



# LEADERS.

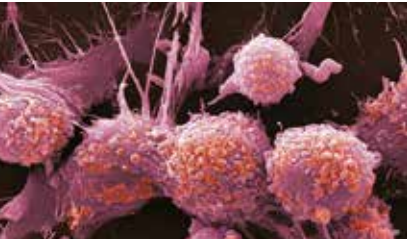
**Annual Report  
and Accounts 2015**

# Introduction


Clinigen Group is a global pharmaceutical and services company with a unique business model. Clinigen’s mission is to deliver the **right drug** to the **right patient** at the **right time**, to improve the quality of people’s lives around the world. The Group consists of four synergistic businesses that provide medicines to patients with unmet need; through clinical trials, licensed and unlicensed supply.

## LEADERS...

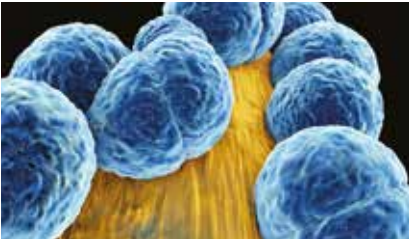
➔ Ethical




We are the leading global patient access specialist working to provide ethical and compliant access to unlicensed and licensed medicines for healthcare providers and their patients with high unmet medical need.

 To read more see page **08**

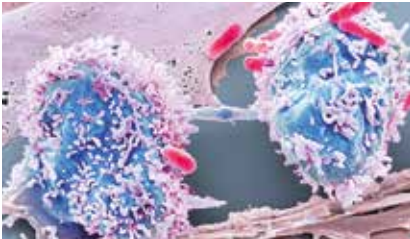
➔ Unique




The combination of businesses we have is unique and synergistic, we are able to centrally manage treatment access for patients via the clinical trial, licensed and unlicensed routes. In an industry that is typically divided into pharmaceutical companies and service businesses, we are the only organisation to provide global access to medicines across the various routes.

 To read more see page **12**

➔ Fast growing



We continually deliver strong organic growth supplemented by acquisitional growth. Clinigen has become the global market leader in the supply of medicines for use in clinical trials and the global market leader in providing access to unlicensed medicines. We have expanded our global footprint, supplying to 130 countries worldwide.

 To read more see page **20**

<b>Strategic report</b>	<b>Governance</b>	<b>Financial statements</b>
01 Highlights	40 Board of Directors	45 Independent Auditors’ report
02 Expanding our global footprint	42 Report of the Directors	47 Consolidated statement of comprehensive Income
04 Chief Executive Officer’s statement		48 Consolidated statement of financial position
08 LEADERS. Ethical		49 Consolidated statement of cash flows
10 Market Overview		50 Consolidated statement of changes in Equity
12 LEADERS. Unique		51 Notes forming part of the consolidated financial statements
14 Our business model		82 Independent Auditors’ report
19 KPIs		84 Company balance sheet
20 LEADERS. Fast Growing		85 Notes to the Company balance sheet
22 Operational review		
32 Chief Financial Officer’s statement		
36 A responsible business		

# Business highlights

## ➔ Clinigen Group Acquisition

### Highlight


- Acquisition of Idis in April 2015 established the Group's international market leader status in both unlicensed ethical supply of medicines and in clinical trials supply as well as providing commercialisation opportunities for SP.

## ➔ Clinigen Clinical Trial Services (CTS)

CTS are the global leader in the specialist supply and management of quality-assured comparator drugs and other commercial medicines for patients in clinical trials. CTS is also developing 'Expanded Value Services' to clinical trial sites.

### Highlights

- Clinigen Clinical Trial Services (CTS): strong US performance and increase in customers to 85 (2014: 73)
- Developing new Expanded Value Services; 'Just in Time' smarter supply and labelling and direct to site services


 To read more see page 24

## ➔ Idis Managed Access (MA)

MA manages ethical worldwide access to the most promising, innovative early stage medicines on behalf of pharmaceutical and biotech companies, to meet an unmet patient need.

### Highlight

- Idis Managed Access (MA) (includes Clinigen Global Access Programs): increase in deliveries of innovative early stage medicines to 418,000 units via 62,000 shipments (2014: 263,000 units from 40,000 shipments) with 99 products under active management.


 To read more see page 26

## ➔ Idis Global Access (GA)

GA provides high quality ethical access to post approval and short supply medicines, in regions where patients have low or non-existent access to these often essential drugs. Our aim is to be the go to solution for healthcare professionals, in order to meet this currently unmet patient need.

### Highlight

- Idis Global Access (GA): new business unit created from acquisition of Idis. Combined with the proposed acquisition of Link Healthcare ('Link'), this provides Clinigen with a significant potential to shape the ethical on-demand unlicensed supply market and drug shortages market, estimated at \$5bn.


 To read more see page 28

## ➔ Clinigen Specialty Pharmaceuticals (SP)

SP acquires the rights to and then revitalises essential niche hospital only medicines.

### Highlight

- Clinigen Specialty Pharmaceuticals(SP): acquisition of fifth product, oncology support, Ethyol® (amifostine), widens portfolio and dilutes dependency on Foscavir; lifting of EMA Article 31 referral in place on Cardioxane remains on track.

 To read more see page 30

# How we operate

There are only three ways for a patient to ethically access a drug and we are the only company to globally manage access to all three routes.

Clinigen is unique in its ability to operate across all three stages of the drug lifecycle.

## → The New Clinigen Model



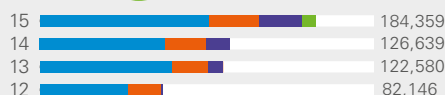
# Financial highlights

## → Financial highlights

- Revenues increased by 45% to £184.4m (2014: £126.6m)
- Gross profit increased 30%, mainly driven by 25% growth in Clinigen Specialty Pharmaceuticals (SP) gross profits and the acquisition of Idis Group Holdings Limited ('Idis') in April 2015
- Underlying EBITDA up 20% to £32.3m (2014: £26.8m)
- Final dividend 2.3p per share proposed; total dividend 3.4p per share (2014: 3.1p per share), up 10%
- Adjusted underlying earnings per share<sup>1</sup> up 14% to 28.0p (2014: 24.5p), reported earnings per share at 6.5p (2014: 19.6p) are after one off acquisition costs and post-acquisition restructuring costs

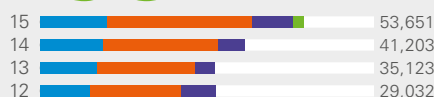
### Turnover

**£184.4m**



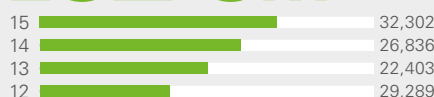
### Gross profit

**£53.7m**



### Underlying EBITDA

**£32.3m**



### Dividend

**2.3p** +10%

### Adjusted underlying EPS<sup>1</sup>

**28.0p** +14%

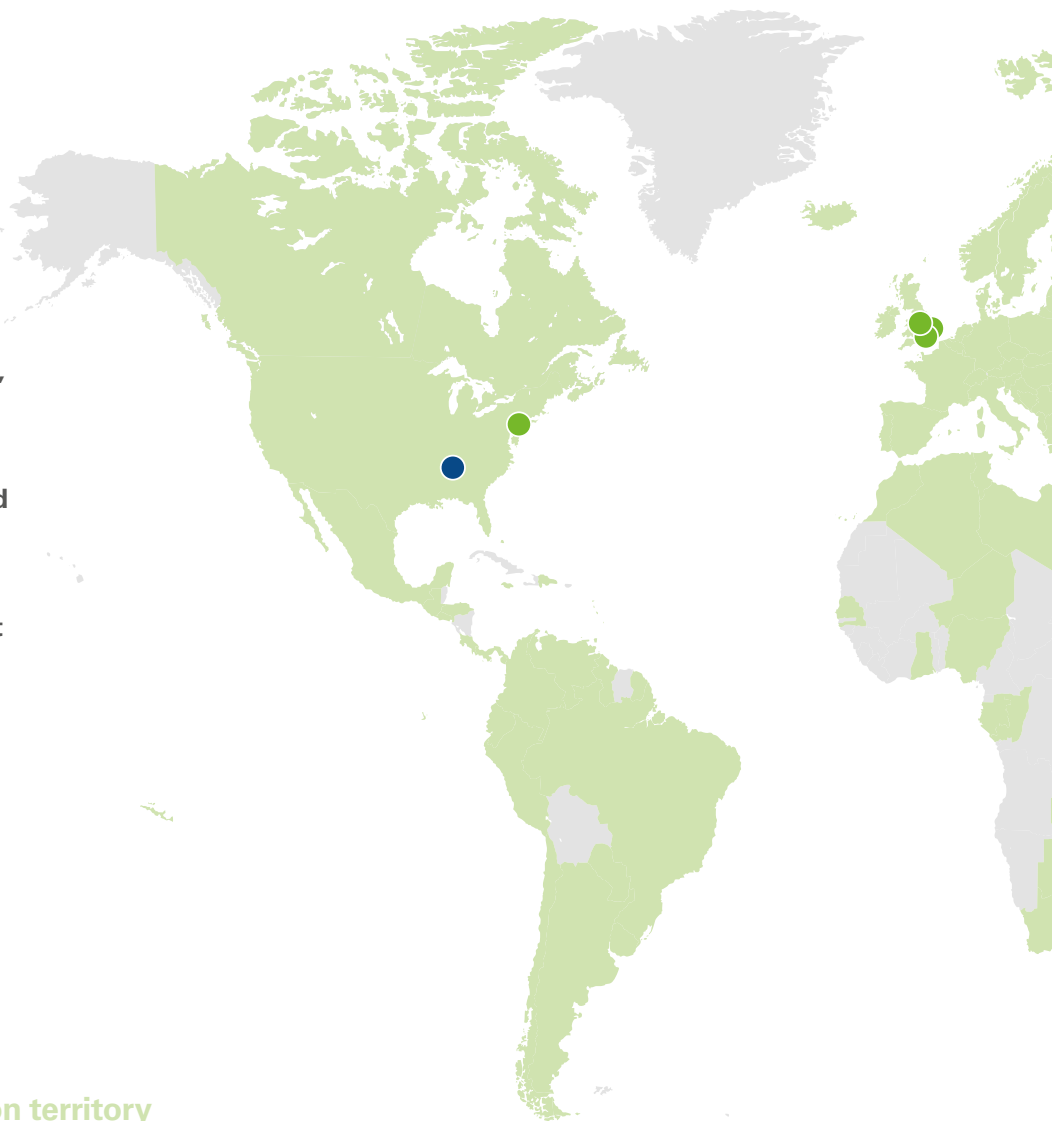
<sup>1</sup> The adjusted earnings per share is based on underlying profit after tax adjusted for amortisation and associated tax for the year and the weighted average number of shares of 87,242,269

# Extending our global footprint

Growing our geographical presence and harnessing our global networks are key strategic priorities for us as they strengthen our capability to ethically deliver the right drug to the right patient at the right time.

**Our global supply and distribution network enables us to manage the supply of medicines in more than 130 countries, ensuring the estimated 5.5bn patients around the world have access to the low or non-existent treatments they need. The proposed acquisition of Link will enrich our presence in the Asia, Africa and Australasia (the AAA region), enabling us to gain local expertise, beneficial relationships and heightened distribution management. Furthermore the strategic alliance with Cumberland Pharmaceuticals ('Cumberland') will build on Clinigen's existing North American relationships by providing complementary support in the development, marketing, promotion and distribution of future products in the US.**

We aim to continue with the organic and acquisitional growth strategy going forward, developing the global capabilities we now have in place, and enhancing the strategic alliance agreements we have in place which provide expansion both geographically and in product availability.



- Clinigen Group distribution territory
- Clinigen Group office locations
- Link Healthcare office locations
- Cumberland Pharmaceuticals office locations



## Delivering the right drug to the right patient at the right time



Operating businesses

4

Countries supplied

130

Units shipped – CTS

556,000

Units shipped – licensed

837,000

Units shipped – unlicensed

977,000

Total units shipped

2,370,000





# Chief Executive Officer's statement

Clinigen had a very strong year, advancing all its key strategic goals, including the acquisition of which has consolidated the Group's market leader position in CTS and taken it to global market leader in unlicensed supply. The recently announced proposed acquisition of Link will significantly strengthen our global footprint, particularly in Asia, Africa and Australasia. In addition our strategic alliance with Cumberland will build on Clinigen's existing North American relationships by providing complementary support from Cumberland in the development, marketing, promotion and distribution of future products in the US, with Clinigen supporting Cumberland outside the US.

It is also very satisfying to note that all operating divisions have contributed to growth; not only as shown in these audited results (10 months Clinigen plus two months with Idis) but, possibly more importantly for the underlying business, there is strong organic growth on a full year pro forma basis.<sup>1</sup>

## Overview of results

Overall sales at £184.4m showed 45% growth pro forma, with gross profit of £53.7m up 30%. On a pro forma basis, this was 27% and 24% growth respectively. All four divisions contributed to this growth with at least double digit organic profit growth on a pro forma basis; 17% for CTS,

38% for MA, 10% for GA and 26% SP. This indicates very strong underlying performance, validating our acquisition decision, furthermore we expect to see this strong performance carry through into FY16. The underlying EBITDA at £32.3m showed an impressive 20% growth, which remained strong at +25% on a pro forma basis.

The integration of the Idis business has gone very well. Both the CTS and MA divisions were fully amalgamated post-acquisition seamlessly with immediate effect. The Idis Clinical Trial Procurement (Idis CTP) business was quite small and rolled up into Clinigen's CTS business very easily. With MA it was the reverse,

1. Year on year comparisons, referred to as 'pro forma' are calculated from the aggregated unaudited results taken from management information of both Clinigen and Idis, for the 12 months ended 30 June 2015 and for the 12 months ended 30 June 2014, respectively. Pro forma information is being presented to aid the reader's understanding of the enlarged group's combined performance.



“There is a global healthcare crisis related to access to medicines which **Clinigen is well positioned to address.**”

**Peter George**  
Chief Executive Officer

#### Overall sales

**£184.4m**

⬆ 45%

#### Overall gross profit

**£53.7m**

⬆ 30%

Clinigen's smaller managed access business (Clinigen GAP) was rolled into Idis' MA business, again easily. The immediate full integration leaves it impossible to distinguish between the legacy business unit's activities and their performance which has been fully combined for the final two months of FY15 and going forward into FY16. Both SP (Clinigen alone) and GA (Idis alone) were unaffected by the combination of the businesses as they had no counterpart in the respective business.

### Our people and values

We try to instill in our people an understanding that the patient, who is the ultimate beneficiary of our products or services, should be thought of as a friend or family member; if we do that we are motivated to care more, if we care more we are all motivated to provide outstanding customer service and the patient and healthcare professional receives a world-leading customer experience. This has been recognised in 2015 with the Service Mark Award from the Institute of Customer Services for World Class Customer Service. During this survey the Clinigen culture was described as 'unique and as 'feel it, not see it' which resonates throughout the various departments and teams'. This is an approach and accolade we are very proud of.

Clinigen has a culture of rewarding its employees for working hard and going the extra mile. We do this in many different and novel ways, with individual awards and group experiences that recognise their efforts: if they give us their goodwill we repay it with ours.

### Market positioning

Since its inception just five years ago, Clinigen has had a clear mission: to get the **right drug** to the **right patient** at the **right time**. One key observation has driven our strategies to achieve this, which is that some 80% of the world's population, an estimated 5.5bn people, have low or non-existent access to medicines, many of which are essential medicines. This global health and medicines crisis has occurred for many reasons, some of which we have seen as opportunities to build a high-growth global pharmaceutical company.

As discussed in the market overview on pages 10 to 11, there are many reasons why there is high unmet need across the world. Consequently, there is increasing demand for medicines not necessarily available or licensed where the patient is being treated; these are the drivers behind Clinigen's specialty pharma and unlicensed supply businesses.

### Acquisitions

Clinigen's acquisition of Idis in April 2015, our strategic alliance with Cumberland and recently announced proposed acquisition of Link are all aimed at addressing this global health and medicines crisis and reaching our stated ambition, as outlined in last year's annual report; 'to become a recognised world-leading specialty pharmaceutical company, with an unrivalled global distribution capability for licensed and unlicensed medicines'.

Idis was acquired through a placing which raised £135m and by £106m of new debt. The acquisition fulfilled a number of Clinigen's strategic goals, including accelerating Clinigen to market-leader status in the unlicensed supply of medicines, adding commercialisation opportunities for SP and becoming market-leader in clinical trials supply.

Clinigen is looking to become the 'go to' ethical provider of good quality unlicensed or short-supply medicines on a global basis. This service will be targeted at the healthcare professional (the pharmacist, the key opinion leader) managing those difficult to treat patients under their care, wherever they are in the world.

## Chief Executive Officer's statement continued

The combination of Idis' brand and market-leading status and Link's local knowledge and distribution capabilities in the AAA region, with Clinigen's reputation and hub and spoke distribution network, including Cumberland, makes the new larger organisation a strong global leader in this sector and capable of shaping the market.

### Progressing our strategy

These businesses together with CTS's market-leading position in clinical trial drug supply and SP's revitalisation model for niche hospital-only drugs, makes the Group unique. There are only three routes to get a medicine into a human subject: as part of a clinical trial, as a licensed marketed drug or as an unlicensed medicine, and Clinigen is the only company that manages the supply of all three routes to market.

In last year's annual report we also stated that 'two key strategic goals will be prioritised in FY15: the strengthening of the Group's global capabilities and the revitalisation of the new products in our portfolio'. We have made great strides in progressing both of these.

Firstly, all four operating businesses will benefit from the strengthening of the Group's global footprint. Whether it is licensed and unlicensed product distribution or clinical trial sourcing and distribution, greater global capabilities are a benefit. This is true whether it be in developed markets like North America where we are establishing a strategic alliance with Cumberland to manage our future Specialty Pharmaceuticals assets or emerging markets where we have acquired Link to strengthen our footprint in the AAA region (Asia, Africa and Australasia).

Secondly, revitalisation: Clinigen's newer assets (Cardioxane, Savene and Ethylol) are all progressing to plan. The biggest single project is the lifting of the EMA Article 31 referral in place on Cardioxane. In 2011, prior to our ownership, the referral led to a significant decrease in Cardioxane's usage when the contraindication for use in children and adolescents was imposed. In our pursuit to have this lifted, we have gained significant support from the academic community and have taken our case to the EMA through the Agence Nationale de Sécurité du Médicament (ANSM), as France is the reference member state for Cardioxane. We await a final timeline for the review outcome but expect it to be in the next six months. Savene is now fully under Clinigen's control and the transfer of manufacturing for Ethylol is proceeding to plan.

### Looking ahead

#### Our markets, trends and developments

Clinigen operates in two clearly defined, reasonably well recognised, markets and one less defined but rapidly developing sector.

Clinical trial services and drug supply is well defined, continues to grow strongly with many trends that drive outsourcing to global specialists like Clinigen. As the market-leader in the sector, we have identified areas of underserved needs where we are well positioned to provide a range of higher value services to our customers, enabling us to differentiate and stay ahead of our competitors. For example we can offer more 'just in time' and demand-driven labelling and delivery services; smarter supply and distribution solutions which avoids waste of unused products and our

first agreed programs will start in FY16. Also with the changing nature of the clinical trial environment specialist sourcing and the generation of Real World Data, we have the opportunity to provide direct to site services. These services started in FY15 and to date we offer this to eight companies, covering 22 active studies, supplying 33 medicines to 252 sites, we expect this to grow in FY16 also. This discreet market is estimated to be worth around \$1bn and growing.

The specialty pharmaceutical market is also clearly defined and Clinigen is a niche player, supplying hospital-only medicines. Clinigen takes a different position to most competitors insofar as we target mature medicines which we think could be revitalised and returned to growth. The potential to acquire such assets remains strong and we will continue our pursuit of building our portfolio to ten assets over the next five years.

The market for the supply of unlicensed medicines is less well defined. Through Idis MA, Clinigen enables access to newly-developed medicines at the pre- or early-marketing stage. Here we are supporting the pharmaceutical companies developing these medicines and the clinicians who want early access to new treatments. Idis MA is by some way the global market-leader in this sector and currently most direct competitors are local and small. CROs (Contract Research Organisations) are exploring this market sector and it is possible that a number may become competitors over the coming years.

However, there is another sector of unlicensed medicines supply which is driven by the prescriber or hospital pharmacist. This sector is rapidly growing, in no small part due to increased patient and clinician awareness of therapies available to treat disease but not necessarily licensed or in stock where the patient is being treated. Clinigen has sized the addressable global market here as \$5bn annually and currently, so far as we are aware, no one is offering a credible ethical global solution. Through GA, it has supplied circa 1,600 different products in the last 12 months, with over 1,300 held as stock lines, to 3,000 different customers, of which over 1,000 are hospitals, in over 70 different countries. But this is just scratching the surface of this huge unaddressed market. The Group already supplies over 5,000 hospitals in more than 130 countries through its MA and SP businesses and we are making these aware of our GA services also. In addition the Link acquisition will significantly enhance our 'local capabilities' in this 'global' service offering. Clinigen wants to become the 'go to' provider of high-quality ethical unlicensed or short-supply or withdrawn medicines on a global basis and we intend to develop our strong Idis GA brand and Link businesses to enable us to achieve this goal.



**Peter George**  
Chief Executive Officer  
24 September 2015

## LEADERS. Ethical

# UNLICENSED MEDICINE MARKET – OPPORTUNITY FOR CLINIGEN AS THE LEADING ETHICAL SUPPLIER

- 
- ➔ **80% of the world's population, an estimated 5.5bn people, have low or non-existent access to medicines, many of which are essential medicines.**

### **'Unethical' unlicensed supply**

- Market size estimated minimum of \$5bn
- Internet pharmacy, uncontrolled import, direct to patient, parallel import, illegal medicines
- Some estimates range up to \$200bn for counterfeit medicines

### **Ethical on-demand unlicensed supply**

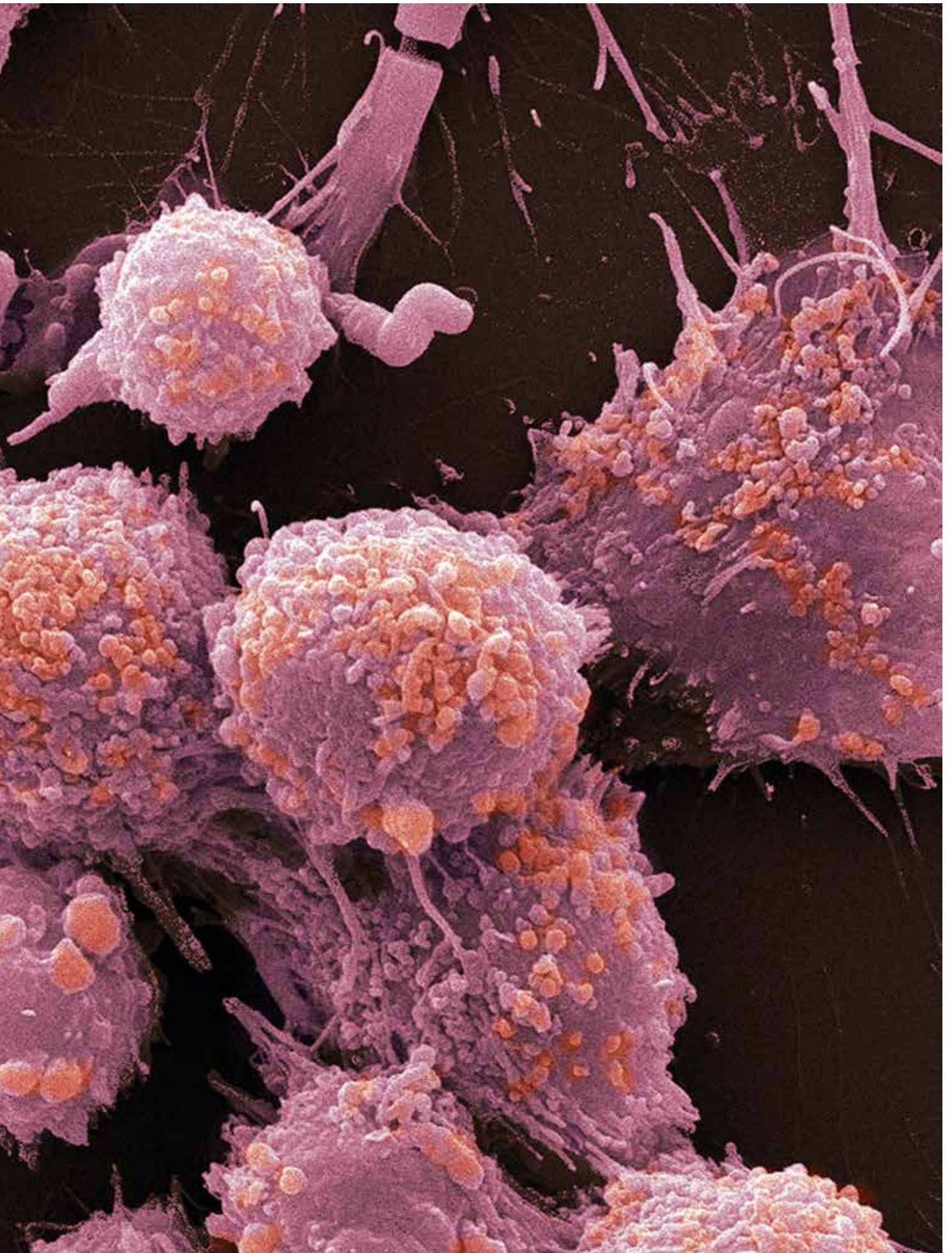
- Market size c.\$2.2bn
- In Europe, GA dominates
- In RoW, demand met by local wholesalers and agents
- An ethical supplier can offer a compelling wider solution

### **Exclusive managed access programs**

- Market size c.\$500 – 600m
- MA are the market-leaders
- A significant proportion of this is managed in-house and some early access by CROs

Prostate cancer cell





# Market overview

## Huge Potential

### Exclusive managed access programs

Market size c.\$500–600m

Extended access (non launch)

Early access

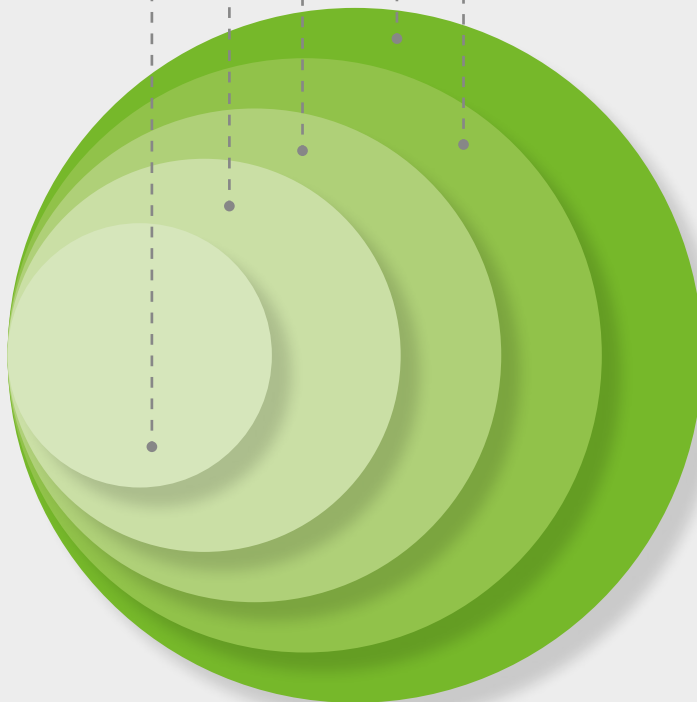
Mature access


### General unethical unlicensed supply

Market size estimated minimum of \$5bn

### Ethical on-demand unlicensed supply

Market size c.\$2.2bn



 To read more about our risks see page 38

## Unmet need

80% of the world's population, an estimated 5.5bn people, have low or non-existent access to medicines, many of which are essential medicines.<sup>1</sup> This global health and medicines crisis is the result of many factors; where the patients live or are being treated, the type of drug they require, the war on narcotics has restricted access to certain pain medications, it may be because of the disease they suffer from, or drug resistance, discontinued production of unprofitable existing medicines or the prohibitive price of many drugs. Globally, greater patient knowledge, population growth, the increasing elderly population and incidence of chronic diseases, as well as higher disposable incomes are all factors driving demand for medicines not necessarily licensed where the patient is being treated.

