rights in July 2018. Proleukin is the Group's second biologic and is indicated for use in metastatic renal cell carcinoma, as well as for metastatic melanoma in certain markets. The acquisition will be highly earnings enhancing and is an interesting and important medicine with long-term potential. It will also transform the Group's US position, combining well with CSM's existing US capabilities and giving the Group a platform from which to develop its presence in the world's biggest pharmaceutical market. See pages 34 to 35 which provides a case study on Proleukin.

The second product acquisition was the acquisition in July 2018 of the global rights (excluding US, Canada and Japan) to Imukin (recombinant human interferon gamma-1b). Imukin is licensed to reduce the frequency of serious infections in patients with chronic granulomatous disease and for the treatment of severe malignant osteopetrosis.

As with Proleukin, Imukin is also a biologic and marks an extension to the previous acquisition strategy for global specialty medicines as they have a greater inbuilt future generic protection than small molecule products, because of a more difficult manufacturing process.

We continue to target products which, while non-core to the owner, we feel we can revitalise through the Clinigen global platform.

Having made each of the acquisitions, integration and identifying further commercial opportunities remains the priority.

#### **OPERATIONAL PERFORMANCE**

Once again, this year the Group has benefited from the strength and diversity of our portfolio of businesses. As mentioned, the strong performance was driven by our acquisitions and supplemented by good areas of underlying growth across the Group which has been partially offset by areas which have faced some headwinds.

In Commercial Medicines, we continue to revitalise each of the specialty medicines in the owned product portfolio. The main headwind as expected in this business, was to Foscavir which faced some pressure from an alternative therapy. The strategy remains to mitigate against the competitive landscape by extending the Foscavir franchise through new presentations of the product and new indications, as demonstrated by the approval in March 2019 for the treatment of HHV-6 encephalitis in Japan.

The acquisition of the US rights to Proleukin has created an ideal platform to expand our existing footprint in the higher value US market. In order to build upon the commercial infrastructure further we announced in May 2019 that we would transition the marketing, promotion, and distribution of Ethyol and Totect in the US back from Cumberland Pharmaceuticals. Following the completion of the transition later in 2019, the Group will then have direct control of all three of its oncology products currently available in the US.

Regionally, the number of local marketed licences increased as a result of the marketing authorisations transferring to Clinigen from the partnership agreement with Bristol-Myers Squibb ('BMS') in South Africa and in Japan, we signed our first exclusive licensing agreement with GC Pharma to commercialise Hunterase (Idursulfase-beta). The agreement with GC Pharma in Japan demonstrates our ability to partner with pharmaceutical companies outside their home geographies to commercialise their products.

Finally, in Commercial Medicines, Melatonin was the latest product to come through the developed unlicensed-to-licensed ('UL2L') pipeline and follows the successful launch of previous products in the portfolio, such as Glycopyrronium Bromide Oral Solution 1mg/5ml ('Glyco'). Melatonin is expected to be a modest contributor of growth to the business in the future.

"ON BEHALF OF THE BOARD, I WOULD LIKE TO TAKE THE OPPORTUNITY TO THANK ALL OUR EMPLOYEES FOR THEIR PROFESSIONALISM AND EXPERTISE DURING THE PAST YEAR, HELPING THE GROUP IN ITS GUIDING PRINCIPLE TO BECOME THE TRUSTED GLOBAL LEADER IN ACCESS TO MEDICINES."

1,133

In Unlicensed Medicines, our Managed Access business has continued to win programs throughout the year. strengthening our market-leading status in the supply of early access to medicines globally. Our online customisable, scalable web portal, Cliniport continues to be an invaluable part of Clinigen's service offering for its clients in Managed Access and strengthens the interaction with the HCP customer. To strengthen the relationship further with the HCPs and to facilitate the growth of our Global Access business, we launched Clinigen Direct, a complementary digital service offering for HCPs to source hard to access medicines. The Global Access business will be the main beneficiary of Clinigen Direct in the medium-term. Both these digital offerings are capable of supporting the business as it grows, and I expect to see the momentum build further in the year ahead. See pages 32 to 33 which provides a case study underlining the importance and impact of the Group's digital offering.

On a regional basis in Unlicensed Medicines, the Africa and Asia Pacific region delivered good growth across all geographies. The UK was a headwind with the UK Specials business which faced modest pricing pressure from products going onto drug tariffs and volume pressure from increased competition. This headwind is likely to continue in the medium-term, however, identifying and developing unlicensed products to offer licensed options is an example of the Group's UL2L strategy and remains a key differentiator against our competitors.

As expected, the CTS business recovered strongly in the year driven by good activity amongst its traditional client base and from an increase in the number of large programs in which we were asked to source comparator medicines. We believe that with the acquisition of CSM, our service and capability is immediately enhanced, and the client base significantly expanded. We have already seen the benefits to both businesses in Clinical Services and fully expect these to increase in the year ahead.

#### **PEOPLE**

The Group now has over 1,100 employees, with over half operating overseas from the UK in one of our 14 international locations located in North America, Europe, Africa or Asia Pacific. On behalf of the Board, I would like to take the opportunity to thank all our employees for their professionalism and expertise during the past year, helping the Group in its guiding principle to become the trusted global leader in access to medicines.

I would also like to thank my current and previous Board colleagues for their support and guidance over the past year. Alan Boyd joined the Board on 15 November 2018, Nick Keher joined on 19 March 2019, whilst Martin Abell stepped down from the Board on 31 March 2019.

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

#### OUTLOOK

I believe the Group is well-positioned to continue to develop the business as well as drive organic growth over the medium-term and deliver another good year of progress.

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

#### **OUR BUSINESS EXPLAINED**

## **OVERVIEW**

Clinigen is a global pharmaceutical and services company with a unique combination of businesses focused on providing ethical access to medicines.

Its mission is to deliver the right medicine, to the right patient, at the right time through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines. The Group has sites in North America, Europe, Africa and Asia Pacific ('AAA'). Clinigen now has over 1,100 employees across five continents in 14 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 22 of the top 25 pharmaceutical companies; interacting with over 15,000 registered users across over 100 countries, shipping approximately 6.4 million units in the year.

#### **PLATFORM**

Clinigen has built a global operating platform that can supply and distribute medicines at the key stages in the pharmaceutical product lifecycle.

See pages 10 to 11

#### **PROPOSITION**

Clinigen proposition has the capability to provide added value to two key customers: pharmaceutical and biotech clients; and HCPs customers.

See pages 12 to 13

#### **PRODUCT**

Clinigen has the capability to expand the life and value of a medicine and provide distribution services and solutions in complex regulatory situations.

See pages 14 to 15

PRE-LAUNCH



#### **CLINICAL SERVICES**

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

See page 37

#### OF ADJUSTED GROUP GROSS PROFIT



POST-LAUNCH



#### **UNLICENSED MEDICINES**

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



#### **COMMERCIAL MEDICINES**

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

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

See page 38

See pages 39 to 41

OF ADJUSTED GROUP GROSS PROFIT



OF ADJUSTED GROUP GROSS PROFIT



**OUR BUSINESS EXPLAINED CONTINUED** 

### **PLATFORM**

Building out the infrastructure

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

PRE-LAUNCH



#### **CLINICAL SERVICES**

4-5
MARKET (USSBN)

**532**PHARMACEUTICAL AND BIOTECH CLIENTS

#### **CSM**

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

#### CTS

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

## ACQUISITIONS REINFORCING LINKS BETWEEN ALL THREE BUSINESSES CSM Expands service capabilities, diversifies client base, adds EU infrastructure and reinforces links across the Group. See pages 30 to 31 IQUNE Supports growth and revitalisation of product portfolio in the EU and enhances proposition as a commercial partner. See pages 30 to 31

CSM CTS

POST-LAUNCH



#### **UNLICENSED MEDICINES**

5-10
MARKET (US\$BN)

157
EXCLUSIVE GLOBAL CLIENT SUPPLY AGREEMENTS

#### **MANAGED ACCESS**

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

#### **GLOBAL ACCESS**

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



#### **COMMERCIAL MEDICINES**

#### OWNED ACQUIRED

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

#### **DEVELOPED**

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

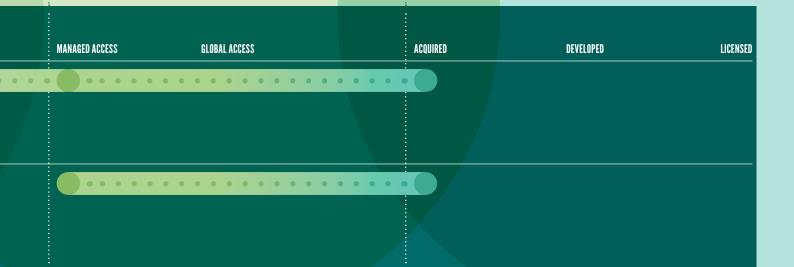
PRODUCTS

14 PRODUCTS

#### LICENSED

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

**241** LICENCES



#### **OUR BUSINESS EXPLAINED CONTINUED**

## PROPOSITION

Linking pharmaceutical and biotech clients with HCP customers

PRE-LAUNCH

CSM



#### **CLINICAL SERVICES**

#### PHARMACEUTICAL AND BIOTECH CLIENTS

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

#### SPECIALIST SUPPLY AND DISTRIBUTION

- Global infrastructure
- Supply chain experience

- Sourcing capability

#### PARTNERSHIP CAPABILITY

- Project management and strategic guidance
- Ability to partner throughout lifecycle
- Broad service and product offering

#### EXPAND AND EXTEND LIFECYCLE

- to medicine
- Acquisition and revitalisation capability

- Facilitate early access
- Provide valuable insights resulting in sustained value

#### CLINIGEN'S VALUE PROPOSITION

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





. . . . . . . . . . . . . .

#### **HCP CUSTOMERS**

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

#### **ACCESS TO EXTENSIVE PORTFOLIO OF MEDICINES**

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

#### **BROAD ENGAGEMENT OFFERING**

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

#### **EFFICIENT SERVICE OFFERING**

- Rapid response times
- World class quality standard

POST-LAUNCH





	UNLICENSED	MEDICINES	COMMERCIAL	<b>MEDICINES</b>	
	MANAGED ACCESS	GLOBAL ACCESS	ACQUIRED	DEVELOPED	LICENSED
• • •	•••••	•••		• • • • • • • • •	• •
• • •		•••		• • • • • • • • •	•••
• • •	0	• • • • • • • • • • • • • • • • • • • •	•••••	• • • • • • • • •	•••
	•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • •	• •
	:				
	CLINIPORT	CI INIGI	ENDIRECT		
	OLIMII OMI	See pages 32 to 33	INDINLO I		
• • •		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • •	••
• • •		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • •	•••

**OUR BUSINESS EXPLAINED CONTINUED** 

## **PRODUCT**

Extending the pharmaceutical product lifecycle

PRE-LAUNCH



#### **CLINICAL SERVICES**

CSM				CTS													
>>>>	>>:	>>	>	>>	>	>	>	>	>	>	>	>	>	>	>		>
••••	• •	• •			• •	•	•	•	•	•	•	•	•	•	•	•	•
>>>>	>>	>>	>	>>	>	>	>	>	>	>	>	>	>	>	>	)	>
••••	• •	• •			• •	•	•	•	•	•	•	•	•	•	•	•	•
· · ·	• •	• •	•		• •	•	•	•	•	•	•	•	•	•	•	•	•
<<<<	< <	< <	<	< <	<b>.</b> <	<	<	<	<	<	<	<	<	<		,	
					• •	•	•	•	•	•	•	•	•	•	•	•	
					• •	•	•	•	•	•	•	•	•	•	•	•	

<<<<<<<<<<<<<<<<<

#### PARTNERSHIPS AND RELATIONSHIPS

CLIENT AND CUSTOMER RELATIONSHIPS ARE ESTABLISHED AND STRENGTHENEI From Being involved early in the Pharmaceutical product lifecycle

#### **EXPANDING THE LIFECYCLE OPPORTUNITY**

**CROSS SELLING SERVICES** 

**VISIBILITY OF R&D PIPELINE** 

UNLICENSED PARTNERSHIPS PROVIDE ALTERNATIVE COMMERCIALISATION ROUTES

**UNLICENSED TO LICENSED GEOGRAPHICAL EXPANSION** 

**UNLICENSED TO LICENSED DEVELOPMENTS** 

**IDENTIFIES ASSETS TO ACQUIRE** 

#### EXTENDING THE LIFECYCLE OPPORTUNITY

SUPPLY AND DISTRIBUTE INTO UNLICENSED MARKETS

**SUPPLY INTO CLINICAL TRIALS** 

**ABILITY TO PARTNER EARLIER IN THE LIFECYCLE** 

#### **EXAMPLE PRODUCT**

#### DRNI EIIKII

Diversified portfolio, formed the foundatio to expand footprint in the US and has significant potential for revitalisation.



See pages 34 to 35

POST-LAUNCH





	UNLICENSE	ED MEDICINES	COMMER	CIAL MEDICINES	
	MANAGED ACCESS	GLOBAL ACCESS	ACQUIRED	DEVELOPED	LICENSED
>>>	>>>>>	>>>>>>>>	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	·>>>>>>>>	>>>>>
• • •		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •	
>>>	>>>>>	>>>>>>>>>	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>	>>>>>>>>>	>>>>>
• • •		• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •	• • • •
• • •					
	<b>•••••</b>	• • •			
		••••	• • • • • • • • •	• • • • • • • •	• • • •
		••••	• • • • • • • • • •	• • • • •	
		••••	•••••		
<<	<<<<<	<<<<<<	<<<<<<<	<<<<<<<	<b>&lt;&lt;&lt;&lt;</b>
		••••	•••••	• • • •	
	• • • • • •	• • • • • • • • •	• • • • • •		
• • •	• • • • • •	• • • • • • • •	• • • • • •		
<b>&lt;&lt;&lt;</b>	<b>&lt;&lt;&lt;&lt;&lt;</b>	<<<<<<<	. < < < < < < < < < <	<<<<<<<	<b>&lt;&lt;&lt;&lt;</b>
• • •		••••	• • • • • • •		
	:				

#### RELATIONSHIPS WITH KEY STAKEHOLDERS

#### OUR KEY RELATIONSHIPS UNDERPIN OUR BUSINESS MODEL

Since its inception, the Group has been building out its infrastructure platform, refining its value proposition and driving the synergies between its three business operations to deliver the right medicine, to the right patient, at the right time. By investing in our business model, the Group is able to create sustained value for our stakeholders; patients, clients, customers, employees and shareholders.

#### **STAKEHOLDERS**



#### **PATIENTS**

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

#### REPRESENTATIVE

"WE REGULARLY HEAR ABOUT THE IMPACT WE HAVE ON PATIENTS WHEN SOURCING HARD TO ACCESS MEDICINES AND SUPPLYING AND DISTRIBUTING OUR OWN SPECIALTY MEDICINES. IT IS REALLY REWARDING FOR EMPLOYEES TO GET A GLIMPSE OF THE DIFFERENCE WE'VE MADE TO AN INDIVIDUAL PATIENT'S LIFE."

Patient Advocacy Manager



#### PHARMACEUTICAL AND BIOTECH CLIENTS

Our pharmaceutical and biotech clients are broadening their relationship with Clinigen to enable ethical, secure and compliant global access to their medicines at the key stages of the product lifecycle.

"FINDING A TRUSTED LONG-TERM PARTNER THAT CAN
DELIVER VALUE IS KEY TO OUR PHARMACEUTICAL AND
BIOTECH CLIENTS. BY DELIVERING EXCEPTIONAL SERVICE
IN EACH OF OUR BUSINESSES, WE SEE OUR CLIENTS
INCREASINGLY REFERRING TO CLINIGEN AS THEIR
PARTNER OF CHOICE."

Global Head of Business Development



#### **HCP CUSTOMERS**

We offer ethical access to medicines to HCPs through a combination of a global reach and local knowledge, providing a safe and compliant route for them to access hard to access medicines.

"OUR SERVICES ARE ALL DELIVERED IN-HOUSE COVERING
A GLOBAL BASE OF CUSTOMERS. WE OPERATE AN ACCOUNT
MANAGEMENT AND REGION BASED MODEL WHERE
HCPS HAVE THEIR OWN DEDICATED RELATIONSHIP. OUR
STRUCTURE IS DESIGNED TO PROVIDE A WORLD CLASS
SERVICE, ESTABLISH WORLD CLASS AND STAY THERE."

**Customer Service Director** 



#### **EMPLOYEES**

We employ over 1,100 people in 14 international locations and are committed to a policy of equal opportunities in the recruitment, engagement and retention of employees.

"AS OVER HALF OUR EMPLOYEES ARE NOW BASED INTERNATIONALLY, THE MULTINATIONAL DIVERSITY OF OUR EMPLOYEE BASE NOT ONLY SUPPORTS OUR GLOBAL SERVICE OFFERING BUT DEMONSTRATES ITS LACK OF BARRIERS TO EMPLOYMENT."

Global HR Director



#### **SHAREHOLDERS**

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

"WE ENGAGED WITH APPROXIMATELY 200 INTERNATIONAL INVESTORS DURING THE YEAR, HOLDING ONE-TO-ONE MEETINGS, CONFERENCE CALLS AND GROUP MEETINGS. WE VISITED FOUR COUNTRIES AND ATTENDED FIVE INTERNATIONAL INVESTOR CONFERENCES IN ORDER TO RAISE THE PROFILE OF CLINIGEN."

Head of Investor Relations

#### **HOW WE ENGAGE**

This year, Clinigen launched the Patient Innovation Lab ('PIL'), a global, internal network of representatives who are motivated to act as knowledge-sharers and mediators for the patient-centred activity that is undertaken, to share success stories where a patient's life has been impacted, and to champion patient advocacy for the Group as it grows.

#### **VALUE WE CREATE**

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

NUMBER OF UNITS SHIPPED (M)

6.4

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

Partnering with Clinigen across the product lifecycle enhances value for our pharmaceutical and biotech clients by driving resource efficiencies, simplifying the supply chain model and mitigates the need for multiple vendors. The solution is replicated across the client's product portfolio to ensure the client fully benefits from Clinigen's expertise.

NUMBER OF TOP 25 PHARMACEUTICAL COMPANIES WHO HAVE WORKED WITH ALL THREE BUSINESS OPERATIONS

4

We have built Cliniport and Clinigen Direct, proprietary online management platforms, which allow us to operate globally to build deep relationships with our customers. These digital systems help ensure a HCP with a patient in need, anywhere in the world, can always get the right medicine for their individual patient – quickly, easily and safely.

Cliniport and Clinigen Direct both make our services more accessible and convenient for HCPs, increasing the number of HCPs in our community and improving access to medicines. The vast majority of medicines available on Cliniport and Clinigen Direct are unlicensed medicines and these digital systems will ensure a safe and compliant way for HCPs to obtain access.

NUMBER OF REGISTERED USERS ON ITS PROPRIETARY DIGITAL PLATFORM

>15,000

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

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

SPEND ON EMPLOYEE REMUNERATION (£M)

**52.3** 

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

Clinigen has delivered long-term value to shareholders through share price appreciation and a progressive dividend policy. Clinigen's total shareholder return ('TSR') versus the FTSE SmallCap Index (ex Investment Trusts) for the seven-year period between IPO on 24 September 2012 until 30 August 2019 was +364%<sup>1</sup>.

TSR%

+364

1. Group TSR (defined as share price growth including reinvested dividends).

#### **MARKET OVERVIEW**

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

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

#### **MICRO MARKET TRENDS**

#### **CLINICAL SERVICES**

#### MARKET DRIVERS

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

#### UNLICENSED MEDICINES

#### MARKET DRIVERS

- Increased role of patient advocacy groups and online resources leading to greater patient demand
- Clients increasingly wanting a global partner to manage supply and distribution beyond managed access
- Increased risk of counterfeit and substandard medicines entering the supply chain

#### **COMMERCIAL MEDICINES**

#### MARKET DRIVERS

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

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

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

#### CLINIGEN RESPONSE AND DIFFERENTIATORS

- Global supply chain and distribution network
- Qualified supply chain certifies product for authenticity
- Integrated service offering from clinical trial, to IITs to early access
- Regulatory expertise
- Broad and embedded relationships with both pharmaceutical and biotech clients and HCP customers

#### CLINIGEN RESPONSE AND DIFFERENTIATORS

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

#### CLINIGEN RESPONSE AND DIFFERENTIATORS

- Broad and embedded relationships with pharmaceutical companies
- Proven revitalisation capability
- Expert understanding of complex regulatory environments globally
- Capability to convert unlicensed medicines to licensed medicines
- Growing MSL and sales capability in the US, EU and selected AAA territories

#### **MACRO MARKET TRENDS**

#### INCREASED DEMAND FOR ACCESS TO MEDICINES

STRATEGIC LINK: 3 + 4 + 5 + 6

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

The world is in a period of unprecedented change and nowhere is this more evident than in the healthcare and the pharmaceutical markets in particular. The global population is growing and people are living longer, leading to increased demand for healthcare provision. At the same time the demands from patients are becoming more personalised, areas of unmet or underserved medical need are gaining greater focus from a development perspective and patient power is leading to demand for earlier access of medicines globally. A major disruptor to all of this and a factor that is accelerating and magnifying these changes is the degree to which the internet, social media and digital platforms are connecting the industry, HCPs and patients. HCPs and patients are potentially much better informed about disease and potential treatment options thanks to the sheer amount of information now publicly available online. This has created both enormous opportunities and serious challenges to governments, regulators and pharmaceutical and biotech companies.

Clinigen has the infrastructure platform in place, has a value proposition that links pharmaceutical and biotech companies with HCPs, and has the expertise and capability to expand and extend the lifecycle of a medicine whilst maintaining the integrity of the global supply chain to ensure prescribers and patients receive the right medicine at the right time.

#### NUMBER OF COUNTRIES SUPPLIED

102

NUMBER OF UNITS SHIPPED (M)

6.4

#### INCREASED PREVALENCE OF COUNTERFEIT MEDICINES STRATEGIC LINK: 5

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

The increased demand for access to medicines has increased the risk and dangers of counterfeit and substandard medicines entering the supply chain.

Evidence suggests that over a million people a year die due to taking a counterfeit medicine; millions of units of medicines are seized; thousands of unregulated websites are shut down every year as the regulators and governments try to deal with and contain the situation. Counterfeit and substandard medicine supply is escalating rapidly and has resulted in some high-profile global collaborations to attempt to combat the problem.

Operation Pangea was organised to target the advertisement, sale, and supply of counterfeit and illicit medicines and medical devices that threaten worldwide public health and safety. It has evolved significantly over the past decade, rising from eight countries at its launch in 2008 to 123 countries in 2017. Police, customs and health regulatory authorities targeted the illicit online sale of medicines and medical products, resulting in 859 arrests worldwide, the seizure of US\$14m worth of potentially dangerous pharmaceuticals and 3.671 websites, social media pages and online marketplaces closed down.

Clinigen is committed to the fight against counterfeit medicines and closely cooperates with the various stakeholders. It works closely with the regulatory authorities, partner with the appropriate associations and regularly helps raise awareness of counterfeit medicines. Clinigen is the trusted global marketleader in providing an ethical, compliant way for HCPs to source medicines.

#### WEBSITES TAKEN OFFLINE IN 2018

3,671

#### **INCREASED RATIONALISATION OF TERRITORIES**

**STRATEGIC LINK:** 4 + 5 + 6 Impacts: ULM/CM<sup>1</sup>

Pharmaceutical products nowadays are only launched or made commercially available in a relatively small number of pharmaceutical markets (c.25 markets) and so the challenge is how to manage access for the remaining markets where the medicine is therefore not licensed. This is what is meant by an unlicensed medicine. Every country in the world has extensive regulations detailing how to manage access to a medicine in this scenario. Physicians can ethically access medicines not available in their country to treat patients where they have exhausted all commercially available/ licensed alternatives. How demand is managed in these markets plays an important part of a company's access to medicine strategy and plans. Supply into these unlicensed markets can account for 15-20% of a medicine's global revenues and profits, and if not managed well, this can put further pressure on demand and supply forecasting for the company.

Therefore, companies of all shapes and sizes need a partner or partners around the world that can work with them to achieve access to medicines and a supply chain that manages that access ethically, compliantly and risk-free. While there are many companies capable of managing the commercial/licensed element, there are very few that can handle both the licensed and unlicensed elements. Clinigen is one such company that can handle both of these elements globally and is why our corporate mission is to deliver the right medicine, to the right patient, at the right time.

#### NUMBER OF MARKETS WHERE PRODUCTS CAN TYPICALLY REMAIN UNLICENSED

90-95

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

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

Clinigen CEO, Shaun Chilton discusses the Group's performance in 2019 and addresses some common questions received from investors over the past year.



"AS A TEAM WE ATTENDED APPROXIMATELY 200 INVESTOR MEETINGS IN THE YEAR. THESE MEETINGS ALLOW US TO COMMUNICATE THE GROUP'S PERFORMANCE AND STRATEGY BUT ALSO PROVIDE AN OPPORTUNITY FOR US TO LISTEN TO INVESTOR FEEDBACK AND CONCERNS DIRECTLY. THIS Q&A PROVIDES A FORUM TO ILLUSTRATE THE KEY QUESTIONS FROM THESE MEETINGS TO A WIDER AUDIENCE."

#### 0

#### CAN YOU EXPLAIN THE CLINIGEN BUSINESS MODEL SIMPLY?

Clinigen exists to make sure a HCP anywhere in the world with a patient in need can always get the right medicine for their individual patient, quickly, easily and safely whether licensed or unlicensed. We have three businesses (Clinical Services, Unlicensed Medicines and Commercial Medicines) that operate directly with pharmaceutical companies and hospital physicians and pharmacists, using our global operating platform, to provide the required solution and deliver the right medicine, to the right patient, at the right time (see pages 8 to 15 which illustrate the business model in more detail).

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

As the global leader in access to medicines, Clinigen is building a synergistic business that has the capability to provide added value to two key customers:

- For physicians and pharmacists; we provide the most straightforward, compliant, safe and ethical way to obtain difficult to access, often unlicensed medicines
- For pharmaceutical and biotech companies; we are a long-term partner with the capability to expand and extend the life and value of a medicine and provide distribution services and solutions in complex regulatory situations

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

#### Q

#### THE GROUP HAS BEGUN PROVIDING ORGANIC GROWTH RATES, HOW WOULD YOU VIEW HOW THE GROUP HAS PERFORMED ORGANICALLY THIS YEAR?

Providing further disclosure on organic growth is important for the Group as it demonstrates what we consider a key metric to assess the performance of our business and is in line with our desire to provide further transparency to our shareholders.

Once again, this year's results have demonstrated the benefits of the Group's portfolio of businesses. Organically, there were good performances in Clinical Services from CTS: in Unlicensed Medicines, from Managed Access and from the African and Asia Pacific regions in Global Access; in Commercial Medicines, there was good growth from the developed product portfolio in the UK. These performances offset pressure both on Foscavir, from an alternative therapy, and on the UK Specials business within Unlicensed Medicines. Excluding these, growth in adjusted gross profit on an organic basis\* was 7% Therefore overall, I believe on an organic basis the performance of the Group was robust and we are well positioned to drive organic growth this year. A more detailed breakdown of organic growth by business is included in the operational review (see pages 36 to 41).

#### 0

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

Overall, we have had another good year with excellent progress made on delivering against the Group's strategic objectives.

The acquisitions made during the year, both corporate and product acquisitions, strengthen our offering and capabilities as well as diversifying our portfolio of businesses and products. The expansion of our geographical footprint by building on our existing commercial infrastructure in the US and EU will provide notable benefit to all our businesses.

Operationally, the areas where we have done well are in the AAA region where the performance was strong, and in developing our portfolio of developed products, where Melatonin was the latest product to be taken through the UL2L regulatory pathway.

Improvements can always be made within a Group as complex as Clinigen. One area which we are trying to improve, is to drive the synergies that exists between the businesses, what is known internally as 'joining-the-dots' (see overleaf).

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

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

"OVERALL, WE HAVE HAD ANOTHER GOOD YEAR WITH EXCELLENT PROGRESS MADE ON DELIVERING AGAINST THE GROUP'S STRATEGIC OBJECTIVES."

#### Q

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

The greatest opportunity for the Group is by 'joining-the-dots' between each of the three business operations and central operating platform. In recent years, the Group has expanded its service capabilities and extended its geographical footprint by making both transformational and bolt-on acquisitions, both corporate and product in nature.

By 'joining-the-dots' more effectively, for example in consolidating our drug sourcing and procurement and in leveraging global and regional pharmaceutical and biotech senior relationships across Clinigen, we will continue to drive growth.

I have tasked the Chief Business Officer with 'joining-the-dots' and it has become another strategic priority which we will report against to show progress.

#### Q

#### WHAT ARE CLINIGEN'S GREATEST THREATS AND CHALLENGES?

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

#### 0

### CLINIGEN HAS MADE BOTH CORPORATE AND PRODUCT ACQUISITIONS DURING THE YEAR, COULD YOU EXPLAIN THE STRATEGIC RATIONALE BEHIND THEM?

In October 2018, the Group acquired CSM, a specialist provider of packaging, labelling, warehousing and distribution services with infrastructure in the US, Belgium and Germany. This acquisition expanded our capabilities, diversified our global client and customer base, added important continental EU infrastructure, and reinforces the links between the Group's three business operations.

Also in October 2018, the Group acquired iQone, a Swiss-based specialty pharmaceutical business. This acquisition is helping support growth of Clinigen's Commercial Medicines portfolio in key EU markets and differentiates the Managed Access business within Unlicensed Medicines from its competitors by providing EU MSL capability.

A case study on CSM and iQone can be seen on pages 30 to 31.

Finally, in April 2019, the Group acquired the US rights to Proleukin, adding to the rights Clinigen already owned outside the US. Proleukin is an excellent fit within the Group's existing oncology and infectious disease medicines in Commercial Medicines, and the product has significant potential for revitalisation, which will provide further breadth and diversity to the portfolio and material increases in revenues. In addition, it creates an ideal platform to expand the existing footprint in the higher value US market, enabling Clinigen to exploit other opportunities across the business.

A case study on Proleukin can be seen on pages 34 to 35.

#### WHAT PROGRESS HAS BEEN MADE ON INTEGRATING THE TWO CORPORATE ACOUISITIONS INTO THE GROUP?

CSM has been largely integrated into the CS business, with the business development and strategic sourcing teams working under one leadership and management structure, whilst the iQone integration is ongoing.

Overall in the nine months since acquisition, the integration of both CSM and iQone are going to plan and both businesses are performing well. We will continue to look at where we can obtain efficiencies in the way we operate and fully utilise the top-line synergies to drive an improved business performance.

#### 0

#### WHAT CAN WE EXPECT ON M&A GOING FORWARD?

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

#### Q

### NOW THAT THE GROUP'S ENTERPRISE RESOURCE PLANNING ('ERP') IS ALMOST COMPLETE, WHAT WILL BE THE MAIN BENEFITS?

We have already benefited from the installation of several of the ERP modules with the remainder scheduled to be completed in 2019.

I am confident that when completed in 2019, it will drive operational efficiency and allow the Group to compete better on a global scale.

#### Q

#### WHAT ARE THE MAJOR MILESTONES TO LOOK OUT FOR IN 2020? WHAT DOES SUCCESS LOOK LIKE?

We shall continue to drive organic growth across our portfolio and look to capitalise on the substantial opportunity in our markets to deliver another good year of progress. We have so many exciting opportunities, but we also need to remain disciplined on making the expected progress against the core KPIs in each of the three businesses and for the Group as a whole. If we can continue to 'join-the-dots', as described above, then I am very excited about what the future holds for us.

#### 0

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

At Clinigen's IPO in 2012, the market capitalisation was £135m, in the subsequent seven years, Clinigen's market capitalisation has grown to over £1.2bn, and we are now one of the largest companies on AIM. We have made six corporate and six product acquisitions, therefore, being on AIM has been useful for the Group and to many of our stakeholders.

We have in the past and continue to assess our status on AIM and take the appropriate counsel from our advisers. There are clearly some advantages of moving to the Main Market but there are also some disadvantages. We need to ensure that we consider these and make the right decision, at the right time.

#### Q

#### COULD YOU GIVE AN UPDATE ON HOW BREXIT COULD IMPACT THE GROUP?

As a business that operates globally and with 65% of the Group's revenues being from international markets, then we are in a good position already. Specific to the challenges and opportunities created from Brexit, we have a number of plans in place. The Group has established a Dutch entity to hold the Group's proprietary marketing authorisations for our owned products. Whilst the outcomes are not yet clear, the Group has implemented a contingency plan in the event of a 'no-deal' Brexit to ensure continuity of supply to European markets for the critical lifesaving medicines which the Company supply. I am confident we have a flexible business model, and can store and ship product, from our own depots in the UK, Australia, Singapore and South Africa as well as utilise our existing third-party wholesalers in other countries. We continue to monitor any decisions made by the government in respect of Brexit.

