

22 September 2015



UNAUDITED PRELIMINARY RESULTS ANNOUNCEMENT FOR YEAR ENDED 30 JUNE 2015

Great Strides Made in Strategic Priorities, with Underlying EBITDA up 20%

Clinigen Group plc (AIM: CLIN, 'Clinigen', or the 'Group'), the global specialty pharmaceuticals business, has today published its full year results for the 12 months ended 30 June 2015.

The Group has also announced today a proposed acquisition of Link Healthcare ('Link') to strengthen Clinigen's global footprint in Asia, Africa and Australasia, for an initial consideration of £44.5m (rising to a maximum of £100m if performance milestones over two years are achieved) – see separate release.

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)
- Adjusted underlying earnings per share¹ up 14% to 28.0 pence (2014: 24.5 pence), reported earnings per share at 6.0 pence (2014: 19.6 pence) are after one off acquisition costs and post-acquisition restructuring cost
- Final dividend 2.3 pence per share proposed; total dividend 3.4 pence per share (2014: 3.1 pence per share), up 10%

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

Business highlights

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

Peter George, Chief Executive Officer, Clinigen, said

“Strategically, we have made great strides in progressing our two priorities – the continued revitalization of our speciality products portfolio and the strengthening of our global capabilities. We have also had a very strong financial performance reflecting our strengthening international position in growing markets.

“Our newer assets - Cardioxane, Savene and Ethyol - are all progressing to plan with the lifting of the EMA Article 31 referral on track.

“The addition of Idis in April, the strategic alliance with Cumberland in the US and today’s proposed acquisition of Link, have and will transform our international reach and capabilities, and will continue to accelerate our growth.

“With Idis, we are now the market leader in the \$5+ billion unlicensed medicine supply sector and in the \$2 billion clinical trial supply market. The addition of Link will substantially increase our international footprint into the Asia, Africa and Australasia region.

“Looking forward, the integration of Idis is progressing well and trading is in line with the Board’s expectations at this early stage of the year. The Board remains confident about the outlook for the full year.”

-Ends-

Analyst briefing will be held at 8:30am on Tuesday, 22 September 2015 at the offices of Instinctif Partners, 65 Gresham Street, London EC2V 7NQ.

An audio replay file will be made available shortly afterwards via the Group’s website: www.clinigengroup.com.

To see a recorded message from Peter George describing the impact of the Link proposed acquisition, see <https://vimeo.com/139592580>.

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Clinigen Group is a global pharmaceutical and services company with a unique combination of businesses dedicated to delivering the right drug to the right patient at the right time. The Group consists of four synergistic businesses that provide medicines to patients with unmet medical need; through Clinigen CTS we manage the supply of commercial medicines for clinical trials, through Idis Managed Access we run early access programs for our own and other companies' portfolios, our Idis Global Access team works directly with healthcare providers to enable ethical compliant access to unlicensed medicines, and through Clinigen SP, we market our own portfolio of niche commercial products.

We are global leaders in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need.

For more information, please visit www.clinigengroup.com.

Forward-looking statement

This announcement contains certain projections and other forward-looking statements with respect to the financial condition, results of operations, businesses and prospects of Clinigen Group plc ('Clinigen'). These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances that may or may not occur in the future. There are a number of factors which could cause actual results or developments to differ materially from those expressed or implied by these forward-looking statements. Any of the assumptions underlying these forward-looking statements could prove inaccurate or incorrect and therefore any results contemplated in the forward-looking statements may not actually be achieved. Recipients are cautioned not to place undue reliance on any forward-looking statements contained herein.

Overview

Clinigen had a very strong year, advancing all its key strategic goals, including the acquisition of Idis which has consolidated the Group's market leader position in CTS and taken it to global market leader in unlicensed supply.

All operating businesses contributed to growth; not only as shown in these results (10 months Clinigen plus two months with Idis) but, possibly more importantly, for the underlying business, delivering strong organic growth on a full year pro forma basis.

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.