Whichever of these reasons is paramount, there is a high global unmet need for the ethical supply of good quality unlicensed medicines.

## Counterfeit medicines

This unmet need has created an opportunity for criminals who produce and supply counterfeit or sub-standard medicines. This has resulted in profit margins for counterfeit medical products often being higher than for narcotics. In an article published in December 2014 by the Guardian, the World Customs Organisation highlighted that the global market for counterfeit drugs was worth \$200bn (£130bn). This supersedes the prostitution market and the heroin and cocaine markets, which are worth \$160bn.<sup>2</sup>

Visually, it can be almost impossible to tell a counterfeit medicine from a genuine one which makes it easy for some falsified drugs to enter the supply chain. When a counterfeit version of a cholesterol-lowering drug was discovered in the UK in 2005, only 40% of the 120,000 products recalled from almost 240 pharmacies were found to be genuine.<sup>3,4</sup>





An estimated 50% of all drugs sold online are falsified drugs. In emerging economies counterfeit drugs account for 10% of the total medicines market; the proportion is 20% in the former Soviet republics and in Latin America, South East Asia and Sub-Saharan Africa an estimated 30% of medicines are fake.<sup>5</sup>

One of the major challenges of addressing the issue of counterfeit medicines lies in their wide geographical distribution. The OECD reported that during an investigation, the same counterfeit drugs manufactured at one plant in China were being sold in over 40 countries.<sup>6</sup>

Borders and customs agencies have taken action to tackle the illegal trafficking of counterfeit medicines; in 2006 EU officials seized 2.7m items. In 2008, a two month operation codenamed MEDI-FAKE confiscated 34m counterfeit items ranging from antibiotics to erectile dysfunction drugs, and including chemicals used in their manufacture.<sup>7</sup>

### Internet pharmacies

Internet pharmacies are also targeting this high unmet need. Most internet pharmacies are not ethical and do not require a prescription to supply. In addition, the medicines ordered on-line are often dangerous drugs which, when self-prescribed pose a serious health risk. According to the US Drug Enforcement Agency, 85% of internet drug sales are controlled drugs but only 11% of those drugs are available through traditional pharmacies. The European Alliance for Access to Safe Medicines (EAASM) estimates that 62% of websites which conceal their physical address supply counterfeits.<sup>8</sup>

According to a 2012 report and data collected from 2008-2012 by the US-based National Association of Boards of Pharmacy (NABP), 96% of approximately 9,000 websites reviewed were not compliant with state and federal laws, pharmacy practice, and/or patient safety standards, therefore posing a significant risk to consumers.<sup>9</sup>

Surveys undertaken in the US around brand infringement for six prescription only medicines (POMs), found 110,000 fraudulent sites and 2,986 online pharmacies. Most were hosted in the US, China and Russia, with 12% in the UK. Estimates of annual sales through such sites increased from \$4bn to \$12bn in 2007 to 2008. These sites declared fake accreditation, rarely required a prescription or sold drugs at significant discounts compared with genuine sources.

### Global economy

80% of the world's population live in Africa, Asia and South America, the vast majority of these people have low or non-existent access to medicines,<sup>10</sup> accounting for only 10% of the global pharmaceutical market sales. Five of the eight fastest growing economies fall into these regions, however, many of these countries do not recognise intellectual property rights or have poorly defined regulatory systems in pharmaceuticals. As a result, if a patient is able to gain access to a medicine, the risk of that medicine being sub-standard or a counterfeit is significant.

Global political policy can further restricted access to certain medicines. The licensing and monitoring of certain types of drug, such as narcotics, is rigorously controlled with complex and demanding standards of compliance. This, coupled with concerns about the security of the supply chain for legal drugs and the threat of their being used illegally, prevents many countries who lack the expertise and resources from meeting the standards required.

As an example, Talking Drugs reported in April 2015 that 92% of the global usage of morphine, which has been named an 'essential medicine' by the World Health Organization is concentrated on just 17% of the world's population, all of whom live in wealthier countries that can afford to meet the strict regulatory and logistical standards. This leaves 150 countries with very limited or no access to morphine at all.<sup>1</sup>

In addition, predominantly profit driven R&D also means that research into the health needs of people in developing countries has come to a near standstill.<sup>2</sup> An assessment of 2,257 new products that were brought to market in France between 1981 and 2000 showed that 63% of new products were 'me too' drugs which are structurally very similar to an already existing drug with only minor differences, and only seven products (0.13%) represented real therapeutic breakthroughs. In the US, less than 5% of the drugs introduced by top twenty-five pharma were therapeutic advances. Of these, 70% were developed with government involvement. Similarly, 68% of the 1,393 new chemical entities registered worldwide for marketing over the prior 25 years were classified as 'me too' drugs, only 1% were for tropical diseases and tuberculosis; diseases that together account for over 11% of the worldwide disease burden.

### Environmental growth drivers

- Rapid innovation in drug development
- Internet, social media, advocacy groups
- Publications, press releases, online communities
- Patients and families more educated and empowered than ever before
- Physicians who are motivated by their empowered patients to help gain access to new medicines
- Increased demand to find alternative routes to access innovative new drugs

### New legislation

Following the introduction of 'Right to Try' legislation in early 2014, more than 20 states in the US have introduced so called these bills, and a similar number are in the process of introducing the law. Right to Try aims to provide a legal framework to allow terminally ill patients to request access to experimental, and potentially life-saving treatments more easily. The legislation was developed as an additional route to access to the US Federal Drug Administration's (FDA) 'Compassionate Use' process which has recently been reviewed to vastly simplify the application process, making it faster for physicians to apply for compassionate use to unlicensed medicines for their patients. Idis MA has been working with pharmaceutical and biotech companies in the US to provide compassionate access to their drugs for a number of years and is well placed to support companies with the potential increase in requests for access as a consequence of both the FDA and Right to Try legislation.

In early August this year, the US court ruled in favour of a pharmaceutical company in a case against the FDA where it accused the regulator of suppressing its First Amendment rights in off-label drug use. This decision is expected to have wide-reaching implications for pharmaceutical marketing practices in the US. Although the ruling does not broadly allow drug makers to market off-label information about their products, even if it is truthful and misleading, it does create a pathway that other companies can follow to reach a similar decision in the same legal jurisdiction.

1 [www.talkingdrugs.org/dying-for-relief-access-to-pain-medication](http://www.talkingdrugs.org/dying-for-relief-access-to-pain-medication) 24 April 2015

2 [www.theguardian.com/society/2014/dec/28/drugs-medicines-sold-illegally-online-internet](http://www.theguardian.com/society/2014/dec/28/drugs-medicines-sold-illegally-online-internet)

3 UK Parliamentary Office of Science and Technology – Postnote, January 2010, Number 352

4 [www.mhra.gov.uk/index.htm](http://www.mhra.gov.uk/index.htm)

5 World Health Organisation, [www.who.int/en/](http://www.who.int/en/)

6 OECD, The Economic Impact of Counterfeiting and Piracy, 2007

7 Community Customs Activities on Counterfeit and Piracy: Results at the European Border, EC Taxation & Customs Union, 2007

8 <http://www.eaasm.eu/cache/downloads/5dhbepyu124gkoc4kgsW48os/PPP%20to%20print%20FINAL.pdf>

9 NABP Reports, 2012 [http://www.nabp.net/programs/assets/IDOI\\_Report\\_01-12.pdf](http://www.nabp.net/programs/assets/IDOI_Report_01-12.pdf)

10 Patrice Trouiller et al, Drug development for neglected diseases. A deficient market and a public health policy failure, 359 The Lancet 2188 (2002)



**LEADERS. Unique**

# UNIQUE COMBINATION OF BUSINESSES

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## ➔ Evidence of strategic opportunity

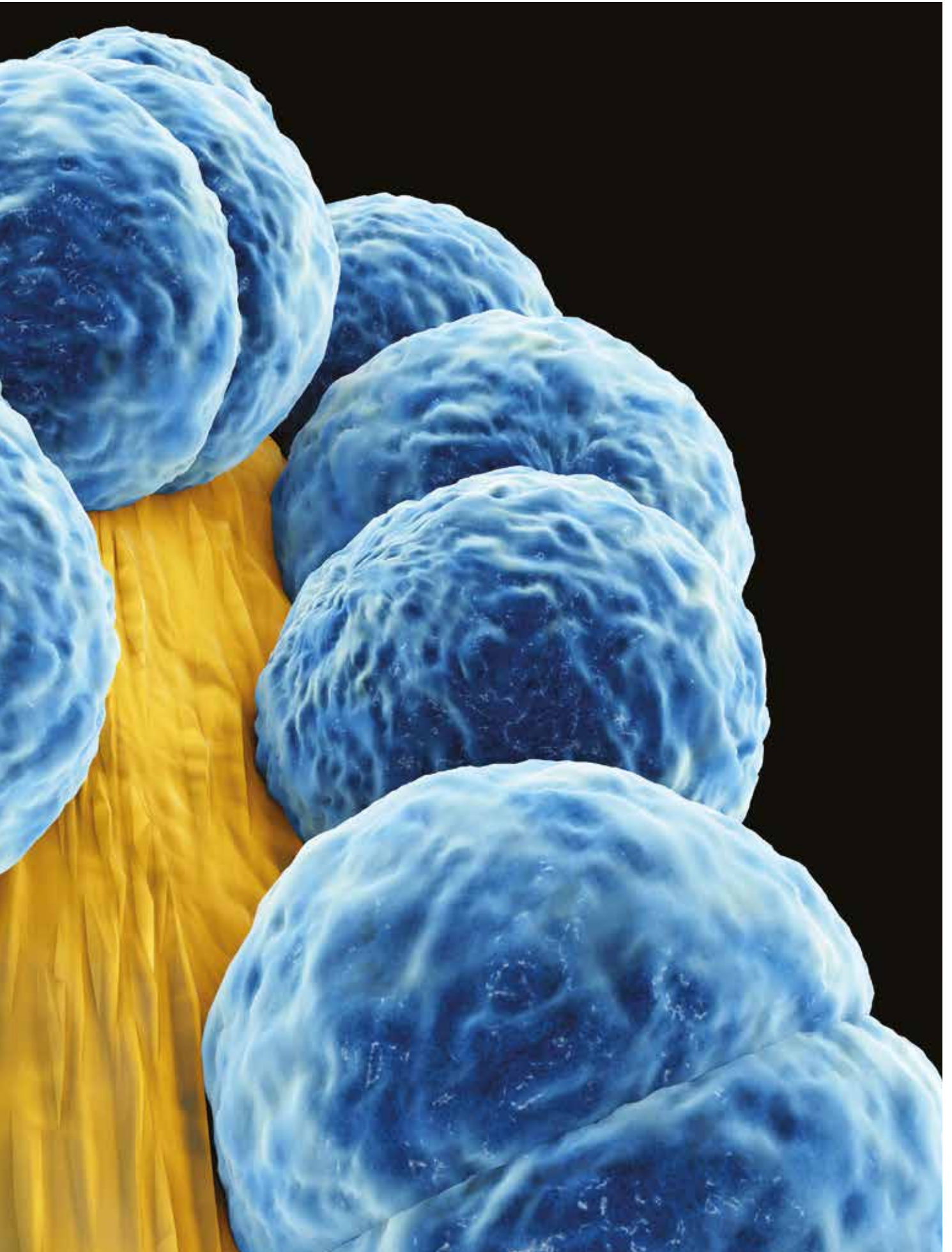
Clinigen's combination of businesses is unique, in an industry that is typically divided into pharmaceutical companies and service businesses, we have both, providing global access to medicines across all three routes to a patient. It allows us to get licensed and unlicensed medicines to patients all over the world, whilst also understanding the challenges of our customers.

Idis has enriched the unique combination of businesses with the addition of GA and the expansion of MA and CTS. Providing access to a wider customer base and additional programmes with top 25 pharmaceutical companies. The new enlarged Group provides access to many more early stage medicines.

Link and Cumberland will enhance the unique combination of businesses, providing further global reach and enabling more efficient distribution to healthcare professionals in North America, Asia, Africa and Australasia.

We use our expertise and resources to assure every step of our service and supply is efficient, effective and ethical. Our 24/7 support teams ensure patients in extreme circumstances will get the treatment they need. We also care for products closely and guard against any risk of counterfeit products entering the supply chain.

MRSA cell



# Our business model

- ➔ **There are only three ways for a patient to ethically access a drug and we are the only company to globally manage access to all three routes.**
- ➔ **We add insight, expertise and value at every stage of the product lifecycle.**
- ➔ **Critically, our ability to manage licensed and unlicensed medicines is what truly differentiates us.**

Our complementary set of businesses works across a medicine's lifecycle: sharing customers, opportunities and expertise. We source and supply our own and other pharmaceutical companies' products in licensed and unlicensed territories. We provide comparator drugs and a range of services for Clinical trials and we also acquire, license and revitalise niche, critical-care medicines worldwide.

## Our resources and relationships

Our values

Our people

Our expertise

Our global scale

Our partners

Resources

## Our businesses

**Clinigen Clinical Trial Services**

**Idis Managed Access**

**Idis Global Access**

**Clinigen Specialty Pharmaceuticals**

**Clinical development phase**

**Regulatory and marketing launch phase**

..... Across all stages of the

**We are committed to the patient and meeting their needs; this underpins every aspect of our business.**

#### **We source**

We supply and manage quality-assured comparator drugs and other commercial medicines for patients in clinical studies around the world, including comparator drugs, adjuvant and rescue therapies.

#### **We provide**

We enable high-quality ethical access to unlicensed medicines, working with pharmaceutical companies, pharmacists and physicians to provide critically-ill patients access to potentially life-saving treatments.

#### **We revitalise**

We acquire the rights to and then revitalise essential, niche medicines worldwide.

### **Operating model**

**Provide a unique combination of niche products and services**

**Across our global distribution network**

**Build relationships with customers and KOLs, gain insight from them and provide unrivalled customer service**

**Regulatory and logistical expertise ensuring timely supply to critically ill patients anywhere in the world**

### **Outputs**

**Shareholder returns**

**Financial returns**

**Employee job satisfaction**

**Benefits to customers and patients – ultimately saving lives**



**Supply and late stage product withdrawal phase**

**product lifecycle**



## Our business model continued

We serve an extensive customer base of contract research organisations, pharmaceutical companies and healthcare professionals through a set of diverse but interconnected businesses with a common operating platform.

### ➔ Clinigen Clinical Trial Services (CTS)

- World-class clinical trial services
- Global reach with local expertise, connections and a track record of excellence through understanding of complex regulatory environments and specialist knowledge
- Robust and secure specialist supply chain, audited and tightly controlled to eliminate the risk of counterfeit medicines
- Outstanding customer service with a dedicated team at each office providing global support in all times zones and multiple languages
- Wide range of expanded value services for clinical trial sites

### ➔ Idis Managed Access (MA)

- Truly global leaders and specialists in MA programs, developing ethical and regulatorily compliant strategic solutions to enable access to innovative early-stage medicines for pharmaceutical and biotechnology companies
- An international service and distribution network allowing a fast and efficient response to patient demand outside of traditional access routes
- Global network of partnerships to meet increasing demand for ethically-supplied unlicensed medicines, arising from greater patient knowledge, increasing and aging population and higher disposable incomes
- Risk mitigation by enabling centralised control over who will gain early access to medicines, helping reduce the potential risks associated with adverse event occurrences and product counterfeits
- Commercial launch readiness; we provide strategic insight to help identify global usage patterns which enables us to understand and resolve any supply chain challenges and harvest a wealth of additional information and data

### ➔ Idis Global Access (GA)

- GA is the leader in providing high-quality, ethical access to post-approval and short-supply medicines and the go to solution for pharmacists and physicians, meeting a currently unmet patient need
- Growing international distribution network to meet the demand of pharmacists and physicians for medicines not available in that particular country
- Strong expertise and local knowledge of regulatory frameworks required to effectively access post-approved medicines into regions where they are not commercially available
- Ability to leverage unlicensed supply to avoid drug shortages for pharmacists, physicians and pharmaceutical companies
- Supplies high-quality medicines sourced directly from pharma companies to ensure consistency and quality
- Provides niche drugs to meet high unmet medical need, focused on medicines for hospital-based oncology, anti-infective, orphan and other crucial drugs

### ➔ Clinigen Specialty Pharmaceuticals (SP)

- SP acquires the rights to and then revitalises essential niche medicines, maintaining access and upholds the product's reputation by maintaining patients' access to the medicines they rely on
- Unique global capability and able to operate anywhere in the world, in both licensed and unlicensed markets
- The revitalisation model is key opinion leader and hospital driven and expertise includes logistical, regulatory and global market intelligence enabling SP to take on a medicine in its entirety – giving our partners the opportunity to divest to a single, responsible new owner with a single, global solution

## Synergies



### Clinigen CTS

CTS raises awareness of ability to source and supply pre-approval drugs outside of a clinical trial environment via MA. CTS also provides MA and GA with valuable access to relationships gained through its operations in the clinical trial market.



### Idis MA

MA has helped CTS expand their knowledge on the additional services that can be offered for clinical trials. MA provides GA with relationships and insights gained from the pre-approval through to the phased launch markets which enables GA to continue the supply chain for unlicensed medicine and meet the unmet needs of the patient.



### Idis GA

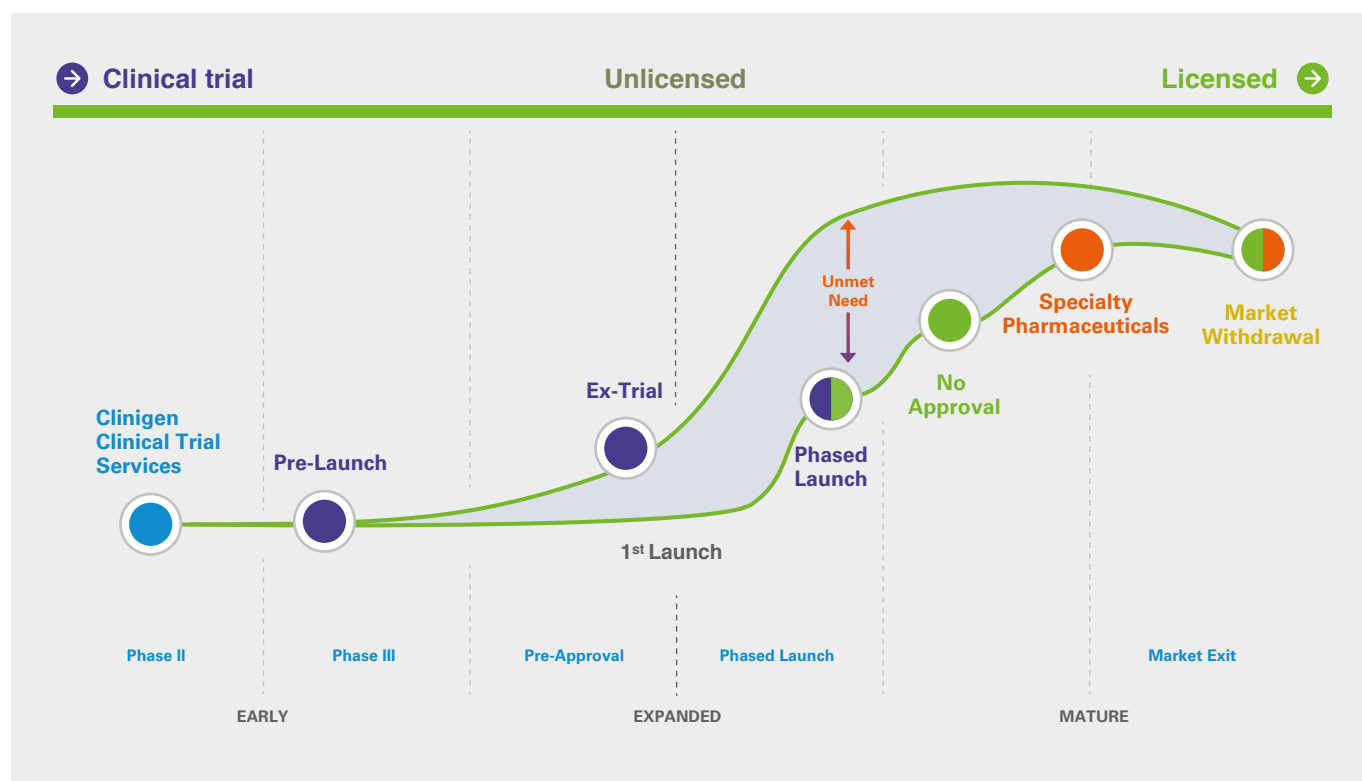
Provides the Group with significant opportunity to expand in the pharma emerging markets and become the ethical supplier of choice in a number of such countries. GA also contributes relationships and insights gained from late-stage product withdrawals to SP in order to identify potential candidates for acquisition.



### Clinigen SP

Shares experience of regulatory, pharmacovigilance and quality systems gained as a specialty pharmaceutical company, with CTS, MA and GA.

## Access across the lifecycle



## Our business model continued

### Synergies and strengths

The combination and synergies between the divisions of our unique business model bring key benefits to maximising value for the Group. However, the difference goes beyond our business model; many cultural qualities set us apart from the rest.

#### People

Our impressive in-house capabilities ensure consistently high-quality and the best service across all aspects of our business. Our people are motivated, highly skilled and dedicated to what they do. We have been recognised by Investors in People as a Bronze company, an accolade awarded to just 3% of Investors in People companies, and our multilingual customer service team received the prestigious ServiceMark accreditation in 2015 from the UK's Institute of Customer Service.