#### **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

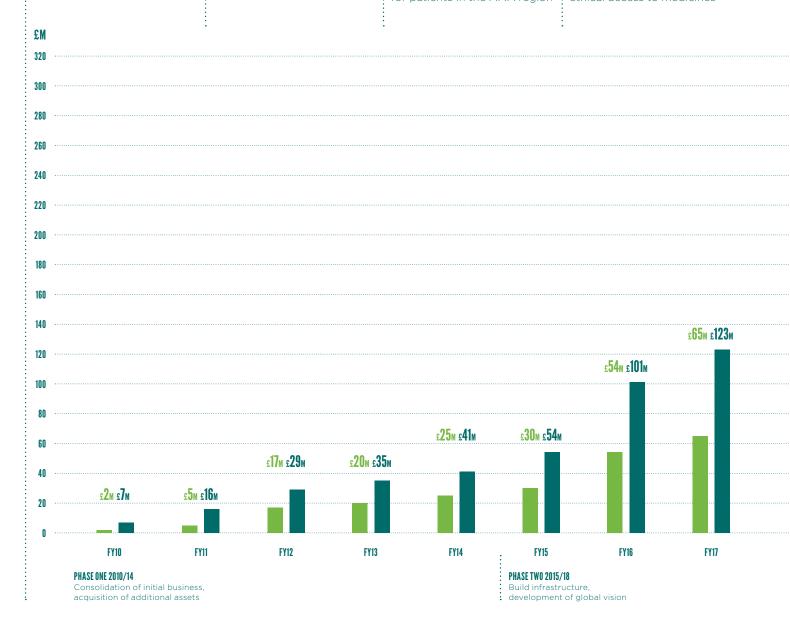
Acquires Idis to become the global leader in providing ethical compliant access to unlicensed medicines.
Acquires Link Healthcare ('Link') to expand its ability to provide access to medicines for patients in the AAA region

#### 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



## 440/0 CAGR GROWTH IN ADJUSTED GROSS PROFIT

## **57%**CAGR GROWTH IN ADJUSTED EBITDA

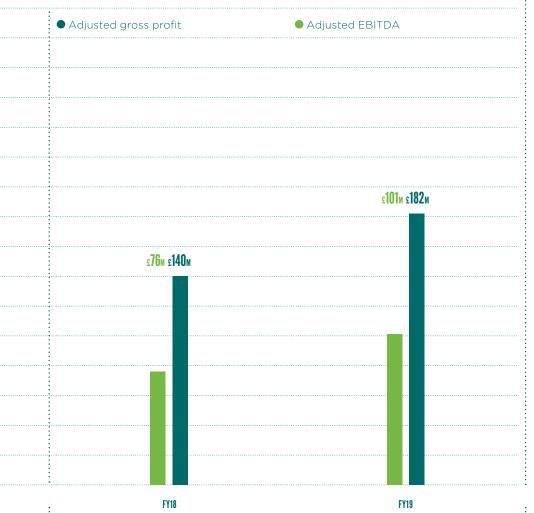
#### 2018

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

 CAGR growth covers the nine-year period between FY10 and FY19.



#### **OUR FUTURE ASSUMPTIONS**

- Proleukin revitalisation within new indications would lead to above upper end growth guidance achieved
- Revenue synergies across the Group leading to top-end growth expectations
- Continued revitalisation of Acquired product portfolio with further upside potential beyond guidance period
- Further 'program' to 'partner' and regional partner agreements signed
- Underlying market dynamics remaining positive
- Continued delivery from Developed product pipeline
- Modest expectations for lower revenue visibility businesses
- Modest decline in 'UK specials' market
- Modest decline to Foscavir on assumption of a generic entrant over the medium-term in one of the core markets

## ORGANIC GROSS PROFIT CAGR 05%-10%

#### PHASE THREE 2018 ONWARDS

Global positioning, differentiation of businesses, genuine lifecycle partnership

#### **STRATEGY**

**PRIORITY** 

STRATEGIC OBJECTIVES

**CULTURE** 

DEVELOP AND RETAIN TALENTED PEOPLE

**TECHNOLOGY** 

UPGRADE TECHNOLOGY
PLATFORM TO DRIVE
ORGANIC GROWTH

**CUSTOMER** 

EXPAND AND EMBED A GLOBAL COMMUNITY OF HCPS AND OPINION LEADERS

#### 2019 PROGRESS

- 29 employees completed the Clinigen Management Academy training program
- Long service recognition awards introduced globally
- Launched online survey tool for employees, providing weekly engagement data
- Growth of Cliniport (proprietary web-based operating system) enabling the Group to better interact with the customer
- Launch of Clinigen Direct, a new digital service offering for HCPs to source hard to access medicines
- Continued implementation of Clinigen One ERP modules
- Growth of Cliniport (proprietary web-based operating system) enabling the Group to better interact with the customer
- Launch of Clinigen Direct, a new digital service offering for HCPs to source hard to access medicines
- Building out US commercial infrastructure following acquisition of Proleukin
- EU MSL capability through acquisition of iQone will help interaction with HCP customers

PERFORMANCE METRICS

**EMPLOYEE ENGAGEMENT SCORE** 

NUMBER OF PRODUCTS AVAILABLE ON CLINIPORT AND CLINIGEN DIRECT

NUMBER OF REGISTERED USERS On Cliniport

**7.1** 

>1,800

15,580

2019			15,580
2018		11,267	
2017	6,593		

#### **2020 OBJECTIVES**

- Launch a bespoke leadership development program
- Introduce a global employee wellbeing initiative
- Improve engagement and retention levels
- Complete implementation of Clinigen One ERP
- Increase number of programs and products available on Cliniport and Clinigen Direct
- Embed Cliniport and Clinigen Direct functionality including extended real world data ('RWD') capability
- Increase number of users and amount of activity through Cliniport and Clinigen Direct
- Expand MSL and commercial capability in the US and the EU
- Drive Key Opinion Leader ('KOL'), hospital pharmacist and pharmacy group engagement across markets

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

Number of exclusive supply agreements includes Managed Access Programs, exclusive Global Access client supply agreements and exclusive customer supply agreements in LIK Specials business

#### **BUSINESS**

EXPAND PORTFOLIO OF GLOBAL, REGIONAL AND LICENSED ASSETS

BECOME THE 'GO TO'
LEADER IN ETHICAL
ACCESS TO UNLICENSED
MEDICINES

EXTEND GLOBAL FOOTPRINT INTO REMAINING KEY MARKETS

LINK THE BUSINESSES
TO REALISE SYNERGISTIC
OPPORTUNITIES
AND INCREASE
PHARMACEUTICAL
CUSTOMER BASE

- Acquisition of Proleukin and Imukin strengthen our offering in Commercial Medicines
- Approval of Foscavir for the treatment of HHV-6 in Japan
- Launch of Melatonin demonstrating further success of the UL2L development pipeline
- Exclusive licensing agreement signed with GC Pharma in Japan. Clinigen's first such agreement in Japan
- Acquisition of CSM reinforces links between Clinical Services and Unlicensed Medicines
- Acquisition of iQone provides MSL capability, a key differentiator in the Managed Access business within Unlicensed Medicines from its competitors
- Increase in number of MAPs and exclusive Global Access client supply agreements
- Launch of Clinigen Direct, a new digital service offering for HCPs to source hard to access medicines

- Acquisition of Proleukin provides an ideal platform to expand existing footprint in the US
- Acquisition of CSM provides important EU infrastructure
- Acquisition of iQone helps support Clinigen's Commercial Medicines portfolio in key EU markets
- Partnership agreement with Accord signed to supply and distribute Cardioxane and Savene in Poland
- Acquisition of CSM increases the size of the customer base at an early stage of product lifecycle and additional capabilities have enhanced proposition across the Group's three business operations
- Acquisition of iQone provides capability to partner with pharmaceutical and biotech companies to commercialise products earlier in the lifecycle and support partner company products
- Creation of Group Heads of Business Development Network to work more effectively and realise links between the businesses

NUMBER OF LOCAL, REGIONAL AND GLOBAL ASSETS UNDER MANAGEMENT

NUMBER OF EXCLUSIVE SUPPLY AGREEMENTS IN UNLICENSED MEDICINES

ADJUSTED GROSS PROFIT BY REGION

NUMBER OF TOP 50 PHARMACEUTICAL Companies who have worked with all three Business operations

4

**262** 

2019	262
2018	232
2017	197

192





O RoW

- Further conversion of UL2L pipeline
- Internationalisation of developed commercial product portfolio
- Continue to search for selective acquisitions
- Conversion of MAPs to regional licensing opportunities
- Expand and deepen our client base in Managed Access
- Develop our portfolio of exclusive supply agreements
- Build an excellence in Customer Services
- Leverage Group sourcing and procurement capability
- Further partnership agreements signed to expand geographical reach, particularly in the LATAM and the Middle East
- Further expansion of commercial infrastructure in US and EU
- Embed a culture that seeks to maximise value through extending product commercial relationships through the lifecycle
- Increase the number of top 50 companies working with all business operations
- Increase the number of companies working with at least two business operations
- Ensure alignment of objectives across business divisions and support functions with scorecards developed at each level

#### **KEY PERFORMANCE INDICATORS**

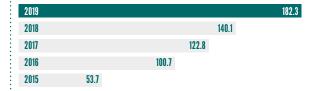
Our performance is measured against a number of KPI targets. Our performance is measured against a number of KPI targets. These KPIs contribute to the success of the Group and form a component of the Executive Directors' and senior management's incentives.

#### **FINANCIAL**

ADJUSTED GROSS PROFIT (£M)

182.3

**^30**%



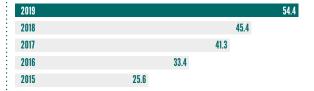
Why we measure it: Adjusted gross profit is viewed by the Board as the best measure of top-line performance. It allows management to assess the performance of the business after removing transactions that are not reflective of the routine business operations.

**Performance:** Adjusted gross profit increased by 30%, driven primarily by acquisitions with each contributing towards the Group's strong performance.

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

54.4

**^20**%



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

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

#### ADJUSTED EBITDA (£M)

100.8

**^33**%

2019				100.8
2018			76.0	
2017		1	65.1	
2016		53.7		
2015	30.0			

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 routine business operations.

**Performance:** Adjusted EBITDA increased 33% benefiting from the increase in gross profit, good operational leverage, and robust cost control.

#### **NON-FINANCIAL**

NUMBER OF LOCAL, REGIONAL AND GLOBAL ASSETS UNDER MANAGEMENT<sup>1</sup>

**STRATEGIC LINK: 4** 

262

**^13**%

2019		262
2018	232	
2017	197	
2016	180	

Why we measure it: Measures the quantity of products in the Commercial Medicines portfolio, demonstrating the business's potential for future growth.

**Performance:** Growth in the number of products in the portfolio was driven by an increase in the number of local marketed licences and branded generic products in the AAA region.

COMMUNITY OF REGISTERED USERS ON CLINIPORT

STRATEGIC LINK: 3

15,580

2019			
2018			11,267
2017		6,593	
2016	3,037		

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

**Performance:** Growth has been driven by an increase in the number of assets under management and exclusive supply agreements.

#### NUMBER OF EXCLUSIVE SUPPLY AGREEMENTS IN UNLICENSED MEDICINES<sup>2</sup>

STRATEGIC LINK: 5

192



2019	192	
2018	20	08
2017	138	
2016	136	

Why we measure it: Measures the quantity of exclusive supply agreements in Unlicensed Medicines, demonstrating the business's potential for future growth.

**Performance:** The decline in the number of products in the portfolio was driven as a result of a reduction in the number of exclusive customer supply agreements in the UK Specials business.

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

- 1 Develop and retain talented people
- **2** Upgrade technology platform to drive organic growth
- **3** Expand and embed a global community of hcps and opinion leaders
- Expand portfolio of global, regional and licensed assets
- **5** Become the 'go to' leader in ethical access to unlicensed medicines
- **6** Extend global footprint into remaining key markets
- 7 Link the businesses to realise synergistic opportunities and increase pharmaceutical customer base
- Number of local, regional and global assets under management includes all products in the Commercial Medicines portfolio.
- Number of exclusive supply agreements includes MAP, exclusive Global Access client supply agreements and exclusive customer supply agreements in the UK Specials business.

STRATEGY IN ACTION

**PLATFORM** 

## BUILDING OUT INFRASTRUCTURE

Clinigen's vision to be the trusted global leader in access to medicine has not fundamentally changed since its inception in 2010.

Strategically, the Group has evolved quickly particularly since IPO, expanding its services and the portfolio of niche hospital medicines it owns. The Group has created, and will continue to develop, a supply, management and distribution platform that operates globally in a synergistic way between its three business operations. In October 2018, the Group made two further corporate acquisitions, CSM and iQone, which were in line with its strategy to expand its geographical footprint and extend its capabilities.

EXISTING TERRITORY

**EXPANDED TERRITORY** 



CSM is a specialist provider of packaging, labelling, warehousing and distribution services with infrastructure in the US, Belgium and Germany. The acquisition expands Clinigen's capabilities, diversifies the Clinical Services business operation global client and customer base, adds important EU infrastructure, and reinforces the links between the Group's three business operations.

The acquisition is highly complementary to the Group, not just Clinical Services, has been straightforward to integrate and will help to link better and drive the synergies between its existing businesses.

- It provides insight to thousands of compounds in development at an earlier stage in the pharmaceutical product lifecycle
- It provides access to hundreds of additional clients which have previously been operating in a faster growing adjacent market
- It provides significant barriers to entry from its expanded service offering

#### IOONE

iQone is a Swiss-based specialty pharmaceutical business with MSL capability in the EU. It was acquired to support growth and drive the revitalisation of the Commercial Medicines portfolio in key EU markets. However, the acquisition also brings further benefits to the rest of the Group:

- It differentiates the Managed Access business within Unlicensed Medicines from its competitors
- It creates an opportunity for the Group to secure exclusive long-term unlicensed agreements where products are not commercially viable
- It enhances the Group's proposition as a commercial partner for pharmaceutical companies

#### **LINK TO STRATEGIC OBJECTIVES**

Become the 'go to' leader in ethical access to ... unlicensed medicines

acquisitions which will strengthen the service offering within Unlicensed Medicines and provide a further differentiation against the Group's competitors.

Extend global footprint ... into key markets

CSM adds high-quality facilities in Belgium and Germany and complementary sites and warehouses in the US extending the Group's supply and distribution reach. iQone provides commercial roles and MSLs in Switzerland, France, Italy, Spain, Austria and Germany.

Link the businesses to realise synergistic opportunities and increase pharmaceutical customer base

CSM increases size of customer base at early stage of product lifecycle and additional capabilities have enhanced proposition across the Group's three business operations.



#### STRATEGY IN ACTION CONTINUED

#### **PROPOSITION**

## BUILDING A DIGITAL ECOSYSTEM

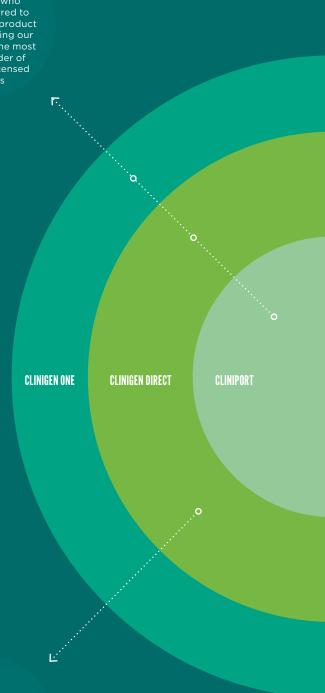
In the next 12 months, three digital systems will come together to form a single platform designed to help ensure a HCP with a patient in need, anywhere in the world, can always get the right medicine for their individual patient – quickly, easily and safely.

The Group has built a portfolio of products where it has exclusive agreements with the owner of the product, to be able to supply and distribute their medicines. This means the customer has to come to Clinigen to be able to access the product. These exclusive agreements include those from both Managed Access and Global Access businesses in Unlicensed Medicines, and from the acquired products and developed products which we own in Commercial Medicines.

By leveraging the 'pull' of the products for which we have exclusive distribution agreements, we can showcase our related products and services to HCPs and become established as their 'go to' partner for hard to find medicines. The proprietary demand data generated by this community of HCPs then informs our unlicensed and commercial business development activities – identifying further exclusivity and commercialisation opportunities.

#### **EXCLUSIVITY**

Exclusive products
pull in users who
are often referred to
Clinigen by the product
owner, reinforcing our
positioning as the most
trusted provider of
access to unlicensed
medicines



SEO

Search Engine
Optimisation maximises
Clinigen's visability
of assets

#### DATA

Proprietary demand data helps to identify and/or secure exclusive distribution opportunities

#### **CLINIPORT**

>400

- Primarily an ordering platform for MAPs
- Customisable to individual program requirements
- Password protected

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

#### **CLINIGEN DIRECT**

>1,400

- Sourcing service
- Educational content for HCPs
- Public website: www.clinigendirect.com

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

#### **CLINIGEN ONE**

- Integrates Cliniport, Clinigen Direct, warehousing and supply chain, finance and HR

Clinigen One is an ERP system that will support the operational delivery of the customer requests placed through Cliniport and Clinigen Direct, with which it is to be integrated.

#### **LINK TO STRATEGIC OBJECTIVES**

Upgrade technology platform to drive organic growth The Group has advanced its technology

platform with the launch of Clinigen Direct. In addition, work has continued throughout the year with the implementation of the Group ERP system.

**Expand and embed a global community** Clinigen Direct and Cliniport both make our HCPs and improving access to medicines.

access to unlicensed medicines and compliant way for HCPs to obtain

#### MARKETING

**Key Account** Managers, MSLs and marketing drives awareness

#### STRATEGY IN ACTION CONTINUED

#### **PRODUCT**

## EXTENDING THE LIFECYCLE

CENTRAL NERVOUS SYSTEM

AMYOTROPHIC
LATERAL
SCLEROSIS

• • • •

Clinigen acquires pharmaceutical medicines with the aim of revitalising them back to sustained growth.

These products do not fit the standard portfolios of larger pharmaceutical companies who are looking to divest to an attractive partner. The worldwide rights to Proleukin is the latest niche hospital medicine to be acquired and brings the total of owned products in the Group's portfolio to seven.



PHASE 1-3 000



# **PROLEUKIN**

Proleukin (aldesleukin or interleukin-2, 'IL-2') is indicated for the treatment of adults with metastatic renal cell carcinoma ('metastatic RCC') and in certain markets is also indicated for the treatment of adults with metastatic melanoma. Proleukin is one of two biologics Clinigen owns which are more attractive than small molecule products due to their greater inherent protection against generic threat.

#### **BENEFITS**

Proleukin's acquisition brings several benefits:

- It becomes Clinigen largest product, has further diversified the Commercial Medicines portfolio and will also be highly earnings enhancing
- For the Group, the product creates opportunities in Clinical Services around the provision of Proleukin for comparator studies and IITs
- It has formed the foundation of the Group's plans to expand its existing footprint in the US market by building out its commercial infrastructure obtained through the acquisition of CSM
- In addition, it has significant potential for revitalisation. This applies not only to its current indication, but across multiple disease areas

# **REVITALISATION**

Revitalisation is the term the Group gives to driving the revenues associated with an acquired product. Proleukin has significant potential for revitalisation, the greatest of which relates to extending its lifecycle by partnering with pharmaceutical and biotech companies who use Proleukin in the development of their own innovative asset. Proleukin is currently playing an important role in many immuno-oncology regimens where products are being developed using a low dose of Proleukin. An example of the breadth of activity in this area is illustrated by the number of clinical trials in which Proleukin is being used. There are currently over 150 active studies across multiple therapeutic areas and indications. This not only creates an opportunity to increase sales into these clinical trials, an area in which the Group has already benefitted from since the acquisition was completed, but also provides a mid-term opportunity by increasing the IL-2 market if any of these trials are successful.

# LINK TO STRATEGIC OBJECTIVES

4

# Expand portfolio of acquired, global and regional assets

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

6

# Extend global footprint into key markets

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

**OPERATIONAL REVIEW** 

# 'JOINING-THE-DOTS'

"THE GROUP HAS THE CAPABILITY
TO PROVIDE A ONE-STOP SOLUTION
TO MANY OF THE PRODUCT ACCESS
CHALLENGES A PHARMACEUTICAL
AND BIOTECH COMPANY WILL
FACE AS IT GOES THROUGH THE
PROCESS OF DEVELOPING AND
COMMERCIALISING A MEDICINE."

NUMBER OF TOP 50 PHARMACEUTICAL COMPANIES WHO HAVE WORKED WITH ALL THREE BUSINESS OPERATIONS

This year's acquisition of CSM and iQone have been important in creating a platform that enables Clinigen to support its pharmaceutical partners through the product lifecycle. CSM has significantly increased the number of companies that the Group engage with early in the lifecycle and has provided it with a suite of capabilities that can be utilised across the Group. iQone has given the Group a scalable commercial and medical platform that provides an opportunity to support the Group's own and its partner's products in the pre and post marketing authorisation approval periods across key EU markets. The Group is now looking to realise the opportunity the platform has created.

What is meant by 'joining-the-dots'?

In simple terms it means making sure the combined Group is working effectively and identifying revenue generating opportunities that can move through the businesses.

# **OPERATIONAL EFFECTIVENESS**

The Group has spent significant time looking at the way in which it operates the business and understanding where its processes can be improved. As a result, The Group will be making some improvements to its organisational procedures. These range from relatively simple steps such as changing our internal meeting structures and practices through to more in depth activities such as refining the business planning and strategy review processes. One of the main changes which will be introduced is the creation of a Program Office that will report into a newly created Program Board. The Program Board, made up of the operational heads of the business, will be responsible for the governance of key strategic projects that have the potential to impact the whole Group, and the Program Office will be responsible for the coordination and project management of projects such as the integration of future acquisitions.

#### **REVENUE SYNERGIES**

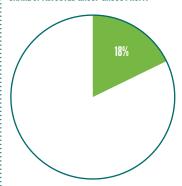
Having created a business that provides services to the pharmaceutical industry right through the product lifecycle, the Group need to 'join-the-dots' to ensure that it is making the most of the opportunities that have the potential to move through the business and provide additional value to the business.

The Group has the capability to provide a one-stop solution to many of the product access challenges a pharmaceutical and biotech company will face as it goes through the process of developing and commercialising a medicine. Engaging early with the Group's Clinical Services business enables companies to run its clinical studies effectively. The Group's Unlicensed Medicines business then provides early access solutions across the world so patients in need who are not eligible for studies can benefit from medicines in development. Subsequently, as the medicine moves through the commercialisation process, the Group can manage supply into markets that are either awaiting marketing authorisations, or into markets where the medicine will never get licensed. Finally, Clinigen's Commercial Medicines business provides an out-licence or partner platform for long term commercial supply.

The Group has made linking the business to realise synergistic opportunities and increase the pharmaceutical customer base a strategic objective and it will measure its effectiveness by the increase in the number of companies that are engaging with multiple parts of the Group. Seeking out opportunities to 'join-the-dots' for the benefit of the overall business will need to become a core behaviour within the Group and it will be building this into the individual objective setting and measurement process where it is appropriate.

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

#### SHARE OF ADJUSTED GROUP GROSS PROFIT



REVENUE (£M)

140.7

ADJUSTED GROSS PROFIT (£M)

33.2 \( \tag{100}\)

427
NUMBER OF CLIENTS

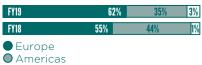
1.5
UNITS SHIPPED (M)

40 COUNTRIES SHIPPED TO

# **ADJUSTED GROSS PROFIT BY PORTFOLIO**



# **GROSS PROFIT BY PORTFOLIO**



O Africa and Asia Pacific

# **CLINICAL SERVICES**

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

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

Clinical Services represents 18% of adjusted Group gross profit. This operation increased gross profit by £19.2m to £33.2m (2018: £14.0m) due to the acquisition of CSM and strong organic growth in CTS. Adjusted gross profit on an organic basis\* increased by 23%.

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

An immediate benefit of the CSM acquisition was the significant expansion of the client base to 427 clients (2018: 100) and the creation of a much expanded, diversified set of value-added clinical services: comparator and ancillary sourcing, on demand specialist packaging, labelling, supply and distribution, and biological sample management.

CSM has been largely integrated into the Clinical Services business, with the business development and strategic sourcing teams working under one leadership and management structure. Further integration steps are expected in due course, from an operational and back-office perspective, alongside further synergies to be realised.

CSM achieved a strong growth performance for the year ending 30 June 2019, growing all major financial metrics, including EBITDA, in excess of 30% year on year.

CSM has exceeded management's expectations, mainly as a result of strong new business signings, customers advancing their programs quicker than expected, and the Group is seeing the benefits of both the CTS and CSM divisions working more closely together.

As expected, the CTS business recovered strongly in the year. The focus was improving service levels amongst the existing client base and becoming more competitive with sourcing and the release of its 'on demand' supply service.

#### **PIPELINE**

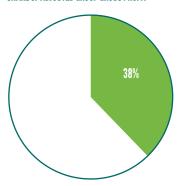
Clinical Services continues to be a trusted partner capable of delivering high-quality services across the world with an extensive understanding of the complex regulatory environment. These strengths, combined with overlaying the services offered by CSM, position the operation well to take advantage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

The book-to-bill ratio in CSM, which is used to indicate the future growth of the business, was excellent at 1.67x for the 12 months ended June 2019. The ratio is expected to remain strong, but it is anticipated to moderate in the coming year.

The CTS pipeline is broadly in line with prior year.

# **OPERATIONAL REVIEW CONTINUED**

#### SHARE OF ADJUSTED GROUP GROSS PROFIT



REVENUE (£M)

205.9

ADJUSTED GROSS PROFIT (£M)

**69.7** ~12%

192
NUMBER OF EXCLUSIVE

SUPPLY AGREEMENTS<sup>1</sup>

NUMBER OF MANAGED ACCESS PROGRAMS

2.9
UNITS SHIPPED (M)

100 COUNTRIES SHIPPED TO

# ADJUSTED GROSS PROFIT BY PORTFOLIO

FY19	39%	61%
FY18	40%	60%
	1. 4	

Manged AccessO Global Access

#### **GROSS PROFIT BY PORTFOLIO**

FY19	61%	14%	25%
FY18	61%	15%	24%

- Europe
- Americas
- O Africa and Asia Pacific

1. Number of exclusive supply agreements includes 117 MAPs (2018: 110), 40 exclusive Global Access client supply agreements (2018: 39) and 35 exclusive customer supply agreements in UK Specials business (2018: 59).

# **UNLICENSED MEDICINES**

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

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

- Developing a rich pipeline based on industry trends and innovation
- Providing a world-class customer service to HCPs, sourcing hard to access medicines for their patients
- Converting MAPs to long-term exclusive supply agreements in Global Access

The Unlicensed Medicines operation represents 38% of adjusted Group gross profit. The operation increased its gross profit by 12% to £69.7m (2018: £62.1m) due to a strong performance in Managed Access, in the AAA regions in Global Access, and a full period's contribution from Quantum. Adjusted gross profit on an organic basis\* increased by 3%.

In June 2019, the Group launched Clinigen Direct, a new digital service for HCPs to source hard to access medicines. Clinigen Direct provides a search tool with over 1,400 medicines available and customer service support to help HCPs navigate the regulatory hurdle in importing unlicensed medicines. This service is complementary to Cliniport, the Group's customisable, scalable web portal which continues to be an invaluable part of Clinigen's offering for its Managed Access clients and strengthens its interaction with the customer. The community of HCPs on Cliniport continues to build and now has 15,580 registered users (2018: 11,267).

# **MANAGED ACCESS**

As at 30 June 2019, there were 117 MAPs (2018: 110), of which 93% of products shipped on behalf of the client were provided free of charge to patients. When the product is 'charged for', the revenue is passed through the Group's accounts. A shift in mix towards 'free of charge' products can have a material impact on the revenue generated without affecting gross profit, which is why the Group views gross profit as the best measure of top-line growth.

Following the 11 programs that began in the first half of the financial year, there were a further 13 programs signed in the second half of the financial year.

Collectively, the top 10 MAPs contributed to 38% of the Managed Access gross profit (2018: 42%) with six of the top ten in the oncology therapy area (2018: ten oncology), demonstrating a more balanced and diverse portfolio of programs.

# **GLOBAL ACCESS**

In Global Access, the Group ethically supplies unlicensed or short supply medicines to patients via their physicians. There are 40 exclusive supply agreements for high demand or niche medicines covering 54 products under management (2018: 52). As well as continuing to seek new agreements to add to the portfolio, the business is also assessing the current portfolio with the aim of rationalising those that it considers to be non-core.

On a regional basis, the AAA region delivered good growth across all geographies. Growth in Asia was excellent, driven by expanding supply from the hub in Singapore into surrounding territories.

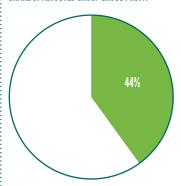
As previously highlighted, the UK Specials business within Unlicensed Medicines is facing modest pricing pressure from products going onto drug tariffs and volume pressure from increased competition. In addition, as a result of launching Melatonin in June 2019, the revenue associated with the product will be recognised in Commercial Medicines where it is expected to be a modest contributor of growth

# **PIPELINE**

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

At the end of the financial year there were 52 programs in the Managed Access pipeline (2018: 40) and 22 partnered products in the Global Access pipeline which the business is looking to partner with on an exclusive basis (2018: 15).

#### SHARE OF ADJUSTED GROUP GROSS PROFIT



REVENUE (£M)

110.3

ADJUSTED GROSS PROFIT (£M)

**79.4** ^24%

262

NUMBER OF LOCAL, REGIONAL AND GLOBAL ASSETS UNDER MANAGEMENT

2.0
UNITS SHIPPED (M)

50
COUNTRIES SHIPPED TO

# ADJUSTED GROSS PROFIT BY PORTFOLIO

FY19	65%	17%	18%
FY18	66%	2	2% 12%

- Acquired products portfolio<sup>2</sup>
- Licensed products portfolio<sup>3</sup>
- O Developed products portfolio<sup>4</sup>

# **GROSS PROFIT BY REGION**

anooo i no	TI DI MEGNOM		
FY19	41%	34%	25%
FY18	37%	30%	33%

- Europe
- Americas
- O Africa and Asia Pacific

# **COMMERCIAL MEDICINES**

The strategy for Commercial Medicines is threefold in order to build a portfolio that can deliver sustainable growth through:

- Continued revitalisation/growth of current portfolio of niche hospital-only and critical care products, coupled with selective product acquisitions
- Being the licensing partner of choice for pharmaceutical and biotech clients in non-core territories through regional licensing agreements
- Developing a long-term pipeline of medicines and launch licensed products through the UL2L model

Commercial Medicines represents 44% of adjusted Group gross profit. Gross profit on an adjusted basis increased 24%, supported by the acquisitions of Proleukin and Imukin, and a full period's contribution from Quantum. On an organic basis\*, gross profit decreased 7% due to competitive pressure primarily on sales of Foscavir\*.

Gross margin was 72.0% (2018: 72.7%) with the slight decrease due to the change in mix from the higher margin owned product portfolio towards the lower margin developed product portfolio.

# ACQUIRED PRODUCTS Anti-infective portfolio (Foscavir and Imukin)

Clinigen strengthened the portfolio with the acquisition in July 2018 of the global rights (excluding US, Canada and Japan) to Imukin (recombinant human interferon gamma-1b). Imukin® is licensed to reduce the frequency of serious infections in patients with Chronic Granulomatous Disease and for the treatment of Severe Malignant Osteopetrosis. Imukin is one of two biologics in the owned products portfolio which provide greater inherent protection against a generic threat than small molecule products, because of a more complex manufacturing process.

Foscavir, the Group's largest product prior to the acquisition of Proleukin, is an anti-viral used to treat cytomegalovirus ('CMV') viraemia and infection primarily in bone marrow transplant patients. In March 2019, Foscavir received approval for the treatment of HHV-6 encephalitis from the Japanese Ministry of Health, Labour and Welfare. This new indication offers a further barrier to entry against competitive threat for Foscavir and diversifies the revenue streams associated with this medicine.

As previously highlighted, Foscavir faced competitive pressure in two of its main markets, the US and Japan. The business continues to mitigate against this by extending the Foscavir franchise through seeking new presentations of the product and new indications (as indicated above). It is anticipated that the decline seen in FY19 will begin to moderate before stabilising completely in the second half of the current financial year. With the acquisition of Proleukin, Foscavir has ceased to be the biggest product in the portfolio.

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

The biggest development in the oncology portfolio was the acquisition of the rest of world rights to Proleukin in July 2018, and the subsequent acquisition of the US rights in April 2019. Together with Imukin, Proleukin changes the whole dynamic of the Group's owned products franchise, particularly in US.

Proleukin is the Group's second biologic and is indicated for use in metastatic renal cell carcinoma, as well as for metastatic melanoma in certain markets. Its acquisition further diversifies the Commercial Medicines product portfolio and is now Clinigen's largest product.