Overall sales at £184.4m showed 45% growth, with gross profit of £53.7m up 30%. On a pro forma basis, this was 27% and 24% growth respectively. All four operating businesses 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.

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 operating businesses 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; 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 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.

The proposed acquisition of Link announced today (see separate announcement) will significantly strengthen our global footprint, particularly in Asia, Africa and Australasia, known as the AAA region.

In addition our recently announced strategic alliance with Cumberland Pharmaceuticals (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.

Strategy

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 the strategies to achieve this; some 80% of the world's population, an estimated 5.5 billion 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.

Access to the best drugs to treat disease should not depend on where the patient lives or is being treated, or because an existing medicine has been discontinued because it is unprofitable or gone into shortage of supply; but it does. These key factors are the drivers behind Clinigen's specialty pharma and unlicensed supply businesses.

However, there are many other issues, such as the type of drug required, restricted access to certain medications, the disease, drug resistance, or the prohibitive price of many drugs which also drive demand for Clinigen's services. This is exacerbated further by greater patient knowledge of the treatments available to them, general and elderly population growth, the increasing incidence of chronic diseases, as well as higher disposable incomes.

Consequently, there is increasing demand for medicines not necessarily available or licensed where the patient is being treated, creating a high global unmet need for ethical supply of good quality unlicensed and short supply medicines.

The demand for an ethical provider is also becoming even more evident as this unmet need is creating an opportunity for criminality in counterfeit or sub-standard medicines. In wealthy countries like the

UK with strong regulatory frameworks, it is estimated that counterfeits are likely to account for only around 1% of the total medicines market, but an estimated 50% of drugs sold online are fake. In emerging economies, the proportion of counterfeits can be as high as 10% to 30% of all medicines particularly in some areas of the AAA region.

Acquisitions

Clinigen's acquisition of Idis on 29 April 2015, our strategic alliance with Cumberland and today's 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 Clinigen 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.

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 Clinigen 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. Clinigen is the only company that manages the supply of all three routes to market.

In last year's annual report we stated that *"two key strategic goals will be prioritized in FY15; the strengthening of the Group's global capabilities and the revitalization of the new products in our portfolio"*. As described above, we have made great strides in strengthening the Group's global footprint which we believe will bring benefit to all four operating businesses.

We have also advanced the revitalization of Clinigen's newer assets (Cardioxane, Savene and Ethylol) and all are progressing to plan. The biggest single project is the lifting of the EMA Article 31 referral in place on Cardioxane and this remains on track, but Savene is now fully under Clinigen's control and the transfer of manufacturing for Ethylol is proceeding to plan.

The Idis acquisition extended the scope and scale of the business from three to four divisions - creating a fourth operating business, Idis GA. The Group therefore now operates through four synergistic businesses and this has further increased our ability to share insights, knowledge and relationships that provide continued commercial benefits to the broader Group.

Following the Idis acquisition, we embarked upon a 100 day process to identify and implement, where possible, integration synergies. What has been most impressive in the final quarter of the year was how well the two sets of 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 integrating the two exclusive unlicensed supply businesses under the Idis Managed Access brand and the two clinical trial supply businesses under the Clinigen 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.

Current trading and outlook

An estimated £2.5m in cost synergies and opportunities for further longer term revenue and cost synergies were identified at acquisition.

Post-acquisition of Idis, the signs indicate promising underlying performance, validating our decision to buy the company. We expect to see this carry through to a good performance in FY16.

As the integration process is progressing so well and current trading is in line with expectations, the Board remains confident about the outlook for the full year.

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. Whilst Clinigen is the global market leader, it is a competitive environment and we are having to develop our service offerings to stay ahead and differentiate. We have made good progress in FY15 developing these new services and we will see the benefit of some of these in FY16 and beyond.

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 10 assets over the next five years.

The market for the supply of unlicensed medicines is less well defined. Through Idis Managed Access, Clinigen enables access to newly developed medicines at the pre or early marketing stage; we support the pharmaceutical companies developing these medicines and the clinicians who want early access to new treatments.

Idis Managed Access 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.