#### Supply

Clinigen has unparalleled knowledge and expertise of the complex global supply chain environment. We deliver to customers in more than 130 countries, each with its own unique legal and regulatory environments. We ethically provide access to licensed and unlicensed medicines by sourcing products from approved suppliers only, ensuring a safe, temperature-controlled, rapid journey from origin to destination. We test every route in and out of a country to anticipate any customs and practical issues, to ensure it is feasible before taking on a project, and we will only accept a route if it can be used in accordance with UK and local country regulations.

#### Relationships

We have a successful track record of working closely with clients, distributors and key opinion leaders. This has helped us gain several exclusive relationships for the supply of clinical trial comparator medicines and has enabled us to count Astra Zeneca as a partner across three of our four businesses. We are proud to count 19 out of 25 of the world's top pharmaceutical companies as our clients.

#### Reputation

We are a recognised leader in the supply of unlicensed medicines. In a recent, external survey, clients from all over the world reported that they found Clinigen easy to do business with, while doctors and pharmacists find the Group a valuable source of information about how to access the medicines they need for their patients.

#### Insight

The combination of businesses we have is unique. It provides us with insight across the product lifecycle. In addition, we believe that no other company can match our knowledge and expertise of the complex global supply chain environment that is required to get medicines to where they are needed fast, wherever in the world that may be.





# Key performance indicators

The Board utilises a number of key performance indicators to enable a consistent method of analysing performance, in addition to allowing the Directors to benchmark performance against similar businesses and the Group's business plan. The key performance indicators utilised by the Board can be split into both key financial performance and non-financial performance indicators.

## → Group performance

### The key financial performance indicators are:

#### Gross profit by operating business

Measures the profit achieved on sales after taking account of the direct costs incurred in bringing the goods to the point of revenue recognition and includes the cost of goods, selling and distribution costs.

Senior management are measured internally on both gross profit and gross profit percentage to ensure an appropriate return on investment.

All the operating businesses show year-on-year growth in gross profit. Details can be seen in note 3.

#### Underlying EBITDA

Measures the profit achieved on sales after taking account of the direct costs and overheads but before interest, depreciation, amortisation and non-underlying costs as defined in note 6.

#### Gross profit

**£53.7m**

15		53,651
14		41,203
13		35,123
12		29,032

#### Increase on underlying EBITDA

**+20%**

The Group achieved an underlying EBITDA for the year of £32.3m representing a 20% increase on the prior year.

#### Working capital

As the Group continues to expand, the servicing of debt and ensuring funds are available for acquisitions has led to increased focus on working capital. Specific internal KPIs focus on: managing stock levels appropriate for each division's business requirements whilst ensuring products do not go into short-supply; debtor days; and ensuring payment of creditors within agreed terms.

A large proportion of Clinigen's business relies on being able to supply hard to source products, therefore Clinigen's reputation, relationships and timely payments are all important.

### The key non-financial performance indicators are:

#### Acquisition of further products

Clinigen has an acquisition strategy in place. The Group has made one acquisition this year, Ethyol, which is on track with the revitalisation plan. The number of products in its own portfolio remains at five and senior management continue to explore acquisition opportunities.

### To become the global go to provider of unlicensed and short-supply medicines

78% revenue growth in MA and the acquisition of Idis establishes the Group as the global market leader in the provision of managed access programs. The Idis acquisition also created for the Group, the GA operating business which provides unlicensed medicines driven by on demand. In addition, the proposed acquisition of Link will enable the further expansion of the supply of unlicensed medicines into the AAA region.

#### Expansion of customer base

As referred to in the Operational Review, CTS and MA have expanded their customer base during the year. In addition, GA introduces new customers to the Group. Opportunities of utilising the expanded customer base across the four operating businesses will be reviewed in FY16.

Overall, the Directors are satisfied with the Group's progress against its key performance indicators for the year.



**LEADERS. Fast growing**

# STRONG ORGANIC AND ACQUISITIONAL GROWTH

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## ➔ Evidence of strategic opportunity

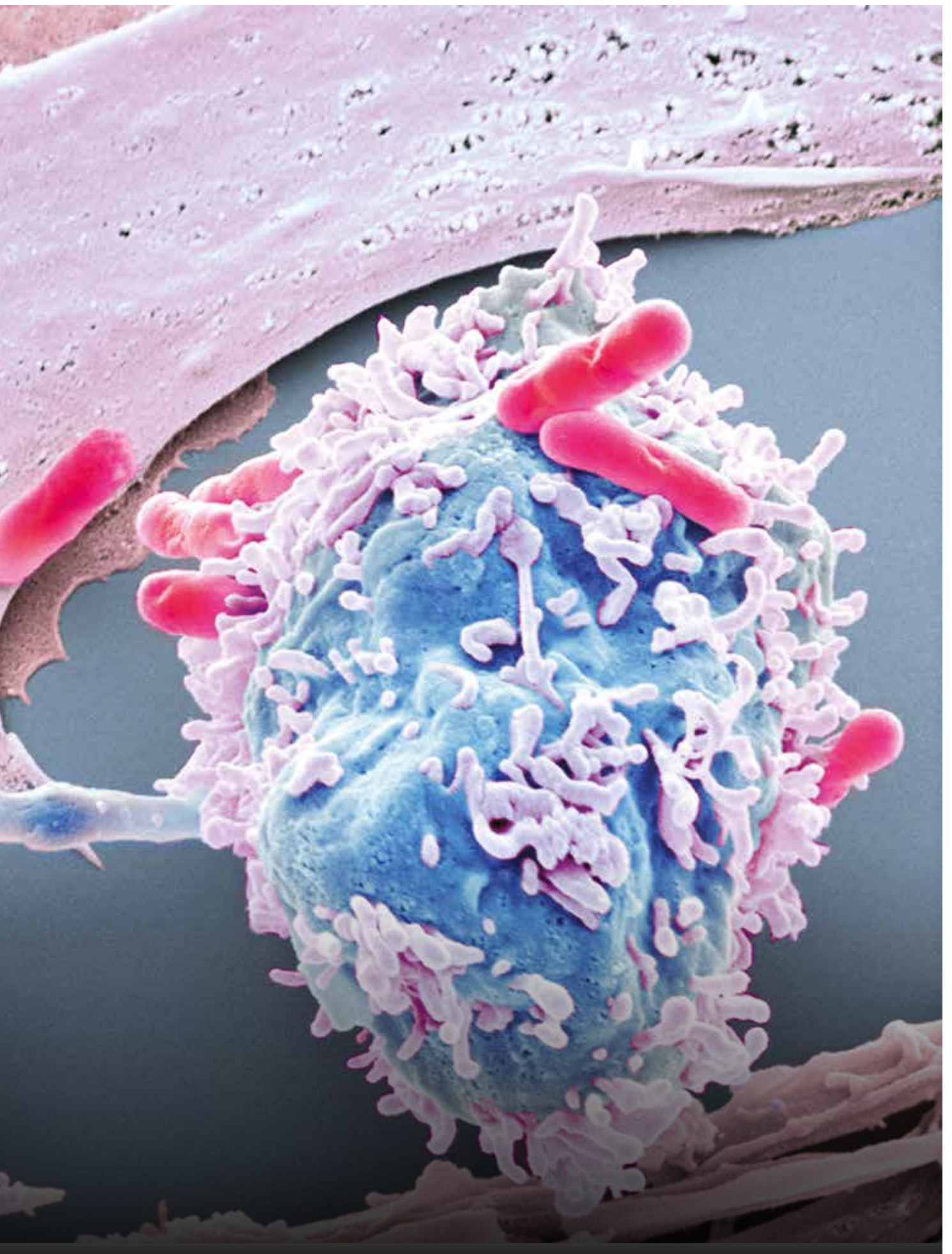
Clinigen's recent acquisition of Idis and proposed acquisition of Link are both aimed at addressing the global health and medicines crisis and reaching our stated ambition, as outlined in last year's annual report; 'to become a recognised world-leading specialty pharmaceutical company, with an unrivalled global distribution capability for licensed and unlicensed medicines'. Idis' brand and market-leading status, Link's local knowledge and distribution capabilities in the AAA region, together with Clinigen's reputation and hub and spoke distribution network, makes the new larger organisation a strong global leader in the unlicensed medicine sector and capable of shaping this market.

These businesses together with CTS's new market-leading position in clinical trial drug supply and SP's unique revitalisation model for niche hospital-only drugs, makes the Group one of the fastest growing companies listed on AIM.

When Clinigen completed their initial public offering in September 2012 the market capitalisation was £135.4m, in just under three years the market capitalisation has grown to c.£800m.

Cancer cell







# Operational review

This year saw the business take two significant steps forward in terms of fully realising the increasing number of opportunities and synergies created by Clinigen's unique business model.

Firstly, the Idis acquisition extended the scope and scale of the business from three to four divisions – the acquisition creating a fourth division, GA. The Group therefore now operates through four synergistic businesses and this has only further increased our ability to share insights, knowledge and relationships that provide continued commercial benefits to the broader Group. While we had identified the 'on demand' unlicensed supply sector as a hugely significant growth opportunity previously, the introduction of GA rapidly accelerates our

ability to respond to this opportunity and establish an ethical global platform that can respond to pharmacists' underserved and unmet needs globally.

Secondly, as part of our stated strategy of increasing our global capabilities, we have spent the last year investing significantly in the people within the business particularly at the management and leadership levels to ensure that we have not just the right structure but also the right people to drive sustained and meaningful growth. Post-acquisition, each of the four business divisions is now led by a Managing Director and in these four individuals there is a collective and highly complementary senior industry expertise and experience. Together with adding management strength into all

key operational areas, we now have the bandwidth and capability to really shape and develop the markets we play in, further extending our market-leader positions in clinical trial services and the management of unlicensed supply of medicines while continuing to expand our portfolio of niche, critical-care pharmaceutical products.

No operational review of the year would be complete without commenting upon the integration post-acquisition. We embarked upon a 100 day process to identify and implement, where possible, integration synergies. This has involved a tremendous amount of effort across the entire business and what has been most impressive in the final quarter of the year was how well the two sets of



**This year saw the business take two significant steps forward in terms of fully realising the increasing number of opportunities and synergies created by Clinigen's unique business model.**

**Shaun Chilton**

Deputy Chief Executive Officer

people involved embraced the change management process, driving operational benefits immediately and being focused not just on the ongoing delivery of business but also working together to establish the foundations for one organisation. We have made rapid progress in some areas; fully amalgamated the two exclusive unlicensed supply businesses under the MA brand and the two clinical trial supply businesses under the CTS brand – and have begun work on a number of business critical longer-term projects including the Oracle ERP platform, a global e-commerce solution and centralising our Quality and Regulatory, Logistics and Customer Services capabilities.

**Shaun Chilton**

Deputy Chief Executive Officer

24 September 2015



## Operational review

### continued

## Clinigen Clinical Trial Services (CTS)



**Steve Glass**  
Managing Director, CTS

Steve has 25 years' experience in the international pharmaceutical and biotech industry. During this time he has held a variety of senior international commercial operations and business development roles, including most recently CEO and founder of Orbona Pharma Ltd. He joined us from Orbona in 2014, bringing insight, experience and a successful track record of product development to the team.

**Number of customers with sales greater than £5.0m has risen from five to seven.**

**It has been a significant year in the development of the CTS business division. The business performed well in FY15 against all key performance indicators compared to prior year. Strong revenue growth of 34% (45% on a pro forma basis) over prior year (£112.7m in FY15 vs £83.6m in FY14) was driven through a strong US performance and an increase in customers from 73 in FY14 to 85 in FY15. Significantly, the number of customers with revenues greater than £5m rose from five to seven in the year. CTS had 1,470 orders (2014: 1,590) to supply clinical trials with 820 different products sourced and supplied in FY15, a rise of 11% over prior year (2014: 741). Gross profit in absolute terms grew by 7% (£13.4m in FY15 from £12.6m in FY14), pro forma gross profit grew by 17.4% over prior year.**

The market dynamics for CTS remain very attractive. The global market for comparator

sourcing is estimated to be around \$2.5bn and is set for continued strong growth driven by: the global R&D pharma and biotech pipeline which is heavily weighted towards oncology, infectious disease and rare/orphan diseases all requiring comparators and co-therapies; the changing regulatory environment is driving the requirement for specialist partners; the more complex requirements of often difficult-to-source and manage large molecules and the rise in development of biosimilars, all points to continued double digit growth in the future.

As the market-leader in the sector, we have identified areas of underserved needs which we are well positioned to provide a range of higher value services for. The Tufts Centre for Drug Research has identified that 30 – 50% of all clinical trial drugs are either wasted, thrown away or remain unused at the end of a study due to inadequate sourcing and supply management decisions. By providing a more 'just in time' and smarter supply and distribution solution for all clinical trial drugs (including co-therapies and ancillary products), we are able to offer a comprehensive solution, a more valuable higher margin service. The changing nature of the clinical trial environment as evidenced by the increasing prevalence and importance of Investigator Initiated Trials (IITs) and the generation of Real World Data in this sector is also providing us with an opportunity to offer specialist sourcing, labelling and direct to site services. This discreet market is estimated to be worth around \$1bn and is growing.

In FY15, we have repositioned and restructured the CTS business and brand following the Idis acquisition and the subtle change of name to Clinical Trial Services reflects the fact that CTS now offers a greater range of services, reinforcing our market-leader status in this sector and establishing a platform to take advantage of the more sizeable growth opportunity in clinical trial supplies and associated services. In repositioning CTS, we have also created synergies with the MA division and the opportunity for collaboration in the management of those clinical trial patients who at the end of the trial require an access program solution.





## Clinigen Clinical Trial Services Key Performance Indicators

Strategic priority	What have we achieved this year	Our long-term goal
<b>Expand business with current customers</b>	18 customers over £1m in sales (18 in FY14), with seven over £5m (five in FY14)	Increase % of total annual spend in top 20 customers, deepen relationship with extended, value added services
<b>Target top 50 pharma, top 20 CRO's/repackers, niche/specialty pharma and biosimilars</b>	New business with key target pharma, CROs and biosimilar developers	Win key target global and regional customers over next three years; exploit business development synergies across the Group to drive new opportunities
<b>Extend value proposition through new services</b>	Direct-to-site delivery and specialist relabelling/repackaging services developed with cornerstone customers	Full launch globally of suite of complementary, higher margin value-added services
<b>Extend and expand global sourcing capabilities</b>	Added MSD to list of exclusive CTS agreements	Centralise our sourcing capabilities across the Group to maximise the combined entity's purchasing power
<b>Respond to changing nature of clinical trial environment</b>	Establish working group from Clinigen CTS and MA to review synergies	Formalise offering around collection of Real World Data and the shift of CTS to adaptive licensing, breakthrough designation and Investigator Initiated Trials

### Number of products

# 820

### Number of customers

# 85

### Number of units shipped

# 556,000

## CTS Case Study



Today treatment protocols are advancing so quickly that best-in-class medicines are sometimes not licensed, approved or available in the countries where clinical trial sponsors are running their studies. Not only is this an ethical dilemma it poses serious challenges when designing clinical studies. However, through our long standing relationships with pharmaceutical companies, our global

network of wholesalers, distributors and our sector-leading Quality, Regulatory and Logistics teams Clinigen is able to provide safe, ethical and reliable access to treatments, regardless of local licensing status or whether they are being used as comparators, co-medications or in the context of standard of care.

Multiple myeloma is a type of cancer affecting bone marrow, and despite advances roughly half of all those contracting the disease will die within five years of diagnosis. During this year CTS has been regularly supplying a pivotal Phase three registration study for an investigational new multiple myeloma treatment with all of the commercial drug, required to ensure the sponsor receives reliable product access and clean data. This is despite the comparator compound not being licensed or available in many trial countries.

Working with both the trial sponsor and the comparator manufacturer Clinigen was able to match demand forecasts to production schedules, significantly decrease standard lead times to manufacture and supply drug, and design a purchase plan that served to significantly reduce waste and overage. Quality, Regulatory and Logistics cleared the way to ensure that unlicensed medicine was not only approved for use in trial countries, but also that it was delivered to them at the right time and at the right temperature.



## Operational review

### continued

## Idis Managed Access (MA)



**Simon Estcourt**  
Managing Director, MA

Following a senior executive sales career in the pharmaceutical industry Simon joined Idis as Business Development Director from Quintiles in 2007. In 2010 he became Senior Vice President, Strategy & Corporate Development, a global role that included strategy, marketing, public affairs and new service development. Currently serving as Managing Director, Idis Managed Access, Simon is able to fully utilise his deep understanding of the environment and international landscape for managed access to lead and further develop the Idis service offering. He is a managed access thought leader and regularly speaks at international conferences on the subject of early access to medicines.

**We are building on our market leader position and raising the competitive barriers to entry even further.**

**The Idis acquisition allowed us to combine the Idis MAP and Clinigen GAP businesses under the Idis Managed Access brand, catapulting the Group into the global market-leader position in the exclusive managed access sector. Revenue growth shows a significant 78% increase (£28.8m in FY15 vs £16.1m in FY14). This is somewhat misleading as it includes two months of the larger Idis element, however, revenue growth on a pro forma basis was still a very impressive 35%. Gross profit also showed an excellent 53% growth (£8.3m in FY15 vs £5.4m in FY14), which on a pro forma basis managed to maintain a still very impressive 38%. Strong growth was also shown by the other key performance indicator of growth: the number of drug units delivered. In taking the combined businesses together, we saw an increase in deliveries to 418,000 units through 62,000 shipments up from 263,000 units from 40,000 shipments in prior year. As the market-leader in this rapidly evolving sector, we now have 99 products under active management and we are working with 19 of the top 25 pharmaceutical and biotechnology companies, shipping unlicensed medicines to 95 countries in FY15.**

The exclusive unlicensed medicines supply market is at a relatively early development stage, estimated to be c.\$500 – 600m annually and predicted to grow strongly at more than 10% a year. As the market-leader with around 30% market share, MA is a very powerful brand with an excellent heritage and having defined the current market (Idis developed the term 'managed access' which is now

the industry standard terminology used by customers) – it provides Clinigen with the opportunity to really shape the future direction of this market.

The key customers in this market are the global pharmaceutical and biotechnology companies and niche/orphan disease drug developers. Strong market dynamics are a marker for long-term sustained growth for the MA business and are driven by: rapid innovation in drug development and the focus of global Research and Development on areas of high unmet need (oncology/haematology; infectious disease; neurology and rare/orphan disease); changes in the regulatory environment facilitating access to unlicensed medicines; the increasing connectivity of the world's Key Opinion Leaders; and much more empowered and educated patients and their carers.

We are building on our market-leader position and raising the competitive barriers to entry even further, as we have recognised that there is an unmet need with key customers for a more strategic approach to assessing the opportunities and challenges involved in managed access, this is being further intensified by the increasing demand for access to innovative new drugs. MA is responding to these unmet needs by the development and launch of a number of strategic support services in FY16.

These services have been borne out of the insights only available to MA due to its long history and database of experience captured over the last ten years working with a significant proportion of the top 25 pharma companies. In adding these complementary strategic services (including policy development, forecasting tools and the capture and management of Real World Data) to the core business, we are creating sustainable competitive advantage and IP which will drive continued strong growth for the future.



## Idis Managed Access Key Performance Indicators

Strategic priority	What have we achieved this year	Our long-term goal
<b>Grow business with current customers</b>	Added more multi-program customers in FY15	All customers are multi-program; use MA contacts as a route to cross-sell Group products and services
<b>Target top 50 pharma</b>	Eisai, AstraZeneca & Boehringer Ingelheim added in 2014. Post Idis acquisition, now working with 19 of top 25 pharma	Increase annual % win rate for new business to greater than 50%
<b>Develop global footprint</b>	Extended capabilities to more than 90 countries and added US capabilities with Idis acquisition	Develop/acquire distribution and management capabilities in pharmerging markets
<b>Develop value-added services</b>	Developing a range of strategic support services	Full launch of a full suite of strategic services including data management (Real World Data), policy development and market insight reports
<b>Shape the future market by extending thought leadership</b>	Numerous publications and presentations at key events	Direct involvement in key industry, regulatory bodies and influence on global and regional policy development

## MA Case Study



Our client, a top ten global pharmaceutical company, was developing an innovative new treatment option for patients around the world with advanced melanoma and they were experiencing extremely high demand for pre-approval access from advocacy groups, patients and physicians. They required a strategic MA approach flexible enough to meet their evolving program objectives throughout each phase of the product development lifecycle.

The Company began their RFP process with more than 30 potential service providers, ultimately choosing Idis Managed Access (MA) over three large CROs because of our unsurpassed global experience and depth of in-house expertise in meeting high levels of demand for early patient access.

MA developed and launched a global Managed Access Program in 34 countries, providing treatment access to more than 4500 patients with a life-threatening condition across 600 sites.

Units shipped

**418,000**

Number of countries

**95**

Gross profit

**£8.3m**

⬆ 53%

## Operational review continued

### Idis Global Access (GA)



**Mark Corbett**  
Managing Director, GA

Mark joined Clinigen in mid-2010, on the acquisition of Idis by Clinigen in April 2015 Mark moved to be Managing Director of the newly acquired Idis Global Access. In this role he has overall commercial, financial and operational responsibility for Idis Global Access which specialises in compliant, ethical access to unlicensed medicines for healthcare professionals treating patients with unmet medical needs. Over the last eight years, Mark has specialised in the area of and has regularly spoken at a number of industry congresses on the subject of access to unlicensed medicines, Named Patient/Early Access/Expanded Access and Compassionate Use Programs.

**A major strategic driver of the Idis acquisition was to enable the Group to enter the 'on demand' ethical unlicensed supply and drug shortages market sector, a market estimated at \$2.2bn.**

**A major strategic driver of the Idis acquisition was to enable the Group to enter the 'on demand' ethical unlicensed supply and drug shortages market sector, a market estimated at \$2.2bn with a major unmet need in providing a regional and local solution to hospital pharmacists charged with sourcing unavailable medicines and dealing with drug shortages. Formerly known as Idis General Access, we have now rebranded this business as Idis Global Access, keeping the Idis heritage and strong brand name recognition in the UK and Europe but reflecting the intent to offer a much more compelling solution to these customers on a global scale, creating a unique position as the only company capable of offering this ethical unlicensed supply service.**

As with the other market sectors we compete in, this 'on demand' unlicensed supply sector has very strong underlying dynamics driven by: developing regional health demands, health cost controls, more knowledgeable and informed patients and pharmaceutical companies changing their product launch strategies to focus on the priority commercial markets and no longer launching in all markets.

The GA business has been focused to date on the UK and mainland Europe and whilst sales in these regions has been fairly flat it showed good Gross Profit growth in FY15 with margins of 24%. The reported revenues shown of £9.2m reflect the two months post-acquisition and as a new service to Clinigen have no prior year comparator. On a pro forma basis, revenues of £61m showed an 8% decline on FY14 (£66.4m), this is wholly accounted for by one margin commercial contract which Clinigen is looking to exit and is likely to close during FY16. The pro forma gross profit performance, however, was good in GA, at £14.6m, it shows 10% growth on FY14 (£13.3M). The major operational initiatives in FY16 and opportunity in this business will involve rapid geographical expansion in building our global footprint, particularly in the 'pharmerging' markets of the Asia-Pacific and Latin American regions along with major investments in marketing to the key regional and local hospital pharmacist and patient advocacy groups. Critical success factors in growing rapidly in this exciting developing market are our ability to provide a robust, global e-commerce platform to our customers as well as being able to translate our global expertise into regional and local benefits to the hospital pharmacist.

In repositioning the GA division for a global proposition, we also have created an important synergy with the Idis MA division as we are now able to offer our clients and the key regional/local hospital pharmacist customers, a total management approach covering the entire lifecycle of the product. From its early pre-approval stage of development (managed within MA) to the later post-approval stages of the lifecycle (managed through GA), we are able to provide an ethical route of access to these critically important products.



## Idis Global Access Key Performance Indicators

Strategic priority	What have we achieved this year	Our long-term goal
<b>Build out a global e-commerce platform</b>	Acquired iStore, the foundation of a future global e-commerce platform	Launch of global e-commerce platform allowing 24/7 access by end of 2016
<b>Rapid brand building and marketing campaigns</b>	Acquired dedicated marketing expertise with Idis acquisition	Multi-channel marketing and education campaign at key regional and local pharmacists; patient advocacy groups and regulatory bodies in 2016
<b>Rapid geographical expansion/develop global footprint</b>	Extended distribution capabilities to more than 90 countries	Develop/acquire distribution & management capabilities in pharmerging markets
<b>Ensure customer service capability supports and drives business growth</b>	Acquired significant additional resources in Weybridge and the US	A global customer service function fully integrated with the e-commerce platform to offer a total 24/7 service

## GA Case Study



A hospital pharmacist in the US was facing a drug supply problem following the recall of a marketed oncology drug for acute myeloid-like leukaemia, or AML. With four patients in the hospital needing access to that drug, it was critical for the hospital pharmacist to find an alternative source.

The product was available in Europe, but due to the complex regulatory and legal issues surrounding the import of drugs into the US, the hospital pharmacist was unable to get access and that's when she turned to us.