- Number of local, regional and global assets under management includes all products in the Commercial Medicines portfolio.
- Cardioxane, Savene, Totect, Imukin and Proleukin.
  3. Licensed products refers to the local marketed licenses including branded and generic products in

2. Acquired products refers to Foscavir, Ethyol,

the AAA region.
4. Developed products refers to the commercialised products developed through the UL2L regulatory process.

# **OPERATIONAL REVIEW CONTINUED**

"PROLEUKIN HAS SIGNIFICANT
POTENTIAL FOR REVITALISATION,
ESPECIALLY BY EXTENDING ITS
LIFECYCLE THROUGH PARTNERING
WITH PHARMACEUTICAL AND
BIOTECH COMPANIES WHO USE
PROLEUKIN IN THE DEVELOPMENT
OF THEIR OWN INNOVATIVE ASSETS
AND ALSO NEW INDICATIONS
WHERE A LOW DOSE VARIATION OF
PROLEUKIN COULD BE BENEFICIAL."

Proleukin has significant potential for revitalisation, especially by extending its lifecycle through partnering with pharmaceutical and biotech companies that use Proleukin in the development of their own innovative assets and also new indications where a low dose variation of Proleukin could be beneficial. Proleukin is currently being used in over 150 active studies across multiple therapeutic areas and indications. This not only creates an opportunity to increase sales into these clinical trials, an area in which the Group has already benefitted from since the acquisition was completed, but also provides a mid-term opportunity by increasing the IL-2 market if any of these trials are successful.

The performance of Proleukin since its acquisition has been ahead of management's expectations as a result of normalising pricing differentials that existed in the supply and distribution of the product into clinical trials and increased demand due to the availability of product with a longer shelf life. This outperformance has been driven by Proleukin in the US markets. However the RoW franchise has been impacted by a lower margin on sales, as the cost of goods increased for the product overall post the acquisition of the US rights. Management aim to reverse this impact over the coming years.

The acquisition has also created an ideal platform to expand Clinigen's existing footprint in the higher value US market. The Group appointed Jim Meyer as General Manager in May 2019 to help expand the existing commercial infrastructure in the US and to capitalise on other opportunities across the business.

In May 2019, the Group decided to transition the marketing, promotion and distribution of Ethyol and Totect in the US back from Cumberland Pharmaceuticals. This is a further example of the Group building out its commercial infrastructure in the US. Following the completion of the transition of Ethyol and Totect later this calendar year, the Group will have direct control of all three of its oncology products currently available in the US. As previously guided, the management believes that this will be incrementally positive to profitability, but only in the first full year (FY21) with a limited impact in FY20.

For the dexrazoxane products (Cardioxane, Savene and Totect), the focus is to maximise demand and extend the market opportunity by expanding the clinical understanding and utilising commercial expertise in key markets. In June 2019, the Group announced it had partnered with Accord Healthcare to supply and distribute Cardioxane and Savene in Poland. Clinigen is forming such partnerships to expand the geographical reach and commercial presence of its own products in order to accelerate growth.

In October 2018, the Group acquired iQone, a Swiss-based specialty pharmaceutical business. This acquisition will enhance Clinigen in a number of ways: supporting Clinigen's Commercial Medicines business in key EU markets; extending and enhancing services provided by the Managed Access business within Unlicensed Medicines by providing EU MSL support which is increasingly requested by clients; and enhancing the Group's proposition as a commercial licensing and/or divestment partner for pharmaceutical companies.

Collectively these seven acquired products, along with iQone, contributed 65% of Commercial Medicines' adjusted gross profit (2018: 66%). The slight decrease in the relative percentage is due to a full year's contribution from Quantum and demonstrates further breadth of the Group's product portfolio.

# LICENSED PRODUCTS

The Group continues to make good progress in extending the commercial strategy in converting medicines from UL2L. In the AAA region, the Group has 241 (2018: 214) specialist pharmaceutical and medical-technology actively marketed licensed products. The increase is a result of the marketing authorisation (product registration certificates) transferring to Clinigen from the partnership agreement with Bristol-Myers Squibb in South Africa.

"IN JUNE 2019, THE GROUP WAS
GRANTED MARKETING
AUTHORISATIONS FOR TWO
MELATONIN PRODUCTS BY THE
MEDICINES AND HEALTHCARE
PRODUCTS REGULATORY AGENCY
(MHRA). THE GROUP EXPECTS
THE PRODUCTS TO BE A MODEST
CONTRIBUTOR OF GROWTH TO
THE BUSINESS IN THE FUTURE."

In April 2019, Clinigen signed an exclusive licensing agreement with GC Pharma in Japan to commercialise Hunterase (Idursulfase-beta). This is the first Japanese licensing agreement with an international company signed by Clinigen and demonstrates the ability to partner with pharmaceutical companies outside their home geographies to commercialise their products.

# **DEVELOPED PRODUCTS**

The Commercial Medicines business also develops, licenses and commercialises medicines that are currently prescribed as unlicensed medicines in the UK. By year end, the business had 14 products in its portfolio.

The lead product in the developed product portfolio, Glyco continues to perform strongly.

In June 2019, the Group was granted marketing authorisations for two Melatonin products by the Medicines and Healthcare products Regulatory Agency ('MHRA'). The Group expects the products to be a modest contributor of growth to the business. Identifying and developing unlicensed products to offer licensed options is one example of the UL2L strategy in Commercial Medicines and follows the successful launch of previous products in the portfolio.

#### **PIPELINE**

The Group continues to seek selective product acquisitions that fit within the acquired product portfolio, and in the AAA region, looks to further increase the number of regional licensed products. In addition, the business continues to develop its pipeline of UL2L products, as well as complementary larger niche generic products. There are currently 17 products in the developed product pipeline which are due to be launched in the next two to three years (2018: 16).

**FINANCIAL REVIEW** 

# A ROBUST FINANCIAL PERFORMANCE

Nick joined Clinigen in March 2019 from Royal Bank of Canada ('RBC') where he was Managing Director and Head of RBC's European healthcare equity research team. Prior to joining RBC, Nick was a senior analyst at Investec. A full biography can be read on page 52.



# HIGHLIGHTS

- Adjusted gross profit up 30% (+1% on an organic basis\*) to £182.3m (2018: £140.1m); with adjusted gross profit growth on an organic basis\* ex Foscavir and UK Specials business +7%
- Adjusted EBITDA up 33% (+4% on an organic basis\*) to £100.8m (2018: £76.0m); with adjusted EBITDA growth on an organic basis\* excl. Foscavir and UK Specials business +23%
- Adjusted EPS up 20% to 54.4p (2018: 45.4p), continuing double digit EPS growth each year since IPO
- Reported EPS of 4.0p (2018: 22.9p)
- Profit before income tax of £12.3m (2018: £35.9m)
- Net debt as at 30 June 2019 of £252.4m, representing a strong cash flow performance and pro forma leverage of 1.99x
- Full year dividend increased 20% to 6.7p (2018: 5.6p)
- Future organic adjusted gross profit is targeted to grow by at least 5% to 10%, with FY20 expected to be towards the upper end of this guidance

N.L

#### NICK KEHER

Group Chief Financial Officer 18 September 2019 Clinigen has achieved another year of solid financial performance. Against the backdrop of both the ongoing Brexit risk and macro-economic uncertainty this performance demonstrates the value of the platform that has been built, the people within and the robustness of the end-markets it operates in. Investment in product development, people, infrastructure and IT systems to establish the platform that will enable organic growth over a long-term view has continued in the period whilst delivering EPS (adjusted EPS) growth of 20%, representing a solid return for shareholders.

In the year, Clinigen made four acquisitions which have been the key drivers of absolute growth, but the underlying performance has also been encouraging. This is especially so when considering the external macro risks and in-light of expected headwinds materialising against the Group's once largest product, Foscavir, and the UK Specials business. Whilst organic adjusted gross profit growth of 1% is below management's medium-term growth expectation it is more robust at +7% when specifically excluding Foscavir competition and the UK Specials business with any further financial impact set to naturally lessen in the following years.

A number of adjusted measures are used which are considered by the Board in reporting, planning and decision making. Adjusted results reflect the Group's trading performance and exclude amortisation of acquired intangibles and products, and non-underlying costs relating to acquisitions which are explained in note 7 of the consolidated financial statements.

Overall, the Group achieved a strong growth in profits with its three key financial metrics; adjusted gross profit up 32% on a constant currency basis, adjusted EBITDA up 36% on a constant currency basis and adjusted EPS up 20%.

Group revenues increased by 20% (20% on a constant currency basis) to £456.9m (2018: £381.2m). Adjusting for Managed Access pass through costs, revenue grew by 36% (36% on a constant currency basis).

# SUMMARY ADJUSTED INCOME STATEMENT

			GROWTH		
YEAR ENDED 30 JUNE Adjusted results	2019 £M	2018 £M	REPORTED	CONSTANT CURRENCY	ORGANIC*
Revenue	456.9	381.2	20%	20%	(4)%
Gross profit	182.3	140.1	30%	32%	1%
Administrative expenses	(82.6)	(65.2)	(27)%		
EBITDA from joint venture	1.1	1.1	(5)%		
EBITDA	100.8	76.0	33%	36%	4%
Depreciation and amortisation	(3.9)	(1.7)			
EBIT	96.9	74.3	30%		
Finance cost	(8.6)	(5.3)			
Profit before tax	88.3	69.0	28%		
Basic EPS	54.4p	45.4p	20%		
Dividend per share	6.7p	5.6p	20%		

This summary adjusted income statement presents Group results on an adjusted basis excluding amortisation of acquired intangibles and products, and other non-underlying items relating to acquisitions (see note 4 and 7 of the consolidated financial statements). Adjusted EBITDA includes the Group's share of EBITDA from its joint venture. Constant currency growth is derived by applying the prior year's actual exchange rate to this year's result.

# ADJUSTED GROSS PROFIT BY DIVISION

			GROWTH			
YEAR ENDED 30 JUNE	2019 £M	2018 £M	REPORTED	CONSTANT CURRENCY	ORGANIC*	
Commercial Medicines	79.4	64.0	24%	25%	(7)%	
Unlicensed Medicines	69.7	62.1	12%	14%	3%	
Clinical Services	33.2	14.0	>100%	>100%	23%	
	182.3	140.1	30%	32%	1%	

The growth in adjusted gross profit was driven primarily by the acquisitions, with each contributing towards the Group's performance. On an organic basis\*, there were good performances in Clinical Services from CTS; in Unlicensed Medicines, from Managed Access and from the African and Asia Pacific regions in Global Access; in Commercial Medicines there was good growth from the developed product portfolio in the UK. These performances offset pressure; both on Foscavir, from an alternative therapy, and on the UK Specials business within Unlicensed Medicines. Excluding these two factors, growth in adjusted gross profit on an organic basis\* was 7%.

Adjusted EBITDA increased by 33% (36% on a constant currency basis) to £100.8m (2018: £76.0m). The growth was higher than the growth in adjusted gross profit due to operational leverage and the change in business mix following the acquisitions. Adjusted EBITDA on an organic basis\* increased by 4% benefitting from a reduction in underlying overheads excluding the acquisitions, reflecting the continued focus on driving efficiencies across the Group. The management continue to see further cost saving opportunities from the enlarged platform, from better sourcing of product for its CTS and GA businesses, from moving to single source opportunities on key spend lines and on challenging non-drug procurement costs. These cost saving opportunities are set to help fund growth across other areas of the business through targeted reinvestment.

Despite investment in the US and EU infrastructure as part of the Proleukin US rights and iQone acquisitions, growth in the cost base on an organic basis is expected to be marginally lower than growth in gross profit on an organic basis in FY20, with operational leverage expected to increase further beyond FY20.

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

# FINANCE COST

The adjusted net finance cost was £8.6m (2018: £5.3m). The increase is due to the Group's higher net debt position following the recent acquisitions. The average interest charge on gross debt, which increases as leverage increases, was 2.8% (2018: 2.2%) during the year. The reported net finance cost was £12.8m (2018: £6.4m), after taking account of the non-cash £4.1m unwind of discount on the contingent consideration relating to the acquisitions (2018: £1.1m).

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

# FINANCIAL REVIEW CONTINUED

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

YEAR ENDED 30 JUNE	2019 £M	2018 £M
Adjusted profit before tax	88.3	69.0
Amortisation of acquired intangibles and products	(37.8)	(22.1)
Acquisition costs	(5.4)	(3.9)
Restructuring costs	(6.4)	(5.3)
Increase in the fair value of contingent consideration	21.4	-
FX revaluation on deferred consideration	(0.4)	-
Unwind of discount on contingent consideration and other acquisition finance costs	(4.2)	(1.1)
Tax on joint venture in South Africa	(0.4)	(0.3)
Adjustment for fair value of acquired stock sold in the period	-	(1.4)
NuPharm legal settlement	-	1.0
Total adjustments	(76.0)	(33.1)
Reported profit before tax	12.3	35.9

The table above shows the reconciling items between the adjusted profit before tax of £88.3m (2018: £69.0m) and the reported profit before tax of £12.3m (2018: £35.9m).

The adjustments to profit before tax comprise costs relating to amortisation, acquisitions and the Group's share of the tax charge on the joint venture earnings of £0.4m (2018: £0.3m).

Total amortisation was £39.3m (2018: £22.6m), of which £31.1m (2018: £18.4m) related to acquired intangibles, £6.7m (2018: £3.7m) related to acquired product licences and £1.2m (2018: £0.4m) related to software.

Acquisition costs amounted to £5.4m (2018: £3.9m) relating predominantly to the CSM acquisition. The main acquisition costs were professional advisory and due diligence fees of £2.5m and £2.4m for securing certain funds for the CSM acquisition.

Restructuring costs relating to the acquisitions are £6.4m (2018: £5.3m), most of which are redundancy costs resulting from streamlining the senior management teams and removing duplicate functions following the acquisitions, and costs for termination of third-party contracts as part of the integration process.

The performance of the CSM acquisition has exceeded management's original expectations and the profit forecast for the earn out period has been increased (this is described in more detail in the cash flow and net debt section).

# **TAXATION**

Taxation was £7.1m (2018: £8.5m), based primarily on the prevailing UK and overseas tax rates. This charge is calculated as £17.7m based on the adjusted profit of £88.3m, offset by a credit of £10.6m in respect of the adjusted items.

The Group's adjusted effective tax rate (ETR) decreased to 20.0% (2018: 21.0%) due to a higher proportion of earnings in the UK and the reduction in the corporation tax rate in the US. Given the increasing proportion of activity from the US, the Group expects the ETR to be broadly 21% for FY20.

#### F<sub>P</sub>S

Adjusted basic EPS, calculated excluding amortisation of acquired intangibles and products, and other non-underlying items, increased by 20% to 54.4p (2018: 45.4p). The increase

reflects the Group's higher adjusted profit from operations, offset by dilution and higher finance costs following the acquisitions and the related placing and debt refinancing.

Reported basic EPS was 4.0p (2018: 22.9p). The decrease is due to the additional amortisation and exceptional costs arising from the acquisitions.

#### DIVIDEND

The Directors are proposing to increase the final dividend to 4.75p per share (2018: 3.84p), resulting in a 20% increase in the full year dividend to 6.7p per share (2018: 5.6p).

The final dividend will be paid, subject to shareholder approval, on 29 November 2019 to shareholders on the register on 8 November 2019.

# **CASH FLOW AND NET DEBT**

Cash flow performance continues to be strong, with operating cash flow of £89.8m (2018: £64.1m). Net working capital increased by £6.0m in the year (excluding the effect of acquisitions, non-underlying items and exchange adjustments) due to the growth in the service business. The low levels of working capital in the business reflect a strong focus on credit control and general working capital management.

Capital expenditure (excluding product acquisitions) was £19.0m (2018: £12.3m), which includes £6.1m related to warehouse, IT and other infrastructure investments, including preparation for the introduction of serialisation in February 2019, £4.3m related to the Group ERP system, £4.0m on new product development and £4.6m related to the development of owned products. Capital expenditure for FY20 is expected to fall slightly versus the prior year as spend on the ERP system and serialisation fall away and are not fully offset by increased costs on Proleukin product development.

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

For CSM, the Group paid initial consideration of £115.5m (US\$151.9m) in cash with additional contingent consideration which had a fair value at 30 June 2019 of £55.0m (US\$69.8m). The contingent consideration is payable in the year ending 30 June 2020 and is contingent on the adjusted EBITDA generated by CSM in the 12 months to 31 December 2019. The business has performed ahead of expectation since its acquisition and the undiscounted fair value of the contingent consideration has been revised upward, resulting in an additional £21.4m (US\$27.1.0m) liability which has been recognised in non-underlying administrative expenses. The final payment could be in the range of nil to US\$90m and is expected to be paid in March 2020. For iQone, the Group paid initial consideration of £6.9m (€7.7m) cash and £2.2m (€2.5m) in Clinigen shares, with additional contingent consideration payable in five years which had a fair value of £5.2m (€5.8m).

The Group also spent £114.3m on two product acquisitions, Proleukin and Imukin, and deferred consideration on Foscavir bags.

The other main cash flows were tax paid of £13.6m (2018: £12.6m), interest paid of £7.9m (2018: £3.9m) and dividends paid of £7.7m (2018: £6.3m).

As a result of the acquisitions, net debt increased during the year by £115.9m to £252.4m. Net debt is expected to increase marginally in the current financial year as expected strong operational cash flow is offset by deferred consideration payments for CSM and Proleukin alongside capital expenditure and working capital.

# TREASURY MANAGEMENT

The Group's operations are financed by retained earnings and bank borrowings, and on occasion, the issue of shares to finance acquisitions. During the year, the debt facilities have been refinanced as part of the financing arrangements for the acquisition of CSM and the subsequent acquisition of the US rights to Proleukin. The new financing has increased the debt facility from £220m to £375m, which is composed of an unsecured £150m term loan with a single repayment in 2023 and an unsecured revolving credit facility of up to £225m.

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 3.0x. As at 30 June 2019, interest cover was 14.7x and the net debt/adjusted EBITDA leverage was 1.99x. The leverage ratio in the current financial year is expected to remain broadly constant to the prior year before reducing in-line with cash generation thereafter.

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

Clinigen reduces its exposure to currency fluctuations on translation by typically managing currencies at Group level using bank accounts denominated in foreign currencies. Where there is sufficient visibility of currency requirements, forward contracts are used to hedge exposure to foreign currency fluctuations. The Group's treasury function does not engage in speculative transactions and does not operate as a profit centre.

The Group has applied hedge accounting where permissible to match hedges to the transactions to which they relate thereby reducing volatility in the results which may arise from gains and losses on hedging instruments.

# MID-TERM GUIDANCE AND PROPOSED FUTURE CHANGE TO REPORTING STRUCTURE

The fundamentals of the business remain strong and the Group is well positioned to capture further share from its Service focused end-markets whilst revitalising and growing the Product business. With the overall outlook for the markets in which it operates remaining positive, the Group is for the first time, providing formal guidance. Future organic adjusted gross profit is targeted to grow by at least 5% to 10%, with FY20 expected to be towards the upper end of this guidance. In the short term, this view is being driven by the developed assets within Commercial Medicines, plus continued growth of Clinical Services and despite expected continued headwinds to Foscavir and the UK Specials business. Over the medium-term, growth is expected to come more broadly from each division as these known headwinds lessen and as the Group's end-market dynamics remain positive. Management then see the potential for higher organic growth yet again as Proleukin revitalisation takes place.

Management intends to invest in the platform, particularly in its US and EU infrastructure, digital capabilities, the ERP platform and product development to help drive longer-term organic growth. As such, organic EBITDA growth is expected to marginally exceed organic gross profit growth in FY20 with operational leverage expected to increase further beyond FY20.

Alongside the commitment to the medium-term guidance issued, the Group expects to change its reporting structure to a divisional EBITDA profit-level model, akin to industry peers, with the first reporting date set to be by the end of FY20. The management believes this will lead to better internal cost control and P&L accountability whilst allowing for easier interpretation of results by external stakeholders.

# CASH FLOW PERFORMANCE (£M)



# CAPITAL ALLOCATION

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

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

# PRINCIPAL RISKS FACING THE BUSINESS

Clinigen operates an embedded risk management framework, which is monitored and reviewed by the Board. There are a number of potential risks and uncertainties that could have a material impact on the Group's financial performance and position. These include risks relating to the political environment, competitive threat, counterfeit products penetrating the supply chain, compliance, reliance on technology, cyber risk, foreign exchange, people and the identification, strategic rationale and integration of acquisitions. These risks and the Group's mitigating actions are set out on pages 46 to 49.

# **USES OF CASH FLOW**

Total

	£M
CSM and iQone acquisition	119.3
Product acquisitions	114.3
Acquisition and restructuring costs	7.9
Capex	19.0
Dividend	7.7
Other	2.4
Total	270.6
Financed by:	
Free cash flow	76.0
Placing	78.7
Increase in net debt	115.9

270.6

# **PRINCIPAL RISKS**

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

# **RISK MANAGEMENT FRAMEWORK**

The Group's risk management framework provides the structure by which the principal risks are managed. The Board believe this risk management framework provides enough structure to ensure the risk assessment process is able to manage the current risks identified and has the appropriate procedures in place to identify emerging risks.

#### BOARD

- Ensures comprehensive risk management and internal controls are in place and operating effectively
- Reviews the principal risks
- Determines the Group's risk appetite

# **AUDIT AND RISK COMMITTEE**

- Oversees the effectiveness of the Group's risk management and internal controls
- Monitors and has oversight of external audit
- Reviews and monitors the Group's principal risks

# **EXECUTIVE MANAGEMENT TEAM**

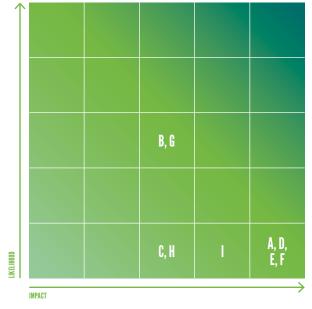
- Responsible for consolidating the key risks across the Group
- Oversees the implementation and operation of the risk management and internal control systems
- Reviews and monitors the Group's key risks

# **BUSINESS OPERATIONS**

II OKING

- Identifies and assesses operational risk
- Implements risk management processes, procedures, controls and reporting

# **RISK HEAT MAP**



- A. POLITICAL RISK
- B. COMPETITIVE THREAT
- C. SUPPLY CHAIN
- D. COMPLIANCE
- E. RELIANCE ON TECHNOLOGY
- F. CYBER RISK
- G. FOREIGN EXCHANGE
- H. ACQUISITIONS
- I. PEOPLE

>

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

RISK MANAGEMENT ACTIONS TO MITIGATE RISK TREND

# A. POLITICAL 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.

The impact of Brexit could affect the Group's ability to ship product efficiently in and out of the UK and the EU. For example, in the immediate aftermath of the UK leaving the EU, it is possible that the capacity at major ports both in the UK and the EU may be materially reduced for a period. The longer-term effects of Brexit are difficult to predict, but could include financial instability and slower economic growth or economic downturn in the UK, the EU and/or the global economy. Brexit could also impact the Group's ability to recruit EU employees.

STRATEGIC LINK
1+4+5+6

The Group mitigates this risk by having an increasingly broad product, service and geographical range, limiting the impact of events in any single territory.

The Group regularly monitors developments in key geographies and maintains strong relationships with regulatory bodies to enable the Group to respond rapidly to local changes in circumstances or events. The Group also takes account of political risk when assessing new contracts or product acquisitions.

The Group has a long established Brexit team which is implementing a Brexit solution designed to maintain continuity of supply of crucial medicines to patients with unmet medical needs, including in the event of a 'no deal' Brexit. Impacted products which are destined for EU-based HCPs will be moved to, or delivered to, warehouses in mainland Europe operated by the Group or its partners. Procurement and supply transactions in respect of impacted products which are destined for the EU will be completed under the Wholesale Distribution Authorisation of a Group affiliate based in the EU. Impacted clients have been notified of the changes. Whilst the outcomes are not yet clear, it is expected that the Group's flexible operating model and the team's deep understanding of multinational regulatory processes will aid its management of Brexit risk.

# **B. COMPETITIVE THREAT**

The Group faces a threat to its owned products from generic products and/or the development of alternative therapies by competitors. The Group's products are not typically protected by patents and competitor threat could significantly erode sales of our products. The threat of generic risk increases as the Group's product sales increase in size as increasing market size improves the viability for a potential generic product. The competitive landscape could also change during a product's development before commercialisation. The Group also faces competitive threat within the services operations.

The continued diversification of the Group reduces the overall effect if one of its products or services is impacted by significant change in the competitive landscape. Finding and promoting new users of our products and services, and expanding into new geographies are a key part of our strategy and this helps mitigate the impact of competition in a particular geography treatment area or service.

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

STRATEGIC LINK

4+6

# C. SUPPLY CHAIN

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

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

STRATEGIC LINK
5+6

The Group has effective supply chain management only working with trusted manufacturing and global distribution partners which the Group assesses regularly. The Group also seeks to maintain appropriate stock levels of its own products and related Active Pharmaceutical Ingredient ('API') to minimise the risk of shortage of supply.

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

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

>

# PRINCIPAL RISKS CONTINUED

RISK MANAGEMENT ACTIONS TO MITIGATE RISK TREND

# D. COMPLIANCE

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

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

We operate in numerous countries around the world and our industry is also highly regulated. These circumstances increase our exposure to potential bribery or corruption risks. The Group has a business and Group-wide compliance structure which is continually assessed. Employees are regularly trained in key areas including policies relating to Clinigen's approach to good distribution practice and good manufacturing practice activities, including pharmacovigilance, and 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 Group is also regularly audited by customers and regulatory authorities to ensure compliance with relevant legislation and contractual obligations and acts to address any recommendations. Senior management at Clinigen has full responsibility for the quality management system undertaking periodic management reviews and maintains a close working relationship with the competent authorities to ensure compliance.

# ^

# E. RELIANCE ON TECHNOLOGY

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

STRATEGIC LINK

2

The Group's technology strategy is regularly reviewed to ensure that the systems it operates across the Group support its strategic direction.

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

The Group is currently undertaking an implementation of a new ERP system designed to make the business systems more efficient and scalable. The risk attached to this implementation has been mitigated by a significant amount of planning work, the employment of a specialist implementation partner and a robust governance structure managing the implementation.



>

# F. CYBER RISK

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

STRATEGIC LINK

2

The Group has invested in the protection of its data and IT systems from the threat of cyber-attack. Cyber security procedures exist to minimise this risk.







# **G. FOREIGN EXCHANGE**

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

STRATEGIC LINK
4+5+6

The Group's main operational currencies are sterling, US dollar, euro and, to a lesser extent, the South African rand and Australian dollar.

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

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

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

# H. ACQUISITIONS

The Group could fail to integrate acquisitions efficiently, leading to disrupted operations and reduced returns. In addition, the Group could make acquisitions which don't support the business as intended or could fail to identify potential acquisitions to drive future growth aspirations.

STRATEGIC LINK 4+5+6+7

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.

>

>

# I. PEOPLE

The Group's ability to deliver on its strategic objectives could be adversely impacted by failure to recruit, develop and retain the right people.

STRATEGIC LINK

1

The Group has grown rapidly and now employs over 1,100 people in 14 international locations. 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. 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.

# **KEY TO STRATEGIC OBJECTIVES**

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

# CORPORATE SOCIAL RESPONSIBILITY

To fulfil our vision to be the trusted global leader in access to medicines the Group must ensure that it behaves in a socially and environmentally responsible manner.

The Clinigen foundations are based on addressing unmet medical needs and improving access to medicines. Through the Group's global supply and distribution networks it is able to navigate the regulatory hurdles to ensure it delivers the right medicine, to the right patient, at the right time. In the last financial year, the Group shipped approximately 6.4 million units, helping patients in over 100 countries.

# CORPORATE SOCIAL RESPONSIBILITY

Clinigen recognises the importance of balancing the interests of its customers, shareholders, employees, suppliers and the communities in which it operates. Management of the environmental and social issues that play a part in the business is a key factor in the Group's strategy for success and in the practice of good corporate governance. With this in mind, the Group, through its management team and its experienced quality and regulatory department, audits all suppliers and manufacturers regularly to ensure they reach the standards set and responds to any improvement requests made of them.

The Group aspires to carry out its business to the highest ethical standards, treating employees, suppliers and customers in a professional, courteous and honest manner. Compliance standards are included in the Group's audit schedule when reviewing its suppliers and manufacturers to check the standards they follow meet the Group's expectations.

# **EMPLOYEES**

The Group currently employs over 1,100 people in 14 international locations and is committed to a policy of equal opportunities in the recruitment, engagement and retention of employees. The multinational diversity of the Group's team not only supports its global service offering but demonstrates its lack of barriers to employment. In line with the Group's strategic objective of developing and retaining talented people, employees are encouraged and supported to undertake additional training, both internal and external, to develop their skills, which are then often transferred across departments or enable promotion.

The Group believes that the development of talent is important to achieve the long-term strategic goals of the business. The Clinigen Management Academy, a bespoke management development program which is formally recognised in the UK by the Institute of Leadership and Management, was successfully completed by 29 employees during the year, with a further 13 completing the program in August.

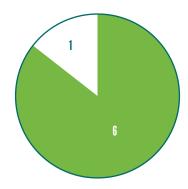
Age, colour, race, gender, disability, ethnic origin, national origin, marital status, sexual orientation, religious or political views are not seen as barriers to employment and are evidenced by the Group's diverse employment base. The Group is committed to providing equal opportunities for individuals in all aspects of employment and considers the skills and aptitudes of disabled persons in recruitment, career development, training and promotion. The Group supports employees with disabilities, ensuring the necessary reasonable adjustments are in place to support them.

It is important the Group listens to its employees and understands their views on Clinigen as an employer. The Group operates a culture of open communication through a range of two-way mediums including: regular employee representative staff forums; a global intranet platform; newsletters; and regular Group and divisional performance updates from the CEO and CFO. The strategic objectives of the Group are communicated to the employees through the regular updates and at the annual all-staff conferences.

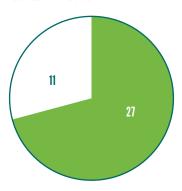
In addition, during the year, the Group launched Peakon, the world's leading platform for measuring and improving employee engagement, Peakon asks employees a small number of questions weekly and enables management to obtain real-time feedback. The external platform ensures anonymity and empowers management to take prompt and informed action.

# **GENDER RATIO**

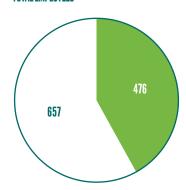




# **BUSINESS LEADERS GROUP**



# TOTAL EMPLOYEES



Male O Female

Details on the Group's gender pay gap reporting can be found on the Group website. Other initiatives launched in the year include Long Service Recognition Awards and an 'Ask the CEO' page on the global intranet.

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

- Make a difference: We go further for patients
- Put best interests first: We manage for best interests, not self-interest
- Show mutual respect: We treat others as we would like to be treated
- Maintain integrity: We're open and transparentNurture success: We reward, recognise
- and develop success
- Measure progress: We know where we are and where we're going

The Group works hard to embed these principles into employees' ways of working; from reward and recognition initiatives such as the Group's 'Making a Difference' awards, to the focus on behaviours in its hiring and performance management processes.

The Group recognises the importance of diversity, including gender, at all levels of the Company. The Group already has a strong female representation in the business leaders group where women comprise 29% of positions. In addition, out of 1,133 employees, approximately 58% are female. The Group continues to actively seek to recruit and advance women into its top management through manager training, application monitoring and robust, transparent selection processes.

#### **MODERN SLAVERY ACT**

The Group fully supports the aims of the Modern Slavery Act 2015 to eradicate human slavery and trafficking. In particular, the Group wishes to ensure that no child labour or servitude of any kind or human trafficking has been involved in the supply and distribution of products or services. This statement is made pursuant to Section 54, Part 6 of the Modern Slavery Act 2015 and sets out the steps the Company has taken to ensure that slavery and human trafficking are not taking place in our supply chains or in any part of our business.

The Group is a worldwide supplier and distributor of pharmaceutical products and services. As part of our initiative to identify and mitigate risk we have put in place, or are in the process of putting in place, systems to:

- Identify and assess potential risk areas in the Group's supply chains
- Mitigate the risk of slavery and human trafficking occurring in the Group's supply chains
- Monitor potential risk areas in the Group's supply chains; and
- Protect whistleblowers

The Group will continue to review the position by a process of contract reviews, third-party audits and ongoing monitoring of our partners within the supply chain.

# **HEALTH AND SAFETY**

The Group recognises that health and safety has positive benefits to the organisation and that a commitment to a high level of safety makes good business sense. It also recognises that health and safety is a legal requirement and must, therefore, continually improve, progress and adapt to change. To achieve this aim, appropriate levels of resource are allocated to ensuring a positive health and safety culture throughout the Company. This is demonstrated by active Health, Safety and Environment ('HSE') Committees, new starter inductions and mandatory online modules for all staff relating to display screen equipment ('DSE'), workplace health and safety, environmental awareness, fire safety awareness and stress management (managers) where the results are assessed upon completion and responded to wherever necessary.