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. Currently, so far as we are aware, no one is offering a credible ethical global solution.

Through Idis GA, the Group has supplied over 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. However, 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 customers 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.

Operational overview

- **Clinigen Clinical Trial Services (Clinigen CTS)**

CTS is the global leader in the specialist supply and management of quality-assured comparator drugs and other commercial medicines for patients in clinical trials. The business is also delivering added value services to clinical trials sites. This has been a significant year in the development of the CTS business division, both organically and with the effect of the Idis acquisition.

The business performed well in FY15 against all key performance indicators compared to prior year. There was strong revenue growth of 35% over prior year (£112.7m in FY15 vs £83.6m in FY14); on a pro forma basis, this growth increased to 45%. 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 drivers for the business were a strong US performance and an increase in customers from 73 in 2014 to 85 in 2015. Significantly, the number of customers with revenues greater than £5m in the year rose from five to seven. In addition, whilst orders dropped to 1,472 (2014: 1,600), CTS sourced and supplied clinical trials with 820 different products in FY15, a rise of 11% over prior year (2014: 741). This suggests we are supplying more efficiently, fewer smaller orders and instead more consolidated larger ones.

The forward looking market dynamics for CTS are very attractive with continued double digit growth and a global market for comparator sourcing estimated at c.\$2.5bn. The growth drivers include the heavy weighting in R&D towards oncology, infectious disease and rare/orphan diseases all requiring comparators and co-therapies; the changing regulatory environment and the rise of more complex, difficult-to-source and manage large molecules and increase in biosimilar development all support the use of specialist partners such as 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. 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.

In FY15, we repositioned and restructured the CTS business and brand following the Idis acquisition. 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 Idis 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.

Given the growing demand for Clinigen's specialist services, evidenced by its work with at least 50% of the top 25 pharmas by R&D spend over the past three years, this operational business is in a solid leadership position.

- **Idis Managed Access (MA)**

The Idis acquisition allowed us to combine the Idis MAP and Clinigen GAP businesses under the Idis MA brand, catapulting the Group into the global market leader position in the exclusive managed access sector. This comprises managing ethical worldwide access to the most promising innovative early stage medicines on behalf of pharma and biotech companies to meet an unmet patient need. We have unparalleled experience compared to other players in the market, from conception of a programme to delivery of products.

Revenue growth showed a significant 78% increase (£28.8m in FY15 vs £16.1m in FY14). This growth is somewhat misleading as it includes two months of the larger Idis element. However, revenue growth on a pro forma basis was still an 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 was again impressive at 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 via 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, Idis MA is a very powerful brand with an excellent heritage. Having defined the current market – Idis developed the term 'managed access' which is now the industry standard terminology – it provides Clinigen with the opportunity to 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 many factors. These include the rapid innovation in drug development and the focus on areas of high unmet need such as oncology/haematology, infectious

disease, neurology and rare/orphan disease. In addition there have been significant changes in the regulatory environment facilitating access to unlicensed medicines and in the connectivity and awareness of the world's Key Opinion Leaders, carers and patients to available treatments.

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.

Idis MA is responding in kind 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 Idis MA due to its long history and database of experience captured over the last 10 years working with many customers on multiple products. In this way, we are creating sustainable competitive advantage and IP which will drive continued strong growth for the future.

- **Idis Global Access (GA)**

A major strategic driver of the Idis acquisition was to enable the Group to enter the 'on demand' unlicensed supply and drug shortages market sector. This market is estimated at \$5bn providing a regional and local solution to hospital pharmacists charged with sourcing medicines not available to patients, either due to country licensing or to drug shortages.

Formerly known as Idis General Access, we have now rebranded this business as Idis GA, retaining the Idis heritage and reputation of 28 years, and strong brand name recognition in Europe. However, we intend 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. These are driven by developing regional health demands, health cost controls and more knowledgeable and informed patients. In addition, pharmaceutical companies are changing their product launch strategies to focus on the priority commercial markets and no longer launching in all markets, exacerbating limited patient access.