Idis Global Access was able to navigate country-specific regulations needed to safely bring the medicine from a source in Switzerland, through the UK border

system, and into the US. There was extensive paperwork to fill in, and a tense 16-hour wait while the package cleared US customs, but when it finally arrived there was an immense sense of relief.

Thanks to the hospital pharmacist's determination to establish an alternative source of the required drug and our expertise, three of those patients are now clear of their leukaemia and two of them have even returned to work. We continue to work directly with pharmacists and physicians throughout the world to provide compliant, ethical access to medicines that have received initial approval, but may not be commercially available in their country.

Units shipped

559,000

Number of customers

3,016

Number of products

1,824



## Operational review continued

### Clinigen Specialty Pharmaceuticals (SP)



**David Moran**  
Managing Director, SP

David has over 25 years' experience in the healthcare sector working at a senior level in both operational and commercial roles. A Chemical Engineer by training David oversaw operations in Eastern Europe and Asia before taking on a global role spending ten years in Spain and Portugal looking after several global brands. A majority of that time was spent with Eli Lilly and SSL before becoming CEO of a global specialty pharma business where he established their Brazilian operation. Latterly he headed his own healthcare consultancy before joining Clinigen in January 2015 as SVP for the Specialty Pharma division.

**A good growth performance for the SP portfolio in FY15 where all five products contributed to sales and profits. Sales of £33.7m were 25% up on prior year (2014: £26.9m) and gross profit of £29.1m was 26% up on prior year (£23.2m). Particularly pleasing was the contribution in sales and profit of some of the newer products to the portfolio, notably Ethyol and Savene, which has helped reduce SP's over-dependence upon Foscavir. At the end of FY15, Foscavir contributed 70% of sales and profit to the division, significantly reduced from 86% of sales at the end of FY14.**

#### Foscavir

Foscavir continues to grow in line with the rate of growth in bone marrow transplantations, c.5% pa, as evidenced by the growth in the level of product 'in-market sales' in FY15 of 273,500 units, an increase of 4% over prior year and the top seven markets (US, Japan, Germany, Italy, UK, France, Spain) accounted for 86% of the units supplied in FY15 in line with FY14.

Key decisions for the product in FY15 included the extension of the partnership agreement with Hospira to supply Foscavir into the US until the end of 2019 and obtaining the license to market and distribute Foscavir in South Korea. We are also looking at the potential for additional indications by supporting investigators in Japan studying the use of Foscavir to treat HHV-6 (Human Herpes Virus – 6).

#### Cardioxane and Savene

An important milestone in allowing Clinigen to undertake the revitalisation of both products in the dexrazoxane portfolio was achieved in FY15 with all marketing authorisations and technical transfers completed.

For Cardioxane, the single biggest driver of potential growth in the product is to ensure that the Article 31 restriction placed upon

it in 2011 is overturned. As has been previously highlighted, the effect of the restriction is to limit the usage of the product to certain adult patient populations. Should the restriction be overturned then we are requesting that the product's label is updated and would mean opening up Cardioxane to a broader patient universe. Clinigen has submitted the clinical overview and position paper and extensive supporting evidence package to the European Medicines Association and we are awaiting their response. It is worth noting that the submission is supported by data from the world-renowned Children's Oncology Group (COG) and the position paper has been co-authored by 25 global Key Opinion Leaders. We anticipate a response from the regulators by the end of calendar year 2015.

With Savene, the benefits to a concerted and pro-active educational and sales campaign to historical customers through our customer services team has been seen in FY15 and Clinigen is now generating sales levels in excess of that of the previous owner. Key product decisions in FY16 will be to concentrate on expanding the customer base and markets such as the US and Latin America.

Now that we have full control of the two dexrazoxane brands, we are the only company globally with the rights to both indications of cardioprotection (Cardioxane) and extravasation (Savene) and we will explore the potential of developing a combination, dual indication pack for global commercial use.

#### Ethyol

The acquisition of Ethyol in August 2014 further strengthened our oncology support portfolio, increasing the number of products in that portfolio to three. It is an excellent fit with the SP business as a niche, hospital-based treatment for xerostomia (dry mouth) for patients with head and neck cancer – it is seen as an essential treatment in some markets – and is also indicated for reducing the renal toxicity associated with patients with ovarian cancer treated with cisplatin. We have made rapid steps in the revitalisation of Ethyol in FY15, transferring the Marketing Authorisations for the US and

#### Sales

**£33.7m**

⬆ 25%

#### Gross profit

**£29.1m**

⬆ 26%

Europe and we are well underway with the technical transfer of the product, which will complete by the end of FY16. We see good potential in the growth of Ethyol since new radiotherapy techniques are not a perfect treatment solution, there is a reasonable incidence of non-treatment of xerostomia with Oncologists and there is no significant competitor currently in development.

### Vibativ

A further important step in the long-term development of Vibativ was achieved

in FY15 following confirmation by the European Commission in September 2014 of the lifting of the suspension of the Marketing Authorisation. In addition, pricing was agreed with the UK, Ireland, Germany and Austria. We have seen some sales in the UK but the availability of a commercially validated diagnostic e-test for Vibativ remains an obstacle in enabling a fully effective launch in Europe. We are working with Theravance from whom we licensed the product in 2013 and Biomerieux, the company responsible for developing the

e-test, and anticipate a commercially available test at the end of FY15. However, agreeing reimbursement at a level that would make Vibativ commercially viable with the on-going regulatory requirements is proving a challenge. Clinigen has requested a meeting with the regulatory authorities to try and resolve this. However, because of the inconsistent reimbursement, the product's current loss making position and uncertain future we have impaired the carrying value of the product.



## Clinigen Specialty Pharmaceuticals Key Performance Indicators

Strategic priority	What have we achieved this year	Our long-term goal
<b>Acquire further products</b>	FY15 Ethyol added	Grow to ten products over next four years Exploit synergies with MA and GA divisions
<b>Develop global footprint</b>	Extended agreement with Hospira in the US; launched product into South Korea	Develop/acquire distribution and management capabilities in pharmerging markets
<b>Revitalisation of acquired products</b>	<p><b>Dexrazoxane:</b> full commercial ownership of Savene; article 31 submission to regulatory authorities</p> <p><b>Ethyol:</b> transfer of US and EU marketing authorisations</p> <p><b>Savene:</b> transfer of all marketing authorisations</p>	<p>Develop dexrazoxane globally to take advantage of unique strategic position</p> <p>Extend KOL relationships within the oncology support portfolio</p> <p>At least double the sales of Ethyol in the next three years</p>

## SP Case Study



*SP continues to be a major contributor to Group margins with increasing contributions from all products, Foscavir acquired from AZ in 2010 has seen sales in that time increase five fold and whilst it is now licensed in 16 markets the unique business model permits access to the product in over 50 countries. The revitalisation approach and KOL led model has seen the product become a key component in International treatment protocols and Foscavir is expected to maintain its performance as the number of Hematopoietic stem cell transplantation procedures increases globally.*

*Savene is at an earlier stage of revitalisation but having been successfully transferred into a Clinigen controlled manufacturing environment it is now seeing sales beyond those achieved previously by the original licence holder. Market penetration, through licensed and unlicensed supply is well underway and it is now sold in over 15 territories with that expected to increase significantly as we aim to reach our initial goal of doubling sales.*



# Chief Financial Officer's statement

Another strong financial year for Clinigen with a gross profit increase of 30%.

## Revenue

Reported Group revenues grew to £184.4m, an increase of 45% (2014: £126.6m). CTS grew by £29.1m (35%) as a result of strong organic growth, and SP grew by £6.8m (25%) driven mainly by the acquisition of Ethylol in August 2014 and the full year impact of Savene (acquired March 2014). MA showed £12.6m (78%) growth benefiting from the Idis acquisition, and the acquired GA business added £9.2m representing two months which traded in line with expectations.

## Gross profit

Group gross profit increased by 30% to £53.7m (2014: £41.2m) with the largest contributor being SP growing £5.9m (26%) driven by Ethylol and the full year impact of Savene. MA grew by £2.9m (53%) benefiting from the Idis acquisition, CTS grew by £0.8m (7%), and the Idis acquired GA business added £2.8m.

## Administrative expenses

Underlying administration costs of £26.7m (2014: £17.9m) grew by £8.8m. The increase is accounted for by the addition of Idis overheads for two months, a £1.2m increase in amortisation and depreciation, and a planned 25% increase in underlying overheads to support growth and the on boarding and revitalisation of acquired products. Total administration costs of £44.5m (2014: £19.7m) include non-underlying costs of £17.8m as follows:

“Continuing strong growth in underlying EBITDA of 20% or more in each of the past three years.”

## Underlying EBITDA

**£32.3m**

**Robin Sibson**  
Chief Financial Officer

## Non-underlying items

	2015 £'000	2014 £'000
Share based payment charge	1,299	1,190
Social security costs in respect of share based payments	1,039	611
Restructuring costs following the acquisition of Idis	3,821	–
Acquisition costs	5,703	–
Impairment of intangible fixed assets	3,810	–
Amortisation of intangible fixed assets acquired through business combinations	2,129	–
	<b>17,801</b>	<b>1,801</b>

The impairment of intangible fixed assets relates to the Vibativ trademark and licences which have been fully impaired as a result of the product's current loss-making position and our review of its commercial viability.

## Profitability

Underlying EBITDA, which excludes the non-underlying items in the table above, increased by 20% to £32.3m (2014: £26.8m). Underlying pre-tax profit increased by 13% to £26.2m (2014: £23.1m) and reported pre-tax profit of £8.4m is down £12.9m on the prior year, (2014: £21.3m) due to the increase in non-underlying costs of £16.0m.

## Taxation

The tax charge for the year of £3.1m is based on prevailing UK and US effective tax rates. This charge is calculated as £5.7m on underlying profits offset by a credit of £2.6m in respect of non-underlying costs. A £3.5m corporation tax refund in respect of FY12 was received in July 2014.

## Earnings

Underlying earnings per share grew by 14% to 28.0p (2014: 24.5p). The reported earnings per share is 6.5p (2014: 19.6p).

## Dividend

The Directors have maintained a progressive dividend policy and expect interim and final dividend payments to be split one-third to two-thirds respectively. In view of trading performance this year the Directors are pleased to propose a final dividend of 2.3p per share, which when added to the interim dividend of 1.1p paid on 2 April 2015, will make a total dividend of 3.4p per share (2014: 3.1p), up 11%.

The final dividend shall, subject to approval at the Company's AGM on 27 October 2015, be payable on 6 November 2015 to all shareholders on the register at 16 October 2015.



# Chief Financial Officer's statement

## continued

### Cash flow

The net cash increase in the period was £6.1m.

Cash generation from underlying operating activities continues to be strong but has been partially offset by non-underlying items generating a net £15.8m, which covered investing activities (excluding Idis) of £8.6m being primarily the acquisition of Ethyol.

Cash of £236.4m was raised for the Idis acquisition from new debt facility (£104.0m) and the issue of new shares (£132.4m). This funded the acquisition of Idis (including repayment of Idis debt and net of cash received) totalling £215.7m.

Other cash outflows were a loan repayment at the start of the year of £16.5m, dividends of £2.6m, and tax and interest payments of £2.7m.

### Idis Acquisition

The Idis Group was acquired on 29 April 2015 and its results have been fully consolidated from that point onwards. Overall the performance of the acquired business has been in line with our expectations and we remain confident that we will achieve annualised costs savings of approximately £2.5m as we indicated when the deal was announced. Acquisition costs relating to the transaction amounted to £5.7m and restructuring costs of £3.8m have been booked in the year including £1.3m of redundancy costs, £1.3m relating to the write down of IT development costs, £0.8m financing costs and £0.4m relating to the exit of an operating site in the US.

The acquisition was financed by a fully underwritten placing raising gross proceeds of £135.0m and by £106.0m drawn down under new debt facilities.

The placing comprised the issue of 27,000,000 new ordinary shares at a price of 500p per share representing a discount of approximately 4.9% to the closing middle market price of 525.5p per ordinary share on 23 April 2015.

Goodwill of £147.9m arises on the acquisition. The consideration of £199.5m compared with net liabilities of £1.4m (prior to fair value adjustments). Fair valuation of the opening balance sheet identified adjustments of £18.4m including £7.6m for the write down of IT software and £7.8m provision for net debtors not recoverable. Intangible assets assessed as part of the acquisition have been recognised at a value of £113.2m with associated deferred tax liability of £22.0m.

Leverage on completion of the acquisition was approximately 2.0x net debt/adjusted EBITDA (based on the pro forma LTM EBITDA for the 2014 financial year for the enlarged Group). The Group is expected to generate significant free cash flow and we expect that this leverage ratio will fall during the current year.

### Balance sheet

#### Intangible assets

Intangible assets increased by £257.7m to £308.2m (2014: £50.5m). The acquisition of Idis in April 2015 added £261.0m in total of which £147.9m was goodwill and £113.2m was the value attributed to the Idis brand, customer contracts and relationships, supplier contracts, and IT software. In August 2014 we acquired the global rights to the product Ethyol, for £7.2m, consisting of trademarks, marketing authorisations and the manufacturing dossier. These additions were offset by amortisation for the year of £7.1m, and full impairment of the in-licensed product Vibativ (trademark and licences) representing a write down of £3.4m. We anticipate annual amortisation in respect of the intangible assets to be £17.8m, of which £12.8m relates to acquired fair valued assets.

### Current assets

#### Inventories

Inventories increased from £2.5m to £11.1m due mainly to the addition of Idis which holds inventory for GA business to meet on demand supply for unlicensed medicines. The acquired fair value of Idis inventories was £6.8m, which included an impairment of £0.3m.

#### Trade and other receivables

Trade receivables increased from £20.1m to £47.4m. The acquired fair value of Idis trade receivables was £23.5m.

Other receivables increased by £16.3m. Prepayments and accrued income increased by £9.9m to £11.9m, the largest items in this are: accrued CTS revenues £1.9m and accrued royalty income of £0.9m. Payments made on account increased by £5.1m, these relate to CTS where suppliers are paid in advance for goods ordered to meet received customer orders.

### Net debt

Cash and cash equivalents at 30 June 2015 of £27.8m (2014: £21.8m) are offset by bank loans of £105.8m (2014: £16.5m), giving net debt of £78.0m (2014: net cash £5.3m). Net debt will increase following the acquisition of Link and is expected to return to current levels in FY16. Funding towards future acquisitions continues to be available through the unutilised part of the bank facility.

## Current liabilities

### Trade and other payables

Trade payables increased from £10.3m to £48.1m. The acquired fair value of Idis trade payables was £26.5m. An increase in trade payables of £4.5m in CTS contributed to the balance of the increase, this was related to normal CTS fluctuations in payment profiles.

### Accruals and deferred income

Accruals increased from £6.1m to £35.6m. The acquired fair value of Idis accruals was £36.9m of which £12.8m was settled by the balance sheet date.

### Loans and borrowings

The Group has a total bank facility of £140.0m (2014: £35.0m) agreed in April 2015 to finance the Idis acquisition. This consists of a five year fixed term repayment loan of £45.0m (2014: £nil) and a five year revolving credit facility of £95.0m (2014: £35.0m). The revolving credit facility (RCF) is repayable within one month. Interest is payable on a tiered scale based on the level of borrowing. Covenant terms apply to the new facilities and comprise Interest Cover, Cash Flow Cover and Adjusted Leverage covenants. The bank loans are secured on the assets of the Group.

At 30 June 2015, the fixed-term loan was fully utilised and £60.8m was borrowed against the revolving credit facility (30 June 2014: £16,500 utilised).

## Events after the reporting date

On 17 September 2015, Clinigen announced a strategic alliance with Cumberland Pharmaceuticals, with no financial terms, which will build on Clinigen's existing North American relationships by providing complementary support from Cumberland in the development, marketing, promotion and distribution of future products in the US, with Clinigen supporting Cumberland outside the US.

On 22 September 2015, Clinigen announced the proposed acquisition of Link Healthcare a specialist pharmaceutical and medical technology business focused on the Asia, Africa and Australasia (AAA) region for a maximum consideration of £100m. Link is being acquired on a debt-free cash-free basis with an initial consideration of £44.5m, payable at completion 50% in cash and 50% in shares. Additional deferred consideration of up to £55.5m is payable if earn out targets are achieved over a two year period. Completion of the acquisition is expected to occur on or around 28 October 2015 after the Clinigen AGM.

For the financial year ended 31 March 2015, Link achieved revenue of £31.6m and EBITDA of £4.2m. The cash element of the acquisition consideration will be financed from the Group's existing debt facility.



**R Sibson**

Chief Financial Officer

24 September 2015

# A responsible business

It is important we listen to our employees and understand their views on Clinigen as an employer and for the senior management as their colleagues.

## Employees

The Group is committed to a policy of equal opportunities in the recruitment, engagement and retention of employees. The multi-lingual diversity of our team not only supports our global service offering but demonstrates our lack of barriers to employment. Employees are supported to undertake additional training, both internal and external, to develop their skills which are then often transferred across departments or enables their promotion.

Age, colour, gender, disability, ethnic origin, national origin, marital status, sexual orientation, religious or political view is not seen as a barrier to employment and is evidenced by the Group's diverse employment base. The Group would support employees if they were to become disabled whilst employed by the Group, those employees would be retained where possible and training provided as required.

It is important we listen to our employees and understand their views on Clinigen as an employer and for the senior management as their colleagues. The Group operates a culture of open communication through a range of two-way mediums including: monthly employee representative staff forum; newsletter; and monthly Group update from the CEO, Deputy CEO and Chief Financial Officer. The strategic objectives



## Employees



## Community



of the Group are communicated to the employees through the monthly updates and at the annual all staff conference. The employees are encouraged to be a part of the Group's success through share ownership and the Group's employee share schemes.



## Corporate, social and ethical policies



## Health and safety



The group has also undertaken a review of the Clinigen Brand from an employment market perspective, which involved employee representatives and external agencies commenting on their experiences working with Clinigen.



### Corporate, social and ethical policies

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 audit all suppliers and manufacturers regularly to ensure they reach the standards set and respond to any improvement requests we make 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. Ethical standards are included in our audit schedule when reviewing our suppliers and manufacturers to check the standards they follow meet those expected.

### Community

Clinigen participates in local community projects that it feels are worthy and appropriate and encourages employees to get involved in local and national charitable events, as well as deciding where charitable donations are placed. An example of this is the League Managers' Association, we work with them to support local schools in their Football Association level coaching.

For FY15, the Group has continued to support Foundation MEM, a charity focussing on developing a better life for a village in Cameroon which is very close to some of our employees, and The Anthony Nolan Trust, a charity very relevant to Foscavir, the first product acquired in 2010. Clinigen work-alongside Patient Group Organisations in the MA division. We believe greater patient involvement in personal healthcare needs and also in the development of local and national healthcare provision is an important part of the future development of effective healthcare services.

The Group made no political donations during the year (FY14: £nil) and made charitable donations of £15k (FY14: £29k).

### Health and safety

The Group recognises that Health and Safety has positive benefits to the organisation and commitment to a high level of safety makes good business sense. It also recognises that Health and Safety is a business function and must, therefore, continually improve and progress – and adapt to change. To achieve this aim, appropriate levels of resource will be allocated to ensuring a positive Health and Safety culture throughout the Company.

The Group 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) and to ensure continual improvement to our Health and Safety standards.



# Principal risks and uncertainties

The Board has overall responsibility for ensuring risk is appropriately managed across the Group.

Below are discussed the principal risks identified in 2015. These risks are not intended to be an extensive analysis of all risk that may arise in the ordinary course of business or otherwise.

## Competitive threat

The pharmaceutical industry as a whole is highly competitive, however the markets/supply chain in which Clinigen operate are niche and require specialist knowledge, therefore they do not see the same level of competition. There are no other companies with Clinigen's unique business model however there are other organisations that operate within the same markets, these include: Contract Research Organisation's; they provide support to the pharmaceutical, biotechnology, and medical device industries. There are also diverse local suppliers who provide access to licensed and unlicensed medicines locally. Many of our peers will be focused on one particular area of access to licensed and unlicensed medicines, unlike Clinigen who operates from the early access stage of unlicensed medicines supply right through to access to mature licensed medicines. There are very few companies that have the global regulatory knowledge and customs expertise that Clinigen has, which has allowed us to expand our global footprint at a much faster rate than other companies within the sector.

## Regulatory environment

As Clinigen is a 'young' pharmaceutical company, it has never been through an MHRA Pharmacovigilance Inspection to date. With the number of our licenced products increasing and as several of the companies that we work with have been recently inspected, it is very likely that Clinigen will also be inspected in the next 12 months. Clinigen uses a well-established Pharmacovigilance service provider and has all the necessary procedures in place to comply with the regulatory requirements.

The new Clinical Trial Regulation goes live on 28 May 2016, however, there will be a long transition period (3 years) between Directive 2001/20/EC and Regulation EU No 536/2014. The Good Manufacturing Practice's (GMP) for clinical trials (2003/94 and Annex 13) will continue to apply until the end of the transition period (~2019). The consultation phase relating to GMP for Investigational Medicinal Products for human use has opened and will be open until 24 November 2015. These regulations will raise the barrier to entry into this market. Until the consultation phase is complete and the practical application evolves over the transition period, it is a case of watch and wait to see what the full effect will be. The majority of Clinigen business operates under Good Distribution Practice (GDP) and it is whether any changes to GMP will have a knock on effect on GDP, that will directly affect Clinigen. Clinigen is well placed to identify, adapt where necessary

and to benefit from the tightening of the regulations around clinical drug supply due to its own expertise and the added expertise that Cumberland offers due to having its own development products.

## International trade: political risk and pharmaceutical regulations.

As the group expands its global footprint, the exposure to adverse political decisions increases, for example, in territories where there is a risk of compulsory government imposed price reductions or limitations are enforced. Although, the adverse decisions may be out of our control we do all we can to mitigate the risk by looking for alternative distribution routes, continually monitoring the situation to ensure timely response once a change in circumstance is identified and discussions with key people, wherever possible.

The Group's activities involve importing and exporting products across many international borders and most activities are covered by numerous pharmaceutical regulations. Any changes to these regulations might affect the Group's trading activities. To mitigate this risk the Management closely monitors any changes to regulations and seeks to adapt its procedures wherever possible to ensure activities are not affected, whilst maintaining compliance. In addition the Group is regularly audited by customers and regulatory authorities to ensure it is compliant.

### Counterfeit product

Falsified Medicines Directive (2011/62/EU). A draft of the EU delegated act on safety features has now been published. It will come into full force three years after publication in the Official Journal of the European Union. The core elements include:

- safety features consisting of a Unique Identifier (UI) on each pack combined with tamper-evidence
- mandatory verification at the point-of-dispense and risk-based verification in the supply chain
- supported by a European-wide repositories system

This new legislation will affect all SP products and CTS supplies and will impact all suppliers in the same way. Our business model within SP of supplying hospitals and healthcare professionals directly, plus industry leading Quality Management System and audited partners means we have mitigated against current risk. With CTS, we already have measures and processes in place that are above the standards laid out in GDP currently. For the future, we are assessing any impact of changing regulation and what and how we will need to respond through our in-house and vastly experienced Qualified Persons. It is not clear on how unlicensed medicines will be impacted at this stage, but Clinigen would not be affected any differently to any other supplier in this market.

Please also refer to the market overview.

### Foreign exchange

Foreign exchange risk arises because the Group sells to clients located in various parts of the world whose functional currency is not the same as the functional currency in which the Group operates. Link Healthcare operates primarily in South African Rand and Australian Dollars. The, recently announced, proposed acquisition of Link will introduce, to Clinigen, increased exposure to foreign currency exchange risk, the South African Rand exchange rate has a higher volatility than the Group's current main operational currencies of sterling, Euro and US dollar.

The Group's net assets arising from such overseas revenues are exposed to currency risk resulting in gains or losses on retranslation into sterling. Foreign currency risk is managed at Group level in order to optimize the matching of currency surpluses generated to the foreign currency needs of the wider group. The Group operates bank accounts in its principal foreign currencies in order to maintain currencies and not expose payments and receipts to foreign currency spot rates.

Clinigen does not issue or use financial instruments of a speculative nature. Where required and possible, significant transactions are hedged.

## Board of Directors

Our experienced Board has a significant track record and a wealth of knowledge across the biotechnology, pharmaceutical and healthcare sectors spanning private and publicly quoted companies.

The Board is committed to ensuring that CTS, MA and GA remain the global market-leaders in their sectors, and the Group is the owner of a high-value portfolio of specialist hospital-only medicines.

**Peter Allen**  
Non-executive Chairman



1 2 3

Peter joined Clinigen as Non-executive Chairman in August 2012. He has a wealth of experience on the Boards of both private and publicly-owned companies, including Chairman, CEO and CFO positions.

He is also currently Chairman of Advanced Medical Solutions Plc, Future Plc, Oxford Nanopore Technologies Plc and Diurnal Ltd.

Peter is Chairman of the Nomination Committee and a member of the Audit and Risk Committee and the Remuneration Committee.