The Group's approach to health and safety is based on the identification and control of risks. Adequate planning, monitoring and reviews of the health and safety policy are carried out in line with our Safety Management System ('SMS') to ensure continual improvement to our health and safety standards. Clinigen was awarded ISO 14001 accreditation in June 2018 and continue to work closely with the British Safety Council to enhance our procedures, compliance and reporting. The Group recognises that certain site-specific variances in procedures and processes are still in evidence that will be reviewed, aligned, communicated and delivered by the HSE Committee during the coming year to ensure that best practise is consistent and measurable across all Clinigen sites.

Complying with its legal obligations, the Group provides a safe working environment for all its employees and visitors, but also strives for best practice standards wherever these are achievable. The Group recognises that staff wellbeing is extremely important and provide free of charge health checks for all employees. In addition, health promotion initiatives and activities are communicated and organised on a regular basis to support this commitment.

# ENVIRONMENT

The Group is an environmentally conscious organisation, which acknowledges the impact its operations and services may potentially have on the environment. The Group fully complies with applicable legal and other compliance obligations, whilst at all times striving for best practice. The Group is committed to continually investigating ways of improving its impact on the environment. Board and senior management are committed to monitoring and continually improving environmental performance.

The Group aims to minimise energy and water consumption, and wherever practicable, reduce, recycle and reuse our resources to prevent the unnecessary waste of materials. This year we are focused on packaging, freight and our warehouse footprint.

In addition, the Group is registered with the Environment Agency as an approved packaging producer which shows that it has met its recovery and recycling obligations under the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (as amended).

# **BOARD OF DIRECTORS**



PETER ALLEN

Independent Non-Executive Chairman

#### APPOINTED

August 2012

#### COMMITTEES

Nomination (Chairman), Audit and Risk, Remuneration

#### PROFILE

Peter has a wealth of experience and has held key senior positions, including Chairman, CEO and CFO in a number of companies in the healthcare industry, and played a significant role in their growth.

Peter spent 12 years at Celltech Group plc (1992/2004) as CFO and Deputy CEO, six years at ProStraken Group plc as Chairman (2007/13) and interim CEO (2010/11) and three years as Chairman of Proximagen plc (2009/12).



**SHAUN CHILTON** 

Chief Executive Officer

#### APPOINTED

Director in July 2013 and CEO in November 2016

#### COMMITTEES

None

#### **PROFILE**

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

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

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



**NICK KEHER** 

Chief Financial Officer

#### APPOINTED

March 2019

# COMMITTEES

None

#### PROFILE

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

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

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



# JOHN HARTUP

Senior Independent Non-Executive Director

#### APPOINTED

June 2011

#### COMMITTEES

Nomination, Remuneration, Audit and Risk

#### **PROFILE**

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

# EXTERNAL APPOINTMENTS

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

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

# EXTERNAL APPOINTMENTS

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

The Board is satisfied that this external appointment does not impact upon the CEO's ability to discharge his role at the Company effectively.

# EXTERNAL APPOINTMENTS

None

#### EXTERNAL APPOINTMENTS

None



IAN NICHOLSON Independent Non-Executive Director

# APPOINTED

September 2012

#### COMMITTEES

Remuneration (Chairman), Audit and Risk, Nomination

#### **PROFILE**

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



**ANNE HYLAND** Independent Non-Executive Director

# APPOINTED

January 2018

#### COMMITTEES

Audit and Risk (Chair)

#### **PROFILE**

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

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



**ALAN BOYD** 

Non-Executive Director

#### APPOINTED

November 2018

COMMITTEES None

#### **PROFILE**

Professor Boyd has accumulated over 30 years 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 Ltd. 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 Ltd where he was responsible for delivering the majority of key development milestones.

In 2005, Professor Boyd left to set up Alan Boyd Consultants Ltd, 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 Ltd, a private specialist biopharmaceutical consultancy company. He is also a Director of BaxterBoyd Ltd and Celentyx Ltd.



AMANDA MILLER General Counsel and Company

APPOINTED June 2017

Secretary

# COMMITTEES

None

#### PRNFII F

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

# EXTERNAL APPOINTMENTS

None

#### EXTERNAL APPOINTMENTS

lan currently holds positions as Non-Executive Director of Consort Medical plc and Bioventix plc, where he is the Non-Executive Chairman. Ian is also Chairman of the Investment Committee at Cancer Research UK Pioneer Fund, Director of Casewell Consulting Ltd, F2G Ltd, and Wells Stores Ltd, and an Operating Partner at Advent Life Sciences LLP.

#### EXTERNAL APPOINTMENTS

Anne is CFO of Kymab Ltd a private biopharmaceutical company. She is also a Non-**Executive Director of Elementis** plc, a FTSE 250 global specialty chemicals company.

# CHAIRMAN'S INTRODUCTION TO GOVERNANCE

# A ROBUST GOVERNANCE FRAMEWORK

# "THE BOARD HAS MADE FURTHER PROGRESS DURING THE YEAR TO TAKE INTO ACCOUNT DEVELOPMENTS IN CORPORATE GOVERNANCE AND BEST PRACTICE."

In . An

# PETER ALLEN

Independent Non-Executive Chairman 18 September 2019



# **DEAR SHAREHOLDER**

I am pleased to present you with the governance section for the year ended 30 June 2019.

Corporate governance is important to us. As the Board of an AIM traded company with a significant market capitalisation, we are committed to ensuring that the Group is managed in accordance with the principles and provisions set out in the UK Corporate Governance Code 2016 (the 'Code'). We believe that effective corporate governance, consistent with best practice for a company of Clinigen's size and with the available resources to the Group, will assist in the delivery of the Group's corporate strategy, the generation of sustainable shareholder value and the protection of shareholders' long-term interests.

The Board has made further progress during the year to take into account developments in corporate governance and best practice. It has used the externally facilitated corporate governance benchmarking exercise conducted last year which compared Clinigen's 2017 practice against other AIM trading companies having a market capitalisation in excess of £1bn and with FTSE 250 companies having a market capitalisation of between £1bn and £1.3bn. The Board made a number of changes last year and continued to implement recommendations this year, notably by conducting a thorough evaluation of the Board and its Committees to ensure effective and appropriate composition and management (see below)

The Board through its Committees, plays a key role in providing the necessary framework, challenge and support to the business and ensuring that a culture of good governance exists throughout the Group.

As Chairman, in order to facilitate the long-term sustainability and success of the Group, my role is to ensure that the Board operates in an open and transparent environment, allowing the Non-Executive Directors an opportunity to critically assess, challenge and support the Executive Directors and senior management team.

#### THROUGHOUT THE YEAR

The Board met nine times during the year. All of the meetings were held in the UK, bar one which took place in Belgium, at the offices of the recently acquired CSM business. Holding meetings outside the UK provides the Board with a great opportunity to engage with employees and solicit their feedback including in relation to strategy.

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

During the year, the Group made two corporate acquisitions, CSM and iQone, and two product acquisitions, Proleukin and Imukin. The process of identifying potential acquisitions that fit with the Group's strategic growth aspirations is extremely complex. The Board has been particularly busy in this respect.

The Board also conducted an internal Board evaluation which was led by the Senior Independent Director, John Hartup, and facilitated externally by Prism Cosec. This was based on the principles and provisions in the 2018 UK Corporate Governance Code, published on 16 July 2018, which will be in force for financial years commencing on or after 1 January 2019 (the '2018 Code'). It included a thorough internal evaluation of the Board and its Committees, with the aim of ensuring that they operate efficiently and effectively, with an appropriate mix of skills and experience in order to help deliver the Group's strategy within an appropriate risk framework. This showed that the Board and its Committees function extremely well and the Board are currently reviewing the recommendations.

In line with the Financial Reporting Council guidance, we are already considering the impact of the 2018 Code and the Guidance on Board Effectiveness. The Company Secretary has conducted a gap analysis during the year to review the Group's current governance framework and practices against the 2018 Code and we are in the process of assessing those recommendations.

In addition, the Board has reviewed and approved the following corporate policies: a US Aggregate Spend Reporting Policy; a US Compliance Policy; and a Disclosure Policy which formalises the way inside information is managed to ensure compliance with applicable legislation.

# **BOARD CHANGES AND BOARD COMPOSITION**

During the year some changes were made to the composition of the Board. Alan Boyd joined the Board on 16 November 2018 as a Non-Executive Director and Nick Keher joined the Board on 19 March 2019 as Chief Financial Officer (following Martin Abell's departure). Alan brings extensive industry experience and expertise in pharmaceutical services, having been in the sector for over 30 years and holding senior roles within Glaxo Group, ICI Pharma, Zeneca Pharmaceuticals and Ark Therapeutics. His appointment strengthens the Board and will help support and deliver the Group's strategy. Nick joined from RBC where he was a Managing Director and Head of RBC's European healthcare equity research team. He had covered the European healthcare space for over eight years at both RBC and Investec. He brings considerable pharmacy and pharmaceutical experience as well as financial expertise, both as an accountant and from working in the financial markets. He has a deep knowledge and insight of our business through his research and analysis of Clinigen since its IPO in 2012 and will be a key addition to the executive management team.

Martin stepped down from the Board on 31 March 2019. On behalf of the Board and everyone at Clinigen, I would like to thank Martin for his substantial contribution over the last three and a half years. We wish him every success for the future.

Board composition is considered regularly by the Board. The question of 'overboarding' has increased in prominence over the last year, arising from concerns that Directors may not be able to properly fulfil their duties where they have too many competing commitments to other listed companies. The Board, always mindful of this, undertakes a regular and detailed review of the nature and scope of its Directors' external appointments, which consciously extends beyond the standard corporate governance guidelines of listed company directorships, and includes appointments to private companies and charities.

The Board is satisfied that none of its Directors are over committed and that each has sufficient time to meet their Board responsibilities at Clinigen. The Board evaluation, which was conducted in June 2019, confirms the prevailing view that the Board operates efficiently and cohesively. The broad and holistic review of each of its Directors' commitments means that the Board is satisfied that none of the Directors is 'overboarded'. Further, the Board finds the additional insight gained by Directors' participation on other Boards to be of enormous benefit. Each of the Non-Executive Directors provides excellent, uncompromising service; that said, the Board maintains a watching brief and is actively engaged in succession planning.

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

# **GOVERNANCE**

Principal risks facing the Group continue to be a focus. Details of our principal risks are set out on pages 46 to 49. The Group has assessed compliance to be an increased risk this year following the acquisition of Proleukin in the US and the commencement of direct selling. All risks, along with the other principal risks are regularly assessed by the Audit and Risk Committee.

# DIVIDEND

The Board has maintained a progressive dividend policy. We propose to pay a final dividend of 4.75p, subject to approval at the AGM on 26 November 2019. Together with the interim dividend of 1.95p paid in April, this makes a combined annual dividend of 6.7p, representing an increase of 20% versus last year.

# **LOOKING AHEAD**

Priorities for the Board in 2020 include continually assessing progress against the strategic priorities, with particular attention on integration of the acquisitions and ensuring that they are supported by appropriate governance structures. We believe that our governance framework is robust and effective, but we recognise that there are improvements we can make given our commitment to follow the Code.

Thank you for your continued support and I look forward to meeting any shareholders who can join us at our AGM on 26 November 2019.

# CORPORATE GOVERNANCE STATEMENT

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

The Board believes that effective corporate governance as best business practice will assist the delivery of the Group's corporate strategy, the management of risk and the generation of shareholder value, improve Board efficiency, boost investor confidence, reduce cost of capital and help protect our shareholders' long-term interests. Clinigen values corporate governance highly, not only in the boardroom but across the whole business of the Group.

After careful consideration of the Company's circumstances and stage in development, and what is in the best interests of its shareholders, while having regard to employees, customers, suppliers and the Group's operational impact on the community, the Board has agreed to report against the Code published by the Financial Reporting Council ('FRC') on 17 June 2016.

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

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

# THE ROLE OF THE BOARD

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

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

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

Matters considered by the Board in 2019 include:

- Approval of the financial statements
- Annual budget
- Strategic review
- Gender pay gap reporting
- Build out of a US compliance structure following the acquisition of the US rights to Proleukin
- Management of inside information by adoption of a formal disclosure policy
- Acquisition strategy
- Board evaluation
- The requirements of the 2018 Corporate Governance Code

In 2019, the Senior Independent Director led a thorough internal evaluation process of the Board and Committees, to ensure that in all aspects they are efficient and effective with an appropriate mix of skills and experience. The review assessed the composition, experience, dynamics, the Chairman's leadership, and the Board's role and responsibilities in connection with the Group's strategy, oversight of risk and succession planning.

#### DIVISION OF RESPONSIBILITIES

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

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

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

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

# **BOARD COMPOSITION**

The Board consists of two Executive Directors, an Independent Non-Executive Chairman, three Independent Non-Executive Directors and a Non-Executive Director. John Hartup is the Company's Senior Independent Director. John's role as the Senior Independent Director is to act as a sounding board for the Chairman and a trusted intermediary for the other Directors. He is also available as an additional point of contact for shareholders. The names of the Directors and the Company Secretary, and their biographies are set out on pages 52 and 53.

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

Alan Boyd joined the Board on 16 November 2018 as a Non-Executive Director and Nick Keher joined the Board on 19 March 2019 as Chief Financial Officer (following Martin Abell's departure). Martin stepped down from the Board on 31 March 2019.

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

The Board continues to assess that its membership has the right qualities required to operate within a robust governance structure which the Board believes fits the requirements of the Group. Priorities for the Board in 2019/20 include continually assessing progress against the strategic priorities and strengthening the Board membership with Independent Non-Executive Directors where it is deemed necessary.

# APPOINTMENT. REMOVAL AND RE-ELECTION OF DIRECTORS

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

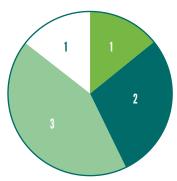
Appointments are made with due regard for the benefits of diversity on the Board (including gender). The Group supports the Code in respect of diversity.

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

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

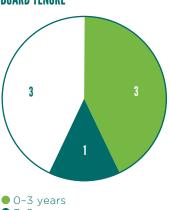
Our Articles of Association state that one-third of the Directors must stand for re-election by shareholders annually in rotation and that each Director appointed by the Board is subject to election by the shareholders at the first AGM after their appointment. However, to underline their accountability to shareholders and the Board's commitment to appropriate corporate governance, each Director will stand for re-election at the upcoming AGM. Following advice from the Nomination Committee, the Board has concluded that each Director is qualified for election or re-election.

# BOARD COMPOSITION



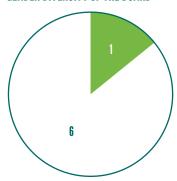
- Independent Non-Executive Chairman Executive Directors
- Independent Non-Executive Directors
- O Non-Executive Director

# **BOARD TENURE**



- 3-6 years
- O >6 years

# GENDER DIVERSITY OF THE BOARD



Female **O** Male

# CORPORATE GOVERNANCE STATEMENT CONTINUED

# **BOARD AND COMMITTEE MEETINGS**

The Board meets on a formal basis regularly throughout the year and met nine times in the year ended 30 June 2019. The Committee meetings are scheduled around the Board meetings. Agendas, Committee papers and other appropriate information are distributed prior to each meeting to allow the Board to meet its duties.

The Directors' attendance during the year ended 30 June 2019 are as follows:

	BOARD	AUDIT AND RISK Committee	REMUNERATION COMMITTEE	NOMINATION COMMITTEE
<b>Current Directors</b>				
S Chilton	9	3 <sup>1</sup>	2 <sup>1</sup>	1 <sup>1</sup>
N Keher (appointed to the Board March 2019)	3	$1^1$	$1^1$	_
P Allen	9	3	3	2
J Hartup	9	3	3	2
l Nicholson	9	3	3	2
A Hyland	9	3	2 <sup>1</sup>	$1^{1}$
A Boyd (appointed to the Board November 2018) <sup>2</sup>	6	2 <sup>1</sup>	$1^1$	-
Past Directors				
M Abell (left the Board March 2019)	6	2 <sup>1</sup>	11	11

- 1. By invitation.
- 2. Invited as a guest to the Board meeting on 8 November 2018.

# INDUCTION AND DEVELOPMENT

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

Occasionally Board meetings are held at operational sites outside the UK to enhance the Board's understanding of the business. This year one Board meeting was held in Belgium with the remainder held in the UK. The Board are also provided with regular updates on strategy from senior management throughout the year and attend a day dedicated to the Group's strategy.

#### **BOARD COMMITTEES**

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

# **NOMINATION COMMITTEE**

The Chairman of the Nomination Committee is Peter Allen, with John Hartup and Ian Nicholson the other members of the Committee. The primary role of the Committee is regularly to review the structure, size and composition of the Board, give full consideration to succession planning for Directors and other senior executives and evaluate the balance of skills, knowledge, experience and independence on the Board. The Committee meets at such times as the Chairman of the Committee requires.

# **AUDIT AND RISK COMMITTEE**

The Chair of the Audit and Risk Committee is Anne Hyland, with Peter Allen, John Hartup and Ian Nicholson being the other members of the Committee. The primary role of the Committee is to monitor, review and challenge the financial statements and regulatory environment, monitor the relationship with the external auditors, monitor the Group's internal control and risk management and ensure compliance with laws and regulations. The Committee meets at such times as the Chairman of the Committee requires. The Committee carefully considers the key judgements applied in preparation of the consolidated financial statements including the estimated future discounted cash flows supporting the carrying value of goodwill and intangibles and the going concern assumption. Each of the relevant estimates and judgements have been confirmed as appropriate.

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

# REMUNERATION COMMITTEE

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

#### RISK MANAGEMENT AND INTERNAL CONTROL

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

# **COMMUNICATION WITH INVESTORS**

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

Following the AGM held in November 2018, the Board contacted the Group's largest institutional investors and proxy companies and provided an opportunity for them to share their feedback on the resolutions past at the AGM and to cover questions more generally. Peter Allen, John Hartup and Ian Nicholson met with the governance representatives and fund managers from these institutions and communicated the feedback back to the wider Board.

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

# **SHARE DEALING**

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

#### **AGN**

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

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

# WHISTLEBLOWING

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

**AUDIT AND RISK COMMITTEE REPORT** 

# SUPPORTING THE BUSINESS STRATEGY

"AS THE GROUP DEVELOPS, IT IS VITALLY IMPORTANT THAT THE COMMITTEE CONTINUES TO PLAY A KEY ROLE IN THE GOVERNANCE AROUND AUDIT AND RISK."

A. Mad

ANNE HYLAND

Chair of the Audit and Risk Committee 18 September 2019



# DEAR SHAREHOLDER,

As Chair of the Audit and Risk Committee, I am pleased to present you with the Committee's report for the year ending 30 June 2019. This is my first full year as Chair of the Committee and the Group's first Audit and Risk Committee Report. This report details the work of the Committee over the past year in fulfilling our responsibilities to provide effective governance over the Group's financial and risk affairs, to ensure that shareholders' interests are properly protected in relation to internal controls, financial reporting and risk management.

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

As has already been mentioned, this year the Group has delivered another strong growth in profits against a backdrop of executing on our strategy with the acquisitions of CSM and iQone, and the two speciality medicines Proleukin and Imukin. As the Group develops, it is vitally important that the Committee continues to play a key role in the governance around audit and risk.

# COMPOSITION

The Audit and Risk Committee was chaired by me throughout the year and my co-members were the Chairman, Peter Allen, Senior Non-Executive Director, John Hartup and Non-Executive Director, Ian Nicholson. The Committee met three times formally in 2019. Other Board members and representatives from the Group's external auditors, PwC, are regularly invited to attend the Audit and Risk Committee meetings.

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

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

# ROLE

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

# MAIN COMMITTEE ACTIVITIES

- Reviewed the annual and half-yearly financial reports and related statements including clarity and completeness of disclosures and use of alternative performance measures
- Approving the annual external audit plan and risk identification
- Approving the level of fees paid to the external auditors for audit and non-audit services
- Discussed the key findings of the external auditors on the interim and annual consolidated financial statements
- Reviewed the independence, objectivity, performance and effectiveness of the external auditors
- Considered significant accounting and reporting judgements and concluded if accounting policies and any amendments thereto were appropriate, particularly in relation to IFRS 9 'Financial Instruments', IFRS 15 'Revenue from Contracts with Customers' and IFRS 16 'Leases'
- Reviewed the integrity and consistency of the key accounting judgements
- Considering if the Annual Report and Accounts taken as a whole are fair, balanced and understandable
- Reviewed principal risks to ensure effective and continual improvement
- Reviewed the Group's accounting for the acquisition of products and corporate acquisitions
- Review of the hedging policy for deferred consideration payments associated with acquisitions
- Review of support for the going concern assumption
- Review of the effectiveness and integrity of the internal financial controls framework which underpins financial reporting by considering reports on internal control
- Monitoring progress on and review of the project governance associated with the Group ERP implementation

As part of the half and full year reporting we carefully consider the key judgements applied in preparation of the consolidated financial statements including the estimated future discounted cash flows supporting the carrying value of goodwill and intangibles and the going concern assumption. In addition, for this financial year, the Committee also considered the key judgements relating to the following areas which were confirmed as appropriate:

- Acquisition accounting associated with the corporate acquisitions of CSM and iQone and product acquisitions of Proleukin and Imukin. This included the judgements in relation to estimates for deferred consideration payments
- Revenue recognition for Proleukin including adjustments for returns, chargebacks and rebates

# INTERNAL AUDIT

The Company does not currently have an internal audit function. The Committee presently consider this to be appropriate given the close involvement of the Executive Directors and senior management on a day-to-day operational basis. In addition, further assurance has been obtained through our external auditors extending its scope of work in areas of potential risk, at the request of the Committee. However, following the recent increases in the size and scope of the Group's business, the Committee is considering the creation of an internal audit function, possibly accessing specialist skills and resource in conjunction with a third-party provider.

# **EXTERNAL INDEPENDENT AUDITORS**

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

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

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

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

# **RISK MANAGEMENT**

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

# CONCLUSIONS

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

# REMUNERATION REPORT

# BALANCING STAKEHOLDER FEEDBACK

"ENGAGEMENT WITH OUR STAKEHOLDERS HAS
BEEN INVALUABLE TO THE COMMITTEE, WHO HAVE
TAKEN INTO CONSIDERATION THE BALANCE OF
FEEDBACK RECEIVED."



#### IAN NICHOLSON

Chairman of the Remuneration Committee 18 September 2019



# DEAR SHAREHOLDER,

On behalf of the Board, I am pleased to present you with the Remuneration Committee's report for the year ended 30 June 2019.

The Remuneration Committee was chaired by me throughout the year and my co-members were Peter Allen and John Hartup. The Committee met three times formally in 2019.

As one of the larger listed companies on the AIM market, the Board and Remuneration Committee take governance seriously and this report is put to advisery vote each year at the AGM. The Committee was aware that a significant minority of shareholders voted against last year's report. As a result, during the year, I and other members of the Board have engaged with the Group's largest institutional investors and proxy voting agencies on various governance matters, including remuneration. Engagement with our stakeholders has been invaluable to the Committee, who have taken into consideration the balance of feedback received. The Committee have also sought the advice of independent remuneration consultants to seek better clarity on the key items to better enhance the 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 1,100 employees in 14 international locations. The governance of the remuneration policy is equally important to ensure it is appropriate for a business the size and profile of the Group.

#### PERFORMANCE HIGHLIGHTS

The Group has once again delivered another strong growth in profits, with:

- Adjusted gross profit of £182.3m up 30%
- Adjusted EBITDA of £100.8m up 33%
- Adjusted EPS up 20% to 54.4p
- Strong cash flow performance with operating cash flow of £89.8m

The strong growth has been driven primarily by acquisitions, with each contributing towards the Group's performance. On an organic basis\*, there were good performances in Clinical Services from CTS; in Unlicensed Medicines, from Managed Access and from the AAA regions in Global Access; in Commercial Medicines, there was good growth from the developed product portfolio in the UK. These performances offset pressure both; on Foscavir, from an alternative therapy, and on the UK Specials business within Unlicensed Medicines.

# **REMUNERATION FOR 2019**

Reflecting the performance in 2019 set out above and the performance of the Group over the last three years, annual bonus payouts and Long-Term Incentive Plan ('LTIP') vesting for the Executive Directors were as follows:

# **ANNUAL BONUS**

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

- Adjusted EBITDA of £100.8m was slightly below the maximum stretch target resulting in partial payout for this element
- The personal objectives were based on expanding our portfolio of acquired product assets, expanding our community of key opinion leaders and customers, and further upgrades to the Company's information technology platforms. In the Committee's view, these objectives were met in full as demonstrated by the acquisitions of Proleukin and Imukin, the growth of Cliniport and the launch of Clinigen Direct, and the continued implementation of Clinigen One ERP
- Shaun Chilton will receive 64% and 100% of the maximum award for financial and personal measures respectively. This amounts to an annual bonus payout of 75% of his maximum opportunity. In line with the stated policy, 20% in excess of 50% of base salary is deferred for one year
- Nick Keher will receive 50% and 100% of the maximum award for financial and personal measures respectively, pro-rated based on his start date to his first full month of employment as per the scheme rules. This amounts to an annual bonus payout of 65% of his maximum opportunity

#### LTIP

Shaun Chilton and Martin Abell were granted an LTIP award in November 2015 which vested in November 2018 and an award in October 2016 which will vest in October 2019, shortly after the end of the 2019 financial year.

In respect of the 2015 award which vested in November 2018:

- 40% of the award was subject to a TSR performance condition measured for the period from 30 November 2015 to 30 November 2018 - TSR for the period was 14% in excess of the Index and this resulted in 37.22% out of 40% vesting
- 40% was subject to cumulative EPS for the three financial years ending 30 June 2018 - cumulative EPS over the period was 120.1p which was above the maximum target of 93.2p and therefore 40% out of 40% vested

- 20% was subject to personal objectives for this element
  Shaun Chilton had 18% out of 20% vesting and Martin Abell
  had 7% out of 20%
  - Therefore, 95.22% of Shaun Chilton's award and 84.22% of Martin Abell's vested

For the 2016 award which will vest in October 2019, the performance criteria and weightings were identical to those applying to the November 2015 award set out above:

- TSR performance condition (40%) the performance period for this part of the award is due to end on 21 October 2019 -TSR based on performance to 30 August 2019 was 23% in excess of the Index and provides an estimated vesting of 40% out of 40% vesting
- Cumulative EPS (40%) cumulative EPS over the three financial years to 30 June 2019 period was 140.8p which is above the maximum target of 127.4p and therefore 40% out of 40% will vest, and
- 20% was subject to personal objectives for this element 20% out of 20% will vest for Shaun Chilton and 10% out of 20% for Martin Abell
- Therefore, it is estimated that 100% of Shaun Chilton's award and 90% of Martin Abell's will vest in October 2019

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

# **MANAGEMENT CHANGES**

On 5 February 2019, the Company announced the departure of Martin Abell as CFO who left the Company on 31 March 2019 and the appointment of Nick Keher as his replacement. Nick joined the business on 19 March 2019.

The Committee deemed Martin Abell to be a good leaver and therefore he will retain an interest in his outstanding LTIP awards. These awards will vest on their normal vesting dates subject to performance and a pro-rata reduction to reflect the vesting period served. Martin Abell received a payment for bonus earned in respect of 2018/19, and a payment in lieu of his remaining contractual notice and accrued annual leave. Full details are provided on page 70. The terms agreed in respect of Martin Abell's departure are fair and in line with good practice, his terms of employment and his contribution to the business

Nick Keher's salary was set at £300,000 p.a., he will receive a matched pension contribution of up to 10% of salary and will participate in the bonus and LTIP schemes as set out in the remuneration policy. Nick joined from a top City institution where he was head of the European healthcare equity research team. Nick Keher was granted an LTIP award on joining with a face value of 300% of salary under the Clinigen LTIP to compensate him for remuneration forfeited at his previous employer. Further details are provided in the Annual Report on Remuneration. The Committee is comfortable that the salary offered to Nick Keher is not excessive for this size of company and that the LTIP award was necessary to buyout his remuneration arrangements.

# **IMPLEMENTATION OF POLICY IN 2020**

Base salaries were reviewed in April 2019 and Shaun Chilton's annual base salary has remained at £600,000 (no change since 1 November 2017) and Nick Keher's salary was also unchanged given he joined the Company on 19 March 2019. The next salary review date shall be 1 April 2020.

# REMUNERATION REPORT CONTINUED

Due to the continuing pressures on executive remuneration, particularly for Main Market-listed companies, the Committee regularly reviews the remuneration policy to ensure it remains appropriate for the business. The Committee has determined that the policy does not require fundamental changes to the way our Executive Directors are remunerated. Therefore, the annual bonus and LTIP schemes will continue to apply as follows:

- Annual bonus opportunity shall be 100% for Shaun Chilton and Nick Keher. 70% will be based on stretching EBITDA targets with the balance based on personal and strategic goals.
- The Committee intends to grant Shaun Chilton an LTIP award with a face value of 125% of salary and Nick Keher an LTIP award with a face value of 100% of salary. 40% of the award will be based on TSR, 40% based on EPS and 20% based on personal objectives. Recognising the Company's significant growth, the TSR condition will be measured against the FTSE 250 index (ex Investment Trusts) rather than the FTSE Small Cap (ex Investment Trusts).

The Committee has decided to operate a share ownership guideline for Executive Directors. Under the guideline, Executive Directors are expected to build and maintain a shareholding equal to at least 200% of base salary over time. The Committee supports strongly the alignment of managements' interests with those of shareholders through building up a significant stake in the Company.

# **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 Code on a comply or explain basis. There were a number of changes to the Code in 2018 and the Committee will report in full on its compliance with the Code in next year's report. However, we are compliant in a number of areas such as the inclusion of malus and clawback provisions in the LTIP, LTIP awards vesting at the normal vesting date for good leavers and, as set out above, the introduction of a share ownership guideline for Executive Directors.

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

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

# IAN NICHOLSON

Chairman of the Remuneration Committee 18 September 2019

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 advisery basis, for shareholder approval at the AGM to be held on 26 November 2019. The current policy set out below came into effect following the AGM on 8 November 2018 and remains unchanged for 2019/20 except for the change in performance metric for the TSR condition to the FTSE 250 index (ex Investment Trusts) and the introduction of a share ownership guideline which will apply from the start of the 2019 financial year.

# **REMUNERATION POLICY**

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

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

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

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

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

# SHAREHOLDERS' VIEWS

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

# **EXECUTIVE DIRECTORS**

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

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

	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. Awards above 100% are unusual and usually a one-off award per individual.	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 Small Cap Index (ex Investment Trusts); FTSE 250 index (ex Investment Trusts); FTSE 250 index (ex Investment Trusts) for awards granted from 1 July 2019  - Personal objectives  The split between these measures, for each grant, is set annually by the Remuneration Committee. In 2019, 40% of the award was based on EPS, 40% on TSR and 20% on personal objectives. The personal objectives component can only vest if a minimum EPS target is achieved.

# REMUNERATION REPORT CONTINUED

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

# SHARE OWNERSHIP GUIDELINE

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

# PAYMENT FOR LOSS OF OFFICE

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

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

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

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

#### NON-EXECUTIVE DIRECTORS

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

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

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

	DATE OF CONTRACT	UNEXPIRED TERM (MONTHS) OR ROLLING CONTRACT	NOTICE PERIOD (MONTHS)
S Chilton	3 January 2012	Rolling	12
N Keher	19 March 2019	Rolling	6
P Allen	1 August 2012	Rolling	3
J Hartup	1 June 2011	Rolling	3
l Nicholson	1 September 2012	Rolling	3
A Hyland	1 January 2018	Rolling	3
A Boyd	15 November 2018	Rolling	3
M Abell		Stood down 31 March 2019	

# REMUNERATION GOVERNANCE

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

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

The key areas of focus for the Remuneration Committee during 2019 included:

- Approved the Remuneration Report
- Reviewed and approved UK and International sharesave plans
- Reviewed performance conditions and targets for 2019 bonus and LTIP
- Reviewed 2018 personal objectives and set 2019 personal objectives for the Executive Directors
- Reviewed and approved the Company's Gender Pay Gap Report
- Reviewed and approved base salary increases for the Executive Directors, senior managers and the Chairman
- Reviewed and approved base salary increases for the Executive Direct
   Prepared the remuneration package for the appointment of the CFO
- Reviewed wider market trends and best practice reporting in remuneration
- Engaged with the Group's largest institutional investors and proxy companies
- Carried out a tender exercise and appointed remuneration consultants

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

- Prepare and publish the Remuneration Report
- Determine performance conditions and targets for 2020 bonus and LTIP
- Review and approve base salary increases for the Executive Board, senior managers and the Chairman
- Consider advice from the remuneration consultants
- Review and approve the Gender Pay Gap Report

During the year, the Remuneration Committee carried out a tender exercise and appointed FIT Remuneration Consultants LLP ('FIT') as the independent adviser to the Committee with effect from May. FIT advised on market trends, corporate governance, Remuneration Report disclosures and on Directors' remuneration arrangements in 2019/20. 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. Prior to appointing FIT, the Committee received advice from AON New Bridge Street.