The Idis GA business has been focused to date on the UK and mainland Europe. Whilst sales in these regions have been fairly flat, the business showed good Gross Profit growth in FY15 with margins of 24%. The reported revenues shown of £9.2m reflect the two months post-acquisition.

As a new operating business within Clinigen there is no prior year comparator, so these results are discussed as pro forma. Pro forma revenues of £61m showed an 8% decline on FY14 (£66.4m). This is wholly accounted for by one low margin commercial contract which Clinigen is looking to exit and is likely to close during FY16. The gross profit performance was good at £14.6m pro forma, showing 10% growth on FY14 (£13.3m).

The major operational initiatives in FY16 aimed to address the 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 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 Idis GA division for a global proposition, our aim is to be the 'go to' solution for physicians and pharmacists. We have also created an important synergy with the Idis MA division in that 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 Idis MA) to the later post-approval stages of the lifecycle (managed through Idis GA), we are able to provide an ethical route of access to these critically important products.

- **Clinigen Specialty Pharmaceuticals (Clinigen SP)**

SP acquires the rights to and then revitalises essential niche hospital only medicines. In FY15, all SP's 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 (2014: £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 Clinigen SP's over-dependence upon its first revitalized product, Foscavir.

At the end of FY15, Foscavir contributed 70% of sales and profit to the division, significantly reduced from 86% at the end of FY14.

- **Foscavir:**

Foscavir continued to grow in line with the rate of growth in bone marrow transplantations, c. 5% p.a. This was 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 US partnership agreement with Hospira, obtaining the license to market and distribute it in South Korea and seeking additional indications by supporting investigators in Japan studying Foscavir's use in the HHV6 virus.

- **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.

The single biggest driver of potential growth is to overturn the EMA Article 31 referral placed upon Cardioxane in 2011 which limits its usage in certain adult patient populations. Clinigen has submitted the clinical overview and position paper and extensive supporting evidence package to the European Medicines Association and we are awaiting its response. Importantly, 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 in the next six months.

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. 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). We will explore the potential of developing a combination, dual indication pack for commercial use.

- **Ethyol:**

The acquisition of Ethyol in August 2014 further strengthened our oncology support portfolio and it is an excellent fit with the Clinigen SP business as a niche, hospital based treatment for xerostomia (dry mouth) for patients with head and neck cancer. It 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 Europe and we are well underway with the technical transfer of the manufacturing, 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. We anticipate a commercially available test at the end of calendar year 2015. 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.

Financial Review

Reported results are based on 10 months Clinigen alone and two months incorporating Idis.

Revenue

Reported group revenues grew to £184.4m, an increase of 45% (2014: £126.6m). CTS grew by £29.1m (34%) as a result of strong organic growth, and SP grew by £6.8m (25%) driven mainly by the acquisition of Ethyol 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 Idis 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 Ethyol 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 £1.3m increase in amortisation and depreciation, and a planned 25% increase in underlying overheads to support growth and the on boarding and revitalization of acquired products.

Total administration costs of £44.5m (2014: £19.7m) include non-underlying costs of £17.8m as follows:

Non-underlying items

	2015	2014
	£'000	£'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 the Idis Group	3,821	—
Acquisition costs	5,703	—
Impairment of intangible fixed assets	3,810	—
Amortisation of intangible fixed assets acquired through business combinations	2,129	—
	17,801	1,801

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 28.0 pence (2014: 24.5 pence). The reported earnings per share is 6.0 pence (2014: 19.6 pence).

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 propose a final dividend of 2.3 pence per share, which when added to the interim dividend of 1.1 pence paid on 2 April 2015, will make a total dividend of 3.4 pence per share (2014: 3.1 pence), up 11%.

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

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 500 pence per share representing a discount of approximately 4.9 per cent to the closing middle market price of 525.5 pence 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 Global Access business to meet “on demand” supply for unlicensed medicines. The acquired fair value of Idis inventories was £8.0m, which included a £0.9m uplift.

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 Healthcare 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 £37.1m. The acquired fair value of Idis accruals was £37.3m of which £12.8m was settled by the balance sheet date.