**Peter George**  
Chief Executive Officer



Peter joined Clinigen when it formed in June 2010 and has been at the forefront of the strategic decisions and resulting growth Clinigen has achieved.

Peter has an extensive range of experience, starting his career in the UK's National Health Service before utilising and strengthening his experience in the pharmaceutical industry where he has held a number of senior international roles including executive VP for Wolters Kluwer Health, with responsibility for European and Asia Pacific regions, CEO at Penn Pharma Limited where he led a £67m management buy-out in 2007 and Chief Operating Officer for Unilabs Clinical Trials International Limited. Peter was CEO of the Year in the 2014 European Mediscience Awards.

**Shaun Chilton**  
Deputy Chief Executive Officer



Shaun joined Clinigen in January 2012 and now holds responsibility for the Group achieving its key performance indicators on a day-to-day basis. He previously held the position of president within KnowledgePoint360 Group, a global pharmaceutical information and services operation.

Shaun has 20 years' experience in the industry across a range of disciplines, including commercial, strategic, operational and sales and marketing roles for companies such as Pfizer and Sanofi.

**Robin Sibson**  
Chief Financial Officer



Robin has over 30 years' experience in the pharmaceutical industry, holding a number of senior, executive, finance roles for companies such as Abbott, Boots and BASF. He joined ADL Healthcare Limited, a forerunner of Clinigen, in 2003 and has provided a consistent, highly knowledgeable and skilled presence through the evolution of Clinigen.

**Martin Abell**  
Chief Financial Officer Elect



Martin joined Clinigen on 3 August 2015 as CFO Elect. Before joining Clinigen, Martin worked at the FTSE250 recruitment group, Hays plc. At Hays, Martin spent the first part of his career as Head of Investor Relations and M&A, and was later appointed Finance Director for the Continental Europe and Rest of World division which operated across 21 countries with revenues of over £1bn. Previously, Martin held several financial roles at the FTSE100 logistics group, Exel plc (now part of Deutsche Post) including Financial Controller of two of the UK divisions. He is a qualified Chartered Accountant, having trained at PwC in the M&A Transaction Services team.

**John Hartup**  
Non-executive Director



1 2 3

John joined Clinigen in May 2011. He has over 30 years' experience as a corporate lawyer dealing with corporate finance and commercial contract issues across a number of industries. Formerly managing partner at Ricksons LLP and subsequently became a partner at DWF LLP. John is also a Director of Wichtig Publishing Srl. John is Chairman of the Audit and Risk Committee and a member of the Nomination Committee and the Remuneration Committee.

**Ian Nicholson**  
Non-executive Director



1 2 3

Ian joined Clinigen as Non-executive Director in September 2012. He has considerable experience as both an Executive Director and as a Non-executive Director and 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, Chief Executive Officer of F2G Limited, Director of Casewell Consulting Limited and an Operating Partner at Advent Life Sciences LLP.

Ian is Chairman of the Remuneration Committee and a member of the Audit and Risk Committee and the Nomination Committee.

#### Committee membership

1 Audit and Risk Committee

2 Remuneration Committee

3 Nomination Committee



# Report of the Directors

## for the year ended 30 June 2015

The Directors present their report together with the Strategic report and the audited consolidated financial statements for the year ended 30 June 2015.

Clinigen Group plc is a public limited company, which is listed on the Alternative Investment Market and incorporated and domiciled in the UK.

### Principal activities

Clinigen is a specialty global pharmaceutical group headquartered in the UK, with offices in the US and Japan. The parent company is a holding company for the Group, holding the product portfolio intangible assets of the Group and providing management services for the other Group companies which undertake the Group's four operating businesses.

During the year, Clinigen acquired Idis Group Holdings Limited and its subsidiary undertakings (the 'Idis Group'). The Idis Group had three operating businesses, two of which, Idis Managed Access Programs and Idis Clinical Trial Procurement operate very similarly to Clinigen Global Access Programs ('Clinigen GAP') and Clinical Trials Supply ('Clinigen CTS'), respectively. Post-acquisition, these operating businesses were fully combined to form Idis Managed Access and Clinigen Clinical Trial Services. Following the restructuring of the enlarged group the Group will operate through four operating businesses, Idis Global Access and Clinigen Speciality Pharmaceuticals were unchanged by the acquisition.

Clinigen SP focuses on acquiring and in-licensing specialist, hospital-only medicines worldwide, commercialising and revitalising them within niche markets.

Idis Managed Access ('Idis MA') specialises in the consultancy, development, management and implementation of managed access programs for biotechnology and pharmaceutical companies.

Clinigen CTS Limited and Clinigen CTS Inc. jointly form the operating business Clinical Trials Services ('Clinigen CTS'), which sources commercial medical products for use in clinical studies, including comparator drugs, adjuvant drugs and rescue therapies.

Idis Global Access works directly with healthcare providers to enable ethical compliant access to unlicensed medicines.

The four operating businesses work in synergy to attain our primary aim of supplying 'the right drug to the right patient at the right time'.

### Business review and future developments

The business review is included within the Operational review and Financial review and can be found on pages 22 to 31.

### Key performance indicators

The Group's key performance indicators are discussed in the Strategic report.

### Financial instruments

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

Further detail is provided in note 21.

### 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 are taken advantage of. The policy will also be applied for FY16.

### Dividend

As explained in the Chief Financial Officer's statement, the Directors propose a final dividend of 2.3p per share, subject to approval at the AGM on 27 October 2015. The dividend will be payable on 6 November 2015 to all shareholders on the register at 16 October 2015. Together with the interim dividend of 1.1p per share paid on 2 April 2015, this makes a combined dividend for the year of 3.4p per share (2014: 3.1p per share).

### Events after the reporting date

Details of significant events since the balance sheet date are contained in note 29 to the financial statements.

### 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:

P George  
R Sibson  
S Chilton  
M Abell (appointed 3 August 2015)  
P Allen (Non-Executive Chairman)  
J Hartup (Non-Executive)  
I Nicholson (Non-Executive)

With regard to the appointment of Directors, the Company is governed by its Articles of Association, the Companies Act and related legislation. Directors are subject to re-election at intervals of not more than three years. P Allen, Non-Executive Chairman and P George, Chief Executive Officer, will be retiring by rotation and offering themselves for re-election at the AGM to be held on 27 October 2015. M Abell, CFO elect was appointed to the Board on 3 August 2015 and will be offered for re-election by the shareholders at the AGM.

### Directors' interests

The interests of the Directors over the Ordinary Share capital of the Company are as follows:

	Number of shares at 30 June 2015	Number of shares at 1 July 2014
P George	5,557,242	5,557,242
R Sibson	2,480,515	2,480,515
S Chilton	303,800	303,800
M Abell	–	–
P Allen	45,732	45,732
J Hartup	10,000	33,934
I Nicholson	10,000	10,000
	<b>8,407,289</b>	<b>8,431,223</b>

There has been no change in the interests set out above between 30 June 2015 and 24 September 2015.

### Directors' responsibilities statement

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

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have prepared the Group financial statements in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union, and the parent company financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standards 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 IFRSs as adopted by the European Union and applicable UK Accounting Standards have been followed, subject to any material departures disclosed and explained in the Group and parent company financial statements respectively; and
- 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 United Kingdom 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 a 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 IFRSs as adopted by the EU, give a true and fair view of the assets, liabilities, financial position and profit of the Group; and
- the Directors' 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.

### Employees

The policies relating to employees are discussed in the Responsible Business Section of the Strategic Report.

## Report of the Directors continued for the year ended 30 June 2015

### 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. 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 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; and
- that 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 27 October 2015, together with an explanation of the resolutions to be proposed at the meeting, is contained in a separate circular to shareholders.

### Independent auditors

The auditors, PricewaterhouseCoopers LLP, have expressed their willingness to continue in office and a resolution to re-appoint them will be proposed at the forthcoming AGM.

This report was approved by the Board and signed by order of the Board:



**R Sibson**  
Company Secretary  
24 September 2015

# Independent Auditors' report

## to the members of Clinigen Group plc

### Report on the group financial statements

#### Our opinion

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

- give a true and fair view of the state of the group's affairs as at 30 June 2015 and of its profit and cash flows for the year then ended;
- have been properly prepared in accordance with International Financial Reporting Standards ('IFRSs') as adopted by the European Union; and
- have been prepared in accordance with the requirements of the Companies Act 2006.

#### What we have audited

The financial statements comprise:

- the consolidated statement of financial position as at 30 June 2015;
- the consolidated statement of comprehensive income for the year then ended;
- the consolidated statement of cash flows for the year then ended;
- the consolidated statement of changes in equity; and
- the notes to the financial statements, which include a summary of significant accounting policies and other explanatory information.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and IFRSs as adopted by the European Union.

In applying the financial reporting framework, the directors have made a number of subjective judgements, for example in respect of significant accounting estimates. In making such estimates, they have made assumptions and considered future events.

#### Opinion on other matter prescribed by the Companies Act 2006

In our opinion, the information given in the Strategic Report and the report of the directors for the financial year for which the financial statements are prepared is consistent with the financial statements.

#### Other matters on which we are required to report by exception

##### Adequacy of information and explanations received

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. We have no exceptions to report arising from this responsibility.

#### Directors' remuneration

Under the Companies Act 2006 we are required to report to you if, in our opinion, certain disclosures of directors' remuneration specified by law are not made. We have no exceptions to report arising from this responsibility.

#### Responsibilities for the financial statements and the audit

##### Our responsibilities and those of the Directors

As explained more fully in the Directors' Responsibilities Statement set out on page 43, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit and express an opinion on the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland) ('ISAs (UK & Ireland)'). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

This report, including the opinions, has been prepared for and only for the 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.

##### What an audit of financial statements involves

We conducted our audit in accordance with ISAs (UK & Ireland). An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of:

- whether the accounting policies are appropriate to the group's circumstances and have been consistently applied and adequately disclosed;
- the reasonableness of significant accounting estimates made by the directors; and
- the overall presentation of the financial statements.

We primarily focus our work in these areas by assessing the directors' judgements against available evidence, forming our own judgements, and evaluating the disclosures in the financial statements.



## Independent Auditors' report continued to the members of Clinigen Group plc

We test and examine information, using sampling and other auditing techniques, to the extent we consider necessary to provide a reasonable basis for us to draw conclusions. We obtain audit evidence through testing the effectiveness of controls, substantive procedures or a combination of both.

In addition, we read all the financial and non-financial information in the Annual Report and accounts to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

### Other matter

We have reported separately on the company financial statements of Clinigen Group plc for the year ended 30 June 2015.



**Andrew Hammond (Senior Statutory Auditor)**

for and on behalf of PricewaterhouseCoopers LLP  
Chartered Accountants and Statutory Auditors  
Birmingham

24 September 2015

# Consolidated statement of comprehensive income

## for the year ended 30 June 2015

	Note	2015			2014		
		Underlying £'000	Non- underlying (note 6) £'000	Total £'000	Underlying £'000	Non- underlying (note 6) £'000	Total £'000
<b>Revenue</b>	3	<b>184,359</b>	–	<b>184,359</b>	126,639	–	126,639
Cost of sales		<b>(130,708)</b>	–	<b>(130,708)</b>	(85,436)	–	(85,436)
<b>Gross profit</b>	3	<b>53,651</b>	–	<b>53,651</b>	41,203	–	41,203
Administrative expenses		<b>(26,675)</b>	<b>(17,801)</b>	<b>(44,476)</b>	(17,887)	(1,801)	(19,688)
<b>Profit/(loss) from operations</b>	4	<b>26,976</b>	<b>(17,801)</b>	<b>9,175</b>	23,316	(1,801)	21,515
Finance income	7	<b>39</b>	–	<b>39</b>	2	–	2
Finance cost	8	<b>(859)</b>	–	<b>(859)</b>	(234)	–	(234)
<b>Profit/(loss) before income tax</b>		<b>26,156</b>	<b>(17,801)</b>	<b>8,355</b>	23,084	(1,801)	21,283
Income tax (expense)/credit	9	<b>(5,718)</b>	<b>3,048</b>	<b>(2,670)</b>	(5,437)	367	(5,070)
<b>Profit/(loss) for the year attributable to owners of the parent</b>		<b>20,438</b>	<b>(14,753)</b>	<b>5,685</b>	17,647	(1,434)	16,213
<b>Other comprehensive income</b>							
<b>Items that may be reclassified to profit or loss:</b>							
Exchange losses arising in the year on translation of foreign operations		<b>(119)</b>	–	<b>(119)</b>	(254)	–	(254)
<b>Total comprehensive income/(expense) attributable to owners of the parent</b>		<b>20,319</b>	<b>(14,753)</b>	<b>5,566</b>	17,393	(1,434)	15,959
<b>Earnings per share for profit attributable to the owners of the parent during the year</b>	10						
Basic (p)				<b>6.5</b>			19.6
Diluted (p)				<b>6.3</b>			19.0

All amounts relate to continuing operations.

The Company has elected to take exemption under section 408 of the Companies Act 2006 not to present the Company Statement of Comprehensive Income.

The notes on pages 51 to 81 form an integral part of the consolidated financial statements.

# Consolidated statement of financial position

## as at 30 June 2015

	Note	2015 £'000	2014 £'000
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	12	1,597	968
Intangible assets	13	308,222	50,508
Deferred tax assets	22	3,843	1,956
<b>Total non-current assets</b>		<b>313,662</b>	53,432
<b>Current assets</b>			
Inventories	15	11,127	2,466
Trade and other receivables	16	67,131	23,644
Corporation tax recoverable		–	3,535
Cash and cash equivalents	17	27,750	21,787
<b>Total current assets</b>		<b>106,008</b>	51,432
<b>Total assets</b>		<b>419,670</b>	104,864
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Loans and borrowings	19	34,530	–
Deferred tax liabilities	22	18,990	–
<b>Total non-current liabilities</b>		<b>53,520</b>	–
<b>Current liabilities</b>			
Trade and other payables	18	87,640	19,502
Provisions	20	1,510	–
Loans and borrowings	19	69,470	16,500
Corporation tax liability		349	2,555
Deferred tax liabilities	22	2,556	–
<b>Total current liabilities</b>		<b>161,525</b>	38,557
<b>Total liabilities</b>		<b>215,045</b>	38,557
<b>Net assets</b>		<b>204,625</b>	66,307
<b>Issued capital and reserves attributable to owners of the parent company</b>			
Share capital	23	110	83
Share premium account	24	141,023	8,660
Merger reserve	24	5,413	5,413
Own shares	24	(3)	(328)
Foreign exchange reserve	24	(264)	(145)
Retained earnings	24	58,346	52,624
<b>Total equity</b>		<b>204,625</b>	66,307

The notes on pages 51 to 81 form an integral part of the consolidated financial statements.

The financial statements on pages 47 to 81 were approved and authorised for issue by the Board of Directors on 24 September 2015 and were signed on its behalf by



**P George**  
Director



**R Sibson**  
Director

# Consolidated statement of cash flows

## for the year ended 30 June 2015

	Note	2015 £'000	2014 £'000
<b>Cash flows from operating activities</b>			
Profit for the year before tax		<b>8,355</b>	21,283
Adjustments for:			
Depreciation of property, plant and equipment	12	<b>441</b>	212
Amortisation of intangible fixed assets	13	<b>7,145</b>	3,290
Impairment of intangible fixed assets	13	<b>3,370</b>	–
Loss on disposal of non-current assets		<b>1,283</b>	18
Provision for restructuring costs	20	<b>1,510</b>	–
Currency gain on contract creditors		–	(367)
Interest receivable	7	<b>(39)</b>	(2)
Interest expense	8	<b>859</b>	234
Share-based payment expense		<b>1,295</b>	1,190
		<b>24,219</b>	25,858
Increase in trade and other receivables		<b>(10,257)</b>	(4,923)
(Increase)/decrease in inventories		<b>(1,824)</b>	685
(Increase)/decrease in trade and other payables		<b>3,707</b>	(1,278)
<b>Cash generated from operations</b>		<b>15,845</b>	20,342
Income taxes paid		<b>(5,227)</b>	(1,067)
Income taxes received		<b>3,368</b>	–
Interest paid	8	<b>(859)</b>	(234)
<b>Net cash generated from operating activities</b>		<b>13,127</b>	19,041
<b>Investing activities</b>			
Purchases of property, plant and equipment	12	<b>(168)</b>	(641)
Purchase of intangible fixed assets	13	<b>(8,466)</b>	(21,371)
Purchase of subsidiary net of cash acquired	30	<b>(179,698)</b>	–
Interest receivable	7	<b>39</b>	2
<b>Net cash used in investing activities</b>		<b>(188,293)</b>	(22,010)
<b>Financing activities</b>			
Proceeds from issue of shares		<b>132,390</b>	–
Proceeds from loan	19	<b>104,000</b>	16,500
Loan repayments		<b>(52,500)</b>	–
Purchase of own shares		–	(340)
Dividends paid	11	<b>(2,642)</b>	(2,476)
<b>Net cash generated from financing activities</b>		<b>181,248</b>	13,684
<b>Net increase in cash and cash equivalents</b>		<b>6,082</b>	10,715
<b>Cash and cash equivalents at beginning of year</b>	17	<b>21,787</b>	11,326
<b>Exchange gains</b>		<b>(119)</b>	(254)
<b>Cash and cash equivalents at end of year</b>	17	<b>27,750</b>	21,787



# Consolidated statement of changes in equity

## for the year ended 30 June 2015

	Share capital £'000	Share premium account £'000	Merger reserve £'000	Own shares £'000	Foreign exchange reserve £'000	Retained earnings £'000	Total equity £'000
<b>At 1 July 2013</b>	83	8,660	5,413	–	109	36,685	50,950
<b>Profit for the year</b>	–	–	–	–	–	16,213	16,213
<b>Other comprehensive income</b>	–	–	–	–	(254)	–	(254)
<b>Total comprehensive income</b>	–	–	–	–	(254)	16,213	15,959
Share-based payment scheme	–	–	–	–	–	1,190	1,190
Deferred taxation on share-based payment scheme	–	–	–	–	–	405	405
Tax credit in respect of tax losses arising on exercise of share options	–	–	–	–	–	619	619
Dividend paid (note 11)	–	–	–	–	–	(2,476)	(2,476)
Own shares acquired in the year	–	–	–	(340)	–	–	(340)
Own shares distributed on exercise of share options	–	–	–	12	–	(12)	–
<b>Total contributions by and distributions to owners of the parent, recognised directly in equity</b>	–	–	–	(328)	–	(274)	(602)
<b>At 30 June 2014 and 1 July 2014</b>	83	8,660	5,413	(328)	(145)	52,624	66,307
<b>Profit for the year</b>	–	–	–	–	–	5,685	5,685
<b>Other comprehensive income</b>	–	–	–	–	(119)	–	119
<b>Total comprehensive income</b>	–	–	–	–	(119)	5,685	5,566
Share-based payment scheme	–	–	–	–	–	1,299	1,299
Deferred taxation on share-based payment scheme	–	–	–	–	–	1,340	1,340
Tax credit in respect of tax losses arising on exercise of share options	–	–	–	–	–	365	365
Dividend paid (note 11)	–	–	–	–	–	(2,642)	(2,642)
Issue of new shares	27	132,363	–	–	–	–	132,390
Own shares distributed on exercise of share options	–	–	–	325	–	(325)	–
<b>Total contributions by and distributions to owners of the parent, recognised directly in equity</b>	<b>27</b>	<b>132,363</b>	<b>–</b>	<b>325</b>	<b>–</b>	<b>37</b>	<b>132,752</b>
<b>At 30 June 2015</b>	<b>110</b>	<b>141,023</b>	<b>5,413</b>	<b>(3)</b>	<b>(264)</b>	<b>58,346</b>	<b>204,625</b>

# Notes forming part of the consolidated financial statements

## for the year ended 30 June 2015

### 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, International Accounting Standards and Interpretations (collectively 'IFRSs') issued by the International Accounting Standards Board ('IASB') as adopted by the European Union ('adopted IFRSs') and with those parts of the Companies Act 2006 that are applicable to companies that prepare financial statements in accordance with IFRSs. 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.

#### 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 acquisitional 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.

#### Presentation of financial statements in accordance with IAS 1 (as amended 2012)

The financial statements are presented in accordance with IAS 1 'Presentation of Financial Statements' (as amended 2012). The Group has elected to present the 'Statement of comprehensive income' in one statement.

#### Changes in accounting policies

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

The following new or recent standards, interpretations and amendments to standards have been adopted by the Group where appropriate or applicable to the Group for the financial year beginning 1 July 2014:

- There were no new standards, interpretations or amendments to standards that are effective to the Group for the financial year beginning 1 July 2015 that have a material impact
- IAS 36 (Amended), 'Impairment of assets' removed certain disclosures of the recoverable amount of Cash Generating Units (CGUs) which had been included by the issue of IFRS 13. The new requirements of IFRS13 have been accepted where relevant

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

At the balance sheet date there are a number of new standards and amendments to existing standards in issue but not yet effective including IFRS 15 'Revenue from contracts with customers' and IFRS 9 'Financial Instruments', both of which are effective for periods beginning on or after 1 January 2018. The Group has not early adopted any of these new standards or amendments to existing standards. The Group is currently assessing the impact of IFRS 9 and IFRS 15.

There are no other new standards, amendments to existing standards or interpretations that are not yet effective that would be expected to have a material impact on the Group.

#### Basis of consolidation

The consolidated financial statements present the results of the Company and entities where the Company has the ability to control the activities of and decisions made by that entity and to receive a variable return that can be affected by that control (the 'Group') as if they formed a single entity. Intercompany transactions and balances between Group companies are therefore eliminated in full.

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 1. Accounting policies continued

#### Business Combinations

The Group uses the acquisition method to account for business combinations of entities not under common control. 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 statement of comprehensive income.

Acquisition costs and post-acquisition restructuring costs are recognised in the statement of comprehensive income as non-underlying costs 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 re-measured. 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 consolidated statement of comprehensive income within administrative expenses.

##### (c) Group companies

The results and financial position of all the Group entities (none of which has the currency of a hyper-inflationary economy) 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 mid 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 period; 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 consolidated statement of comprehensive income 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 chief operating decision maker. The chief operating decision maker has been identified as the Executive Directors.

The Board considers that the Group's activities constitute four operating segments, as defined under IFRS 8. 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 profit measure, as disclosed on the face of the consolidated statement of comprehensive income that is reviewed by the chief operating decision maker at the segmental reporting level. The performance measures used by management are prepared under UK GAAP whereas the figures in the Group financial information have been prepared in accordance with International Financial Reporting Standards ('IFRSs') and IFRIC Interpretations issued by the International Accounting Standards Board as adopted by the European Union.

### 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 consolidated statement of comprehensive income 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 consolidated statement of comprehensive income over the remaining vesting period.

### Non-underlying items

Non-underlying items are those significant items 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. Share-based payments are classified as non-underlying items due to their significance and in order to provide the reader of the consolidated financial statements with a consistent view of the underlying costs of the operating Group. One-off items relating to acquisitions e.g. acquisition costs and the costs of restructuring post-acquisition are shown as non-underlying. Amortisation of intangible fixed assets acquired through a business combination are shown as non-underlying items in order to give a clear view of the underlying results of the business.

### Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation. As well as the purchase price, cost includes directly attributable costs.

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 lives, as follows:

- Leasehold improvements – remaining term of lease to which the improvements relate
- Plant and machinery – 20%
- Fixtures, fittings and equipment – 20% to 33% straight line

### 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 consolidated statement of comprehensive income. 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 consolidated statement of comprehensive income on the acquisition date.

Goodwill is not amortised. Goodwill is assessed for impairment annually or more frequently if events or changes indicate a potential impairment. Goodwill arising on business combinations is allocated on the basis of contribution to gross profit of the associated CGUs. This is then assessed against the discounted cash flows of the CGUs for impairment.

#### Brand

The brand reflects the cashflows associated with the Idis business acquired April 2015. The brand was recognised following a 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 of 20 years. The amortisation expense is recognised within administrative expenses in the consolidated statement of comprehensive income as a non-underlying cost.



# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 1. Accounting policies continued

#### Intangible assets continued

##### Contracts

The contracts relate to managed access programs which, due to their nature, have a short period of economic benefit i.e. until the product is licenced and becomes commercially available. The economic benefits from the contracts are weighted to the early stages of the contract.

The contracts have been initially recognised following a business combination at the fair value of the asset at the acquisition date. The assets are subsequently recognised at initial fair value less accumulated amortisation.

Amortisation is scheduled to follow the expected economic benefits, recognising the fair value cost of acquiring these contracts against the revenues generated from them.

The amortisation expense is recognised within administrative expenses in the consolidated statement of comprehensive income as a non-underlying cost.

##### Customer relationships

The customer relationships within acquired operating businesses CTS & GA 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 calculated on a straight line basis to allocate the fair value cost of each asset over their estimated useful lives, as follows:

- Customer relationships – CTS – seven years
- Customer relationships – GA – between seven years and 14 years

The amortisation expense is recognised within administrative expenses in the consolidated statement of comprehensive income as a non-underlying cost.