# ANNUAL REPORT ON REMUNERATION

Two Directors (2018: one) are members of the defined contribution pension scheme.

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

The amount payable to the highest paid Director in respect of emoluments was £2,558,000 (2018: £1,202,000), comprising basic salary and bonus of £1,050,000 (2018: £842,000), long-term share-based incentives vesting of £1,439,000 (2018: £309,000) and other benefits of £69,000 (2018: £51,000).

# REMUNERATION REPORT CONTINUED

The Executive Directors' and Non-Executive Directors' remuneration for 2019 and 2018 are set out below:

	2019				2018					
£000	SALARY/FEES	BONUS	LTIP <sup>4</sup>	OTHER	TOTAL	SALARY/FEES	BONUS	LTIP <sup>4</sup>	OTHER	TOTAL
S Chilton	600	450	1,439	69	2,558	533	309	309	51	1,202
N Keher¹	85	49	_	_	134	_	_	_	_	-
P Allen	140	_	_	3	143	140	_	_	4	144
J Hartup	70	_	_	_	70	70	_	_	_	70
l Nicholson	70	_	_	_	70	70	_	_	-	70
A Hyland	70	_	_	_	70	35	-	_	1	36
A Boyd²	39	_	_	_	39	_	_	_	_	-
M Abell <sup>3</sup>	212	162	242	24	640	277	161	885	29	1,352

- 1. Nick Keher joined the Board as Executive Director in March 2019.
- 2. Alan Boyd joined the Board as Non-Executive Director in November 2018.
- 3. Martin Abell stood down from the Board in March 2019 and received £139,000 in lieu of his remaining contractual notice
- 4.The 2019 LTIP figure relates to the October 2016 award which is due to vest in October 2019. This award is subject to a TSR performance period ending on 21 October 2019. 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 2019. The value is based on 100% of the award vesting and using the average share price for the period 1 April 2019 to 30 June 2019. The actual vesting value will be updated in next year's report to reflect the share price on vesting date. The 2018 LTIP value relates to the award that was granted on 30 November 2015 and vested on 30 November 2018.

#### **ANNUAL BONUS**

The Executive Directors were eligible to earn an annual bonus of up to 100% of salary, based on the achievement of stretching adjusted Group EBITDA targets and personal objectives. Adjusted Group EBITDA targets unlock up to 70% of maximum bonus potential, whilst personal objectives unlock up to 30%. The personal objectives are set on an individual basis and are linked to the corporate, financial, strategic and other non-financial objectives of the Group.

Shaun Chilton's and Nick Keher's personal objectives related to expanding the Group's portfolio of acquired product assets, expanding the community of key opinion leaders and customers and further upgrades to the Company's information technology platforms. The Committee determined that 100% of the personal objectives element would become payable. Nick Keher's annual bonus was based on a pro-rated salary to reflect his period of employment during the year.

The annual bonuses awarded for the 2019 financial year were as follows:

£000	TOTAL BONUS AWARDED IN SEPTEMBER 2019 (RELATING TO 2019 FINANCIAL YEAR)	CASH BONUS TO BE PAID In September 2019 (Relating to 2019 Financial Year)	DEFERRED BONUS TO BE PAID In September 2020 (Relating to 2019 Financial Year)
S Chilton	450	420	30
N Keher	49	49	-

For the 2019 financial year, the annual bonus awarded to Shaun Chilton was 75% of his base salary. 20% of the bonus earned in excess of 50% of base salary is deferred for one year in line with the stated policy. Nick Keher received a pro-rated bonus payment for the 2019 financial year, which was equivalent to 65% of his total eligible bonus.

The deferred element of the bonus relating to the 2018 financial year was paid in September 2019.

#### LTIP AWARDS VESTING IN THE YEAR

# November 2015 award

Nil cost share options were granted to the Executives Directors in November 2015 and these vested in November 2018. These awards were subject to a performance condition of TSR (40%) for the period from 30 November 2015 to 30 November 2018, cumulative EPS (40%) for the three financial years ending 30 June 2018, and personal objectives (20%).

MEASURE	THRESHOLD VESTING	MAXIMUM VESTING	OUTCOME	VESTING (% OF MAXIMUM)
Relative TSR	Equal to the FTSE SmallCap index (ex Investment Trusts)	Index plus 15% outperformance or higher	Index plus 14.3%	37.22%
EPS growth	5% p.a.	10% p.a.	24%	40%
Personal objectives	<ul><li>Successful integration of a</li><li>Specific divisional growth</li><li>Strengthening market pos</li></ul>	cquired businesses targets		Shaun Chilton - 18% Martin Abell - 7%
				Shaun Chilton - 95.22% Martin Abell - 84.22%

#### October 2016 award

Nil cost share options were granted to Executive Directors in October 2016 and these will vest in October 2019. These awards are subject to a performance condition of TSR (40%) for the period from 21 October 2016 to 21 October 2019, Cumulative EPS (40%) for the three financial years ending 30 June 2018, and personal objectives (20%).

MEASURE	THRESHOLD VESTING	MAXIMUM VESTING	OUTCOME	VESTING (% OF MAXIMUM)
Relative TSR	Equal to the FTSE SmallCap index (ex Investment Trusts)	Index plus 15% outperformance or higher	Index plus 23% - based on an estimate to 30 August 2019	40.00%
EPS growth	5% p.a.	10% p.a.	21% p.a.	40.00%
Personal objectives - Seeking further acquisitions to extend global - Improving the Company's information technology - Increasing the profile of Clinigen with key state.			orint platforms ders	Shaun Chilton - 20.00% Martin Abell - 10.00%
				Shaun Chilton - 100.00% Martin Abell - 90.00%

It is expected that 100.00% of awards will vest on 21 October 2019 for Shaun Chilton. It is expected that 90% of awards will vest on 21 October 2019 for Martin Abell. Martin Abell's awards will be subject to a pro-rata reduction as explained in more detail later in this report.

# LTIP AWARDS GRANTED IN THE YEAR

An award was granted to Shaun Chilton in October 2018 and to Nick Keher in May 2019, with vesting of the awards subject to the performance conditions, as set out below, in October 2021 and May 2022 respectively. The split between these measures, for each grant, is set annually by the Remuneration Committee. 40% of the award is based on TSR, 40% on EPS and 20% on personal objectives. The personal objectives component can only vest if a minimum EPS target is achieved.

The face value of Shaun Chilton's awards was equal to 150% of base salary and 300% for Nick Keher. Nick Keher joined from a top City institution where he was head of the European healthcare equity research team and the higher award was to compensate him for remuneration forfeited at his previous employer.

	NUMBER OF AWARDS GRANTED	FACE VALUE <sup>1</sup>	AMOUNT OF Base Salary	VESTING DATE
Shaun Chilton	106,007	£900,000	150%	31 October 2021
Nick Keher	96,256	£900,000	300%	28 May 2022

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

The performance conditions applying to these awards are as follows:

# **TSR**

TSR AGAINST THE FTSE SMALL CAP INDEX (EX INVESTMENT TRUSTS) OVER THE PERFORMANCE PERIOD (WHICH IS THE THREE-YEAR PERIOD FOLLOWING THE GRANT DATE)	PERCENTAGES OF AWARD THAT VESTS
Less than the Index	0%
Equal to the Index	25%
Between the Index but less than 15% out performance 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% out performance of the Index on a cumulative basis over the TSR performance period	100%

# **EPS**

EPS COMPOUND ANNUAL GROWTH RATE OVER THE PERFORMANCE PERIOD (WHICH ARE THE THREE FINANCIAL YEARS COMMENCING WITH THE 2018 FINANCIAL YEAR)	PERCENTAGE OF AWARD THAT VESTS
< 5% CAGR	0%
5-10% CAGR	Calculated on a straight-line basis between 25% and 100%
> 10% CAGR	100%

#### **Personal objectives**

The element of the award relating to personal objectives shall only vest if the personal objectives have been achieved and the minimum EPS threshold, shown above, is achieved. The personal objectives are based on expanding our portfolio of acquired product assets, expanding our community of key opinion leaders and customers and further upgrades to the Company's information technology platforms.

# REMUNERATION REPORT CONTINUED

# **OUTSTANDING SHARE AWARDS**

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

	DATE OF GRANT	30 JUNE 2018	EXERCISED	LAPSED	30 JUNE 2019
S Chilton	LTIP - 19 June 2015	43,811	-	-	43,811
	LTIP - 30 November 2015	36,182	_	(1,730)	34,452
	LTIP - 21 October 2016	159,893	_	_	159,893
	LTIP - 16 October 2017	34,904	_	_	34,904
	LTIP - 6 November 2017	43,630	_	_	43,630
	LTIP - 31 October 2018	106,007	_	-	106,007
N Keher <sup>1</sup>	LTIP - 29 May 2019	96,256	-	-	96,256
M Abell <sup>2</sup>	LTIP - 30 November 2015	123,172	(98,594)	(24,578)	-
	LTIP - 21 October 2016	36,642	_	(6,827)	29,815
	LTIP - 16 October 2017	23,996	_	(12,371)	11,625
	LTIP - 31 October 2018	33,244	_	(28,664)	4,580
	Clinigen Group Sharesave Plan	3,846	_	_	3,846

<sup>1.</sup> Nick Keher joined the Board as Executive Director in March 2019.

# **DIRECTORS' INTERESTS**

The interests of the Directors over the ordinary share capital of the Company as at 30 June 2019 are as follows:

	NUMBER OF SHARES Owned Outright	NUMBER OF SHARE OPTIONS WITH PERFORMANCE CONDITIONS	NUMBER OF SHARE OPTIONS WITHOUT PERFORMANCE CONDITIONS	NUMBER OF VESTED But unexercised Options
S Chilton	320,044	344,434	-	78,263
P Allen	47,232	_	_	_
N Keher	-	96,256	_	_
J Hartup	10,000	-	_	_
l Nicholson	10,000	-	_	_
A Hyland	4,142	-	_	_
A Boyd <sup>1</sup>	-	_	-	-
Total	391,418	440,690	_	78,263

<sup>1.</sup> Alan Boyd joined the Board as Non-Executive Director in November 2018.

There has been no change in the interests set out above between 30 June 2019 and 18 September 2019.

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.

# THE INCOMING AND DEPARTING CFOS' ARRANGEMENTS

# **Martin Abell**

The Committee agreed to the following for Martin Abell following his departure from the Company on 31 March 2019:

- That he would be treated as a 'good leaver' for the LTIP awards granted in 2016, 2017 and 2018, as per the plan rules, meaning that these awards would be permitted to vest on a pro-rata basis, at the normal vesting date, subject to the performance conditions
- For each award, Martin will receive 50% of the maximum 20% personal component
- That he would receive a pro-rata bonus payment of £162,000, which was based on the Committee's assessment of the likely bonus outcome for the performance year as determined at the time of leaving
- That he would receive payment in lieu of his remaining contractual notice and accrued annual leave
- That he would receive the deferred bonus payment from the financial year 2018  $\,$

The Committee believe that the terms agreed in respect of Martin Abell are fair and appropriate, in line with his terms and contribution

<sup>2.</sup> Martin Abell stood down in from the Board in March 2019.

#### **Nick Keher**

Nick Keher's salary was set at £300,000 p.a., he will receive a matched pension contribution of up to 10% of salary and will participate in the bonus and LTIP schemes as set out in the remuneration policy. Nick joined from a top City institution where he was head of the European healthcare equity research team. Nick Keher was granted an LTIP award on joining with a face value of 300% of salary under the Clinigen LTIP to compensate him for remuneration forfeited at his previous employer. Further details are provided in the Annual Report on Remuneration. The Committee is comfortable that the salary offered to Nick Keher is not excessive for this size of company and that the LTIP award was necessary to buyout his remuneration arrangements.

#### TCE

In the seven years since IPO on 24 September 2012 until 30 August 2019, the Group's TSR, defined as share price growth including reinvested dividends, has outperformed the FTSE All-Share Index by 393%, the FTSE 350 Pharma and Bio Index by 330% and the FTSE SmallCap Index (ex Investment Trusts) by 364%.

## **CEO REMUNERATION**

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

	FINANCIAL YEAR 2016	FINANCIAL YEAR 2017 Restated	FINANCIAL YEAR 2018 Restated	FINANCIAL YEAR 2019	PERCENTAGE Change	PERCENTAGE CHANGE For all employees
Total remuneration (£000)	6,103	1,266	1,202	2,558	113%	6%
Annual bonus (% of maximum)	0%1	100%	58%	75%	17%	7%
LTIP vesting (% of maximum)	100%	100%	95%	100%	5%	5%

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

Peter George stood down as Chief Executive Officer to become a Non-Executive Director in November 2016 where upon Shaun Chilton was promoted to Chief Executive Officer.

#### RELATIVE IMPORTANCE OF SPEND ON PAY

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

YEAR ENDED 30 JUNE 2019	2018 £M	2019 £M	CHANGE %
Total employee pay	40.4	52.3	29%
Dividends	6.3	7.7	22%
Adjusted profit before tax	69.0	88.3	28%

## **GENDER PAY GAP REPORTING**

The Group recognises the importance of diversity and inclusion, including gender, at all levels of the Company.

The Group already has a strong female representation at senior management level. We continue to actively recruit and develop women into our top management structures to enable us to better reflect and serve the diverse communities and cultures in which we operate around the world.

A full compliance statement can be found on the Group website at www.clinigengroup.com/uk-gender-pay-gap-report.

#### IMPLEMENTATION OF REMUNERATION POLICY IN 2020

Along with the salary review timetable for the Company as a whole, the Executive Directors' salaries for 2020 are scheduled to be reviewed in April 2020. 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 and Nick Keher's is 10%. They will both receive standard benefits in line with those provided to the workforce.

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

It is expected that an LTIP award with a face value of 125% of salary will be granted to Shaun Chilton and 100% of salary will be granted to Nick Keher. 40% will be based on relative TSR against the FTSE 250 index (ex Investment Trusts), 40% against EPS growth targets (with a 5% p.a. to 10% p.a. (threshold and maximum range)) and 20% based on personal objectives.

A new 200% of salary shareholding guideline will apply for Executive Directors.

No changes are proposed to the Non-Executive Directors' fees for 2020.

# REPORT OF THE DIRECTORS FOR THE YEAR ENDED 30 JUNE 2019

The Directors present their report together with the Strategic Report and the audited consolidated financial statements for the year ended 30 June 2019.

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

#### PRINCIPAL ACTIVITIES

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

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

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

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

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

# STRATEGIC REPORT

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 51, as the Board considers them to be of strategic importance. Specifically, these are Risk Management on pages 46 to 49, Business Review and Future Developments on pages 36 to 41, and Corporate Social Responsibility on pages 50 to 51. The Strategic Report forms part of this Report of the Directors and is incorporated into it by cross-reference. Both the Strategic Report and the Report of the Directors have been drawn up and presented in accordance with and in reliance upon applicable English company law, and the liabilities of the Directors in connection with those reports shall be subject to the limitations and restrictions provided by such law.

#### **KPIS**

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

#### FINANCIAL INSTRUMENTS

The Group's operations expose it to a variety of financial risks that include credit risk, liquidity risk and foreign exchange risk. The Group has a risk management program that seeks to limit the adverse effects on the financial performance of the Group by monitoring levels of debt finance and related finance costs and managing foreign currency transactions. The Group has implemented policies that require appropriate credit checks before a sale is made. The Group reduces its exposure to currency fluctuations on translation by managing currencies at Group level using bank accounts denominated in foreign currencies. Where there is sufficient visibility of currency requirements, forward contracts are used to hedge its exposure to foreign currency fluctuations.

Further detail is provided in note 20 of the consolidated financial statements.

#### **CREDITOR PAYMENT POLICY**

It is the policy and normal practice of the Group to make payments due to suppliers in accordance with agreed terms and conditions, generally 30 days. Where suppliers offer early settlement discounts, these may be taken advantage of. The policy will also be applied for 2020.

## **MAJOR SHAREHOLDERS**

As at 30 June 2019, the following shareholders held an interest of 3% or more of the Company's issued share capital:

	% OF Total voting Rights
Merian Global Investors	6.5%
Invesco	6.3%
Rathbones	5.6%
AXA Framlington Investment Managers	5.0%
Octopus Investments	4.7%
Janus Henderson Investors	4.7%
Lazard Asset Management	3.6%
Leaver family	3.2%

## DIVIDEND

As explained in the CFO statement, the Directors propose a final dividend of 4.75p per share, subject to approval at the AGM on 26 November 2019. The dividend will be payable on 29 November 2019 to all shareholders on the register on 8 November 2019. Together with the interim dividend of 1.95p per share paid on 12 April 2019, this makes a combined dividend for the year of 6.7p per share (2018: 5.6p per share).

#### **EVENTS AFTER THE REPORTING DATE**

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

## DIRECTORS AND APPOINTMENT OF DIRECTORS

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

S Chilton	
N Keher	(joined in March 2019)
P Allen	(Independent Non-Executive Chairman)
J Hartup	(Senior Independent Non-Executive)
I Nicholson	(Independent Non-Executive)
A Hyland	(Independent Non-Executive)
A Boyd	(Non-Executive) (joined in November 2018)
M Abell	(stood down in March 2019)

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

#### DIRECTORS' RESPONSIBILITIES STATEMENT

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

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

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

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

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

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

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

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

# **DIRECTORS' INDEMNITIES**

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

#### **GOING CONCERN**

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. 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.

#### **EMPLOYEES**

The policies relating to employees are discussed in the Corporate Social Responsibility section of the Strategic Report.

# REPORT OF THE DIRECTORS CONTINUED FOR THE YEAR ENDED 30 JUNE 2019

#### POLITICAL DONATIONS

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

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

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

## PROVISION OF INFORMATION TO THE INDEPENDENT AUDITORS

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

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

#### **AGM NOTICE**

The notice convening the AGM to be held on 26 November 2019, together with an explanation of the resolutions to be proposed at the meeting, is contained in a separate circular to shareholders.

## **INDEPENDENT AUDITORS**

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

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

NICK KFHFR

Group Chief Financial Officer 18 September 2019

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

# REPORT ON THE AUDIT OF THE GROUP FINANCIAL STATEMENTS

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

- give a true and fair view of the state of the group's affairs as at 30 June 2019 and of its profit and cash flows for the year then
- have been properly prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union; and
- have been prepared in accordance with the requirements of the Companies Act 2006.

We have audited the financial statements, included within the Annual Report & Accounts 2019 (the "Annual Report"), which comprise: the consolidated statement of financial position as at 30 June 2019; the consolidated income statement and consolidated statement of comprehensive income, the consolidated statement of cash flows, and the consolidated statement of changes in equity for the year then ended; and the notes to the financial statements, which include a description of the significant accounting policies.

### **BASIS FOR OPINION**

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

#### Independence

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

# OUR AUDIT APPROACH Overview



- Overall group materiality: £2.5 million (2018: £2.3 million), based on 5% of profit before tax before the deduction of non-underlying items, except for amortisation relating to the intangible assets.
- Following our assessment of the risks of material misstatement of the Group financial statements we performed audits of the complete financial statements of six components.
- In addition, certain centralised functions, including those covering acquisition accounting, corporate taxation, goodwill and intangible asset impairment assessments were audited.
- The components on which audits of the complete financial information and centralised work was performed accounted for 70% (2018: 82%) of the Group revenue.
- As part of our supervision process, the Group engagement team has been responsible for the audit of all significant components and for all of the in-scope reporting components.
- Our assessment of the risk of material misstatement also informed our views on the areas of particular focus for our work which are listed below:
- Assessment of the carrying value of acquired intangibles and goodwill.
- Fair value of assets and liabilities identified through acquisition accounting.
- Measurement of a significant new revenue stream entered into in the year.

#### The scope of our audit

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

## **Key audit matters**

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

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

#### KEY AUDIT MATTER

# Assessment of the carrying value of acquired intangibles and goodwill

Refer to the critical accounting estimates and judgements in note 2 to the consolidated financial statements, and note 12 (intangible assets).

We focused on this area because the Directors' assessment of whether impairment triggers have been identified that could give rise to an impairment charge in relation to intangible assets and goodwill, involved complex and subjective judgements and assumptions including the progress and future performance of individual products, in addition to the ongoing business activities of acquired entities.

corroborating evidence and assessing the margin an costs expected to be achieved by reference to histor realised, and where relevant, consideration of actual performance against prior year forecasts.

We validated the inputs used by the Directors to calculate the i

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.

#### HOW OUR AUDIT ADDRESSED 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 nor any impairment charge for goodwill is required to be recognised. We consider that the associated judgements taken were supportable.

# Fair value of assets and liabilities identified through acquisition accounting

The Group made one significant acquisition during the year, CSM Parent Inc. ('CSM'), for consideration of £147 million.

The Group also made one smaller acquisition during the year for consideration of £14 million for which we have tested the fair values ascribed on acquisition.

We have focused our work on the larger acquisition due to the relative size and significance to the Group as a whole. We focused on this area because the accounting treatment for the provisional opening balance sheet is inherently complex and requires the Directors to exercise many judgements, including in respect of the fair values of intangible assets and other assets and liabilities, contingent consideration and the calculation of associated goodwill.

For the significant acquisition:

- We read the Sale and purchase agreement in order to understand the nature of the transaction and ensure that relevant clauses that impact the accounting had been considered by the Directors.
- We tested the fair values ascribed to intangible assets by understanding the assumptions adopted in the valuation model, which critically include sales and margin forecasts, forecast attrition rates in relation to customers and useful economic lives. We engaged and evaluated the work of our valuation specialists who challenged those underlying assumptions and confirmed that the Directors had adopted reasonable assumptions in each circumstance.
- We tested the fair value of contingent consideration, including challenging the forecast EBITDA judgement by comparison to historic performance, and understanding management's assessed probability of achieving different EBITDA scenarios.
   For re-measurements to contingent consideration after the acquisition date, we understood what caused the variances to original forecast and the impact this may have on the remaining measurement period. The contingent consideration balance is highly sensitive to small movements in the EBITDA performance.
- For the remaining fair values of the other material assets and liabilities, we evaluated the Directors' assessment that book values equal fair values, and confirmed this reflects information that was known in relation to events that existed at the transaction dates.

The generated goodwill of £92 million is the residual value of the consideration over and above the fair value of acquired net assets. We consider that the Directors' assessment of the provisional fair value of the opening balance sheets of this acquisition to be supportable.

KEY AUDIT MATTER	HOW OUR AUDIT ADDRESSED THE KEY AUDIT MATTER
Measurement of a significant new revenue stream entered into in the year Refer to the critical accounting estimates and judgements in note 2 to the consolidated financial statements.	For the estimation of likely returns, chargebacks and rebates, we scrutinised management's basis for measuring revenue. This estimation included obtaining and assessing the actual rate of returns, chargebacks and rebates from the previous distributor for the product.
During the year, the group entered into a new significant revenue stream. This revenue stream includes various estimations in order to measure the revenue recorded, the most significant estimates being adjustments for returns, chargebacks and rebates.	We also performed sensitivity analysis on the measurement of revenue to understand the impact that any change in estimate could have.
We focused on this area because there is a material estimate in the measurement of revenue.	Whilst the estimation of the measurement of this revenue is inherently judgement, we consider that the directors have taken their best estimate in light of the available evidence, and that the disclosure in this area is appropriate.

#### How we tailored the audit scope

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

The Group is structured along three segments, being Commercial Medicines, Unlicensed Medicines and Clinical Services, with each segment set up to manage operations on both a regional and functional basis, consisting of a number of reporting entities.

The Group financial statements are a consolidation of 37 reporting entities comprising the Group's operating businesses and centralised functions. These reporting units maintain their own accounting records and controls and report to the head office finance team in the UK.

In establishing the overall approach for the Group audit, we determined the type of work that needed to be performed at each reporting unit. Accordingly, of the Group's 37 reporting entities we identified six which, in our view, required a full audit of their complete financial information in order to ensure that sufficient audit evidence was obtained. The reporting units on which a full audit of their complete financial information was performed accounted for 66% of the Group revenue. In addition, a number of centralised functions were audited by the Group engagement team at the head office. These included, but were not limited to, derivative financial instruments, UK and corporate taxation and goodwill and intangible asset impairment assessments. In total we tested 70% of Group revenues. Furthermore, specified procedures were performed over a significant US revenue stream acquired in the year. We also performed Group level analytical procedures on all of the remaining out of scope active reporting units to identify whether any further audit evidence was needed, which resulted in no extra testing being required.

The Group engagement team are responsible for the audit of all in scope reporting components. The Group engagement team have been directly responsible for the audit of all significant components, including visiting all significant locations in the UK. The Group engagement team also visited the new acquisition of CSM in the US during the year in relation to specific audit procedures performed over the acquisition during the year.

#### Materiality

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

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

Overall group materiality	£2.5 million (2018: £2.3 million).
How we determined it	5% of profit before tax before the deduction of non-underlying items, except for amortisation relating to the intangible assets.
Rationale for benchmark applied	We believe that profit before tax before the deduction of non-underlying items, except for amortisation relating to the intangible assets provides a consistent basis for determining materiality as it eliminates the impact of these items which fluctuate year on year and can have a disproportionate impact on the consolidated income statement.

For each component in the scope of our group audit, we allocated a materiality that is less than our overall group materiality. The range of materiality allocated across components was between £600,000 and £2,200,000. Certain components were audited to a local statutory audit materiality that was also less than our overall group materiality.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £125,000 (2018: £115,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

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

#### **Going concern**

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

REPORTING OBLIGATION	OUTCOME
We are required to report if we have anything material to add or draw attention to in respect of the directors' statement in the	We have nothing material to add or to draw attention to.
financial statements about whether the directors considered it appropriate to adopt the going concern basis of accounting in preparing the financial statements and the directors' identification of any material uncertainties to the group's ability to continue as a going concern over a period of at least twelve months from the date of approval of the financial statements.	However, because not all future events or conditions can be predicted, this statement is not a guarantee as to the group's ability to continue as a going concern. For example, the terms on which the United Kingdom may withdraw from the European Union are not clear, and it is difficult to evaluate all of the potential implications on the group's trade, customers, suppliers and the wider economy.

#### 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, Report of the Directors and Corporate Governance Statement, we also considered whether the disclosures required by the UK Companies Act 2006 have been included.

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

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

In our opinion, based on the work undertaken in the course of the audit, the information given in the Strategic Report and Report of the Directors for the year ended 30 June 2019 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements. (CAO6)

In light of the knowledge and understanding of the group and its environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic Report and Report of the Directors. (CAO6)

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

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

- The directors' confirmation on page 47 of the Annual Report that they have carried out a robust assessment of the principal risks facing the group, including those that would threaten its business model, future performance, solvency or liquidity.
- The disclosures in the Annual Report that describe those risks and explain how they are being managed or mitigated.
- The directors' explanation on page 73 of the Annual Report as to how they have assessed the prospects of the group, over what period they have done so and why they consider that period to be appropriate, and their statement as to whether they have a reasonable expectation that the group will be able to continue in operation and meet its liabilities as they fall due over the period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions.

We have nothing to report in respect of this responsibility.

#### **Other Code Provisions**

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

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

We have nothing to report in respect of this responsibility.

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

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

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

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

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

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

#### Use of this report

This report, including the opinions, has been prepared for and only for the parent company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

#### OTHER REQUIRED REPORTING

#### **COMPANIES ACT 2006 EXCEPTION REPORTING**

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

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

We have no exceptions to report arising from this responsibility.

#### OTHER MATTER

We have reported separately on the parent company financial statements of Clinigen Group plc for the year ended 30 June 2019.

# PAUL NORBURY BSC FCA (SENIOR STATUTORY AUDITOR)

for and on behalf of PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors East Midlands 18 September 2019

# CONSOLIDATED INCOME STATEMENT FOR THE YEAR ENDED 30 JUNE 2019

		2019				2018	
(IN £M)	NOTE	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL
Revenue	4	456.9	-	456.9	381.2	-	381.2
Cost of sales	•	(274.6)	-	(274.6)	(241.1)	(1.4)	(242.5)
Gross profit	4	182.3	-	182.3	140.1	(1.4)	138.7
Administrative expenses	•••	(86.5)	(71.4)	(157.9)	(66.9)	(30.3)	(97.2)
Profit from operations	5	95.8	(71.4)	24.4	73.2	(31.7)	41.5
Finance income	8	0.1	-	0.1	0.3	_	0.3
Finance expense	8	(8.7)	(4.2)	(12.9)	(5.6)	(1.1)	(6.7)
Share of profit of joint venture	14	0.7	-	0.7	0.8	-	0.8
Profit before income tax		87.9	(75.6)	12.3	68.7	(32.8)	35.9
Income tax expense	9	(17.3)	10.2	(7.1)	(14.2)	5.7	(8.5)
Profit attributable to owners of the Company		70.6	(65.4)	5.2	54.5	(27.1)	27.4
EPS (pence)							
Basic	10	•	•	4.0		•	22.9
Diluted	10			4.0			22.5

# **CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME** FOR THE YEAR ENDED 30 JUNE 2019

		2019			2018		
(IN.SM)	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL	
Profit attributable to owners of the Company	70.6	(65.4)	5.2	54.5	(27.1)	27.4	
Other comprehensive income							
Items that may be subsequently reclassified to profit or loss							
Cash flow hedges	0.1	-	0.1	(0.7)	-	(0.7)	
Currency translation differences	7.4	-	7.4	(2.9)	_	(2.9)	
Total other comprehensive income for the year	7.5	-	7.5	(3.6)	-	(3.6)	
Total comprehensive income attributable to owners of the Company	78.1	(65.4)	12.7	50.9	(27.1)	23.8	

All amounts relate to continuing operations.

# **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

**AS AT 30 JUNE 2019** 

(IN £M)	NOTE	2019	2018
Assets			
Non-current assets		•	
Intangible assets	12	811.9	497.6
Property, plant and equipment	13	13.6	6.8
Investment in joint venture	14	6.5	6.6
Deferred tax assets	21	2.8	2.6
Total non-current assets		834.8	513.6
Current assets		•	
Inventories	15	35.4	21.3
Trade and other receivables	16	110.2	95.9
Derivative financial instruments	20	2.2	-
Cash and cash equivalents	17	83.5	36.3
Total current assets		231.3	153.5
Total assets		1,066.1	667.1
Liabilities			
Non-current liabilities		•	
Trade and other payables	18	7.3	_
Loans and borrowings	19	335.9	172.8
Deferred tax liabilities	21	41.1	31.0
Total non-current liabilities		384.3	203.8
Current liabilities		•	
Trade and other payables	18	235.7	106.5
Corporation tax liabilities		7.3	6.8
Derivative financial instruments	20	0.4	0.5
Total current liabilities		243.4	113.8
Total liabilities		627.7	317.6
Net assets		438.4	349.5
Equity attributable to owners of the Company			
Share capital	22	0.1	0.1
Share premium account	23	240.2	161.3
Merger reserve	23	88.2	86.0
Hedging reserve	23	(0.3)	(0.4)
Foreign exchange reserve	23	15.0	7.6
Retained earnings	23	95.2	94.9
Total equity		438.4	349.5

The notes on pages 84 to 110 form an integral part of the consolidated financial statements.