Loans and borrowings

The Group has a total bank facility of £140.0m (FY14: £35.0m) agreed in April 2015 to finance the Idis acquisition. This consists of a five year fixed term repayment loan of £45.0m (FY14: £nil) and a five year revolving credit facility of £95.0m (FY14: £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.

Today Clinigen 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 £100 million. Link is being acquired on a debt-free cash-free basis with an initial consideration of £44.5 million, payable at completion 50% in cash and 50% in shares. Additional deferred consideration of up to £55.5 million 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 after the Clinigen AGM.

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

Unaudited consolidated statement of comprehensive income for the year ended 30 June 2015

	2015			2014			
	Note	Underlying £'000	Non- underlying (note 4) £'000	Total £'000	Underlying £'000	Non- underlying (note 4) £'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		(26,675)	(17,801)	(44,476)	(17,887)	(1,801)	(19,688)
Profit/(loss) from operations		26,976	(17,801)	9,175	23,316	(1,801)	21,515
Finance income		39	—	39	2	—	2
Finance cost		(859)	—	(859)	(234)	—	(234)
Profit/(loss) before income tax		26,156	(17,801)	8,355	23,084	(1,801)	21,283
Income tax (expense)/credit	5	(5,718)	2,622	(3,096)	(5,437)	367	(5,070)
Profit/(loss) for the year attributable to owners of the parent		20,438	(15,179)	5,259	17,647	(1,434)	16,213
Other comprehensive income							
Items that may be reclassified to profit or loss:							
Tax credit on fair value gains			426	426			
Exchange (losses)/gains arising in the year on translation of foreign operations		(119)	—	(119)	(254)	—	(254)
Total comprehensive income/(expense) attributable to owners of the parent		20,319	(14,753)	5,566	17,393	(1,434)	15,959
Earnings per share for profit attributable to the owners of the parent during the year							
Basic (p)	6			6.0			19.6
Diluted (p)	6			5.9			19.0

All amounts relate to continuing operations.

Unaudited consolidated statement of financial position as at 30 June 2015

	Note	2015 £'000	2014 £'000
Assets			
Non-current assets			
Property, plant and equipment		1,597	968
Intangible assets	7	308,222	50,508
Deferred tax assets	11	3,843	1,956
Total non-current assets		313,662	53,432
Current assets			
Inventories	8	11,127	2,466
Trade and other receivables	9	67,131	23,644
Corporation tax recoverable		—	3,535
Cash and cash equivalents		27,750	21,787
Total current assets		106,008	51,432
Total assets		419,670	104,864
Liabilities			
Non-current liabilities			
Loans and borrowings	10	34,530	—
Deferred tax liabilities	11	18,990	—
Total non-current liabilities		53,520	—
Current liabilities			
Trade and other payables		87,640	19,502
Provisions		1,510	—
Loans and borrowings	10	69,470	16,500
Corporation tax liability		349	2,555
Deferred tax liabilities	11	2,556	—
Total current liabilities		161,525	38,557
Total liabilities		215,045	38,557
Net assets		204,625	66,307
Issued capital and reserves attributable to owners of the parent company			
Share capital		110	83
Share premium account		141,023	8,660
Merger reserve		5,413	5,413
Own shares		(3)	(328)
Foreign exchange reserve		(264)	(145)
Retained earnings		58,346	52,624
Total equity		204,625	66,307