##### Trademarks and licences

Separately acquired trademarks and licences are initially recognised at cost, being the purchase price of the asset which comprises the purchase price and any directly attributable cost of preparing the asset for its intended use.

The carrying value of trademarks and licences is calculated as cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of the trademarks and licences over their estimated useful lives of between seven and 15 years.

The amortisation expense is recognised within administrative expenses in the consolidated statement of comprehensive income.

##### Computer software

Computer software purchased to improve the Group's ability to deliver its goods and services and is intended to be used over a number of years is capitalised and recognised at cost, being the purchase price of the asset and any directly attributable cost of preparing the asset for its intended use. No internal cost for time spent is capitalised as part of the asset. The carrying value of computer is calculated as cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of the computer software over their estimated useful lives of three to five years.

The amortisation expense is recognised within administrative expenses in the consolidated statement of comprehensive income.

##### 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.

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; its cash generating units ('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.

### **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' paragraph 23, items are recorded at their individual 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. 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. This is not recognised in the inventories of the Group until the risks and rewards of ownership are transferred.

### **Financial assets**

The Group does not have any financial assets which it would classify as fair value through profit or loss, available for sale or held to maturity. Therefore all financial assets are classed as loans and receivables as defined below.

### **Loans and receivables**

These assets are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. The Group's loans and receivables comprise 'trade and other receivables' and 'cash and cash equivalents' in the consolidated statement of financial position. They are included in current assets, except for maturities greater than 12 months after the end of the reporting period, which are classed as non-current assets.

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 fair value plus transaction costs that are directly attributable to their acquisition or issue and subsequently measured at amortised cost using the effective interest method, less provision for impairment.

Cash and cash equivalents include cash in hand, deposits held at call with banks and other highly-liquid cash investments.

Impairment provisions are recognised when there is objective evidence (such as significant financial difficulties on the part of the counterparty or default or significant delay in payment) that the Group will be unable to collect all of the amounts due under the terms receivable, the amount of such a provision being the difference between the net carrying amount and the present value of the future expected cash flows associated with the impaired receivable. For trade receivables, which are reported net; such provisions are recorded in a separate allowance account with the loss being recognised within administrative expenses in the consolidated statement of comprehensive income. On confirmation that the trade receivable will not be collectable, the gross carrying value of the asset is written off against the associated provision.

### **Financial liabilities**

The Group does not have any material financial liabilities that would be classified as fair value through the profit or loss. Therefore all financial liabilities are classified as other financial liabilities, as defined below.

### **Other financial liabilities**

Other financial liabilities include the following items:

Borrowings are initially recognised at fair value. 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 administrative expenses.

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.

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 1. Accounting policies continued

#### Retirement benefits: defined contribution schemes

Contributions to defined contribution pension schemes are charged to the consolidated statement of comprehensive income in the year to which they relate. The Group has no further payment obligations once the contributions have been paid.

#### Provisions and contingent liabilities

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.

#### Leased assets

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, except where the period to the review date on which the rent is first expected to be adjusted to the prevailing market rate is shorter than the full lease term, in which case the shorter period is used.

#### Dividends

Dividends are recognised when they become legally payable. In the case of interim dividends to equity shareholders, this is when paid. In the case of final dividends, this is when approved by the shareholders.

#### Current and deferred tax

The tax expense for the year comprises current and deferred tax. Tax is recognised in the income statement, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly in equity, respectively.

The current tax charge, including UK corporation tax and foreign tax, is calculated on the basis of the laws that have been enacted or substantively enacted by the balance sheet date. Provisions are established, where appropriate, on the basis of amounts expected to be paid.

Deferred tax assets and liabilities are recognised where the carrying amount of an asset or liability in the consolidated statement of financial position differs from its tax base, except for differences arising on:

- the initial recognition of goodwill;
- the initial recognition of an asset or liability in a transaction which is not a business combination and at the time of the transaction affects neither accounting nor taxable profit; and
- investments in subsidiaries and jointly-controlled entities where the Group is able to control the timing of the reversal of the difference and it is probable that the difference will not reverse in the foreseeable future.

Deferred income tax assets are recognised only to the extent that it is probable that future taxable profit will be available against which the differences can be utilised.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the deferred tax liabilities or assets are settled or recovered, respectively.

Deferred tax assets and liabilities are offset when the Group has a legally enforceable right to offset current tax assets and liabilities and the deferred tax assets and liabilities relate to taxes levied by the same tax authority on either:

- the same taxable Group Company; or
- different Company entities which intend either to settle current tax assets and liabilities on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax assets and liabilities are expected to be settled or recovered.

#### Share capital

Financial instruments issued by the Group are treated as equity only to the extent that they do not meet the definition of a financial liability. The Group's Ordinary Shares are classified as equity instruments.

## Revenue

Revenue represents amounts receivable for goods and services provided in the normal course of business, net of trade discounts, VAT and other sales-related taxes. The revenue recognition for the operational areas of the business is:

### Supply of products

Revenue from the supply of products is recognised when the Group has transferred the significant risks and rewards of ownership to the buyer and it is probable that the Group will receive the previously agreed upon payment. These criteria are considered to be met when the goods are delivered to the buyer. Revenue is recognised at the fair value of consideration received or receivable.

### Managed Access service fees

All services provided in relation to Managed Access are contractually agreed with the product originator, revenue for these services is recognised in the period 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 set up 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 when the contracted milestones are achieved.

Monthly management fees are recognised as revenue in the month to which they relate and once contractual services have been provided.

Revenue in respect of program management fees is recognised 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.

Revenue in all years principally arises from the provision of goods and services. Further information is available in note 3, Segment information.

## 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 30.

### (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 13.

### (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.

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 2. Critical accounting estimates and judgements continued

#### (d) Inventory provisioning

The Company'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 apply 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 Company 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) 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.

### 3. Segment information

The Group has four main reportable segments, being the Group's operating businesses:

Clinigen Clinical Trial Services ('CTS') sources commercial medical products for use in clinical studies, including comparator drugs, adjuvant drugs and rescue therapies. This operating business accounts for the largest proportion of the Group's revenue, generating 61% (2014: 66%) of its external revenues. Post-acquisition, the Clinigen Clinical Trial Supplies (Clinigen CTS) business and the Idis Clinical Trial Procurement (Idis CTP) businesses were fully integrated into Clinigen Clinical Trials Services.

Idis Managed Access ('MA') specialises in the consultancy, development, management and implementation of managed access programs for biotechnology and pharmaceutical companies. Post-acquisition, the Clinigen Global Access Program (Clinigen GAP) business and the Idis Managed Access Program (Idis MAP) business were fully integrated into Idis Managed Access. The combined operating business contributed 16% (2014: 13%) of the Group's external revenues.

Idis Global Access ('GA') provides high quality ethical access to post approval and short-supply medicines, in regions where patients have low or non-existent access to these often essential drugs. In FY15, it contributed 5% to the Group's external revenues; this operating business was acquired as part of Idis and is new to the Group. The revenue and gross profit figures represent the two months of trading since acquisition.

Clinigen Specialty Pharmaceuticals ('SP') manufactures and distributes its own and in-license specialist, hospital-only medicines worldwide and contributed 18% (2014: 21%) of the Group's external revenues.

#### Factors that management used to identify the Group's reportable segments

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



Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker has been identified as the Executive Directors.

#### Measurement of operating segment profit or loss, assets and liabilities

The accounting policies of the operating segments are the same as those described in note 1.

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

#### Classes of business

	2015 £'000	2014 £'000
<b>Revenue arises from:</b>		
Clinical Trial Services (previously Clinical Trials Supply)	112,661	83,622
Managed Access (previously Global Access Programs)	28,792	16,143
Global Access	9,207	–
Specialty Pharmaceuticals	33,699	26,874
	<b>184,359</b>	<b>126,639</b>
<b>Gross profit arises from:</b>		
Clinical Trial Services (previously Clinical Trials Supply)	13,436	12,608
Managed Access (previously Global Access Programs)	8,330	5,436
Global Access	2,796	–
Specialty Pharmaceuticals	29,089	23,159
	<b>53,651</b>	<b>41,203</b>
Administrative expenses relating to underlying operations	(26,675)	(17,887)
Administrative expenses relating to non-underlying operations	(5,939)	–
Costs of restructuring	(3,821)	–
Share-based payment expense	(1,299)	(1,190)
Social security costs in respect of share-based payments	(1,039)	(611)
Acquisition costs	(5,703)	–
Finance income	39	2
Finance costs	(859)	(234)
<b>Profit before tax</b>	<b>8,355</b>	<b>21,283</b>
	2015 £'000	2014 £'000
<b>Breakdown of revenues by products and services:</b>		
Products	168,818	118,449
Services	12,118	8,190
Royalties	3,423	–
	<b>184,359</b>	<b>126,639</b>

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 3. Segment information continued

#### Geographical analysis

	2015 £'000	2014 £'000
<b>Revenue arises from the following locations:</b>		
UK	26,593	19,744
Republic of Ireland	8,544	13,109
Rest of Europe	49,255	37,112
USA	77,684	51,606
Rest of World	22,283	5,068
	<b>184,359</b>	<b>126,639</b>
<b>Gross profit arises from the following locations:</b>		
UK	8,773	7,409
Germany	5,586	5,342
France	6,142	2,326
Rest of Europe	12,539	7,223
USA	17,081	15,282
Rest of World	3,530	3,621
	<b>53,651</b>	<b>41,203</b>
<b>Analysis of concentration of customers (based on customers contributing at least 10% of revenue):</b>		
Customer A – Clinical Trial Services	28,056	17,138
Other	156,303	109,501
	<b>184,359</b>	<b>126,639</b>

Earnings before interest, taxation, depreciation and amortisation ('EBITDA') is calculated as:

	2015			2014		
	Underlying £'000	Non- underlying £'000	Total £'000	Underlying £'000	Non- underlying £'000	Total £'000
Revenue	184,359	–	184,359	126,639	–	126,639
Cost of sales	(130,708)	–	(130,708)	(85,436)	–	(85,436)
Gross profit	53,651	–	53,651	41,203	–	41,203
Administrative expenses excluding depreciation and amortisation (notes 13 and 14)	(21,349)	(10,910)	(32,259)	(14,367)	(1,801)	(16,168)
EBITDA	32,302	(10,910)	21,392	26,836	(1,801)	25,035

#### 4. Profit/(loss) from operations

Profit/(loss) from operations is stated after charging:

	2015 £'000	2014 £'000
Staff costs	<b>12,481</b>	8,695
Amortisation of intangible fixed assets	<b>7,145</b>	3,290
Impairment of intangible fixed assets	<b>3,370</b>	–
Depreciation	<b>325</b>	212
Impairment of tangible fixed assets	<b>116</b>	–
Loss on disposal of non-current assets	<b>1,283</b>	18
Operating lease rentals – land and buildings	<b>535</b>	264
Difference on foreign exchange	<b>827</b>	575
Auditors' remuneration		
Fees payable to the Company's auditors for the audit of the parent company and consolidated financial statements	<b>171</b>	67
Fees payable to the Company's auditors for other services:		
– The audit of the Company's subsidiaries	<b>85</b>	20
– Tax advisory services	<b>94</b>	69
– Tax compliance services	<b>19</b>	20
– Other services	<b>22</b>	12

Included in staff costs are share-based payments of £1.3m (2014: £1.2m).

#### 5. Staff costs

	2015 £'000	2014 £'000
Staff costs (including Directors) comprise:		
Wages and salaries	<b>8,752</b>	6,079
Share-based payments	<b>1,299</b>	1,190
Social security costs	<b>2,125</b>	1,236
Other pension costs	<b>305</b>	190
	<b>12,481</b>	8,695

#### Employee numbers

The average monthly number of staff employed by the Group during the financial year amounted to:

	2015 Number	2014 Number
Directors	<b>3</b>	3
Staff	<b>152</b>	104
	<b>155</b>	107

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 5. Staff costs continued

#### Directors' emoluments

	2015				2014			
	Salary/fees £'000	Bonus £'000	Benefit in kind £'000	Total £'000	Salary/fees £'000	Bonus £'000	Benefit in kind £'000	Total £'000
P George	357	172	2	531	351	239	2	592
R Sibson	221	108	3	332	190	156	2	348
S Chilton	209	101	2	312	178	248	2	428
P Allen	79	–	3	82	78	–	2	80
J Hartup	49	–	–	49	48	–	–	48
I Nicholson	47	–	–	47	47	–	–	47

There were three Directors (2014: three) who were members of the defined contribution pension scheme.

The amount payable to the highest paid Director in respect of emoluments was £0.5m (2014: £0.6m), pension contributions made on their behalf £36,000 (2014: £34,000) and share based payments of £0.3m (2014: £0.3m).

No Directors (2014: nil) exercised share options in the year.

Directors who held share options at 30 June were as follows:

	Plan	2015 Number	2014 Number
P George	Clinigen Group Long-Term Incentive Plan	825,556	825,556
S Chilton	Clinigen Group Long-Term Incentive Plan	662,978	619,167
P Allen	Chairman's Option Agreement	91,464	91,464

All share options are over the Company's ordinary shares of 0.1p each.

#### 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.

	2015 £'000	2014 £'000
Directors' remuneration included in staff costs:		
Wages and salaries	1,353	1,543
Defined contribution pension cost	77	69
Share-based payment expense	637	562
	<b>2,067</b>	<b>2,174</b>

## 6. Non-underlying items

The non-underlying items relate to the following:

	2015 £'000	2014 £'000
a) Share-based payment charge	1,299	1,190
a) Social security costs in respect of share-based payments	1,039	611
a) Credit in respect of deferred tax on share-based payments	(201)	(367)
b) Restructuring costs following the acquisition of the Idis Group	3,821	–
c) Acquisition costs	5,703	–
d) Impairment of intangible fixed assets	3,810	–
e) Amortisation of intangible fixed assets acquired through business combinations	2,129	–
f) Credit in respect of tax on non-underlying costs	(2,847)	–
	<b>14,753</b>	<b>1,434</b>

- a) The share based payment charge of £1.3m (2014: £1.2m), the social security costs relating to the share based payments of £1.0m (2014: £0.6m) and the tax credit in respect of the share based payment charge of £0.2m (2014: £0.4m) are classified as non-underlying items due to their significance and in order to provide the reader of the consolidated financial statements with a consistent view of the underlying costs of the operating Group.
- b) The integration of the Idis Group following acquisition included the removal of overlapping staff, the write off of the development costs of an IT system that will not be used by the combined Group and the commencement of the rationalisation of operating sites in the US. The main items included in the £3.8m of restructuring costs following the acquisition of the Idis Group consist of £1.3m for redundancy costs following the integration, £1.3m write off of development costs of an IT system that will no longer be implemented, £0.8m financing costs written off on settlement of the bank loan Idis previously had, and £0.4m cost of exiting an operating site in the US.
- c) The acquisition costs relating to Idis and those incurred as at 30 June 2015 in pursuit of the proposed acquisition of Link amounted to £5.7m. The main costs included corporate finance advice £2.4m, stamp duty £1.2m, legal advice £0.8m and £0.5m for insurance for warranties and indemnities.
- d) The £3.8m impairment of intangible fixed assets relates to the impairment of the in-licensed product Vibativ which was acquired in 2013. The product's current loss making position and uncertain commercial future has led to the carrying value of the product being fully impaired. The impairment charge includes a full write down of the carrying value of £3.4m, write down of stock of £0.2m and a £0.2m provision for committed future costs relating to the product.
- e) The amortisation of intangible assets acquired as part of the business combination with Idis, namely Brand, customer relationships and contracts, is classified as non-underlying due to their significance and to provide the reader with a consistent view of the underlying costs of the operating Group.
- f) The tax credit in respect of non-underlying items reflects the tax benefit on the costs incurred during the year.

## 7. Finance income

	2015 £'000	2014 £'000
Interest income on short-term bank deposits	39	2
<b>Total finance income</b>	<b>39</b>	<b>2</b>

## 8. Finance cost

	2015 £'000	2014 £'000
Bank interest	689	234
Other loan interest	170	–
<b>Total finance cost</b>	<b>859</b>	<b>234</b>



# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 9. Income tax

	2015 £'000	2014 £'000
<b>Current tax expense</b>		
Current tax on profits of the year	2,854	5,262
Adjustment in respect of prior years	397	37
<b>Total current tax expense</b>	<b>3,251</b>	<b>5,299</b>
<b>Deferred tax expense</b>		
Increase in deferred tax assets (note 22)	(155)	(229)
Decrease in deferred tax liability (note 22)	(426)	
<b>Total deferred tax benefit</b>	<b>(581)</b>	<b>(229)</b>
<b>Income tax expense</b>	<b>2,670</b>	<b>5,070</b>

All income tax is attributable to continuing operations.

The reasons for the difference between the actual tax charge for the year and the standard rate of corporation tax in the UK applied to profit for the year as follows:

	2015 £'000	2014 £'000
Profit before tax	8,355	21,283
Expected tax charge based on corporation tax rate of 20.75% (2014: 22.5%)	1,734	4,789
Depreciation in excess of capital allowances	85	42
Expenses not deductible for tax purposes other than goodwill amortisation and impairment	376	22
Adjustments to tax charge in respect of prior years	397	(192)
Short-term timing differences	(379)	260
Higher rates of taxes on overseas earnings	251	153
Loss on exercise of share options	(25)	–
Deferred tax arising on unexercised share options	(201)	–
Loss arising in year for which no deferred income tax is recognised	448	(4)
Rate differences	(16)	–
<b>Total tax expense</b>	<b>2,670</b>	<b>5,070</b>

#### Amounts recognised directly in equity:

Aggregate current and deferred tax arising in the reporting period and not recognised in net profit or loss or other comprehensive income but directly debited or (credited) to equity:

	2015 £'000	2014 £'000
Deferred tax: unexercised share options and losses arising not allowable in statement of comprehensive income	(1,387)	(1,024)
Adjustment in respect of prior years	(346)	–
	<b>(1,733)</b>	<b>(1,024)</b>

**Tax losses:**

	2015 £'000	2014 £'000
Unused tax losses for which no deferred tax asset has been recognised	<b>1,119</b>	–
Potential tax benefit @ 40%	<b>448</b>	–

The unused tax losses were incurred in the US subsidiary, Idis Inc. Due to the company being loss making, taxable income is not likely to in the foreseeable future.

During the year, the UK corporation tax rate was reduced from 21% to 20%. The relevant deferred tax balances have been measured at the substantively enacted rate of 20%. Further changes to the UK corporation tax rates were announced in the Chancellor's Budget on 8 July 2015. These include reductions to the main rate to reduce the rate to 19% from 1 April 2017 and to 18% from 1 April 2020. As the changes had not been substantively enacted at the balance sheet date their effects are not included in these financial statements. The overall effect of these changes, if they had applied to the deferred tax balance at the balance sheet date, would be to reduce the deferred tax asset by £0.2m.

**10. Earnings per share ('EPS')**

	2015 £'000	2014 £'000
Profit		
Profit used in calculating basic and diluted EPS	<b>5,685</b>	16,213

	Number	Number
Number of shares		
Weighted average number of shares for the purpose of basic EPS	<b>87,242,269</b>	82,555,585
Effect of:		
Employee share options	<b>2,621,694</b>	2,654,055
Weighted average number of shares for the purpose of diluted EPS	<b>89,863,963</b>	85,209,640

	Pence	Pence
EPS		
Basic	<b>6.5</b>	19.6
Diluted	<b>6.3</b>	19.0

EPS is calculated based on the share capital of Clinigen Group plc and the earnings of the combined Group.

Diluted EPS takes account of the weighted average number of outstanding share options being 2,621,694 (2014: 2,654,055).

The adjusted EPS, based on the following earnings figure for the year and weighted average number of shares of 87,242,269 is 28.0p (2014: 24.5p).

	2015 £'000	2014 £'000
Underlying profit after tax	<b>20,438</b>	17,647
Add back of amortisation	<b>5,015</b>	3,290
Less tax associated with amortisation	<b>(1,041)</b>	(740)
<b>Adjusted underlying earnings</b>	<b>24,412</b>	20,197

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 11. Dividends

	2015 £'000	2014 £'000
Final dividend in respect of the year ended 30 June 2014 of 2.1p (2014: 2.0p) per Ordinary Share	1,734	1,651
Dividend waived	–	(1)
Interim dividend of 1.1p (2014: 1.0p) per Ordinary Share paid during the year	908	826
	<b>2,642</b>	<b>2,476</b>

The Board proposes to pay a final dividend of 2.3p per Ordinary Share, subject to approval at the AGM on 27 October 2015.

### 12. Property, plant and equipment

	Leasehold improvement £'000	Plant and machinery £'000	Fixtures, fittings and equipment £'000	Total £'000
<b>Cost</b>				
At 1 July 2013	8	37	880	925
Reclassifications	–	–	(191)	(191)
Additions	563	–	78	641
Disposals	–	–	(29)	(29)
At 30 June 2014	571	37	738	1,346
<b>Accumulated depreciation</b>				
At 1 July 2013	5	6	166	177
Charge for the year	28	7	177	212
On disposals	–	–	(11)	(11)
At 30 June 2014	33	13	332	378
<b>Net book value</b>				
At 30 June 2014	538	24	406	968
At 30 June 2013	3	31	714	748
<b>Cost</b>				
At 1 July 2014	571	37	738	1,346
Acquisition of subsidiary	256	–	653	909
Additions	142	3	23	168
Disposals	–	–	(24)	(24)
<b>At 30 June 2015</b>	<b>969</b>	<b>40</b>	<b>1,390</b>	<b>2,399</b>
<b>Accumulated depreciation</b>				
At 1 July 2014	33	13	332	378
Charge for the year	73	8	244	325
Impairment	116	–	–	116
On disposals	–	–	(16)	(16)
<b>At 30 June 2015</b>	<b>222</b>	<b>21</b>	<b>560</b>	<b>803</b>
<b>Net book value</b>				
<b>At 30 June 2015</b>	<b>747</b>	<b>19</b>	<b>831</b>	<b>1,597</b>

Following the decision to terminate the lease on the US operations centre, the leasehold improvements at that site have been fully impaired.

### 13. Intangible assets

	Brand £'000	Contracts £'000	Customer relationships £'000	Trademarks and licences £'000	Computer software £'000	Goodwill £'000	Total £'000
<b>Cost</b>							
At 1 July 2013	–	–	–	34,568	–	8,742	43,310
Reclassifications	–	–	–	–	191	–	191
Additions	–	–	–	13,693	1,021	–	14,714
At 30 June 2014	–	–	–	48,261	1,212	8,742	58,215
<b>Accumulated amortisation</b>							
At 1 July 2013	–	–	–	4,417	–	–	4,417
Charge for the year	–	–	–	3,232	58	–	3,290
At 30 June 2014	–	–	–	7,649	58	–	7,707
<b>Net book value</b>							
At 30 June 2014	–	–	–	40,612	1,154	8,742	50,508
At 30 June 2013 and 1 July 2013	–	–	–	30,151	–	8,742	38,893
<b>Cost</b>							
At 1 July 2014	–	–	–	48,261	1,212	8,742	58,215
Acquisition of subsidiary (note 30)	49,449	17,720	42,996	–	3,006	147,867	261,038
Additions	–	–	–	7,543	923	–	8,466
Disposals	–	–	–	–	(1,275)	–	(1,275)
<b>At 30 June 2015</b>	<b>49,449</b>	<b>17,720</b>	<b>42,996</b>	<b>55,804</b>	<b>3,866</b>	<b>156,609</b>	<b>326,444</b>
<b>Accumulated amortisation</b>							
At 1 July 2014	–	–	–	7,649	58	–	7,707
Charge for the year	412	1,026	692	4,337	678	–	7,145
Impairment charge	–	–	–	3,370	–	–	3,370
<b>At 30 June 2015</b>	<b>412</b>	<b>1,026</b>	<b>692</b>	<b>15,356</b>	<b>736</b>	<b>–</b>	<b>18,222</b>
<b>Net book value</b>							
<b>At 30 June 2015</b>	<b>49,037</b>	<b>16,694</b>	<b>42,304</b>	<b>40,448</b>	<b>3,130</b>	<b>156,609</b>	<b>308,222</b>

On 29 April 2015, Clinigen Group plc acquired Idis Group Holdings Limited. The Idis brand, contracts for Idis Managed Access Programs and Customer relationships within Idis GA and Idis CTP were identified as separable intangible assets.

#### Brand

The brand represents the Idis brand acquired as part of the business combination, the brand has been fair valued at the acquisition date by reference to the three operating businesses acquired Idis MA, Idis GA and Idis CTP. 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 period is 19 years ten months.

#### Contracts

The acquired Idis Managed Access business has a number of client contracts which have been fair valued at the acquisition date based on the discounted value of future cash flows. These contracts are with large pharma businesses and provide for Idis to manage the access programs on behalf of large pharma business. The fair value of £17.7m represents 142 contracts with an average fair value of £125,000 per contract. The remaining amortisation period is four years ten months.

#### Customer relationships

Within Idis GA and Idis CTP 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 periods are CTS six years ten months and GA ranging from six years ten months to 13 years ten months.