The financial statements on pages 80 to 110 were approved and authorised for issue by the Board of Directors on 18 September 2019 and were signed on its behalf by:

**S CHILTON**Director

N KEHER Director

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 30 JUNE 2019

(IN £M)	NOTE	2019	2018
Operating activities			
Profit for the year before tax	•	12.3	35.9
Share of profit of joint venture	•	(0.7)	(0.8)
Net finance costs	8	12.8	6.4
Profit from operations		24.4	41.5
Adjustments for:	•	***************************************	
Amortisation of intangible fixed assets	12	39.3	22.6
Depreciation of property, plant and equipment	13	2.4	1.2
Dividends received from joint venture	14	0.8	2.9
Movement in fair value of derivative financial instruments		0.2	0.8
Release of fair value on acquired inventory	7	-	1.4
Increase in fair value of contingent consideration	7	21.4	_
Currency revaluation on deferred consideration	7	0.4	-
Equity-settled share-based payment expense	6	3.0	2.1
		91.9	72.5
Increase in trade and other receivables	•	(2.1)	(14.6)
Increase in inventories		(13.4)	(1.4)
Increase in trade and other payables		13.4	7.6
Cash generated from operations		89.8	64.1
Income taxes paid		(13.6)	(12.6)
Interest paid	•	(7.9)	(3.9)
Net cash flows from operating activities		68.3	47.6
Investing activities	•	•	
Purchase of intangible fixed assets (excluding products)	12	(17.0)	(11.1)
Purchase of property, plant and equipment	13	(2.0)	(1.2)
Purchase of specialty pharmaceutical products	12	(114.3)	(1.5)
Purchase of subsidiaries, net of cash acquired		(118.0)	(100.8)
Settlement of Quantum share awards on acquisition		-	(8.6)
Net cash used in investing activities		(251.3)	(123.2)
Financing activities			
Proceeds from issue of shares	•	78.9	0.1
Proceeds from increase in loan	19	179.1	135.6
Loan repayments	19	(20.5)	(45.0)
Dividends paid	11	(7.7)	(6.3)
Net cash flows from financing activities		229.8	84.4
Net increase in cash and cash equivalents		46.8	8.8
Cash and cash equivalents at beginning of year	17	36.3	27.8
Exchange gains/(losses)		0.4	(0.3)
Cash and cash equivalents at end of year	17	83.5	36.3

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2019

(IN £M)	SHARE CAPITAL (NOTE 22)	SHARE PREMIUM Account	MERGER Reserve	HEDGING Reserve	FOREIGN Exchange Reserve	RETAINED Earnings	TOTAL Equity
At 1 July 2018	0.1	161.3	86.0	(0.4)	7.6	94.9	349.5
Profit for the year	-	-	-	-	-	5.2	5.2
Currency translation differences	-	-	-	-	7.4	-	7.4
Cash flow hedges	•	•	•	•	•	•	
- Effective portion of fair value movements	-	-	-	(1.1)	-	-	(1.1)
- Ineffective portion of fair value movements	-	-	-	0.1	-	-	0.1
- Transfers to the income statement (revenue)	-	-	-	1.1	-	-	1.1
Total comprehensive income	-	-	-	0.1	7.4	5.2	12.7
Share-based payment scheme	-	_	-	_	-	3.0	3.0
Deferred taxation on share-based payment scheme	-	-	-	-	-	(0.4)	(0.4)
Tax credit in respect of tax losses arising on exercise of share options	-	-	-	-	-	0.2	0.2
Issue of new shares	-	78.9	2.2	-	-	-	81.1
Dividend paid (note 11)	-	-	-	-	-	(7.7)	(7.7)
Total transactions with owners of the Company, recognised directly in equity	_	78.9	2.2	_	-	(4.9)	76.2
At 30 June 2019	0.1	240.2	88.2	(0.3)	15.0	95.2	438.4
(INSM)	SHARE CAPITAL (NOTE 22)	SHARE PREMIUM Account	MERGER Reserve	HEDGING Reserve	FOREIGN Exchange Reserve	RETAINED EARNINGS	TOTAL Equity
At 1 July 2017	0.1	161.2	5.4	0.3	10.5	71.6	249.1
Profit for the year		_	_	_	_	27.4	27.4
Currency translation differences	_	_	_	_	(2.9)		(2.9)
Cash flow hedges	•••••••••••••••••••••••••••••••••••••••	•••••••••••••••••••••••••••••••••••••••			•••••••••••••••••••••••••••••••••••••••	•••••••••••	
- Effective portion of fair value movements	-	-	_	(0.1)	_	_	(0.1)
- Ineffective portion of fair value movements	-	-	_	(0.4)	-	_	(0.4)
- Transfers to the income statement (revenue)	-	-	-	(0.2)	-	_	(0.2)
Total comprehensive income	-	-	-	(0.7)	(2.9)	27.4	23.8
Share-based payment scheme	_	-	_	_	_	2.1	2.1
Deferred taxation on share-based payment scheme	-	-	-	-	-	(0.1)	(0.1)
Tax credit in respect of tax losses arising on exercise of share options	_	-	_	_	-	0.2	0.2
Issue of new shares	-	0.1	80.6	-	-	-	80.7
Dividend paid (note 11)	-	-	_	-	-	(6.3)	(6.3)
Total transactions with owners of the Company, recognised directly in equity	_	0.1	80.6	-	-	(4.1)	76.6
At 30 June 2018	0.1	161.3	86.0	(0.4)	7.6	94.9	349.5

#### 1. ACCOUNTING POLICIES

The principal accounting policies adopted by the Group and applied in the preparation of these consolidated financial statements are set out below. The policies have been consistently applied to all years presented, unless otherwise stated.

#### **BASIS OF PREPARATION**

The consolidated financial statements of Clinigen Group plc have been prepared in accordance with International Financial Reporting Standards, ('IFRS') as adopted for use in the European Union and IFRS Interpretations Committee interpretations (together 'adopted IFRS') and with those parts of the Companies Act 2006 that are applicable to companies that prepare financial statements in accordance with IFRS. The consolidated financial statements have been prepared under the historical cost convention, as modified by the revaluation of financial assets and financial liabilities (including derivative instruments) at fair value through profit or loss.

The preparation of financial statements in conformity with adopted IFRS requires the use of certain critical accounting estimates. It also requires Group management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 2.

The accounting policies set out below have, unless otherwise stated, been applied consistently throughout the year presented in these financial statements. These financial statements are presented in pounds sterling, which is the Group's functional currency. All financial information presented in pounds sterling has been rounded to the nearest £100,000.

#### **GOING CONCERN**

The Group's strategy and forecasts, taking account of sensitivities within the trading projections and possible changes in trading performance, show that the Group has adequate resources to continue in operational existence for the foreseeable future. The Group has further funds available in the undrawn proportion of the bank facility, which combined with the Group's cash balance and positive cash generation from each of its operations, provides funding for future acquisitions in line with the Group's acquisition-based growth strategy. The Group therefore continues to adopt the going concern basis in preparing its consolidated financial statements. Further information on the Group's borrowing facilities is given in note 19.

#### **CHANGES IN ACCOUNTING POLICIES**

#### (a) New and amended standards, interpretations and amendments adopted by the Group

On 1 July 2018, the Group adopted the following new accounting policies to comply with amendments to IFRS, none of which have had a material impact on the Group's consolidated financial statements.

- IFRS 9 'Financial Instruments'
- IFRS 15 'Revenue from Contracts with Customers'

#### IFRS 9 'Financial Instruments'

IFRS 9 is applicable to financial assets and liabilities, and introduced changes to existing accounting policies concerning classification and measurement, impairment (introducing an expected-loss method), hedge accounting, and on the treatment of gains arising from the impact of own credit risk on the measurement of liabilities held at fair value.

Set out below are the key requirements of the new standard as well as the Directors' assessment of the impact on the Group's consolidated financial statements.

Classification and measurement of financial assets and liabilities: All recognised financial assets within the scope of IFRS 9 are initially measured at fair value plus, in the case of financial assets not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset. Subsequent measurement is at amortised cost or fair value. Receivables and cash which were previously classified as loans and receivables under IAS 39 are now classified as amortised cost under IFRS 9. With regard to the measurement of financial liabilities designated as at fair value through profit or loss ('FVPL'), IFRS 9 requires that the change in the fair value of a financial liability which is attributable to changes in the credit risk of that liability is presented in other comprehensive income, unless the recognition of such changes in other comprehensive income would create or enlarge an accounting mismatch in profit or loss. Changes in fair value attributable to a financial liability's credit risk are not subsequently reclassified to profit or loss. The Directors have confirmed that there is no impact from the change to IFRS 9 on the classification and measurement of financial assets and liabilities, and they will continue to be measured on the same bases as previously adopted under IAS 39.

**Impairment:** In respect of the impairment of financial assets, including trade receivables, IFRS 9 requires an expected credit loss ('ECL') model, as opposed to the incurred credit loss model adopted under IAS 39. The expected credit loss model requires an entity to account for expected future credit losses and changes in those expected credit losses at each reporting date to reflect changes in credit risk since initial recognition. The Group has adopted the simplified approach to provide for ECLs, measuring the loss allowance at a probability weighted amount that considers reasonable and supportable information about past events, current conditions and forecasts of future economic conditions of the customers. The ECLs are updated at each reporting date to reflect changes in credit risk since initial recognition. ECLs are calculated for all financial assets in scope, regardless of whether or not they are overdue or not. Due to the nature of the Group's customer base, being mainly comprised of large pharmaceutical companies, wholesalers and government institutions, the ECLs for the majority of the Group's receivables is considered to be immaterial.

**Hedge accounting:** Under IFRS 9, the general hedge accounting requirements align more closely with risk management practices and establish a more principle-based approach thereby allowing hedge accounting to be applied to a wider variety of hedging instruments and risks. The effectiveness test has been replaced with the requirement for there to be an economic relationship between the hedged item and the hedging instrument, and there is no longer a requirement for the hedge to be 80–125% effective in order to be able to apply hedge accounting. Retrospective assessment of hedge effectiveness is also no longer required. The Directors have determined that all existing hedge relationships continue to qualify as hedge relationships following application of IFRS 9 and there is no impact on the Group's hedging strategy.

Apart from the factors considered specifically above, the Directors have concluded that the application of IFRS 9 has not had any other material impacts on the Group's consolidated financial statements.

#### IFRS 15 'Revenue from Contracts with Customers'

IFRS 15 establishes a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede the current revenue recognition guidance including IAS 18 'Revenue', IAS 11 'Construction Contracts' and the related interpretations when it becomes effective.

The standard establishes a 5-step model to account for revenue arising from contracts with customers. Under IFRS 15, revenue is recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The standard also specifies how to account for the incremental costs of obtaining a contract and the costs directly related to fulfilling a contract as well as requirements covering matters such as licences of intellectual property, warranties, principal versus agent assessment and options to acquire additional goods or services. The Group expects to apply IFRS 15 fully retrospectively, restating the prior year's comparatives as necessary.

It has been determined that there was no material impact on revenue recognition, and therefore no restatement required, on transition to IFRS 15 as the timing of the transfer of risks and rewards coincides with the satisfaction of performance obligations and transfer of control.

There were no other new standards, interpretations or amendments to standards that are effective for the financial year beginning 1 July 2018 that have a material impact on the Group's consolidated financial statements.

#### (b) New standards, interpretations and amendments not yet adopted

The following standards and amendments have been published, endorsed by the EU, and are available for early adoption, but have not yet been applied by the Group in these financial statements.

- IFRS 16 'Leases' (effective for the year beginning 1 July 2019)

In addition to the above, amendments to a number of existing standards have been endorsed by the EU but not yet adopted. These amendments are not expected to have a material impact on the Group's consolidated financial statements.

#### IFRS 16 'Leases'

IFRS 16 requires all leases to be recognised on the balance sheet. Broadly the Group will recognise leases currently treated as operating leases, disclosed in note 24, as a lease liability and a right-to-use asset, after adjusting for extension periods that are reasonably certain to be taken and discounting using the rate implicit in the lease or the incremental cost of borrowing.

The total operating lease cost, currently expensed to the consolidated income statement as incurred will be split into a financing element and an operating element. The financing element will create a front-loaded expense in finance costs. Additional disclosures will be required to support the new accounting requirements.

The Group has concluded a review of its lease contracts and based on the operating leases in place at 30 June 2019 a right to use asset of £17.5m and a lease liability of £19.7m will be recognised resulting in a net decrease in net assets of £2.2m on implementation of the new standard. For the year ended 30 June 2019, EBITDA would increase by £3.7m, depreciation increase by £3.2m and finance expense increase by £0.5m.

#### **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.

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. Joint ventures 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.

#### 1. ACCOUNTING POLICIES CONTINUED

Acquisition costs for business combinations and post-acquisition restructuring costs are recognised as non-underlying costs in the income statement as adjusting items as they do not relate to normal trading activities and to reflect their one-off nature.

#### **FOREIGN CURRENCY**

#### (a) Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the 'functional currency'). The consolidated financial statements are presented in sterling, being the currency of the primary economic environment in which the Company operates. This is the Group's presentation currency.

#### (b) Transactions and balances

Transactions entered into by Group entities in a currency other than the currency of the primary economic environment in which they operate (their 'functional currency') are recorded at the exchange rates prevailing at the dates of the transactions or valuation where items are remeasured. Foreign currency monetary assets and liabilities are translated at the exchange rates prevailing at the reporting date. All foreign exchange gains and losses are presented in the income statement within administrative expenses.

#### (c) Group companies

The results and financial position of all the Group entities that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- a) Assets and liabilities for each balance sheet presented are translated at the closing exchange rate on the date of that balance sheet.
- b) Income and expenses for each income statement are translated at average exchange rates for the financial year; 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.

Following the acquisition of CSM, due to the inter-related nature of the business with the existing 'Clinical Trial Services' segment, they have been combined and renamed 'Clinical Services'. Management reviews the performance of the Group by reference to the results of the operating segments against budget and the total results against budget.

Gross profit is the key profit measure that is reviewed by the CODM at the segmental reporting level.

#### **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 to enable full understanding of the Group's financial performance. These include one-off items relating to acquisitions e.g. acquisition costs and the costs of restructuring post-acquisition; amortisation of intangible assets arising on acquisition and acquired products; movements of deferred or contingent consideration; and the release of the fair value adjustment made to inventory acquired through a business combination. The associated tax impact of these items is also reported as non-underlying.

#### **INTANGIBLE ASSETS**

#### Goodwill

Goodwill represents the excess of the cost of a business combination over, in the case of business combinations completed prior to 1 July 2010, the Group's interest in the fair value of identifiable assets, liabilities and contingent liabilities acquired.

For business combinations completed after 1 July 2010, goodwill represents the excess of the cost of a business combination over the Group's interest in the fair value of identifiable assets, liabilities and contingent liabilities including those intangible assets identified under IFRS 3 'Business Combinations'.

Goodwill is capitalised as an intangible asset with any impairment in carrying value being charged to the income statement. Where the fair value of identifiable assets, liabilities and contingent liabilities exceed the fair value of consideration paid, the excess is credited in full to the income statement on the acquisition date as a non-underlying item.

Goodwill is not amortised, but is assessed for impairment annually or more frequently if events or changes indicate a potential impairment. Goodwill arising on business combinations is allocated to the associated cash-generating units ('CGUs') based on the particular segment that it relates to. This is then assessed against the discounted cash flows of the CGUs for impairment.

#### **Brand**

The brand reflects the cash flows associated with the Idis brand acquired in April 2015; the Link, Homemed and Equity brands purchased in October 2015; the Quantum brand purchased in November 2017, and the CSM brand purchased in October 2018. Each brand was recognised following the associated business combination and is initially recognised at the fair value of the asset at the acquisition date. The carrying value of the brand is calculated as cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the fair value cost of the asset over its estimated useful life. The estimated useful lives range between 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.

#### **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 3 to 5 years. The amortisation expense is recognised within underlying administrative expenses in the income statement.

### Impairment reviews

Impairment reviews are undertaken annually at the end of the financial year or more frequently if events or changes in circumstances indicate a potential impairment. The carrying value of individual intangible and tangible assets are compared to the recoverable amount, which is the higher of value-in-use and the fair value less costs to sell. An impairment loss is recognised for the amount by which the asset's carrying value exceeds its recoverable amount.

### 1. ACCOUNTING POLICIES CONTINUED

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.

Leases of property, plant and equipment where the Group has substantially all the risks and rewards of ownership are classified as finance leases. Such leases are capitalised at inception at the lower of the fair value of the leased asset and the present value of the minimum lease payments.

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% straight-line

#### **INVESTMENTS**

Investments in subsidiaries are recorded at historical cost, less any provision for impairment.

Investments in joint ventures are accounted for using the equity method of accounting. Under the equity method, the investment is initially recorded at cost, and the carrying amount is increased or decreased to recognise the investor's share of the profit or loss of the investee after the date of acquisition.

#### **INVENTORIES**

Inventories are initially recognised at cost and subsequently stated at the lower of cost and net realisable value. Individual units of drugs cannot be interchanged as they are determined by the customer's requirements for product name, dosage strength, pack size, batch number and expiry date. In accordance with IAS 2 'Inventories', items are recorded at their individual actual cost. To minimise obsolescence, cost is selected using first expiry, first out method. Cost comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition. In the case of manufactured inventories and work in progress, cost includes an appropriate share of overheads based on normal operating capacity. Net realisable value is the estimated selling price less applicable variable selling expenses. Provisions are made for slow moving and damaged inventories. Inventories which have expired are fully provided for until they are destroyed, when they are written off.

A number of arrangements exist where the Group holds inventories on consignment. Under these arrangements such Inventories are only recognised in the statement of financial position when the risks and rewards of ownership are transferred to the Group.

## **DERIVATIVE FINANCIAL INSTRUMENTS AND HEDGING ACTIVITIES**

The Group uses derivative financial instruments to mitigate its exposure to foreign currency exchange risk on cash flow transactions. Derivative financial instruments are recognised initially at their fair value and remeasured at fair value at each period end. Where appropriate the Group designates hedge relationships for hedge accounting under IFRS 9 'Financial Instruments'.

Where hedge accounting has been applied, changes in the fair value of derivative financial instruments designated as cash flow hedges are recognised in other comprehensive income to the extent that the hedge is effective. To the extent that the hedge is ineffective, changes in fair value are recognised immediately in the income statement. If the hedging instrument no longer meets the criteria for hedge accounting, expires or is sold, terminated or exercised, then hedge accounting is discontinued prospectively. The cumulative gain or loss previously recognised in other comprehensive income remains there until the forecast transaction occurs. When the hedged item is a non-financial asset, the amount recognised in other comprehensive income is transferred to the carrying amount of the asset when it is recognised. In other cases, the amount recognised in other comprehensive income is transferred to the income statement in the same period that the hedged item affects profit or loss. The designation is re-evaluated at each reporting date.

The gain or loss on remeasurement to fair value of derivatives that have not been designated for hedge accounting is recognised immediately in the income statement. Foreign forward exchange derivative gains and losses are recognised net.

Hedges of net investments in foreign operations are accounted for similarly to cash flow hedges. Any gain or loss on the hedging instrument relating to the effective portion of the hedge is recognised in other comprehensive income and accumulated in reserves.

#### TRADE AND OTHER RECEIVABLES

Trade receivables arise principally through the provision of goods and services to customers in the ordinary course of the business. They are recognised initially at the original invoice value and subsequently original invoice value less provision for impairment.

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. On confirmation that the trade receivable will not be collectable, the gross carrying value of the asset is written off against the associated provision.

#### **CASH AND CASH EQUIVALENTS**

Cash and cash equivalents include cash in hand, deposits held at call with banks and other highly-liquid cash investments.

#### **BORROWINGS**

Borrowings are initially recognised at fair value net of transaction costs, including facility fees incurred. Such interest-bearing liabilities are subsequently measured at amortised cost using the effective interest rate method, which ensures that any interest expense over the period to repayment is at a constant rate on the balance of the liability carried in the consolidated statement of financial position. Facility fees paid on the establishment of facilities and for the maintenance of the facility are capitalised against the loans and borrowings balance. These are amortised as the loan is repaid with the associated amortisation expense recognised in finance costs.

#### TRADE AND OTHER PAYABLES

Trade payables are obligations to pay for goods and services that have been acquired in the ordinary course of business from suppliers. They are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities. Trade payables are initially recognised at fair value and subsequently carried at amortised cost using the effective interest method.

#### **DEFERRED AND CONTINGENT CONSIDERATION**

Deferred consideration payable in cash in respect of the acquisition of intangible assets is recognised initially at its fair value at the date of acquisition. There is no other form of deferred consideration payable. 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.

#### **OPERATING LEASES**

Rentals under operating leases are charged on a straight-line basis over the lease term, even if the payments are not made on such a basis. Benefits received and receivable as an incentive to sign an operating lease are similarly spread on a straight-line basis over the lease term.

#### **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.

#### 1. ACCOUNTING POLICIES CONTINUED

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 and it is probable that the Group will receive the previously agreed upon payment. These criteria are normally considered to be met when the goods are delivered to the buyer, or on fulfilment of a prescription. Revenue is recognised at the fair value of consideration received or receivable.

#### **Service fees**

All services provided in relation to MAPs and product development contracts are contractually agreed with the product originator. Revenue for these services is recognised, at a point in time, when the outcome of the services set out in the contract can be estimated reliably and the stage of completion can be measured reliably.

Contracted program setup fees can be either for the whole project or triggered by milestones being achieved which are laid out in the contract. Revenue is recognised in relation to these fees, at a point in time, when the contracted milestones are achieved.

Monthly management fees are recognised as revenue, at a point in time, in the month to which they relate and once contractual services have been provided.

Revenue in respect of program management fees is recognised, at a point in time, when goods, provided under the program, have been dispatched to the customer for whom the management fee relates. Revenue is recognised at the fair value of consideration received or receivable.

#### **Royalties**

Royalty income is earned on product distribution agreements based upon a percentage of sales, the income is recognised on an accrual basis.

Revenue in all years principally arises from the 3 income streams discussed above. Further information is available in note 4.

### 2. CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The Group makes certain estimates and assumptions regarding the future. Estimates and judgements are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

#### (A) BUSINESS COMBINATIONS

In accounting for business combinations, the identifiable assets, liabilities and contingent liabilities acquired have to be measured at their fair values. In particular, some judgement is required in estimating the fair value of inventory with reference to current selling prices and an assessment of obsolescence and demand for inventory; the fair value of trade debtors with reference to the ageing and recoverability of these and judgements in estimating the valuation of intangible assets with reference to forecast future sales under the pre-existing contracts and relationships where legal contracts are not in place. Details concerning acquisitions and business combinations are outlined in note 29.

#### (B) IMPAIRMENT OF GOODWILL

The Group tests annually whether goodwill has suffered any impairment, in accordance with the accounting policy stated in note 1. The recoverable amount is determined based on value-in-use calculations. The use of this method requires the estimation of future cash flows and the choice of a discount rate in order to calculate the present value of the cash flows. Actual outcomes may vary. More information including carrying values is included in note 12.

#### (C) CARRYING VALUE OF INTANGIBLE ASSETS EXCLUDING GOODWILL

The carrying value of intangible assets is at cost less amortisation and any impairment. Annual impairment trigger reviews are undertaken at the end of the financial year, or more frequently if events or changes in circumstances indicate a potential impairment. Trademarks and licences are not traded in an active market hence the fair value of the asset is determined using discounted cash flows which involves the Group using judgement and assumptions.

#### (D) INVENTORY PROVISIONING

The Group's principal activities during the year related to the management, sale and distribution of pharmaceutical products which have associated expiry dates. As a result it is necessary to consider the recoverability of the cost of the inventory and the associated provisioning required. Management consider the nature and condition of inventory, the remaining expiry period, as well as applying assumptions around expected future demand for the inventory, when calculating the level of inventory provisioning. See note 15 for the net carrying value of inventory and associated provision.

#### **(E) IMPAIRMENT OF TRADE RECEIVABLES**

The Group makes an estimate of the recoverable value of trade and other debtors. When assessing impairment of trade and other receivables, management considers factors including the credit rating and age profile of the receivable and historic experience. See note 16 for the net carrying amount of the receivables and the associated impairment provision.

#### (F) SALE OF PRODUCTS WHOLESALE

Certain products are sold to wholesalers with provisions to return product as a result of expiry dates being reached and for reimbursement from Clinigen for sale of product at below Wholesaler Acquisition Cost ('WAC'), known as chargebacks, where agreements are in place with healthcare providers. Revenue is recognised net of an estimate of reimbursements expected. Accumulated experience is used to estimate and provide for the reimbursements and revenue is only recognised to the extent that it is highly probable that a significant reversal will not occur. A liability (included in trade and other payables) is recognised for expected returns 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 £7.5m of which £7.0m is an outstanding liability at 30 June 2019. A 1% change in the overall estimated reimbursement would result in a £0.3m additional adjustment to revenue.

#### (G) DEFERRED TAXATION

Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profit will be available against which the difference can be utilised. The future taxable profits are based on forecasts and thus actual may vary.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the deferred tax liabilities or assets are settled or recovered. A change in rate would change these calculations.

The deferred tax asset recognised on share options, not yet exercised, is calculated based on the market price of the shares at the end of the reporting period. The market price at the exercise date would be expected to be different, hence the actual asset recognisable at exercise is likely to differ to the one recognised at the reporting date.

# (H) CONTINGENT CONSIDERATION

Contingent consideration is initially measured at the net present value of the expected future cash flows, discounted using an appropriate discount rate, to be paid pursuant to the relevant agreements. The fair value of the contingent liability is remeasured at each period end utilising the latest financial forecasts. The change in fair value is recognised in the income statement as a non-underlying item.

## 3. ALTERNATIVE PERFORMANCE MEASURES

The Group's performance is assessed using a number of financial measures which are not defined under IFRS. These measures are therefore considered alternative performance measures.

Management uses the adjusted or alternative measures as part of their internal financial performance monitoring and when assessing the future impact on operating decisions.

The measures allow more effective year-on-year comparison and identification of core business trends by removing the impact of items occurring either outside the normal course of operations or as a result of intermittent activities such as business combinations and restructuring. The principles to identify adjusting items have been applied to the current and prior year comparative numbers on a consistent basis.

The measures used in the Annual Report are defined in the table below and reconciliations to the IFRS measure are included in note 4.

# 3. ALTERNATIVE PERFORMANCE MEASURES CONTINUED

ALTERNATIVE PERFORMANCE Measure	RELATED IFRS Measure	DEFINITION	USE/RELEVANCE
Adjusted gross profit	Gross profit	Gross profit excluding the adjustment for the fair value of acquired inventory sold in the year.	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:  - Adjustment for fair value of acquired inventory sold in the year  - Acquisition costs and related restructuring costs	Provides management with an approximation of cash generation from operational activities after removing he distortion of large/unusual items or transactions that are not reflective of the routine business operations.
		<ul> <li>Acquisition-related income from settlement of contingent legal claim outstanding at acquisition</li> </ul>	It is used in the covenant calculations for the revolving credit facility.
		- Including share of joint venture EBITDA	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  - Changes in contingent consideration including related unwind of discount  - 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
Adjusted profit after tax	Profit after tax	Profit after tax excluding adjusting items:  - As detailed above for profit before tax but including joint venture tax charge  - Related tax on the adjusting items  - Adjustments to tax charges relating to pre-acquisition periods	is set out in note 4.
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 credifacility.
		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.	Provides management with a view of the level of EBITDA converted into cash.
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:  - Acquisition costs and related restructuring costs  - Acquisition-related income from settlement of contingent legal claims	Provides management with an indication of the amount of cash available for discretionary investing or financing after removing the distortion of large/unusual expenditures that are not reflective of the routine business operations.
		outstanding at acquisition	A reconciliation to adjusted EBITDA is included on page 45.

## 4. SEGMENT INFORMATION

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

Operating segments are reported in a manner consistent with the internal reporting provided to the CODM during the reporting year. The CODM has been identified as the Executive Directors. The Group's operating segments are Commercial Medicines, Unlicensed Medicines and Clinical Services.

#### **OPERATING SEGMENT RESULTS**

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

		_	2019	<u> </u>	2018	3
(IN £M)			REVENUE	GROSS PROFIT	REVENUE	GROSS PROFIT
Commercial Medicines			110.3	79.4	87.9	64.0
Unlicensed Medicines			205.9	69.7	215.6	62.1
Clinical Services			140.7	33.2	77.7	14.0
Segmental result			456.9	182.3	381.2	140.1
Adjustment for fair value of acquired inventory sold in the year		•••••	-	-	_	(1.4)
Reported results		_	456.9	182.3	381.2	138.7
		2019			2018	
(IN £M)	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL

		2019			2018	
(IN £M)	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL	UNDERLYING	NON-UNDERLYING (NOTE 7)	TOTAL
Reconciliation to reported profit						
Segmental gross profit	182.3	-	182.3	140.1	(1.4)	138.7
Administrative expenses excluding amortisation and depreciation	(82.6)	(33.6)	(116.2)	(65.2)	(8.2)	(73.4)
EBITDA	99.7	(33.6)	66.1	74.9	(9.6)	65.3
Analysed as:						
Adjusted EBITDA including joint venture result	100.8	(33.6)	67.2	76.0	(9.6)	66.4
Joint venture EBITDA	(1.1)	-	(1.1)	(1.1)	_	(1.1)
EBITDA excluding joint venture result	99.7	(33.6)	66.1	74.9	(9.6)	65.3
Amortisation	(1.5)	(37.8)	(39.3)	(0.5)	(22.1)	(22.6)
Depreciation	(2.4)	_	(2.4)	(1.2)	_	(1.2)
Profit from operations	95.8	(71.4)	24.4	73.2	(31.7)	41.5
Net finance costs	(8.6)	(4.2)	(12.8)	(5.3)	(1.1)	(6.4)
Share of profit of joint venture	0.7	-	0.7	0.8	_	0.8
Profit before income tax	87.9	(75.6)	12.3	68.7	(32.8)	35.9
Analysed as:						
Adjusted profit before tax excluding share of joint venture tax	88.3	(76.0)	12.3	69.0	(33.1)	35.9
Joint venture tax	(0.4)	0.4	_	(0.3)	0.3	-
Profit before tax including share of joint venture tax	87.9	(75.6)	12.3	68.7	(32.8)	35.9
Income tax	(17.3)	10.2	(7.1)	(14.2)	5.7	(8.5)
Profit after income tax	70.6	(65.4)	5.2	54.5	(27.1)	27.4

# 4. SEGMENT INFORMATION CONTINUED

(IN £M)	2019	2018
Breakdown of revenues by type:		
Products	410.7	339.0
Services	38.0	33.3
Royalties	8.2	8.9
Total	456.9	381.2

All revenue arises from contracts with customers and is recognised at a point in time in accordance with the Group accounting policies.

#### **GEOGRAPHICAL ANALYSIS**

- (IN £M)	2019	2018
Revenue arises from the following locations:		
UK	159.6	97.0
Europe	107.9	87.9
US	90.7	83.5
South Africa	26.9	24.9
Australia	20.4	19.9
Rest of World	51.4	68.0
Total	456.9	381.2

Assets and liabilities are reported to the Executive Directors at a Group level and are not reported on a segmental basis.

# **5. EXPENSES**

# 5.1 EXPENSES

Profit from operations is stated after charging:

(IN £M)	2019	2018
Cost of inventories recognised as an expense in cost of sales	235.6	220.8
Employee benefit expense (net of capitalised costs of £0.9m (2018: £0.6m))	51.4	39.8
Amortisation and depreciation (notes 12 and 13)	41.7	23.8
Operating lease charges	3.7	2.0
Foreign exchange gains	0.3	_

### **5.2 AUDITORS' REMUNERATION**

During the year, the Group (including its overseas subsidiaries) obtained the following services from the Company's auditors and its associates:

(M2M)	2019	2018
Fees payable to the Company's auditor for the audit of the Parent Company and consolidated financial statements	0.3	0.3
Fees payable to the Company's auditor for other services:		
- The audit of the Company's subsidiaries	0.3	0.3
- Audit related assurance services	0.1	0.1
- Other advisory services	-	0.1
- Tax advisory services	0.3	0.3

## **6. EMPLOYEES**

#### **6.1 EMPLOYEE BENEFIT EXPENSE**

(IN £M)	2019	2018
Wages and salaries	43.9	34.0
Share-based payments	3.0	2.1
Social security costs	4.1	3.2
Other pension costs	1.3	1.1
Gross expense	52.3	40.4
Capitalised labour	(0.9)	(0.6)
Net expense	51.4	39.8

#### **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	2019	2018
Directors	2	2
Staff	1,106	725
Total	1,108	727

#### **6.3 DIRECTORS' EMOLUMENTS**

Details of the remuneration, shareholdings, share options and pension contributions of the Directors are included in the Remuneration Report on pages 62 to 71.

#### **6.4 KEY MANAGEMENT PERSONNEL COMPENSATION**

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Group. This is considered to be the Board of Directors.

(IN SM)	2019	2018
Directors' remuneration included in staff costs:		
Wages and salaries	2.0	1.7
Share-based payment expense	0.9	0.9
Total	2.9	2.6

# 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, and movements in deferred and contingent consideration. The associated tax impact is also reported as non-underlying.

(IN £M)	2019	2018
Cost of sales		
a) Adjustment for fair value of acquired inventory sold in the year	-	1.4
Administrative expenses		
b) Acquisition costs	5.4	3.9
c) Restructuring costs (relating principally to acquisitions)	6.4	5.3
d) Increase in the fair value of contingent consideration	21.4	
e) Settlement of Quantum's legal claim	-	(1.0)
f) Foreign exchange revaluation on deferred and contingent consideration	0.4	-
g) Amortisation of intangible fixed assets acquired through business combinations and acquired products	37.8	22.1
	71.4	30.3
Finance costs		
h) Unwind of discount on deferred and contingent consideration	4.1	1.1
i) Acquisition costs	0.1	-
	4.2	1.1
Taxation		
j) Credit in respect of tax on non-underlying costs	(10.2)	(5.7)
Total non-underlying items	65.4	27.1

#### 7. NON-UNDERLYING ITEMS CONTINUED

- a) Under IFRS 3, inventory acquired in a business combination is valued at fair value on acquisition, which includes the profit margin in the inventory's carrying value. The £1.4m recognised in the prior year represents the profit margin on the inventory sold in that year which was acquired with the Quantum business.
- b) The acquisition costs relate to CSM, iQone and Proleukin (2018: Quantum and IMMC) comprising legal, corporate finance, due diligence advice and cost for securing certain funds for the CSM acquisition.
- c) Restructuring costs have been incurred during the year in respect of the integration of acquired businesses and products primarily relating to redundancy and the costs associated with contract terminations.
- d) The performance of the CSM acquisition has exceeded management's original expectations and the profit forecast for the earn out period has been increased.
- e) Following the acquisition of Quantum in the prior year, a settlement was agreed in Quantum's favour in relation to a legal claim with the vendors of a business acquired by Quantum pre-acquisition.
- f) Deferred consideration on Proleukin, Imukin, CSM and iQone is denominated in foreign currency. The revaluation of the liabilities is treated as non-underlying as they relate to one-off items and do not reflect the underlying trading of the Group.
- g) The amortisation of intangible assets acquired as part of business combinations (namely brand, trademarks and licences, customer relationships, and contracts) and acquired products, is included in non-underlying as they relate to one-off items and do not reflect the underlying trading of the Group.
- h) The non-cash unwind of the discount applied to the deferred and contingent consideration on the acquisitions of Foscavir Bags, Proleukin, Imukin, CSM and iQone (2018: Link).
- i) The tax credit in respect of non-underlying items reflects the tax benefit on the costs incurred during the year.

#### 8. FINANCE INCOME AND EXPENSE

2019	2018
7.6	4.5
0.2	0.3
0.9	0.6
-	0.2
8.7	5.6
4.1	1.1
0.1	-
12.9	6.7
(0.1)	(0.3)
12.8	6.4
2019	2018
15.7	12.0
(1.1)	(0.4)
14.6	11.6
(0.6)	0.9
(6.9)	(4.0)
(7.5)	(3.1)
7.1	8.5
	0.2 0.9 0.9 - 8.7 4.1 0.1 12.9 (0.1) 12.8  2019  (1.1) 14.6  (0.6) (6.9) (7.5)

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:

(M2M)	2019	2018
Profit before income tax	12.3	35.9
Expected tax charge based on corporation tax rate of 19.0%	2.3	6.8
Expenses not deductible for tax purposes other than goodwill amortisation and impairment	4.0	0.9
Adjustments to tax charge in respect of prior years	(1.1)	(0.5)
Higher rates of taxes on overseas earnings	1.9	1.3
Total income tax expense	7.1	8.5

#### **AMOUNTS RECOGNISED DIRECTLY IN EQUITY**

The income tax (charged)/credited directly to equity during the year is as follows:

201	2018
ax: unexercised share options and losses recognised directly in equity (0.2	0.1
A another production and respective	

#### **TAX LOSSES**

(IN £M)	2019	2018
Unused tax losses for which no deferred tax asset has been recognised	2.3	2.3
Potential tax benefit at 25%	0.6	0.6

The unused tax losses have been incurred in the US subsidiary, Clinigen Inc. and it is currently uncertain whether these tax losses can be utilised in the future.

Following announcements in the Budget 2018, the UK corporation tax rate will reduce to 17% from 1 April 2020, and so closing deferred tax assets and liabilities have been calculated at this rate.

# 10. EPS

(IN £M)	2019	2018
Profit used in calculating reported EPS	5.2	27.4
Underlying profit used in calculating adjusted EPS	70.6	54.5
Number of shares (million)		
Weighted average number of shares	129.8	119.9
Dilution effect of share options	2.2	1.9
Weighted average number of shares used for diluted EPS	132.0	121.8
Reported EPS (pence)		
Basic	4.0p	22.9p
Diluted	4.0p	22.5p
Adjusted EPS (pence)		
Basic	54.4p	45.4p
Diluted	53.5p	44.7p

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 2,225,514 (2018: 1,939,501).

# 11. DIVIDENDS

(IN.E.M.)	2019	2018
Final dividend in respect of the year ended 30 June 2018 of 3.84p (2018: 3.4p) per ordinary share	5.1	4.2
Interim dividend of 1.95p (2018: 1.76p) per ordinary share paid during the year	2.6	2.1
	7.7	6.3

The Board proposes to pay a final dividend of 4.75p per ordinary share, subject to shareholder approval, on 29 November 2019, to shareholders on the register on 8 November.

## 12. INTANGIBLE ASSETS

	ACQUIRED INTANGIBLES							
(IN£M)	BRAND	CONTRACTS	CUSTOMER Relationships	ACQUIRED Trademarks and Licences	DEVELOPED Trademarks and Licences	COMPUTER Software	GOODWILL	TOTAL
Cost								
At 1 July 2017	55.4	29.5	45.7	68.3	0.6	7.4	182.2	389.1
Acquisition of subsidiaries	9.3	_	33.7	38.0	_	0.4	97.9	179.3
Additions	_	_	_	2.2	2.9	6.0	_	11.1
Disposals	-	-	-	(3.4)	-	-	-	(3.4)
Exchange differences	(0.3)	(0.6)	-	(0.1)	-	(0.2)	(1.6)	(2.8)
At 30 June 2018	64.4	28.9	79.4	105.0	3.5	13.6	278.5	573.3
Acquisition of subsidiaries (note 29)	4.0	-	56.2	-	-	1.4	102.9	164.5
Additions	-	-	-	172.4	4.0	8.4	-	184.8
Disposals	-	-	-	-	-	(0.1)	-	(0.1)
Exchange differences	-	(0.1)	1.0	2.1	-	-	1.6	4.6
At 30 June 2019	68.4	28.8	136.6	279.5	7.5	23.3	383.0	927.1
Accumulated amortisation								
At 1 July 2017	5.8	15.0	9.6	24.2	_	2.0	_	56.6
Charge for the year	3.4	3.7	9.8	5.2	0.1	0.4	-	22.6
Disposals	-	-	-	(3.4)	-	-	-	(3.4)
Exchange differences	-	(0.1)	-	-	-	-	-	0.3
At 30 June 2018	9.2	18.6	19.4	26.0	0.1	2.4	-	75.7
Charge for the year	4.3	2.5	21.8	9.1	0.4	1.2	-	39.3
Disposals	-	-	-	-	-	(0.1)	-	(0.1)
Exchange differences	-	-	0.3	-	-	-	-	0.3
At 30 June 2019	13.5	21.1	41.5	35.1	0.5	3.5	-	115.2
Net book value								
At 30 June 2019	54.9	7.7	95.1	244.4	7.0	19.8	383.0	811.9
At 30 June 2018	55.2	10.3	60.0	79.0	3.4	11.2	278.5	497.6
At 1 July 2017	49.6	14.5	36.1	44.1	0.6	5.4	182.2	332.5

#### BRAND

The brands represent the Idis, Link, Equity, Homemed, Quantum and CSM brands acquired as part of business combinations. Each brand has been fair valued at the acquisition date by reference to the operating businesses acquired which utilise each brand. The fair value is based on a Relief-from-Royalty-Method which calculates the value of the brand as equivalent to the royalty savings accrued over time, as the brand is owned and royalties are not required to be paid to a third party for the branding of products. The remaining amortisation periods are:

Idis - 15 years 10 months
Link - 16 years 4 months
Equity - 11 years 4 months
Homemed - 6 years 4 months
Quantum - 8 years 4 months
CSM - 4 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 1 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 3 and 6 years.

#### **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 690 (2018: 476) trademarks and licences are held. £4.5m (2018: £3.1m) of internally developed trademarks and licences are assets in the course of development at the year end.

In July 2018, the Group acquired the global rights outside the US to Proleukin from Novartis and the global rights to Imukin outside the US, Canada, and Japan from Horizon Pharma. In April 2019, the Group acquired the US rights and assignment of the current distribution and promotion agreement of Proleukin from Novartis. Total consideration for the Proleukin US rights is up to US\$210 million, comprising initial consideration of US\$120 million, deferred consideration of US\$60 million over the 12 months following completion and a further US\$30 million contingent consideration based on sales milestones. This asset is being amortised over a period of 15 years.

#### **COMPUTER SOFTWARE**

The Group is undertaking the development and implementation of a new Oracle ERP system, the costs for which are being recognised as incurred. Amortisation will begin when the first major phase of the new system becomes ready for use.

#### **GOODWILL**

The goodwill is deemed to have an indefinite useful life. It is carried at cost and is reviewed annually for impairment. Where the recoverable amount is less than the carrying value, an impairment results. During the year, goodwill was tested for impairment, with no impairment charge arising. The additions during the year related to the acquisition of CSM and iQone.

The Group allocates goodwill to cash generating units ('CGU's) 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.

(M2NI)	2019	2018
Commercial Medicines	110.6	96.4
Unlicensed Medicines	145.0	148.5
Clinical Services	127.4	33.6
	383.0	278.5

The recoverable amount of all CGUs has been determined based on value-in-use calculations. These calculations use pre-tax cash flow projections and a pre-tax discount rate of 10.5% (2018: 13.0%), equivalent to the Group's weighted average cost of capital.

For each CGU, a terminal growth rate of 2.0% (2018: 2.5%) 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. The long-term assumptions on gross profit growth used in each CGU are laid out in the table below.

	2019	2018
Commercial Medicines	4%	9%
Unlicensed Medicines	9%	4%
Clinical Services	5%	8%

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.

	20	2019 2018		/18	
	RATEREC	RATE REQUIRED TO ELIMINATE HEADROOM IN IMPAIRMENT ASSESSMENT			
	DISCOUNTRATE	TERMINAL Growth Rate	DISCOUNT RATE	TERMINAL Growth Rate	
Commercial Medicines	20.9%	(30.4)%	28.0%	(86.6)%	
Unlicensed Medicines	23.8%	(51.2)%	17.8%	(7.4)%	
Clinical Services	19.9%	(23.5)%	34.2%	n/a	

# 13. PROPERTY, PLANT AND EQUIPMENT

(IN EM)	LAND AND BUILDINGS	LEASEHOLD Improvements	PLANT AND Machinery	FIXTURES, FITTINGS AND EQUIPMENT	TOTAL
Cost					
At 1 July 2017	-	2.4	0.2	2.5	5.1
Acquisition of subsidiaries	2.0	_	0.8	0.8	3.6
Additions	0.1	0.2	0.2	0.7	1.2
Disposals	-	_	-	(0.1)	(0.1)
At 30 June 2018	2.1	2.6	1.2	3.9	9.8
Acquisition of subsidiaries (note 29)	2.4	1.7	-	3.1	7.2
Additions	0.1	0.3	0.2	1.4	2.0
Disposals	-	-	-	(0.3)	(0.3)
Exchange differences	-	-	-	0.2	0.2
At 30 June 2019	4.6	4.6	1.4	8.3	18.9
Accumulated depreciation					
At 1 July 2017	-	0.4	_	1.4	1.8
Charge for the year	0.1	0.3	0.2	0.6	1.2
At 30 June 2018	0.1	0.7	0.2	2.0	3.0
Charge for the year	0.1	0.7	0.3	1.4	2.5
Disposals	-	-	-	(0.3)	(0.3)
Exchange differences	-	-	-	0.1	0.1
At 30 June 2019	0.2	1.4	0.5	3.2	5.3
Net book value					
At 30 June 2019	4.4	3.2	0.9	5.1	13.6
At 30 June 2018	2.0	1.9	1.0	1.9	6.8
At 1 July 2017	-	2.0	0.2	1.1	3.3

The net book value of assets held under finance lease agreements and capitalised in plant and equipment is £0.2m (2018: nil).

# 14. INVESTMENT IN JOINT VENTURE

(INEM)	2019	2018
At 1 July	6.6	8.7
Share of profit	0.7	0.8
Dividends received	(8.0)	(2.9)
At 30 June	6.5	6.6

The joint venture listed below has share capital consisting solely of ordinary shares, 50% of which are held directly by the Group. The registered office is also the principal place of business.

NAME	YEAR END	COUNTRY OF INCORPORATION AND REGISTERED OFFICE	MEASUREMENT METHOD
Novagen Pharma Pty Limited	31 March	100 Sovereign Drive, Nellmapius Drive, Irene 0157, Pretoria, South Africa	Equity

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.

(IN £M)	2019	2018
Summarised statement of financial position		
Non-current assets	1.7	1.9
Cash and cash equivalents	0.7	0.2
Other current assets	3.3	3.6
Current liabilities	(2.0)	(1.7)
Net assets	3.7	4.0
Summarised income statement		
Revenue	12.6	14.7
Profit after tax	1.4	1.6
Reconciliation of the summarised financial information to the carrying amounts in the joint ventures		
Opening net assets	4.0	8.3
Profit for the year	1.4	1.6
Dividend paid	(1.6)	(5.8)
Cumulative currency losses	(0.1)	(0.1)
Closing net assets	3.7	4.0
Interest in joint ventures at 50%	1.9	2.0
Goodwill	4.6	4.6
Carrying value	6.5	6.6
15. INVENTORIES		
(IN £M)	2019	2018
Raw materials and consumables	4.8	3.7
Work in progress	2.5	1.0
Finished goods and goods for resale	28.1	16.6
	35.4	21.3

The cost of inventories recognised as an expense and included in cost of sales amounted to £235.6m (2018: £220.8m).

## **16. TRADE AND OTHER RECEIVABLES**

(IN £M)	2019	2018
Trade receivables	74.8	75.6
Less: provision for impairment of trade receivables	(1.6)	(2.4)
Trade receivables - net	73.2	73.2
Prepayments and accrued income	13.7	10.7
Payments made on account	16.2	4.4
Other receivables	7.1	7.6
Total trade and other receivables	110.2	95.9

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.

## **16. TRADE AND OTHER RECEIVABLES CONTINUED**

The following table provides information on the movement in the provision for impairment in the year:

(M2NI)	2019	2018
At 1 July	2.4	4.0
Acquisition of subsidiaries (note 29)	0.3	0.3
Utilised in respect of debts written off	(0.4)	(0.5)
Released to the income statement	(1.0)	(1.4)
Charged to the income statement	0.3	_
At 30 June	1.6	2.4

The ageing analysis of the gross trade receivables balances and loss allowances is as follows:

_			LOSS ALLOWANCE	
(IN£M)	2019	2018	2019	2018
Neither past due nor impaired	51.7	61.4	-	-
Up to 3 months past due	18.5	11.3	-	_
3 to 6 months past due	2.5	2.0	0.2	1.6
More than 6 months past due	2.1	0.9	1.4	0.8
	74.8	75.6	1.6	2.4

# 17. CASH AND CASH EQUIVALENTS

(IN EM)	2019	2018
Cash at bank and in hand	83.5	36.3

Due to the short-term nature of cash at bank and short-term deposits, the carrying value approximates to their fair value. The credit risk of the banks was very low and therefore the carrying amount has not been adjusted; their S&P credit ratings were RBS: BBB, HSBC: A, ABSA: AA+ and JP Morgan: A+.

# 18. TRADE AND OTHER PAYABLES

	2019	1	2018	
(IN£M)	CURRENT	NON-CURRENT	CURRENT	NON-CURRENT
Trade payables	69.5	-	69.6	-
Payments received on account	9.2	-	0.8	-
Tax and social security	4.3	-	3.6	_
Other payables	1.0	-	0.5	-
Accruals and deferred income	47.9	1.5	29.1	-
Deferred consideration	48.8	-	2.9	-
Contingent consideration	55.0	5.8	-	-
	235.7	7.3	106.5	-

Deferred consideration is payable within the next 12 months in respect of the acquisition of the Foscavir product extension, Imukin and Proleukin.

Contingent consideration is payable on the CSM and iQone acquisitions based on the adjusted earnings of the businesses. Further detail on the conditions and valuation of the contingent consideration can be found in note 29.

Due to the short-term nature of current trade and other payables, the fair value approximates to their book value. Creditors are unsecured.

# **19. LOANS AND BORROWINGS**

The book value of loans and borrowings are as follows:

(IN £M)	2019	2018
Bank borrowings	335.7	172.8
Finance leases	0.2	-
Total loans and borrowings	335.9	172.8

During the year, the debt facilities were refinanced as part of the financing arrangements for the acquisition of CSM. The new financing increased the debt facility from £220m to £300m, extending the facility to October 2023. In March 2019, the debt facilities were further increased to finance the acquisition of the US rights to Proleukin. The revised facility has been increased by £75m to £375m. This comprises an unsecured £150m term loan with a single repayment in 2023 and an unsecured revolving credit facility ('RCF') of up to £225m.

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 3.0x. As at 30 June 2019, interest cover was 14.7x and the net debt/adjusted EBITDA leverage was 1.99x. There were no instances of default, including covenant terms, in either the current or the prior year.

During the year, interest was payable on a tiered scale based on the level of borrowing. The applicable interest rate on amounts drawn down was up to 2.0% plus LIBOR.

#### **MATURITY OF LOANS AND BORROWINGS**

The maturity profile of the carrying amount of the Group's borrowings at the year end was as follows:

	2019			2018			
(IN EM)	GROSS Borrowings	UNAMORTISED Issue Costs	NET Borrowings	GROSS Borrowings	UNAMORTISED ISSUE COSTS	NET Borrowings	
Within 1 year	-	-	-	-	-	-	
In more than 1 year but less than 2 years	0.2	-	0.2	-	-	-	
In more than 2 years but less than 5 years	338.8	(3.1)	335.7	174.7	(1.9)	172.8	
	339.0	(3.1)	335.9	174.7	(1.9)	172.8	

#### **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**

(IN £M)	TERM LOAN	RCF	FINANCE LEASES	UNAMORTISED ISSUE COSTS	TOTAL Borrowings	CASH AND CASH Equivalents	NET DEBT
At 1 July 2018	-	174.7	-	(1.9)	172.8	(36.3)	136.5
Increase in cash	-	-	-	-	_	(42.5)	(42.5)
Acquisition of subsidiaries (note 29)	-	1.0	0.4	_	1.4	(4.3)	(2.9)
Amendment of facility	150.0	(107.8)	_	(2.1)	40.1	_	40.1
Proceeds from increase in loan	-	139.0	_	_	139.0	_	139.0
Loan repayments	-	(20.3)	(0.2)	_	(20.5)	_	(20.5)
Amortisation of facility issue costs	-	-	_	0.9	0.9	_	0.9
Exchange differences	1.3	0.9	_	_	2.2	(0.4)	1.8
At 30 June 2019	151.3	187.5	0.2	(3.1)	335.9	(83.5)	252.4

# 20. 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.

#### 20. FINANCIAL INSTRUMENTS - RISK MANAGEMENT CONTINUED

A summary of the financial instruments held by category is provided below:

(IN £M)	2019	2018
Financial assets measured at amortised cost		
Cash and cash equivalents	83.5	36.3
Trade and other receivables	91.7	85.2
Derivatives used for hedging		
Derivative financial instruments	2.2	-
Total financial assets	177.4	121.5
Financial liabilities measured at amortised cost		
Trade and other payables	238.7	102.9
Borrowings	339.0	174.7
Derivatives used for hedging		
Derivative financial instruments	0.4	0.5
Total financial liabilities	578.1	278.1

#### **RISK MANAGEMENT**

A description of the Group's treasury policy and controls is included in the Financial Review on page 45.

#### 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 and payments made on account to suppliers. It is Group policy, implemented locally, to assess the credit risk of new customers by obtaining credit ratings before entering contracts or offering credit terms. The credit terms are then continually assessed on an individual basis, and amended accordingly, as a trading history is developed with the customer. Purchase limits are established for each customer, which represents the maximum open amount without requiring approval from the Group Financial Controller or Chief Financial Officer.

Quantitative disclosures of the credit risk exposure in relation to financial assets are set out below. Further disclosures regarding trade and other receivables at the end of the financial year, which are past due but not impaired, are provided in note 16.

(IN £M)	2019	2018
Financial assets - maximum exposure		
Cash and cash equivalents	83.5	36.3
Trade and other receivables	91.7	85.2
Derivative financial instruments	2.2	_
Total financial assets	177.4	121.5

#### 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 35% (2018: 22%) 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.

	2019		2018	2018	
(M£M)	ASSETS	LIABILITIES	ASSETS	LIABILITIES	
Forward foreign exchange contracts - cash flow hedges	2.2	0.4	-	0.5	

The notional principal amounts of the outstanding forward foreign exchange contracts at 30 June 2019 were US\$90.4m and €12m (2018: US\$36.7m and €7.7m). The maturity dates range from July 2019 to June 2020. 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\$1.34:£1 and €1.11:£1.

In FY19 the Parent Company drew down €90 million of its multi-currency debt facility to fund the CSM acquisition which is treated as a net investment hedge against €90 million of the consolidated net assets of CSM.

The valuation of financial instruments at the reporting date is impacted by the foreign exchange rate at that date, primarily in respect of the US dollar and euro. At 30 June 2019, if sterling had weakened/strengthened by 10% against both the US dollar and euro with all variables held constant, profit for the year would have been £3.9m (2018: £1.4m) higher/lower as a result of foreign exchange gains/losses on translation of US dollar/euro trade receivables, cash and cash equivalents, and trade payables. The figure of 10% used for sensitivity analysis has been chosen because it represents a range of reasonable fluctuations in exchange rates.

#### **Liquidity risk**

Liquidity risk arises from the Group's management of working capital and the finance charges and principal repayments on its debt instruments. It is the risk that the Group will encounter difficulty in meeting its financial obligations as they fall due.

The Group's policy is to ensure that it will always have sufficient cash to allow it to meet its liabilities when they become due.

The Board receives cash flow projections based on working capital modelling, as well as information regarding cash balances and net debt monthly. At the end of the financial year, these projections indicated that the Group expected to have sufficient liquid resources to meet its obligations under all reasonably expected circumstances.

The following table sets out the contractual maturities (representing undiscounted contractual cash flows) of financial liabilities:

(IN SM)	LESS THAN 3 months	BETWEEN 3 MONTHS AND 1 YEAR	BETWEEN 1 and 2 years	BETWEEN 2 And 5 years
At 30 June 2019				
Trade and other payables	130.1	108.2	1.6	11.1
Borrowings	-	0.1	0.1	338.8
At 30 June 2018				
Trade and other payables	101.5	1.5	_	_
Borrowings	-	_	_	174.7

### Valuation hierarchy

The table below shows the financial instruments carried at fair value by valuation method:

(IN SM)	2019 Level 1	2019 LEVEL 2	2019 Level 3	2018 Level 1	2018 Level 2	2018 LEVEL 3
Assets/(liabilities)						
Derivative financial instruments - forward foreign exchange contracts	_	1.8	_	-	(0.5)	_
Contingent consideration	-	-	60.8	-	-	-

The Level 2 forward foreign exchange valuations are derived from mark-to-market valuations as at 30 June 2019. Fair value losses of £1.0m (2018: £0.8m) relating to the movement on open forward foreign exchange contracts have been recognised in underlying administrative expenses. The Level 3 contingent consideration liability is the discounted amount payable in respect of the CSM and iQone acquisitions. The amounts payable have been calculated based on the latest forecast of earnings during the respective earn out periods.

#### 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 19.

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.

## 20. FINANCIAL INSTRUMENTS - RISK MANAGEMENT CONTINUED

The Group sets the amount of capital it requires in proportion to risk. The Group manages its capital structure and makes adjustments to it in the light of changes in economic conditions and the risk characteristics of the underlying assets. In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

Net debt is calculated as total borrowings (as detailed in note 19) less cash and cash equivalents.

## 21. DEFERRED INCOME TAX

The analysis of deferred income tax assets and liabilities is as follows:

(INEM)	2019	2018
Deferred tax assets:		
Deferred tax assets to be recovered after more than 12 months	(2.8)	(2.6)
Deferred tax liabilities:		
Deferred tax liabilities to be recovered after more than 12 months	34.0	27.0
Deferred tax liabilities within 12 months	7.1	4.0
	41.1	31.0

The gross movement on the deferred income tax account is as shown below:

DEFERRED TAX LIABILITIES (IN £M)	FAIR VALUE GAINS
At 1 July 2017	20.1
Acquisition of subsidiaries	15.0
Credited to the income statement	(4.0)
Exchange differences	(0.1)
At 30 June 2018	31.0
Acquisition of subsidiaries (note 29)	16.9
Credited to the income statement	(6.9)
Exchange differences	0.1
At 30 June 2019	41.1

DEFERRED TAX ASSETS (IN £M)	UNEXERCISED SHARE OPTIONS	TAX LOSSES	TIMING DIFFERENCES	TOTAL
At 1 July 2017	1.2	1.1	1.3	3.6
Credited to the income statement	0.3	(8.0)	(0.4)	(0.9)
Charged direct to equity	(0.1)	-	_	(0.1)
At 30 June 2018	1.4	0.3	0.5	0.6
Credited/(charged) to the income statement	0.1	-	(0.2)	(0.1)
Charged direct to equity	(0.4)	-	-	(0.4)
At 30 June 2019	1.1	0.3	1.4	2.8

Deferred income taxes are recognised for tax losses carried forward to the extent that the realisation of the related tax benefit through future taxable profits is probable. The Group did not recognise deferred income tax assets of £0.6m in respect of tax losses of £2.3m that can be carried forward against future taxable income.

Deferred tax is calculated in full on temporary differences under the liability method using the enacted tax rate for the period when the temporary difference is expected to reverse. These rates are 19% for the period to 31 March 2020 and 17% thereafter.

## 22. SHARE CAPITAL

		NUMBER OF SHARES ('000S)
ISSUED AND FULLY PAID		ORDINARY SHARES OF 0.1P EACH
At 1 July 2017		115,154
Issue of new shares		7,132
At 30 June 2018		122,286
Issue of new shares		10,193
At 30 June 2019		132,479
(IN £M)	2019	2018
Ordinary shares of 0.1p each	0.1	0.1

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

The Company does not have a limited amount of authorised share capital.

#### 23 RESERVES

The following describes the nature and purpose of each reserve within equity:

RESERVE	DESCRIPTION AND PURPOSE
Share premium account	Amount subscribed for share capital in excess of nominal value, except where recognition in merger reserve is used (see below).
Merger reserve	Amount subscribed for share capital in excess of nominal value when shares are issued in exchange for at least a 90% interest in the shares of another company.
Hedging reserve	Gains/losses arising on cash flow hedges.
Foreign exchange reserve	Gains/losses arising on retranslating the net assets of overseas operations into sterling.
Retained earnings	All other net gains and losses and transactions with owners (e.g. dividends) not recognised elsewhere.

The issue of new equity share capital on the acquisition of iQone required the application of merger relief under the Companies Act 2006. As a result, the difference between the nominal value and fair value of shares issued has been recognised in the merger reserve.

Included within the retained earnings reserve as at 30 June 2019 is £6.1m (2018: £4.2m) relating to unexercised share options which is not distributable.

## 24. OPERATING LEASE COMMITMENTS

The Group has a number of lease commitments relating to property, vehicles and IT equipment which are treated as operating leases. A number of the property lease contracts contain break clauses and/or options to extend, and in all cases it has been assumed that the option to extend will be taken when determining future lease payments. The total future value of minimum lease payments under non-cancellable operating leases are:

(IN £M)	2019	2018
Land and buildings:		
In 1 year or less	3.7	1.7
Between 1 and 5 years	11.1	5.6
In 5 years or more	7.1	6.1
	21.9	13.4
Other:		
In 1 year or less	0.3	0.2
Between 1 and 5 years	0.4	0.2
	0.7	0.4

## **25. CAPITAL COMMITMENTS**

At 30 June 2019, the Group had committed £1.1m (2018: £1.6m) of expenditure for the design and implementation of the Oracle ERP system.

# NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2019

## **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 £1.3m (2018: £1.1m).

## **27. SHARE-BASED PAYMENTS**

An equity-settled share-based payment charge of £3.0m (2018: £2.1m) has been recognised in the year.

The Company operated the following schemes:

PLAN	TAX AUTHORITY STATUS	EMPLOYEES	GRANTING, VESTING CONDITIONS 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 Small Cap Index (excluding investment companies) over a 3 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 2 dealing days preceding the date of invitation, less 20%.
			3 year vesting period.
			If options remain unexercised after a period of 6 months from the vesting date the options expire.
			If monthly contributions are not made for more than 6 months over the 3 year period, the options lapse.
Clinigen Group Company Share Option Plan	HMRC approved for UK employees	All employees	Options granted to employees who have invested in the shares of the Company.
Орион гіан	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.
			3 year vesting period.
			Options vest if employee still owns shares in 3 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 2 dealing days preceding the date of invitation, less 15%.
			2 year vesting period.
Clinigen Group Long Term Incentive Plan 2015	Unapproved	All employees	Subject to performance criteria comparing total shareholder return versus the FTSE Small Cap Index (excluding investment companies) over a 3 year vesting period and a performance condition measuring the EPS of the Group against target EPS over a 3 year period. For certain individuals, vesting is also subject to achievement of personal objectives.
			If the individual leaves earlier than the earliest vesting date, entitlement is at the discretion of the Remuneration Committee.
Clinigen Group All Staff Long Term Incentive Plan	Unapproved	All employees	Subject to performance criteria comparing total shareholder return versus the FTSE Small Cap Index (excluding investment companies) over a 3 year vesting period and a performance condition measuring the EPS of the Group against target EPS over a 3 year period.
			If the individual leaves earlier than the earliest vesting date, their share option lapses.

Details of the share options outstanding are as follows:

	<u></u>	2019		2018
	WEIGHTED AVERAGE Exercise price (P)	NUMBER	WEIGHTED AVERAGE Exercise price (P)	NUMBER
Outstanding at 1 July		1,553,074		1,831,000
Granted during year	1.03	1,370,359	0.27	592,171
Forfeited during the year	1.11	(310,455)	0.43	(651,562)
Exercised during year	2.95	(333,873)	0.56	(218,535)
Outstanding at 30 June	0.93	2,279,105	1.35	1,553,074

Of the total number of options outstanding at 30 June 2019, 162,021 share options had vested (2018: 85,999).

The weighted average share price (at the date of exercise) of options exercised during the year was £9.10 (2018: £10.79).

The exercise price of options outstanding at 30 June 2019 ranged between nil and £9.25 and their weighted average contractual life was 2 years 9 months.

The weighted average fair value of each option granted during the year was £6.70 (2018: £8.77).

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.

	2019	2018
Weighted average share price at grant date (£)	£9.13	£11.09
Exercise price (£)	nil to £9.25	nil to £9.25
Weighted average contractual life (in years)	2.8	2.9
Expected volatility (%)	30.0	31.1
Expected dividend yield (%)	N/A	N/A
Risk-free interest rate (%)	0.5 to 0.8	0.5 to 0.8

Expected volatility was determined by calculating the historical volatility of the Company's share price over the performance period immediately prior to the date of grant.

The Group did not enter into any share-based payment transactions with parties other than employees during the current or previous year.

## 28. RELATED PARTY TRANSACTIONS

## **ULTIMATE CONTROLLING PARTY**

The Company's shares are listed on AIM and are widely held. There is no one controlling party or group of related parties who have control of the Group.

## TRANSACTIONS WITH RELATED PARTIES

The remuneration payable to the Directors of the Company is disclosed in note 6.

Novagen Pharma Pty Limited ('Novagen') is a joint venture in which the Group has a 50% interest. During the year the Group charged distribution fees of £0.9m (2018: £0.8m) to Novagen, and recharged costs of £0.5m (2018: £0.4m) for goods and services provided. At 30 June 2019, the Group had a receivable of £0.1m owing from Novagen (2018: £0.1m).

There were no other transactions with related parties during the year.

### 29. BUSINESS COMBINATIONS

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

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

In order to fund the cash element of the consideration, the Group's borrowing facilities were increased as detailed in note 19.

## NOTES FORMING PART OF THE CONSOLIDATED FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2019

#### 29. BUSINESS COMBINATIONS CONTINUED

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

(IN £III)	CSM	IQONE	TOTAL
Intangible assets	60.4	1.2	61.6
Property, plant and equipment	7.1	-	7.1
Inventories	0.2	0.1	0.3
Trade and other receivables	10.4	0.7	11.1
Corporation tax recoverable	0.3	_	0.3
Cash and cash equivalents	2.1	2.3	4.4
Trade and other payables	(6.9)	(1.2)	(8.1)
Borrowings	(1.0)	-	(1.0)
Finance lease liabilities	(0.4)	-	(0.4)
Provision for deferred tax	(16.7)	(0.2)	(16.9)
Net assets acquired	55.5	2.9	58.4
Goodwill arising on acquisition	91.5	11.4	102.9
Total consideration	147.0	14.3	161.3
Satisfied by:		***************************************	
Cash consideration paid	115.5	6.9	122.4
Consideration settled by shares in Clinigen Group plc	-	2.2	2.2
Discounted fair value of contingent consideration	31.5	5.2	36.7
	147.0	14.3	161.3
Other information:			
Revenue from date of acquisition	46.3	1.4	47.7
Loss before tax from date of acquisition	4.2	0.5	4.7
Pro forma revenue for the 12-month period ended 30 June 2019	58.2	2.0	60.2
Pro forma loss before tax for the 12-month period ended 30 June 2019	7.2	0.8	8.0

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

The contingent consideration is payable in the year ending 30 June 2020 and is contingent on the adjusted EBITDA generated by CSM in the 12 months to 31 December 2019. The undiscounted fair value of the contingent consideration as of the acquisition date was estimated at US\$45.7m based on forecasts available to management at the time. Subsequently the business has performed ahead of expectations and the undiscounted fair value of the contingent consideration has been revised upward to US\$75.0m resulting in an additional £21.4m (US\$27.1m) liability which has been recognised in non-underlying administrative expenses (see note 7). The final payment could be in the range of nil to US\$90m and is expected to be paid in March 2020.