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 13. Intangible assets continued

#### Trademarks and licences

On 18 August 2014, Clinigen Group plc acquired the intellectual property for the product Ethyol, this consisted of the trademarks, marketing authorisations and manufacturing dossier. The cost of the addition recognised is the purchase price plus the directly attributable costs incurred as a result of the acquisition, the costs of transferring the trademarks, marketing authorisations and the technical transfer of the manufacturing process incurred to date. Future costs expected to be incurred in respect of the manufacturing technical transfer will be recognised as incurred.

The current financial expectations for the in-licensed product, Vibativ, based on the product's current loss making position and most recent discussions on reimbursement and uncertain commercial viability the carrying value has been fully impaired. This is an additional charge to the Statement of Comprehensive Income of £3.4m.

A total of 276 trademarks and licences are held, with an average carrying value per trademark/licence is £146,500 and the average remaining amortisation period is five years eight months.

#### Computer software

Prior to the acquisition of Idis, the Group had been implementing a new ERP system. Idis had implemented Oracle in June 2014, therefore as part of the restructuring of the enlarged group, the Clinigen implementation has been ceased in favour of a group-wide solution. The capitalised costs to date of £1.3m have been written off to the Statement of Comprehensive Income.

The value recognised on acquisition of Idis reflects the fair value of the Oracle system software.

#### Goodwill

The goodwill is deemed to have an indefinite useful life. It is currently carried at cost and is reviewed annually for impairment.

The goodwill relates to the three operating businesses CTS, GA & MA. The addition in the year of £147.9m relates to goodwill arising on the acquisition of Idis Group Holdings Limited. This goodwill relates to the three operating business acquired Idis CTP, Idis MA and Idis GA.

An impairment test is a comparison of the carrying value of assets of a business or cash-generating unit (CGU) to their recoverable amount. The Group has defined its CGUs as CTS, MA, GA and SP. Where the recoverable amount is less than the carrying value, an impairment results. During the year, the goodwill on the acquisition of Keats Healthcare was tested for impairment, with no impairment charge arising. The goodwill arising on the acquisition of Idis Group Holdings Limited was tested for impairment on recognition and at year end with no impairment charge arising.

	Opening £'000	Addition £'000	Total £'000
2015			
CTS	8,742	23,525	32,267
MA	—	105,641	105,641
GA	—	18,701	18,701
Total	8,742	147,867	156,609
2014			
CTS	8,742	—	8,742

Following the integration performed post-acquisition, resulting in the creation of a CTS segment and a MA segment including both of the legacy Clinigen and IDIS segments the goodwill has been allocated in the same proportions as on acquisition to these CGUs as they represent the lowest level at which management review the performance of the business. Goodwill was allocated to the CGUs on a pro-rated Gross Profit contribution basis to the Idis business.

The recoverable amounts in 2015 were measured based on post-tax value in use (2014: based on post-tax value in use). This methodology is considered reasonable given the significant levels of headroom noted from this assessment. The pre-tax discount rate has been calculated as being 14.7%.



**CTS**

Details relating to the discounted cash flow model used in the impairment tests are as follows:

Valuation basis	Value in use	
Key assumptions	Sales growth	2.5% per annum
	Profit margins	14%
	Discount rate	12%
	Terminal growth rate	2.5%
Determination of assumptions	<p>Detailed forecasts for the next three years have been used which are based on approved annual budgets and strategic projections representing the best estimate of future performance.</p> <p>Margins are based on past experience and cost estimates.</p> <p>Discount rate is based on weighted average cost of capital, and is a post-tax rate of 12%.</p>	

If any one of the following changes were made to the assumptions, the carrying amount and recoverable amount would be equal. These have been calculated based on sensitivity analysis for each category listed.

Valuation basis	Value in use
Terminal growth rate	A reduction from 2.5% to 15.7%
Discount rate	Increase from 13.4% to 24.8%

**MA**

Details relating to the discounted cash flow model used in the impairment tests are as follows:

Valuation basis	Value in use	
Key assumptions	Sales growth	13.75% per annum
	Profit margins	26%
	Discount rate	12%
	Terminal growth rate	2.5%
Determination of assumptions	<p>Detailed forecasts for the next three years have been used which are based on approved annual budgets and strategic projections representing the best estimate of future performance.</p> <p>Margins are based on past experience and cost estimates.</p> <p>Discount rate is based on weighted average cost of capital, and is a post-tax rate of 12%.</p>	

If any one of the following changes were made to the assumptions, the carrying amount and recoverable amount would be equal. These have been calculated based on sensitivity analysis for each category listed.

Valuation basis	Value in use
Terminal growth rate	A reduction from 2.5% to 0.9%
Discount rate	Increase from 12% to 13.4%

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 13. Intangible assets continued

#### GA

Details relating to the discounted cash flow model used in the impairment tests are as follows:

Valuation basis	Value in use	
Key assumptions	Sales growth	(6.5)% per annum
	Profit margins	30%
	Discount rate	12%
	Terminal growth rate	2.5%
Determination of assumptions	Detailed forecasts for the next three years have been used which are based on approved annual budgets and strategic projections representing the best estimate of future performance. Margins are based on past experience and cost estimates. Discount rate is based on weighted average cost of capital, and is a post-tax rate of 12%.	

If any one of the following changes were made to the assumptions, the carrying amount and recoverable amount would be equal. These have been calculated based on sensitivity analysis for each category listed.

Valuation basis	Value in use
Terminal growth rate	A reduction from 2.5% to 1.6%
Discount rate	Increase from 12% to 12.8%

Management do not consider any of the above sensitivities to be probable.

### 14. Subsidiaries

The principal 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	Country of incorporation	Nature of business
Clinigen Healthcare Limited	United Kingdom	Sales and distribution of pharmaceutical products
Keats Healthcare Limited	United Kingdom	Dormant
Clinigen CTS Inc.	USA	Sales and distribution of pharmaceutical products
Clinigen Pharma Limited	United Kingdom	Dormant
Clinigen Clinical Trials Limited	United Kingdom	Holding company
Clinigen CTS Limited	United Kingdom	Sales and distribution of pharmaceutical products
Clinigen GAP Limited	United Kingdom	Dormant
Clinigen SP Limited	United Kingdom	Dormant
Idis Group Holdings Limited	United Kingdom	Holding company
Idis Group Limited	United Kingdom	Holding company
Idis Limited	United Kingdom	Sales and distribution of pharmaceutical products
Idis Inc	USA	Provision of business development services
Idis Pharma Private Limited	India	Dormant
Idis SAS	France	Dormant
Idis Trustee (UK) Limited	United Kingdom	Non trading trustee of Employee Benefit Trust
Employee Benefit Trust 1	Jersey	Employee Benefit Trust
Employee Benefit Trust 2	Jersey	Employee Benefit Trust

All shareholdings in subsidiaries are owned 100% (2014: 100%) through the subsidiaries' ordinary share capital.

## 15. Inventories

	2015 £'000	2014 £'000
Raw materials and consumables	721	914
Work in progress	244	340
Finished goods and goods for resale	10,162	1,212
	<b>11,127</b>	<b>2,466</b>

Finished goods include an amount of £6.8m (2014: £nil) carried at fair value less costs to sell. Inventory acquired as part of the acquisition of Idis Group has been fair valued at the acquisition date. The fair valuation resulted in a write down of the carrying value of inventories of £0.3m. No further write downs have been recognised throughout the year.

The cost of inventories recognised as an expense and included in cost of sales amounted to £127.3m (2014: £83.5m).

## 16. Trade and other receivables

	2015 £'000	2014 £'000
Trade receivables	56,328	20,388
Less: provision for impairment of trade receivables	(8,949)	(237)
Trade receivables – net	47,379	20,151
Prepayments and accrued income	11,871	2,003
Payments made on account	6,118	1,004
Other receivables	1,763	486
<b>Total trade and other receivables</b>	<b>67,131</b>	<b>23,644</b>

Due to the short-term nature of trade and other receivables and as the credit risk has been adjusted for through the provision for impairment of trade receivables, the book value approximates to their value. When assessing for impairment, the trade receivables are reviewed for age and due date. The past payment history with the customer is taken into account, where applicable.

The following table provides information on the movement in the provision for impairment in the year:

	£'000
At 1 July 2014	237
Transfer on acquisition of subsidiary	8,871
Released to the Consolidated income statement	(286)
Charged to the Consolidated income statement	127
	<b>8,949</b>

The £8.9m provision recognised on acquisition of Idis Group Holdings Limited, represents the ageing of the trade receivables acquired and the potential risk of default on those balances.

As at 30 June 2015 trade receivables of £15.1m (2014: £8.9m) were past due but not impaired, of which, £11.5m was received after the year end.

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 16. Trade and other receivables continued

They relate to the customers with no default history. The ageing analysis of these receivables is as follows:

	2015 £'000	2014 £'000
Up to three months	13,516	7,591
three to six months	1,567	1,271
	<b>15,083</b>	8,862

### 17. Cash and cash equivalents

	2015 £'000	2014 £'000
Cash at bank and in hand	27,750	21,787
	<b>27,750</b>	21,787

Due to the short-term nature of cash at bank and short-term deposits, and as the credit risk has been adjusted for where required, the carrying value approximates to their value. The credit risk of the banks was very low and therefore the carrying amount has not been adjusted; their credit ratings were RBS: BBB+, HSBC: AA- and JP Morgan A+.

### 18. Trade and other payables

	2015 £'000	2014 £'000
Current		
Trade payables	48,100	10,275
Payments received on account	1,047	2,326
Tax and social security	2,087	791
Other payables	834	53
Accruals and deferred income	35,572	6,057
	<b>87,640</b>	19,502

Due to the short-term nature of trade and other payables, the fair value approximates to their value. Creditors are unsecured.

### 19. Loans and borrowings

The book value of loans and borrowings are as follows:

	2015 £'000	2014 £'000
<b>Non-current liability</b>		
Bank borrowings	34,530	—
<b>Current liability</b>		
Bank borrowings	69,470	16,500
<b>Total loans and borrowings</b>	<b>104,000</b>	16,500

The Group has a total bank facility of £140.0m available (2014: £35.0m), this consists of a five year fixed term repayment loan of £45.0m (2014: £nil) a revolving credit facility (RCF) of £95.0m (2014: £35.0m). The RCF is repayable within one month and therefore included within current liabilities.

Interest is payable on a tiered scale based on the level of borrowing. The applicable interest rate on amounts drawn down is up to 2.75 percent, plus LIBOR/EURIBOR (as applicable) on both the RCF and the Term Loan Facility. The margin payable is dependent on the adjusted leverage ratio and will reduce to a minimum of 1.25 percent, plus LIBOR/EURIBOR (as applicable) as adjusted leverage decreases.

The bank loans are secured on the intangible fixed assets of the Group.

### Maturity of loans and borrowings

The maturity profile of the carrying amount of the Group's borrowings at the period end was as follows:

	2015			2014		
	Gross borrowings £'000	Unamortised issue costs £'000	Net borrowings £'000	Gross borrowings £'000	Unamortised issue costs £'000	Net borrowings £'000
Within one year	69,838	(368)	69,470	16,500	–	16,500
In more than one year but less than two years	9,000	(368)	8,632	–	–	–
In more than two years but less than five years	27,000	(1,102)	25,898	–	–	–
	105,838	(1,838)	104,000	16,500	–	16,500

### Fair value of borrowings

The carrying amount and the fair value of the Group's borrowings are as follows:

	Carrying amount		Fair value	
	2015 £'000	2014 £'000	2015 £'000	2014 £'000
Bank borrowings	105,838	16,500	101,167	16,500
	105,838	16,500	101,167	16,500

The fair values of the Group's borrowings are within Level 2 of the fair value hierarchy.

At 30 June 2015, the fixed term loan was fully utilised at £45.0m and £60.8m was borrowed against the revolving credit facility. All borrowings are in pounds sterling. There were no instances of default, including covenant terms, in either the current or the preceding period.

## 20. Provisions

	Restructuring
<b>At 1 July 2014</b>	–
Charged to the income statement	1,510
<b>At 30 June 2015</b>	<b>1,510</b>

The integration of the Idis Group following acquisition included the identification and proposed removal of overlapping staff and the commencement of the rationalisation of operating sites in the US. Whilst the integration was ongoing at the balance sheet date, discussions with affected employees and the US based landlords had taken place. The estimated staff restructuring costs to be incurred were £1.0m, this is expected to be fully utilised during the first half of FY16. The costs of exiting operating sites in the US were £0.5m.

## 21. Financial instruments – risk management

The Group is exposed through its operations to the following financial risks:

- credit risk;
- foreign exchange risk; and
- liquidity risk.

In common with all other businesses, the Group is exposed to risks that arise from its use of financial instruments. This note describes the Group's objectives, policies and processes for managing those risks and the methods used to measure them. Further quantitative information in respect of these risks is presented throughout these financial statements.



# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 21. Financial instruments – risk management continued

#### 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; and
- loans and borrowings.

The Group does not issue or use financial instruments of a speculative nature.

A summary of the financial instruments held by category is provided below:

	2015 £'000	2014 £'000
<b>Loans and receivables</b>		
Cash and cash equivalents	27,750	21,787
Trade and other receivables	55,260	21,641
<b>Total financial assets</b>	<b>83,010</b>	43,428
<b>Financial liabilities measured at amortised cost</b>		
Trade and other payables	85,553	18,711
Loans and borrowings	105,838	16,500
<b>Total financial liabilities</b>	<b>191,391</b>	35,211

#### General objectives, policies and processes

The Board has overall responsibility for the determination of the Group's risk management objectives and policies and, whilst retaining ultimate responsibility for them, it has delegated the authority for designing and operating processes that ensure the effective implementation of the objectives and policies to the Group's finance function. The Board receives monthly reports from the Chief Financial Officer through which it reviews the effectiveness of the processes put in place and the appropriateness of the objectives and policies it sets.

The overall objective of the Board is to set policies that seek to reduce risk as far as possible without unduly affecting the Group's competitiveness and flexibility. Further details regarding these policies are set out below:

#### 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 Finance Controller or Group Finance Director.

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 reporting period, which are past due but not impaired, are provided in note 16.

	2015 £'000	2014 £'000
<b>Financial assets – maximum exposure</b>		
Cash and cash equivalents	27,750	21,787
Trade and other receivables	55,260	21,641
<b>Total financial assets</b>	<b>83,010</b>	43,428

### 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 29% (2014: 19%) 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. When currency is to be repatriated to the UK, this is planned in order to minimise the exposure to foreign exchange rate fluctuations. The Group's net assets arising from such overseas operations are exposed to currency risk resulting in gains or losses on retranslation into sterling. Given the levels of materiality, the Group does not hedge its net investments in overseas operations as the cost of doing so is disproportionate to the exposure.

Foreign exchange risk also arises when individual Group entities enter into transactions denominated in a currency other than their functional currency where these transactions are significant to the Group. The Group hedges currency transactions internally through currency bank accounts, this limits 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 contracts for supply of product within the Clinigen CTS operating business where the contract is not naturally hedged. This eliminates the risk to fluctuating foreign exchange rates and permits the management of that operating business to have visibility of gross profit margins.

At the reporting date the Group had entered into time option contracts with the bank for Swiss francs, US dollars, euros and sterling. These options all mature within six months of the reporting date, and have an immaterial fair value so have not been separately identified from trade and other payables.

### 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 annual 12-month cash flow projections based on working capital modelling as well as information regarding cash balances 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:

	Up to 3 months £'000	Between 3 and 12 months £'000
<b>At 30 June 2015</b>		
Trade and other payables	<b>85,553</b>	–
<b>At 30 June 2014</b>		
Trade and other payables	18,711	–

More details in regard to the line items are included in the respective notes:

- Trade and other payables – note 18
- Loans and borrowings – note 19

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 21. Financial instruments – risk management continued

#### General objectives, policies and processes continued

##### Capital management

The Group monitors 'adjusted capital' which comprises all components of equity (ie share capital, share premium account, merger reserve, foreign exchange reserve and retained earnings) and long-term debt.

The Group's objectives when maintaining capital are:

- to safeguard the entity's ability to continue as a going concern, so that it can continue to provide returns for shareholders and benefits for other stakeholders; and
- to ensure the Group has the cash available to develop the products and services provided by the Group in order to provide an adequate return to shareholders.

Pricing, sale and acquisition decisions are made by assessing the level of risk in relation to the expected return.

The Group sets the amount of capital it requires in proportion to risk. The Group manages its capital structure and makes adjustments to it in the light of changes in economic conditions and the risk characteristics of the underlying assets. In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, return capital to shareholders, issue new shares or sell assets to reduce debt.

Net debt is calculated as total debt (as shown in the consolidated statement of financial position) less cash and cash equivalents.

### 22. Deferred income tax

The analysis of deferred income tax assets and liabilities is as follows:

	2015 £'000	2014 £'000
Deferred tax assets:		
Deferred tax assets to be recovered after more than 12 months	(3,843)	(1,956)
Deferred tax liabilities:		
Deferred tax liabilities to be recovered after more than 12 months	18,990	–
Deferred tax liabilities to be recovered within 12 months	2,556	–
	<b>21,546</b>	–

The gross movement on the deferred income tax account is as shown below:

	Unexercised share options	Tax losses	Fair value gains Total
Deferred tax liabilities			
At 1 July 2013, 30 June 2014 and 1 July 2014			–
Acquisition of subsidiary			21,972
Credited to the income statement			(426)
<b>At 30 June 2015</b>			<b>21,546</b>
Deferred tax assets			
At 1 July 2014	934	1,022	1,956
Credited to the income statement	201	–	201
Credited direct to equity	1,340	346	1,686
<b>At 30 June 2015</b>	<b>2,475</b>	<b>1,368</b>	<b>3,843</b>

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 £0.5m in respect of tax losses amount to £1.1m that can be carried forward against future taxable income.

Deferred tax is calculated in full on temporary differences under the liability method using a tax rate of 20% (2014: 20%).

## 23. Share capital

	Number of Shares (‘000s)
Authorised, issued and fully paid	Ordinary shares of 0.1p each
At 1 July 2013 and at 30 June 2014	82,556
<b>At 1 July 2014</b>	<b>82,556</b>
Issue of new shares	27,153
<b>At 30 June 2015</b>	<b>109,709</b>

	2015 £’000	2014 £’000
Ordinary shares of 0.1p each	110	83

On 28 April 2015, 27,153,011 new ordinary shares of 0.1p each were issued for £132.4m after deducting expenses of £3.4m.

## 24. Reserves

The following describes the nature and purpose of each reserve within equity:

Reserve	Description and purpose
Share premium account	Amount subscribed for share capital in excess of nominal value, except where recognition in merger reserve is used (see below).
Merger reserve	Amount subscribed for share capital in excess of nominal value when shares are issued in exchange for at least a 90% interest in the shares of another company.
Own shares	Acquisition price of shares purchased and held to satisfy share options on exercise.
Foreign exchange reserve	Gains/losses arising on retranslating the net assets of overseas operations into sterling.
Retained earnings	All other net gains and losses and transactions with owners (e.g. dividends) not recognised elsewhere.

Included within the retained earnings reserve as at 30 June 2015 is £5.2m (2014: £2.2m) which is not distributable.

## 25. Leases

### Operating leases

The total future value of minimum lease payments under non-cancellable operating leases are:

	2015 £’000	2014 £’000
<b>Land and buildings:</b>		
In one year or less	894	331
Between one and five years	1,200	1,233
In five years or more	479	1,238
	<b>2,573</b>	<b>2,802</b>

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 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 £0.3m (2014: £0.2m).

### 27. Share-based payments

The Company operated the following schemes:

Plan	Tax authority status	Employees	Granting, vesting conditions and exercise of share options
Chairman's Option Agreement	Unapproved	Chairman	<p>The option vests at the earliest of a change in control or 18 September 2015.</p> <p>If the Chairman ceases to be a Director of any Group Company, the option may be exercised for a period of twelve months from the date he ceases to be a Director.</p>
Clinigen Group Long-Term Incentive Plan	Unapproved	All employees	<p>Performance condition based on growth in total shareholder return (TSR) over a 3-year period. Share options granted at IPO have a requirement of at least 25% growth. Other grants under the Scheme require Clinigen growth in TSR to be in excess of the FTSE Small Cap Index (excluding investment companies).</p> <p>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.</p>
Clinigen Group Sharesave Plan	HMRC approved	All employees	<p>Options are exercisable at a price equal to the average opening price as published in the Financial Times on the date of invitation and the two dealing days preceding the date of invitation, less 20%.</p> <p>3-year vesting period.</p> <p>If options remain unexercised after a period of six months from the vesting date the options expire.</p> <p>If monthly contributions are not made for more than six months over the three year period, the options lapse.</p>
Clinigen Group Company Share Option Plan	HMRC approved for UK employees  Unapproved for US employees	All employees	<p>Options granted to employees who have invested in the shares of the Company.</p> <p>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.</p> <p>3-year vesting period.</p> <p>Options vest if employee still owns shares in three years or exercises their options under the Sharesave or US Stock Purchase Plan.</p>
Clinigen Group US Stock Purchase Plan	US tax authority approved	All employees	<p>Options are exercisable at a price equal to the average opening price as published in the Financial Times on the date of invitation and the two dealing days preceding the date of invitation, less 15%.</p> <p>Two year vesting period.</p>
Clinigen Group Employee Share Scheme October 2013	Unapproved	All employees excluding Directors	Options vested for employees who were still employed on 1 October 2014. All options under the scheme vested during the year.



Details of the share options outstanding during the year are as follows:

	2015		2014	
	Weighted average exercise price (p)	Number	Weighted average exercise price (p)	Number
Outstanding at start of year	<b>42.35</b>	<b>2,623,465</b>	42.13	2,269,961
Granted during year	–	<b>324,671</b>	34.85	701,272
Forfeited during the year	<b>145.80</b>	<b>(98,911)</b>	26.27	(342,076)
Exercised during year	–	<b>(77,822)</b>	–	(5,692)
Outstanding at end of year	<b>34.88</b>	<b>2,771,403</b>	42.35	2,623,465

Of the total number of options outstanding at 30 June 2015, none had vested.

The weighted average share price (at the date of exercise) of options exercised during the period was 471p (2014: 486p).

The exercise price of options outstanding at 30 June 2015 ranged between £nil and £4.42 and their weighted average contractual life was two years three months. None of these were exercisable at 30 June 2015.

The weighted average fair value of each option granted during the year was 425.1p (2014: 320.4p).

The following information is relevant in the determination of the fair value of options granted during the period under the equity-settled share-based remuneration schemes operated by the Group. The Black-Scholes pricing model is used for all schemes except for the Long-Term Incentive Plan and the Chairman's Award, where a Stochastic valuation model is used.

	2015	2014
Option pricing model	<b>Black-Scholes</b>	Black-Scholes
Weighted average share price at grant date (pence)	<b>457.0</b>	467.9
Exercise price (pence)	<b>nil</b>	nil to 442
Weighted average contractual life (in years)	<b>nil</b>	2.7
Expected volatility (%)	<b>39.5</b>	39 to 40
Expected dividend yield (%)	<b>0.7</b>	0.4 to 0.6
Risk-free interest rate (%)	<b>0.7</b>	0.4 to 0.9

Expected volatility was determined by calculating the historical volatility of the Company's share price over the period since the Company listed.

The share-based remuneration expense comprises equity-settled schemes of £1.3m (2014: £1.2m).

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 the Alternative Investment Market ('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 5.

During the year and the preceding year, the Group had no transactions with related parties.

# Notes forming part of the consolidated financial statements continued

## for the year ended 30 June 2015

### 29. Events after the reporting date

On 17 September 2015, Clinigen announced a strategic alliance with Cumberland Pharmaceuticals, with no financial terms, which will build on Clinigen's existing North American relationships by providing complementary support from Cumberland in the development, marketing, promotion and distribution of future products in the US, with Clinigen supporting Cumberland outside the US.

On 22 September 2015, Clinigen Group plc announced the proposed acquisition of Link Healthcare a specialist pharmaceutical and medical technology business focussed on the Asia, Africa and Australasia (AAA) region for a maximum consideration of £100m. Link is being acquired on a debt-free cash-free basis with an initial consideration of £44.5m, payable at completion 50% in cash and 50% in shares. Additional deferred consideration of up to £55.5m is payable if earn out targets are achieved over a two year period. Completion of the acquisition is expected to occur on or around 28 October 2015 after the Clinigen AGM.

For the financial year ended 31 March 2015, Link achieved revenue of £31.6m and EBITDA of £4.2m. The cash element of the acquisition consideration will be financed from the Group's existing available debt facility.

### 30. Business combinations

On 29 April 2015 the Group acquired the share capital of a competitor, Idis Group Holdings Limited including its subsidiaries Idis Group Limited, Idis Limited, Idis Inc, Idis SAS and Idis SAS and Idis Pharma Private Limited. The main operations of the acquired entities are based in the UK and US.

The transaction will allow the Group to benefit from greater market penetration in the MA segment, access to management expertise in the GA segment and synergies arising from the close alignment of the acquired business segments to those in the Group.