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

The contingent consideration is payable in the years ending 30 June 2023 and 2024 which is contingent on the adjusted EBITDA generated by iQone in the 12 months to 31 December 2022 and 2023. The undiscounted fair value of the contingent consideration as of the acquisition date has been estimated at €12.3m and could be in the range of nil to €50.0m. As all of the contingent consideration is payable in more than 1 year from the balance sheet date, it is included in non-current liabilities. The liability falls within Level 3 of the fair value hierarchy.

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

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

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

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

## REPORT ON THE AUDIT OF THE PARENT COMPANY FINANCIAL STATEMENTS

In our opinion, Clinigen Group plc's parent company financial statements (the "financial statements"):

- give a true and fair view of the state of the parent company's affairs as at 30 June 2019;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards, comprising FRS 101 "Reduced Disclosure Framework", and applicable law); and
- have been prepared in accordance with the requirements of the Companies Act 2006.

We have audited the financial statements, included within the Annual Report & Accounts 2019 (the "Annual Report"), which comprise: the company balance sheet as at 30 June 2019; 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



- Overall materiality: £3.0 million (2018: £2.9 million), based on 0.5% of net assets.
- We conducted a full scope audit of the parent company.
- Our assessment of the risk of material misstatement also informed our views on the area of particular focus for our work which related to the assessment of the carrying value of intangible assets.
- Our assessment of the risk of material misstatement also informed our views on the areas of particular focus for our work which are listed below:
  - Assessment of the carrying value of acquired intangible assets.

#### The scope of our audit

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

#### **Key audit matters**

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

KEY AUDIT MATTER

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

## Assessment of the carrying value of acquired intangible

Refer to the critical accounting estimates and judgements in note 2 and note 12 (intangible assets) to the consolidated financial statements.

We focused on this area because the Directors' assessment of whether impairment triggers have been identified that could give rise to an impairment charge in relation to intangible assets, involved complex and subjective judgements and assumptions including the progress and future performance of individual products.

The Directors' have prepared impairment assessment models which include a number of assumptions. The assumptions which are deemed to be the most significant in respect of these models are the revenue forecasts.

#### HOW OUR AUDIT ADDRESSED THE KEY AUDIT MATTER

For each separate intangible assets we focused on the key assumptions relating to future revenue forecasts, margin expectations and associated selling costs. We were able to evaluate the reasonableness of the Directors' forecasts and expectations by corroborating evidence and assessing the margin and selling costs expected to be achieved by reference to historical margins realised, selling cost improvement plans and, where relevant, consideration of actual performance against prior year forecasts.

As a result of our audit work, we agreed with the Directors' assessment that no impairment triggers for acquired intangible assets were identified. We consider that the associated judgements taken were supportable.

#### How we tailored the audit scope

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

The Company is comprised of one component, and the Group engagement team performed a full scope audit over this component.

#### Materiality

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

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

Overall materiality	£3.0 million (2018: £2.9 million).
How we determined it	0.5% of net assets.
Rationale for benchmark applied	We believe that net assets are an appropriate basis for determining materiality as the parent company is not a profit orientated entity.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above £109,000 (2018: £105,000) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

## Going concern

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

We are required to report if we have anything material to add or We have draw attention to in respect of the directors' statement in the	nothing material to add or to draw attention to.
appropriate to adopt the going concern basis of accounting in predicted company identification of any material uncertainties to the parent company's ability to continue as a going concern over a period of at least twelve months from the date of approval of the pote	because not all future events or conditions can be d, this statement is not a guarantee as to the parent o's ability to continue as a going concern. For example, s on which the United Kingdom may withdraw from the Union are not clear, and it is difficult to evaluate all of Intial implications on the parent company's trade, rs, suppliers and the wider economy.

#### 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, Report of the Directors and Corporate Governance Statement, we also considered whether the disclosures required by the UK Companies Act 2006 have been included.

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

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

In our opinion, based on the work undertaken in the course of the audit, the information given in the Strategic Report and Report of the Directors for the year ended 30 June 2019 is consistent with the financial statements and has been prepared in accordance with applicable legal requirements. (CAO6)

In light of the knowledge and understanding of the parent company and its environment obtained in the course of the audit, we did not identify any material misstatements in the Strategic Report and Report of the Directors. (CAO6)

## The directors' assessment of the prospects of the parent company and of the principal risks that would threaten the solvency or liquidity of the parent company

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

- The directors' confirmation on page 47 of the Annual Report that they have carried out a robust assessment of the principal risks facing the parent company, including those that would threaten its business model, future performance, solvency or liquidity.
- The disclosures in the Annual Report that describe those risks and explain how they are being managed or mitigated.
- The directors' explanation on page 73 of the Annual Report as to how they have assessed the prospects of the parent company, over what period they have done so and why they consider that period to be appropriate, and their statement as to whether they have a reasonable expectation that the parent company will be able to continue in operation and meet its liabilities as they fall due over the period of their assessment, including any related disclosures drawing attention to any necessary qualifications or assumptions.

We have nothing to report in respect of this responsibility.

#### **Other Code Provisions**

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

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

We have nothing to report in respect of this responsibility.

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

## RESPONSIBILITIES FOR THE FINANCIAL STATEMENTS AND THE AUDIT

#### Responsibilities of the directors for the financial statements

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

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

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

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

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

#### Use of this report

This report, including the opinions, has been prepared for and only for the parent company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

### OTHER REQUIRED REPORTING

#### **COMPANIES ACT 2006 EXCEPTION REPORTING**

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

- we have not received all the information and explanations we require for our audit; or
- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- certain disclosures of directors' remuneration specified by law are not made; or
- the financial statements are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

## OTHER MATTER

We have reported separately on the group financial statements of Clinigen Group plc for the year ended 30 June 2019.

## PAUL NORBURY BSC FCA (SENIOR STATUTORY AUDITOR)

for and on behalf of PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors East Midlands 18 September 2019

# **COMPANY BALANCE SHEET** AS AT 30 JUNE 2019

(IN £M)	NOTE	2019	2018
Assets			
Non-current assets	•	•	
Tangible fixed assets	4	0.9	0.7
Intangible fixed assets	5	57.7	51.4
Investments	6	744.9	444.8
Deferred tax assets	11	1.4	1.6
Total non-current assets		804.9	498.5
Current assets			
Debtors	7	362.4	341.9
Derivative financial instruments		2.3	_
Cash and cash equivalents		1.9	1.4
Total current assets		366.6	343.3
Total assets		1,171.5	841.8
Current liabilities			
Creditors: amounts falling due within one year	8	218.3	89.6
Total current liabilities		218.3	89.6
Net current assets		148.3	253.7
Total assets less current liabilities		953.2	752.2
Non-current liabilities			
Creditors: amounts falling due after more than one year	9	5.8	_
Loans and borrowings	10	335.1	172.8
Total non-current liabilities		340.9	172.8
Net assets		612.3	579.4
Capital and reserves			
Called up share capital	12	0.1	0.1
Share premium account	•	240.2	161.3
Merger reserve		88.2	86.0
Hedging reserve		(0.1)	_
At 1 July		332.0	344.8
Loss for the year attributable to the owners		(43.2)	(8.7)
Other changes in retained earnings		(4.9)	(4.1)
Retained earnings		283.9	332.0
Total equity		612.3	579.4

The financial statements on pages 115 to 124 were approved by the Board of Directors on 18 September 2019 and were signed on its behalf by:

S CHILTON Director N KEHER Director

# COMPANY STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2019

(IN £M)	SHARE Capital (Note 12)	SHARE PREMIUM Account	MERGER Reserve	HEDGING Reserve	RETAINED EARNINGS	TOTAL EQUITY
At 1 July 2018	0.1	161.3	86.0	-	332.0	579.4
Loss for the year	-	-	-	-	(43.2)	(43.2)
Cash flow hedges	-	-	-	(0.1)	-	(0.1)
Share-based payment scheme	-	-	-	-	3.0	3.0
Deferred taxation on share-based payment scheme	-	-	-	-	(0.4)	(0.4)
Tax credit in respect of tax losses arising on exercise of share options	-	_	-	-	0.2	0.2
Dividend paid	-	-	-	-	(7.7)	(7.7)
Issue of new shares	-	78.9	2.2	-	-	81.1
Total contributions by, and distributions to, owners of the Company, recognised directly in equity	_	78.9	2.2	_	(4.9)	76.4
At 30 June 2019	0.1	240.2	88.2	(0.1)	283.9	612.3
(INEM)	SHARE Capital (Note 12)	SHARE PREMIUM Account	MERGER RESERVE	HEDGING Reserve	RETAINED EARNINGS	TOTAL Equity
At 1 July 2017	0.1	161.2	5.4	_	344.8	511.5
Loss for the year	_	_	-	_	(8.7)	(8.7)
Loss for the year				······································		2.1
Share-based payment scheme	_	_	-	-	2.1	2.1
	-	<u>-</u> -	- -		(0.1)	(0.1)
Share-based payment scheme	- -	- - -	- - -			
Share-based payment scheme  Deferred taxation on share-based payment scheme  Tax credit in respect of tax losses arising on exercise of share	- - -	- - -	- - -		(0.1)	(0.1)
Share-based payment scheme Deferred taxation on share-based payment scheme Tax credit in respect of tax losses arising on exercise of share options	- - - -	- 0.1	- - - 80.6	- - - -	(0.1)	0.1
Share-based payment scheme Deferred taxation on share-based payment scheme Tax credit in respect of tax losses arising on exercise of share options Dividend paid	- - - - -	- - - 0.1	- - - 80.6	- - - - -	(0.1)	(0.1) 0.2 (6.3)

The following describes the nature and purpose of each reserve within equity:

RESERVE	DESCRIPTION AND PURPOSE
Share premium account	Amount subscribed for share capital in excess of nominal value, except where recognition in merger reserve is used (see below).
Merger reserve	Amount subscribed for share capital in excess of nominal value when shares are issued in exchange for at least a 90% interest in the shares of another company.
Retained earnings	All other net gains and losses and transactions with owners (e.g. dividends) not recognised elsewhere.

The issue of new equity share capital on the acquisition of iQone required the application of merger relief under the Companies Act 2006. As a result, the difference between the nominal value and fair value of shares issued has been recognised in the merger reserve.

## NOTES TO THE COMPANY FINANCIAL STATEMENTS FOR THE YEAR ENDED 30 JUNE 2019

## 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The financial statements of the Parent Company present information about the Company as a separate entity and not about its Group.

The accounting policies, set out in the consolidated financial statements, unless otherwise stated have been applied consistently to the period presented in these Company financial statements.

The Company financial statements have been prepared and approved by the Directors in accordance with FRS 101.

#### **BASIS OF PREPARATION**

The Company financial statements are prepared on the going concern basis under the historical cost convention and in accordance with Financial Reporting Standard 101 'Reduced Disclosure Framework'. In preparing these financial statements, the Company applies the recognition, measurement and disclosure requirements of International Financial Reporting Standards as adopted by the EU ('Adopted IFRS'), but makes amendments where necessary in order to comply with Companies Act 2006. The financial statements are presented in sterling and all values are rounded to the nearest £100,000 except when otherwise stated.

No income statement is presented for the Company as permitted by Section 408(2) and (3) of the Companies Act 2006. The loss for the year was £35.2m (2018: £8.7m). Fees paid to PricewaterhouseCoopers LLP and its associates for audit and non-audit services to the Company itself are not disclosed in the individual financial statements of Clinigen Group plc because the Group financial statements are required to disclose such fees on a consolidated basis (see note 5.2 of the consolidated financial statements).

#### **INVESTMENTS**

Investments in subsidiaries are recorded at historical cost, less any provision for impairment.

The Company has elected to apply the exemption in Section 408 of the Companies Act and has not presented its separate statement of comprehensive income and related notes. It has also taken advantage of the exemptions under FRS 101 not to disclose related party transactions entered into between two or more members of the Group and not to prepare a cash flow statement. The Company has elected not to prepare disclosures under IFRS 7 in accordance with the exemptions under FRS 101. The Company's information relating to these disclosures are included within the consolidated financial statements of Clinigen Group plc.

Judgements made by the Directors in the application of these accounting policies that have significant effect on the financial statements, and estimates with a significant risk of material adjustment in the next year, are discussed in note 2 of the consolidated financial statements.

## 2. STAFF COSTS

(IN £M)	2019	2018
Staff costs (including Directors) comprise:		
Wages and salaries	8.3	7.0
Social security costs	1.5	1.3
Share-based payment expense	3.0	2.1
Other pension costs	0.2	0.2
Gross staff costs	13.0	10.6
Capitalised labour	(0.5)	(0.4)
Net staff costs	12.5	10.2

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 during the financial year amounted to:

NUMBER	2019	2018
Directors	2	2
Staff	128	120
	130	122

## NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED

FOR THE YEAR ENDED 30 JUNE 2019

## 2. STAFF COSTS CONTINUED

## **KEY MANAGEMENT PERSONNEL COMPENSATION**

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company. This is considered to be the Board of Directors.

(INEM)	2019	2018
Directors' remuneration included in staff costs:		
Wages and salaries	2.0	1.7
Share-based payment expense	0.9	0.9
	2.9	2.6

Total emoluments of Directors (including pension contributions) amounted to £2.9m (2018: £2.6m). Information relating to Directors' emoluments, share options and pension entitlements is set out in the Remuneration Report on pages 62 to 71.

## 3. DIVIDENDS

(INEM)	2019	2018
Final dividend in respect of the year ended 30 June 2018 of 3.84p (2018: 3.4p) per ordinary share	5.1	4.2
Interim dividend of 1.95p (2018: 1.76p) per ordinary share paid during the year	2.6	2.1
	7.7	6.3

The Board proposes to pay a final dividend of 4.75p per ordinary share, subject to shareholder approval, on 29 November 2019, to shareholders on the register on 8 November.

## 4. TANGIBLE FIXED ASSETS

(IN £M)	LEASEHOLD Improvement	PLANT AND Machinery	FURNITURE, FITTINGS And Equipment	TOTAL
Cost				
At 30 June 2018	0.7	0.1	1.0	1.8
Additions	-	_	0.4	0.4
At 30 June 2019	0.7	0.1	1.4	2.2
Accumulated depreciation				
At 30 June 2018	0.3	0.1	0.7	1.1
Charge for the year	_	-	0.2	0.2
At 30 June 2019	0.3	0.1	0.9	1.3
Net book value				
At 30 June 2019	0.4	-	0.5	0.9
At 30 June 2018	0.4	-	0.3	0.7

## **5. INTANGIBLE FIXED ASSETS**

TRADEMARKS And Licences	COMPUTER Software	TOTAL
57.0	9.5	66.5
4.6	5.3	9.9
61.6	14.8	76.4
15.0	0.1	15.1
3.5	0.1	3.6
18.5	0.2	18.7
43.1	14.6	57.7
42.0	9.4	51.4
	15.0 3.5 18.5	SOFTWARE   SOFTWARE

### **6. INVESTMENTS**

(M2M)	2019	2018
Cost or valuation		
At 1 July 2017 and 30 June 2018	444.8	296.2
Additions	300.1	148.6
At 30 June 2019	744.9	444.8

On 2 October 2018, the Group acquired the entire share capital of CSM Parent, Inc., a company registered in the US, and its subsidiaries with a presence in the US, Belgium and Germany. The total consideration for CSM was £147.0m, which is made up of initial cash consideration of £114.0m (US\$150.0m), payment for working capital of £1.5m (US\$1.9m) and contingent consideration of £31.5m (US\$40.2m). The contingent consideration is payable in the year ending 30 June 2020 and is contingent on the adjusted EBITDA generated by CSM in the 12 months to 31 December 2019. The undiscounted fair value of the contingent consideration as of the acquisition date was estimated at US\$45.7m based on forecasts available to management at the time. Subsequently the business has performed ahead of expectations and the undiscounted fair value of the contingent consideration has been revised upward to US\$64.0m resulting in an additional £13.4m (US\$17.0m) liability which has been recognised in non-underlying administrative expenses (see note 7). The final payment could be in the range of nil to US\$90m and is expected to be paid in March 2020.

On 9 October 2018, the Group acquired the entire share capital of iQone Healthcare Holding, a company registered in Switzerland, and its subsidiaries with a presence in France, Germany, Switzerland, Italy and Spain. The total consideration for iQone was £14.3m, which is made up of initial cash consideration of £6.9m ( $\epsilon$ 7.7m) cash, an issue of 241,744 shares in Clinigen Group plc which had a fair value of £2.2m ( $\epsilon$ 2.5m), and contingent consideration of £5.2m ( $\epsilon$ 5.8m). The contingent consideration is payable in the years ending 30 June 2023 and 2024 which is contingent on the adjusted EBITDA generated by iQone in the 12 months to 31 December 2022 and 2023. The undiscounted fair value of the contingent consideration as of the acquisition date has been estimated at  $\epsilon$ 12.3m and could be in the range of nil to  $\epsilon$ 50.0m.

On 22 May 2019, the Company increased its investment in Clinigen Holdings Limited by £138.7m in exchange for the issuance of equity.

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

The Company directly holds interests in the whole of the issued share capital of the following undertakings.

NAME	COUNTRY OF INCORPORATION	NATURE OF BUSINESS
Clinigen Holdings Limited	UK	Holding company
Clinigen Pharma Limited	UK	Holding company
Clinigen Asia Pte. Limited	Singapore	Holding company
Quantum Pharma Holdings Limited	UK	Holding company
CSM Parent, Inc.	US	Holding company
iQone Healthcare Holding (Suisse) SA	Switzerland	Holding company

All shareholdings in subsidiaries are owned 100% (2018: 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

(INEM)	2019	2018
Amounts owed by Group undertakings	359.8	339.1
Prepayments and taxes receivable	2.6	2.8
	362.4	341.9

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

(IN £M)	2019	2018
Trade creditors	2.5	2.0
Amounts owed to Group undertakings	154.2	77.8
Tax and social security	1.7	1.3
Other creditors	0.1	0.1
Accruals and deferred income	3.3	5.5
Deferred consideration	1.5	2.9
Contingent consideration	55.0	-
	218.3	89.6

## NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2019

#### 8. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR CONTINUED

Amounts owed to Group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

Deferred consideration is payable within the next 12 months in respect of the acquisition of the Foscavir product extension and Impukin

Contingent consideration is expected to be paid in March 2020 on the CSM acquisition based on the adjusted EBITDA generated by CSM in the 12 months to 31 December 2019.

## 9. CREDITORS: AMOUNTS FALLING DUE AFTER MORE THAN ONE YEAR

(IN £M)	2019	2018
Contingent consideration	5.8	-
	5.8	_

Contingent consideration is payable in the years ending 30 June 2023 and 2024 on the iQone acquisition based on the adjusted EBITDA generated by iQone in the 12 months to 31 December 2022 and 2023.

### **10. LOANS AND BORROWINGS**

The book value of loans and borrowings are as follows:

	2019			2018		
(IN£M)	CURRENT	NON-CURRENT	TOTAL	CURRENT	NON-CURRENT	TOTAL
Bank borrowings	-	335.1	335.1	-	172.8	172.8

During the year, the debt facilities were refinanced as part of the financing arrangements for the acquisition of CSM. The new financing increased the debt facility from £220m to £300m, extending the facility to October 2023. In March 2019, the debt facilities were further increased to finance the acquisition of the US rights to Proleukin. The revised facility has been increased by £75m to £375m. This comprises an unsecured £150m term loan with a single repayment in 2023 and an unsecured RCF of up to £225m.

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 3.0x. As at 30 June 2019, interest cover was 14.7x and the net debt/adjusted EBITDA leverage was 1.99x. There were no instances of default, including covenant terms, in either the current or the prior year.

During the year, interest was payable on a tiered scale based on the level of borrowing. The applicable interest rate on amounts drawn down was up to 2.0% plus LIBOR.

### 11. DEFERRED TAX

The movement on the deferred tax account is as shown below:

DEFERRED TAX ASSETS (IN EM)	LOSSES	UNEXERCISED Share options	TOTAL
At 1 July 2017	1.1	1.2	2.3
(Charge)/credit to the income statement	(0.9)	0.3	(0.6)
Charge recognised in equity	-	(0.1)	(0.1)
At 30 June 2018	0.2	1.4	1.6
Credit to the income statement	0.1	0.1	0.2
Charge recognised in equity	-	(0.4)	(0.4)
At 30 June 2019	0.3	1.1	1.4

## 12. CALLED UP SHARE CAPITAL

	NUMBER OF SHARES ('000S)
ISSUED AND FULLY PAID	ORDINARY SHARES OF 0.1P EACH
At 1 July 2017	115,154
Issue of new shares	7,132
At 30 June 2018	122,286
Issue of new shares	10,193
At 30 June 2019	132,479

(IN £M)	2019	2018
Ordinary shares of 0.1p each	0.1	0.1

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

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)

(IN £M)	2019 Level 1	2019 LEVEL 2	2019 Level 3	2018 Level 1	2018 Level 2	2018 Level 3
Assets/(liabilities)						
Derivative financial instruments – forward foreign exchange contracts	_	2.3	_	-	-	-
Contingent consideration	-	-	55.0	-	-	_

The Level 2 forward foreign exchange valuations are derived from mark-to-market valuations as at 30 June 2019. Fair value losses of nil (2018: nil) relating to the movement on open forward foreign exchange contracts have been recognised in underlying administrative expenses. The Level 3 contingent consideration liability is the discounted amount payable in respect of the CSM and iQone acquisitions. The amounts payable have been calculated based on the latest forecast of earnings during the respective earn out periods.

There have been no transfers between Level 1, Level 2 or Level 3 during the year.

#### **FAIR VALUES OF FINANCIAL INSTRUMENTS**

The fair values of all financial assets and financial liabilities by class together with their carrying amounts shown in the balance sheet are as follows:

(IN SM)	FAIR VALUE 2019	CARRYING Amount 2019	FAIR VALUE 2018	CARRYING Amount 2018
Loans and receivables				
Cash and cash equivalents	1.9	1.9	1.4	1.4
Debtors excluding prepayments and taxes (note 7)	359.8	359.8	339.1	339.1
Total loans and receivables	361.7	361.7	340.5	340.5
Total financial assets	361.7	361.7	340.5	340.5
Financial liabilities measured at amortised cost				
Loans and borrowings	(335.1)	(335.1)	(174.7)	(174.7)
Creditors: amounts falling due within one year (note 8)	(216.6)	(216.6)	(88.3)	(88.3)
Creditors: amounts falling due after more than one year (note 9)	(5.8)	(5.8)	-	_
Total financial liabilities measured at amortised cost	(557.5)	(557.5)	(263.0)	(263.0)
Total financial liabilities	(557.5)	(557.5)	(263.0)	(263.0)
Total financial instruments	(195.8)	(195.8)	77.5	77.5

Management considers that the carrying amount of financial assets and liabilities recognised at amortised cost in the financial statements approximate their fair value. The fair value of the financial assets and liabilities is included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2019

## 14. RELATED PARTY TRANSACTIONS ULTIMATE CONTROLLING PARTY

The Company's shares are listed on AIM and are widely held. There is no one controlling party or group of related parties who have control of the Group.

### TRANSACTIONS WITH RELATED PARTIES

The remuneration payable to the Directors of the Company is disclosed in note 2.

There were no transactions with related parties, other than the Company's subsidiaries, during the year or the preceding year.

#### **SUBSIDIARIES**

The subsidiaries of Clinigen Group plc at each reporting date have been included in these consolidated financial statements.

Subsidiaries at the end of the reporting year were as follows:

NAME	NATURE OF BUSINESS	COUNTRY OF INCORPORATION
Clinigen Holdings Limited	Holding company	UK <sup>1</sup>
Clinigen International Holdings Limited	Holding company	UK <sup>1</sup>
Clinigen Healthcare Limited	Supply of pharmaceutical products and services	UK <sup>1</sup>
Clinigen Inc.	Supply of pharmaceutical products and services	US <sup>1</sup>
Clinigen SP Limited	Supply of pharmaceutical products	UK¹
Clinigen Healthcare B.V.	Holding company	Netherlands
Clinigen Clinical Trials Limited	Holding company	UK¹
Clinigen Pharma Limited	Holding company	UK¹
Clinigen GAP Limited	Dormant	UK <sup>1</sup>
Clinigen CTS Limited	Dormant	UK¹
Clinigen Consulting Limited	Dormant	UK <sup>1</sup>
Keats Healthcare Limited	Dormant	UK <sup>1</sup>
Clinigen CTS Inc.	Dormant	US <sup>1</sup>
Clinigen GAP Inc.	Dormant	US <sup>2</sup>
dis Group Holdings Limited	Holding company	UK¹
dis Group Limited	Holding company	UK <sup>1</sup>
dis Limited	Dormant	UK <sup>1</sup>
dis MA Limited	Dormant	UK <sup>1</sup>
dis GA Limited	Dormant	UK <sup>1</sup>
dis Pharma Private Limited	Dormant	India
Clinigen Asia Pte. Limited	Holding company	Singapore
ink Healthcare Singapore Pte. Limited	Supply and distribution of pharmaceutical products	Singapore
_ink Healthcare KK	Supply and distribution of pharmaceutical products	Japan
Clinigen KK	Supply and distribution of pharmaceutical products	Japan
MMC	Supply and distribution of pharmaceutical products	Japan
_ink Healthcare Sdn Bhd	Supply and distribution of pharmaceutical products	Malaysia
ink Healthcare Hong Kong Limited	Supply and distribution of pharmaceutical products	Hong Kong
ink Medical Products (Pty) Limited	Supply and distribution of pharmaceutical products	Australia
_ink Pharmaceuticals Limited	Supply and distribution of pharmaceutical products	New Zealand
Clinigen South Africa (Pty) Limited	Holding company	South Africa
Homemed Pty Limited	Supply and distribution of pharmaceutical products	South Africa
Equity Pharmaceuticals (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
Equity Medical Technologies (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
Equipharm Specialised Distribution (Pty) Limited	Supply and distribution of pharmaceutical products	South Africa
ink Healthcare (Pty) Limited	Holding company	Australia
ink Holding 1 (Pty) Limited	Holding company	Australia
ink Holding 2 (Pty) Limited	Holding company	Australia
PMIP (Pty) Limited	Dormant	Australia
Plurilinx (Pty) Limited	Dormant	South Africa

NAME	NATURE OF BUSINESS	COUNTRY OF INCORPORATION
Chloromix (Pty) Limited	Dormant	South Africa
Quantum Pharma Holdings Limited	Holding company	UK²
Quantum Pharma 2014 Limited	Holding company	UK²
Quantum Pharma Group Limited	Holding company	UK²
Quantum Pharmaceutical Limited	Manufacture and supply of pharmaceutical products	UK²
UL Medicines Limited	Supply and distribution of pharmaceutical products	UK²
Colonis Pharma Limited	Development of pharmaceutical and related products	UK²
Pern Consumer Products Limited	Supply and distribution of body care products	UK²
Protomed Limited	Supply and distribution of pharmaceutical products	UK²
Lamda Pharma Limited	Holding company	UK²
Lamda UK Limited	Development of pharmaceutical and related products	UK²
_amda Laboratories SA	Development of pharmaceutical and related products	Greece
_amda Pharma SA	Development of pharmaceutical and related products	Greece
QM Specials Limited	Manufacture and supply of pharmaceutical products	Ireland
Quantum Specials Trustee Limited	Corporate trustee	UK²
Quantum Specials Limited	Dormant	UK²
NuPharm Group Limited	Dormant	UK²
NuPharm Laboratories Limited	Dormant	UK²
CSM Parent, Inc.	Holding company	US³
Clinical Supplies Management Holdings, Inc.	Provision of packaging, labelling, warehousing, and distribution services	US <sup>3</sup>
Clinical Supplies Management Europe SA	Provision of packaging, labelling, warehousing, and distribution services	Belgium
Clinical Supplies Management Europe GmbH	Provision of packaging, labelling, warehousing, and distribution services	Germany <sup>1</sup>
CSM Biomedical Sample Management, Inc.	Provision of packaging, labelling, warehousing, and distribution services	US <sup>4</sup>
Clinical Supplies Management Belgium SPRL	Holding company	Belgium
3&C Invest SA	Holding company	Belgium
B&C Group Holding SA	Holding company	Belgium
Qone Healthcare Holding (Suisse) SA	Provision of medical information services	Switzerland
Qone Healthcare Export Sàrl	Provision of medical information services	Switzerland
Qone Healthcare France Sàrl	Provision of medical information services	France
iQone Healthcare Europe GmbH	Provision of medical information services and supply of medical products	Germany²
iQone Healthcare Italy Srl	Provision of medical information services	Italy
iQone Healthcare Spain S.L.	Provision of medical information services	Spain

# NOTES TO THE COMPANY FINANCIAL STATEMENTS CONTINUED FOR THE YEAR ENDED 30 JUNE 2019

## 14. RELATED PARTY TRANSACTIONS CONTINUED

COUNTRY OF INCORPORATION	REGISTERED OFFICE	
UK <sup>1</sup>	Pitcairn House, Crown Square, Centrum 100, Burton-on-Trent, Staffordshire, DE14 2WW	
UK²	Quantum House, Hobson Industrial Estate, Burnopfield, Co Durham, NE16 6EA	
UK³	Unit 3, Ardane Park, Phoenix Avenue, Green Lane Industrial Estate, Featherstone, WF7 6EP	
US <sup>1</sup>	Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808	
US <sup>2</sup>	Registered Office Service Company, 203 NE Front Street, Suite 101, Milford, Delaware 19963	
US <sup>3</sup>	Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801	
JS <sup>4</sup>	180 Gordon Dr Suite 109, Exton, Pennsylvania 19341	
Singapore	133 Cecil Street, #13-03 Keck Seng Tower, 069535	
Japan	1-16-3, Nihonbashi, Chuo-Ku, Tokyo, 103-0027	
Malaysia	Upper Penthouse, Wisma RKT, No. 2 Jalan Raja Abdullah, 50300 Kuala Lumpur	
Hong Kong	Room 1901, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay	
Australia	5 Apollo Street, Warriewood NSW 2102	
New Zealand	RSM New Zealand, Ford Building, 86 Highbrook Drive, Highbrook, Auckland 2013	
South Africa	100 Sovereign Drive, Nellmapius Drive, Irene 0157, Pretoria	
Vetherlands	WTC Schiphol Airport, D Tower, 11th floor, Schiphol Boulevard 359, 1118 BJ Amsterdam Schiphol	
3elgium	Rue Granbonpré 11, 1435 Mont-Saint-Guibert	
=rance	24 Avenue Joannes Masset, 69009 Lyon	
Germany <sup>1</sup>	Am Kronberger Hang 3, 75824 Schwalbach	
Germany²	Stefan-George-Ring 2, 81929 Munich	
taly	Viale Abruzzi, 94, 20131 Milan	
Spain	Plaza de Castilla, 3 - 15° E2, 28046 Madrid	
Switzerland	Modulis Business Park, Route de Suisse 162, 1290 Versoix	
reland	Mayfield Business Park, Lismore, County Waterford	
Greece	59, Ioannou Metaxa str., 19400 Koropi	
India	302, 3rd Floor, A-Wing, Rutu Business Park, Thane West, Mumbai 400606	

QM Specials Limited is owned 50% (2018: 50%), however it has been determined that the Group has control of the entity as defined by IFRS 10. All other shareholdings in subsidiaries are owned 100% (2018: 100%) through the subsidiaries' ordinary share capital.

## **15. CAPITAL COMMITMENTS**

At 30 June 2019, the Company had committed £1.1m (2018: £1.6m) of expenditure for the design and implementation of the Oracle ERP system.

## **COMPANY INFORMATION**

Clinigen Group plc is a public limited company, incorporated and registered in the UK with company number 06771928.

#### **DIRECTORS**

S Chilton

N Keher

P Allen (Independent Non-Executive Chairman)

J Hartup (Senior Independent Non-Executive)

I Nicholson (Independent Non-Executive)

A Hyland (Independent Non-Executive)

A Boyd (Non-Executive)

### **COMPANY SECRETARY AND REGISTERED OFFICE**

A Miller Pitcairn House Crown Square Centrum 100 Burton-on-Trent Staffordshire DE14 2WW

## **ADVISER AND INVESTOR CONTACTS**

#### **INDEPENDENT AUDITORS**

PricewaterhouseCoopers LLP Donington Court Pegasus Business Park Herald Way East Midlands DE74 2UZ

### NOMINATED ADVISER

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

Clinigen Group plc Pitcairn House Crown Square Centrum 100

www.clinigengroup.com