Clinigen Group plc paid a total of £199.5m in consideration by cash funding. Cash paid by Clinigen Group plc on acquisition was raised by a combination of bank loans and borrowings and an issue of share capital to the market; all consideration was transferred on completion on 29 April 2015.

The provisional fair value of assets acquired and liabilities assumed was as follows:

	£'000
Intangible Assets	113,171
Property, plant and equipment	909
Inventories	6,837
Trade and other receivables	32,577
Cash	19,777
Trade and other payables	(64,355)
Loans and borrowings	(35,338)
Provision for deferred tax	(21,972)
<b>Net assets acquired</b>	<b>51,607</b>
Goodwill arising on acquisition	147,867
<b>Total consideration</b>	<b>199,474</b>

The fair values set out above are provisional figures which will be finalised in the 2016 financial statements following management's final review of key reconciliations and judgemental areas relating to acquired creditor balances.

The fair value of intangible assets recognised on business combination comprise the Idis brand at £49.4m, customer relationships at £43.0m, supplier contracts at £17.7m and computer software of £3.0m.

The fair value of acquired inventories represents inventories valued at the sale price in line with IFRS 3 (revised) less provision for obsolescence and slow moving inventory following the application of Clinigen's group accounting policies. This provision takes account of the condition of inventory, the remaining expiry period and applies assumptions around expected future demand for the inventory.

The fair value of trade and other receivables takes account that there were significant amounts of overdue debt at the time of acquisition, and four months on from acquisition, these amounts are still outstanding. This resulted in a reduction in the fair value of the asset by £7.8m to reflect the profile of the balance.

The amounts included in the consolidated statement of comprehensive income since 29 April 2015 included revenue of £30.4m and there was a gross profit of £6.4m over the same period. Had the transaction occurred on the first day of the financial year, then estimated contribution to Group revenues would have been £200m and net profits of £1.3m before one off items.

# Independent Auditors' report

## to the members of Clinigen Group plc

### Report on the company financial statements

#### Our opinion

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

- give a true and fair view of the state of the company's affairs as at 30 June 2015;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- have been prepared in accordance with the requirements of the Companies Act 2006.

#### What we have audited

The financial statements comprise:

- the company balance sheet as at 30 June 2015; and
- the notes to the financial statements, which include a summary of significant accounting policies and other explanatory information.

The financial reporting framework that has been applied in the preparation of the financial statements is applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice).

In applying the financial reporting framework, the directors have made a number of subjective judgements, for example in respect of significant accounting estimates. In making such estimates, they have made assumptions and considered future events.

#### Opinion on other matter prescribed by the Companies Act 2006

In our opinion, the information given in the Strategic Report and the report of the directors for the financial year for which the financial statements are prepared is consistent with the financial statements.

#### Other matters on which we are required to report by exception

##### Adequacy of accounting records and information and explanations received

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 company, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

#### Directors' remuneration

Under the Companies Act 2006 we are required to report to you if, in our opinion, certain disclosures of directors' remuneration specified by law are not made. We have no exceptions to report arising from this responsibility.

#### Responsibilities for the financial statements and the audit

##### Our responsibilities and those of the Directors

As explained more fully in the Directors' Responsibilities Statement set out on page 43, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit and express an opinion on the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland) ('ISAs (UK & Ireland)'). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

This report, including the opinions, has been prepared for and only for the 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.

##### What an audit of financial statements involves

We conducted our audit in accordance with ISAs (UK & Ireland). An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of:

- whether the accounting policies are appropriate to the company's circumstances and have been consistently applied and adequately disclosed;
- the reasonableness of significant accounting estimates made by the directors; and
- the overall presentation of the financial statements.

We primarily focus our work in these areas by assessing the directors' judgements against available evidence, forming our own judgements, and evaluating the disclosures in the financial statements.

We test and examine information, using sampling and other auditing techniques, to the extent we consider necessary to provide a reasonable basis for us to draw conclusions. We obtain audit evidence through testing the effectiveness of controls, substantive procedures or a combination of both.

In addition, we read all the financial and non-financial information in the Annual Report and accounts to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

### Other matter

We have reported separately on the group financial statements of Clinigen Group plc for the year ended 30 June 2015.



**Andrew Hammond (Senior Statutory Auditor)**

for and on behalf of PricewaterhouseCoopers LLP  
Chartered Accountants and Statutory Auditors  
Birmingham

24 September 2015



# Company balance sheet

## as at 30 June 2015

	Note	2015		2014	
		£'000	£'000	£'000	£'000
<b>Fixed assets</b>					
Tangible fixed assets	3	<b>762</b>		951	
Intangible assets	4	<b>37,838</b>		37,522	
Investments	5	<b>244,709</b>		9,141	
			<b>283,309</b>		47,614
<b>Current assets</b>					
Debtors	6	<b>2,842</b>		4,328	
Deferred tax asset	10	<b>1,890</b>		1,956	
Cash at bank and in hand		<b>1,493</b>		8,125	
		<b>6,225</b>		14,409	
<b>Creditors: amounts falling due within one year</b>	7	<b>(95,421)</b>		(19,840)	
<b>Net current liabilities</b>			<b>(89,196)</b>		(5,431)
<b>Total assets less current liabilities</b>			<b>194,113</b>		42,183
<b>Creditors: amounts falling due after more than one year</b>	8		<b>(34,530)</b>		–
<b>Net assets</b>			<b>159,583</b>		42,183
<b>Capital and reserves</b>					
Called up share capital	11		<b>110</b>		83
Share premium account	12		<b>141,023</b>		8,660
Merger reserve			<b>5,413</b>		5,413
Profit and loss account	12		<b>13,037</b>		28,027
<b>Total shareholders' funds</b>	13		<b>159,583</b>		42,183

The prior year balance sheet has been restated to separately disclose the merger reserve; this was previously shown within share premium account.

The financial statements on pages 84 to 93 were approved by the Board of Directors on 24 September 2015 and were signed on its behalf by:



**P George**  
Director



**R Sibson**  
Director

# Notes to the Company balance sheet

## for the year ended 30 June 2015

### 1. Accounting policies

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

#### Basis of preparation

These financial statements have been prepared on a going concern basis, under the historical cost convention and in accordance with the Companies Act 2006 and applicable accounting standards in the United Kingdom.

The Company has elected to take exemption under section 408 of the Companies Act 2006 not to present the Company Statement of Comprehensive Income.

#### Cash flow statement

The Company has taken advantage of the exemption conferred by Financial Reporting Standard 1 'Cash Flow Statements (Revised 1996)' not to prepare a cash flow statement on the grounds that at least 90% of the voting rights in the Company are controlled within the Group headed by Clinigen Group plc and the Company is included in consolidated financial statements.

#### Going concern

The forecast trading activity and the financial position of the Company has been reviewed for a period of 12 months from the signing of the accounts and there are no going concern issues. The borrowings of the Company are secured against the assets of the Company and its subsidiaries.

#### 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 profit and loss account 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 profit and loss account over the remaining vesting period.

On the exercise of share options the charges recognised during the vesting period are recharged to the subsidiary undertaking where the associated benefit generated by the employee is recognised.

#### Property, plant and equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation. As well as the purchase price, cost includes directly attributable costs.

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 lives, as follows:

- Leasehold improvements – remaining term of lease to which the improvements relate
- Plant and machinery – 20%
- Fixtures, fittings and equipment – 20% to 33% straight line

#### Intangible assets

##### Trademarks and licences

Separately acquired trademarks and licences are initially recognised at cost, being the purchase price of the asset which comprises the purchase price and any directly attributable cost of preparing the asset for its intended use. Where licences have outstanding capital commitments at the time of acquisition, these are accrued for and capitalised as part of the purchase cost. The carrying value of trademarks and licences is calculated as cost less accumulated amortisation.

Amortisation is calculated using the straight-line method to allocate the cost of the trademarks and licences over their estimated useful lives of 15 years.

# Notes to the Company Balance Sheet continued

## for the year ended 30 June 2015

### 1. Accounting policies continued

#### Intangible assets continued

##### 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 trademarks and licences is compared to the recoverable amount, which is the higher of value in use and the fair value less costs to sell. An impairment loss is recognised for the amount by which the asset's carrying value exceeds its recoverable amount.

Where it is not possible to estimate the recoverable amount of an individual asset, the impairment test is carried out on the smallest group of assets to which it belongs for which there are separately identifiable cash flows; its cash generating units ('CGUs').

#### Investments

Investments in subsidiaries are recorded at historical cost, less any provision for impairment.

#### Provisions

A provision is made when an obligation exists for a future liability relating to a past event and where it is probable there will be an outflow of economic benefit. The provision is measured at the best estimate of the expenditure required to settle the obligation at the reporting date.

#### Retirement benefits: defined contribution schemes

Contributions to defined contribution pension schemes are charged to the profit and loss account in the year to which they relate. The Company has no further payment obligations once the contributions have been paid.

#### Leased assets

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 and operating lease are similarly spread on a straight-line basis over the lease term, except where the period to the review date on which the rent is first expected to be adjusted to the prevailing market rate is shorter than the full lease term, in which case the shorter period is used.

#### 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

UK corporation tax is provided at amounts expected to be paid using the tax rates and laws that have been enacted or substantially enacted by the balance sheet date.

Deferred tax is recognised in respect of all timing differences that have originated but not reversed at the balance sheet date, where transactions or events that result in an obligation to pay more tax in the future or a right to pay less tax in the future have occurred on the balance sheet date.

A net deferred tax asset is recognised as recoverable and therefore recognised only when, on the basis of all available evidence, it can be regarded as more likely than not that there will be suitable taxable profits against which to recover carried forward tax losses and from which the future reversal of underlying timing differences can be deducted.

Deferred tax is measured at the average tax rates that are expected to apply in the periods in which the timing differences are expected to reverse, based on tax rates and laws that have been enacted or substantively enacted by the balance sheet date. Deferred tax is measured on an undiscounted basis.

#### Share capital

Financial instruments issued by the Company are treated as equity only to the extent that they do not meet the definition of a financial liability. The Company's Ordinary Shares are classified as equity instruments.

## 2. Staff costs

	2015 £'000	2014 £'000
Staff costs (including Directors) comprise:		
Wages and salaries	3,658	3,386
Share-based payments	1,299	1,190
Defined contribution pension cost	141	120
Social security costs	1,549	1,012
	<b>6,647</b>	<b>5,708</b>

### Employee numbers

The average monthly number of staff employed by the Company during the financial year amounted to:

	2015 Number	2014 Number
Directors	3	3
Staff	62	57
	<b>65</b>	<b>60</b>

### 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.

	2015 £'000	2014 £'000
Directors' remuneration included in staff costs:		
Wages and salaries	1,353	1,543
Defined contribution pension cost	77	69
Share-based payment expense	637	562
	<b>2,067</b>	<b>2,174</b>

There were three Directors (2014: 3) who were members of the defined contribution pension scheme.

The amount payable to the highest paid Director in respect of emoluments was £0.5m (2014: £0.6m), pension contributions made on their behalf £36,000 (2014: £34,000) and share based payments of £0.3m (2014: £0.3m).

No Directors (2014: nil) exercised share options in the year.

Directors who held share options at 30 June were as follows:

	Plan	2015 Number	2014 Number
P George	Clinigen Group Long-Term Incentive Plan	825,556	825,556
S Chilton	Clinigen Group Long-Term Incentive Plan	662,978	619,167
P Allen	Chairman's Option Agreement	91,464	91,464

All share options are over the Company's Ordinary Shares of 0.1p each.

# Notes to the Company balance sheet continued

## for the year ended 30 June 2015

### 3. Tangible fixed assets

	Leasehold improvement £'000	Plant and machinery £'000	Furniture, fittings and equipment £'000	Total £'000
<b>Cost</b>				
At 1 July 2014	570	37	720	1,327
Additions	40	3	22	65
Disposals	–	–	(24)	(24)
<b>At 30 June 2015</b>	<b>610</b>	<b>40</b>	<b>718</b>	<b>1,368</b>
<b>Accumulated depreciation</b>				
At 1 July 2014	32	13	331	376
Charge for the year	58	8	180	246
On disposals	–	–	(16)	(16)
<b>At 30 June 2015</b>	<b>90</b>	<b>21</b>	<b>495</b>	<b>606</b>
<b>Net book value</b>				
<b>At 30 June 2015</b>	<b>520</b>	<b>19</b>	<b>223</b>	<b>762</b>
At 30 June 2014	538	24	389	951

### 4. Intangible assets

	Trademarks and licences £'000	Computer software £'000	Total £'000
<b>Cost</b>			
At 1 July 2014	38,990	862	39,852
Additions	7,543	430	7,973
Disposals	–	(1,275)	(1,275)
<b>At 30 June 2015</b>	<b>46,533</b>	<b>17</b>	<b>46,550</b>
<b>Accumulated amortisation</b>			
At 1 July 2014	2,330	–	2,330
Charge for the year	3,012	–	3,012
Impairment charge	3,370	–	3,370
<b>At 30 June 2015</b>	<b>8,712</b>	<b>–</b>	<b>8,712</b>
<b>Net book value</b>			
<b>At 30 June 2015</b>	<b>37,821</b>	<b>17</b>	<b>37,838</b>
At 30 June 2014	36,660	862	37,522

On 18 August 2014, Clinigen Group plc acquired the intellectual property for the product Ethyol, this consisted of the trademarks, marketing authorisations and manufacturing dossier. The cost of the addition recognised is the purchase price plus the directly attributable costs incurred as a result of the acquisition, the costs of transferring the trademarks, marketing authorisations and the technical transfer of the manufacturing process incurred to date. Future costs expected to be incurred in respect of the manufacturing technical transfer will be recognised as incurred.

The current financial expectations for the in-licensed product, Vibativ, based on the product's current loss making position and most recent discussions on reimbursement and uncertain commercial viability the carrying value has been fully impaired. This is an additional charge to the Statement of Comprehensive Income of £3.4m.

Prior to the acquisition of Idis Group Holdings Limited, the Group had been implementing a new ERP system. Idis Group had implemented Oracle in June 2014, therefore as part of the restructuring of the enlarged group, the Clinigen implementation has been ceased in favour of a group-wide solution. The capitalised costs to date of £1.3m have been written off to the Profit and Loss Account.

## 5. Investments

	Investments in subsidiary companies £'000
<b>Cost or valuation</b>	
At 1 July 2014	9,141
Additions	235,568
<b>At 30 June 2015</b>	<b>244,709</b>
<b>Net book value</b>	
<b>At 30 June 2015</b>	<b>244,709</b>
At 30 June 2014	9,141

The addition during the year reflects the acquisition of Idis Group Holdings Limited for £199.5m plus the settlement of the bank loan Idis had outstanding at acquisition of £30.6m which was made via a capital contribution to Idis Group Holdings Limited.

### Subsidiary undertakings

Subsidiaries at the end of the reporting year were as follows:

Name	Country of incorporation	Nature of business
Clinigen Healthcare Limited	United Kingdom	Sales and distribution of pharmaceutical products
Keats Healthcare Limited	United Kingdom	Dormant
Clinigen CTS Inc.	USA	Sales and distribution of pharmaceutical products
Clinigen Pharma Limited	United Kingdom	Dormant
Clinigen Clinical Trials Limited	United Kingdom	Holding company
Clinigen CTS Limited	United Kingdom	Sales and distribution of pharmaceutical products
Clinigen GAP Limited	United Kingdom	Dormant
Clinigen SP Limited	United Kingdom	Dormant
Idis Group Holdings Limited	United Kingdom	Holding company
Idis Group Limited	United Kingdom	Holding company
Idis Limited	United Kingdom	Sales and distribution of pharmaceutical products
Idis Inc	USA	Provision of business development services
Idis Pharma Private Limited	India	Dormant
Idis SAS	France	Dormant
Idis Trustee (UK) Limited	United Kingdom	Non trading trustee of Employee Benefit Trust
Employee Benefit Trust 1	Jersey	Employee Benefit Trust
Employee Benefit Trust 2	Jersey	Employee Benefit Trust

All shareholdings in subsidiaries are owned 100% (2014: 100%) through the subsidiaries' Ordinary Share capital.

The Directors have reviewed the carrying value of the investments and believe the value is recoverable.



# Notes to the Company balance sheet continued

## for the year ended 30 June 2015

### 6. Debtors

	2015 £'000	2014 £'000
Trade debtors	3	177
Amounts owed by Group undertakings	1,058	3,501
Other debtors	342	256
Corporation tax recoverable	–	84
Prepayments and accrued income	1,439	310
	<b>2,842</b>	<b>4,328</b>

### 7. Creditors: amounts falling due within one year

	2015 £'000	2014 £'000
Bank loan (note 9)	69,470	16,500
Trade creditors	255	598
Amounts owed to Group undertakings	21,024	11
Tax and social security	1,806	791
Other creditors	105	44
Accruals and deferred income	2,761	1,896
	<b>95,421</b>	<b>19,840</b>

Amounts owed to Group undertakings are unsecured, interest free, have no fixed date of repayment and are repayable on demand.

### 8. Creditors: amounts falling due after more than one year

	2015 £'000	2014 £'000
Bank loan (note 9)	34,530	–
	<b>34,530</b>	<b>–</b>

All amounts are due within five years.

### 9. Loans and borrowings

The book value and fair value of loans and borrowings are as follows:

	2015 £'000	2014 £'000
Bank borrowings	104,000	16,500
<b>Total loans and borrowings</b>	<b>104,000</b>	<b>16,500</b>

The Group has a total bank facility of £140.0m available (2014: £35.0m), this consists of a five year fixed term repayment loan of £45.0m (2014: £nil) a revolving credit facility (RCF) of £95.0m (2014: £35.0m). The RCF is repayable within one month and therefore included within current liabilities.

Interest is payable on a tiered scale based on the level of borrowing. The applicable interest rate on amounts drawn down is up to 2.75 percent. plus LIBOR/EURIBOR (as applicable) on both the RCF and the Term Loan Facility. The margin payable is dependent on the adjusted leverage ratio and will reduce to a minimum of 1.25 percent. plus LIBOR/EURIBOR (as applicable) as adjusted leverage decreases.

The bank loans are secured on the intangible fixed assets of the Group.

At 30 June 2015, the fixed term loan was fully utilised at £45.0m and £60.8m was borrowed against the revolving credit facility. All borrowings are in pounds sterling. There were no instances of default, including covenant terms, in either the current or the preceding period.

### Maturity of loans and borrowings

The maturity profile of the carrying amount of the Group's borrowings at the period end was as follows:

	2015			2014		
	Gross borrowings £'000	Unamortised issue costs £'000	Net borrowings £'000	Gross borrowings £'000	Unamortised issue costs £'000	Net borrowings £'000
Within one year	69,838	(368)	69,470	16,500	–	16,500
In more than one year but less than two years	9,000	(368)	8,632	–	–	–
In more than two years but less than five years	27,000	(1,102)	25,898	16,500	–	–
	105,838	(1,838)	104,000	16,500	–	16,500

### 10. Deferred tax

Deferred tax consists of the following and is calculated using the effective tax rate of 20% (2014: 20%). The movement on the deferred tax account is as shown below:

	2015 £'000	2014 £'000
Deferred tax (asset)/liability – opening balance	(1,956)	(887)
<b>Recognised</b>		
Adjustment in respect of prior years	267	(977)
Charge to the profit and loss account	(201)	(229)
Utilised in the year	–	382
Tax expense recognised in equity		(412)
Effect of change in rate in the year	–	167
Deferred tax (asset)/liability – closing balance	(1,890)	(1,956)

The deferred tax balance is made up as follows:

	2015 £'000	2014 £'000
Losses	(1,368)	(1,022)
Share-based payment scheme	(522)	(934)
	(1,890)	(1,956)

### 11. Called up share capital

Ordinary Shares of 0.1p each	Number of shares ('000s)	£'000s
	Ordinary shares of 0.1p each	Ordinary shares of 0.1p each
Authorised, issued and fully paid		
At 1 July 2013 and at 30 June 2014	82,556	83
<b>At 1 July 2014</b>	<b>82,556</b>	<b>83</b>
Issue of new shares during the year	27,153	27
<b>At 30 June 2015</b>	<b>109,709</b>	<b>110</b>

On 28 April 2015, 27,153,011 new Ordinary Shares of 0.1p each were issued for £132.4m after deducting expenses of £3.4m.

# Notes to the Company balance sheet continued

## for the year ended 30 June 2015

### 12. Reserves

	Share capital £'000	Share premium account (restated) £'000	Merger reserve (restated) £'000	Profit and loss account £'000
At 1 July 2014	83	8,660	5,413	28,027
Loss for the year	–	–	–	(13,102)
Dividend paid	–	–	–	(2,642)
Share-based payment scheme	–	–	–	1,299
Own shares distributed on exercise of share options	–	–	–	(325)
Issue of new shares during the year	27	132,363	–	–
Tax credit in respect of tax losses arising on exercise of share options	–	–	–	(220)
<b>At 30 June 2015</b>	<b>110</b>	<b>141,023</b>	<b>5,413</b>	<b>13,037</b>

The prior year balance sheet has been restated to separately disclose the merger reserve; this was previously shown within share premium account. Included within profit and loss account as at 30 June 2015 is £3.3m (2014: £2.2m) which is not distributable.

### 13. Reconciliation of movements in shareholders' funds

	2015 £'000	2014 £'000
Opening shareholders' funds	<b>42,183</b>	35,299
(Loss) / profit for the year	<b>(13,102)</b>	6,933
Dividend paid	<b>(2,642)</b>	(2,476)
Share-based payment scheme	<b>1,299</b>	1,190
Own shares distributed on exercise of share options	<b>(325)</b>	(12)
Deferred taxation on share-based payment scheme	–	405
Tax credit in respect of tax losses arising on exercise of share options	<b>(220)</b>	844
Issue of new shares	<b>132,390</b>	–
	<b>159,583</b>	42,183

The Company has taken advantage of the exemption contained within section 408 of the Companies Act 2006 not to present its own profit and loss account.

The loss for the year ended 30 June 2015 in the accounts of the Company was £13.1m (2014: profit of £6.9m). This includes dividends received of £nil (2014: £6.7m).

### 14. Related party transactions

#### Ultimate controlling party

The Company's shares are listed on the Alternative Investment Market ('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 during the year or the preceding year.

## 15. Events after the reporting date

On 17 September 2015, Clinigen announced a strategic alliance with Cumberland Pharmaceuticals, with no financial terms, which will build on Clinigen's existing North American relationships by providing complementary support from Cumberland in the development, marketing, promotion and distribution of future products in the US, with Clinigen supporting Cumberland outside the US.

On 22 September 2015, Clinigen Group plc announced the proposed acquisition of Link Healthcare a specialist pharmaceutical and medical technology business focussed on the Asia, Africa and Australasia (AAA) region for a maximum consideration of £100m. Link is being acquired on a debt-free cash-free basis with an initial consideration of £44.5m, payable at completion 50% in cash and 50% in shares. Additional deferred consideration of up to £55.5m is payable if earn out targets are achieved over a two year period. Completion of the acquisition is expected to occur on or around 28 October 2015 after the Clinigen AGM.

For the financial year ended 31 March 2015, Link achieved revenue of £31.6m and EBITDA of £3.5m. The cash element of the acquisition consideration will be financed from the Group's existing debt facility.

i [www.theguardian.com/society/2014/dec/28/drugs-medicines-sold-illegally-online-internet](http://www.theguardian.com/society/2014/dec/28/drugs-medicines-sold-illegally-online-internet)

ii UK Parliamentary Office of Science and Technology – January 2010 Number 352

iii [www.mhra.gov.uk//index.htm](http://www.mhra.gov.uk//index.htm)

iv World Health Organisation, [www.who.int/en/](http://www.who.int/en/)

v OECD, The Economic Impact of Counterfeiting and Piracy, 2007

vi Community Customs Activities on Counterfeit and Piracy: Results at the European Border, EC Taxation & Customs Union, 2007

## Adviser and investor contacts

### Country of incorporation

United Kingdom

### Company number

06771928

### Directors

P George  
R Sibson  
S Chilton  
M Abell (appointed 3 August 2015)  
P Allen (Non-executive Chairman)  
J Hartup (Non-executive)  
I Nicholson (Non-executive)

### Company Secretary and registered office

#### R Sibson

Pitcairn House  
Crown Square  
Centrum 100  
Burton on Trent  
Staffordshire DE14 2WW

### Independent auditors

#### PricewaterhouseCoopers LLP

Cornwall Court  
19 Cornwall Street  
Birmingham B3 2DT

### Nominated Advisor

#### 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

#### Peel Hunt LLP

Moor House  
120 London Wall  
London EC2Y 5ET





**Clinigen Group plc**

Pitcairn House  
Crown Square  
Centrum 100  
Burton-on-Trent  
Staffordshire  
DE14 2WW

**T:** 01283 495010

**F:** 01283 495011

**E:** [info@clinigengroup.com](mailto:info@clinigengroup.com)

[www.clinigengroup.com](http://www.clinigengroup.com)