Unaudited consolidated statement of cash flows for the year ended 30 June 2015

	Note	2015	2014
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	£'000	£'000
Cash flows from operating activities		
Profit for the year before tax	8,355	21,283
Adjustments for:		
Depreciation of property, plant and equipment	441	212
Amortization of intangible fixed assets	7,145	3,290
Impairment of intangible fixed assets	3,370	—
Loss on disposal of non-current assets	1,283	18
Provision for restructuring costs	1,510	—
Currency gain on contract creditors	—	(367)
Interest receivable	(39)	(2)
Interest expense	859	234
Share based payment expense	12	1,190
	24,219	25,858
Increase in trade and other receivables	(10,257)	(4,923)
(Increase) / decrease in inventories	(1,824)	685
Increase/ (decrease) in trade and other payables	3,707	(1,278)
Cash generated from operations	15,845	20,342
Income taxes paid	(5,227)	(1,067)
Income taxes received	3,368	—
Interest paid	(859)	(234)
Net cash generated from operating activities	13,127	19,041
Investing activities		
Purchases of property, plant and equipment	(168)	(641)
Purchase of intangible fixed assets	(8,467)	(21,371)
Purchase of subsidiary net of cash acquired	(179,697)	—
Interest receivable	39	2
Net cash used in investing activities	(188,293)	(22,010)
Financing activities		
Proceeds from issue of shares	132,390	—
Proceeds from loan	104,000	16,500
Loan repayments	(52,500)	—
Purchase of own shares	—	(340)
Dividends paid	(2,642)	(2,476)
Net cash generated from financing activities	181,248	13,684
Net increase in cash and cash equivalents	6,082	10,715
Cash and cash equivalents at beginning of year	21,787	11,326
Exchange gains	(119)	(254)
Cash and cash equivalents at end of year	27,750	21,787

Unaudited consolidated statement of changes in equity for the year ended 30 June 2015

	Share		Merger reserve £'000	Own shares £'000	Foreign		Total equity £'000
	Share premium capital £'000	account £'000			exchange reserve £'000	Retained earnings £'000	
At 1 July 2013	83	8,660	5,413	—	109	36,685	50,950
Profit for the year	—	—	—	—	—	16,213	16,213
Other comprehensive income	—	—	—	—	(254)	—	(254)
Total comprehensive income	—	—	—	—	(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	—	—	—	—	—	(2,476)	(2,476)
Own shares acquired in the year	—	—	—	(340)	—	—	(340)
Own shares distributed on exercise of share options	—	—	—	12	—	(12)	—
Total contributions by and distributions to owners of the parent, recognized directly in equity	—	—	—	(328)	—	(274)	(602)
At 30 June 2014 and 1 July 2014	83	8,660	5,413	(328)	(145)	52,624	66,307
Profit for the year	—	—	—	—	—	5,259	5,259
Other comprehensive income	—	—	—	—	(119)	426	307
Total comprehensive income	—	—	—	—	(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	—	—	—	—	—	(2,642)	(2,642)
Issue of new shares	27	132,363	—	—	—	—	132,390
Own shares distributed on exercise of share options	—	—	—	325	—	(325)	—
Total contributions by and distributions to owners of the parent, recognized directly in equity	27	132,363	—	325	—	37	132,752
At 30 June 2015	110	141,023	5,413	(3)	(264)	58,346	204,625

Notes forming part of the unaudited consolidated financial statements
for the year ended 30 June 2014

1. Basis of preparation and publication of unaudited results

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 information contained within the preliminary announcement is unaudited and has 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 financial information contained in this announcement which does not constitute statutory accounts as defined in Section 434 of the Companies Act 2006, has been derived from the unaudited statutory consolidated accounts for the year ended 30 June 2015. The statutory accounts for the year ended 30 June 2014 have been filed with, and are available from, the Registrar of Companies. The auditors’ report on those accounts was unqualified and did not contain a statement under Section 498 of the Companies Act 2006. The statutory accounts for the year ended 30 June 2015 will be finalised on the basis of the financial information presented by the Directors in the unaudited preliminary announcement and will be delivered to the Registrar of Companies following the Annual General Meeting.

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.

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 judgement in estimating the valuation of intangible assets and pre-existing relationships 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 13.

(b) Impairment of goodwill

The Group tests annually whether goodwill has suffered any impairment, in accordance with the Group's accounting policy. 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 7.

(c) Carrying value of intangible assets excluding goodwill

The carrying value of intangible assets is at cost less amortization and any impairment. Annual impairment trigger reviews are undertaken at the end of the financial year or more frequently if events or changes in circumstances indicate a potential impairment. Trademarks and licences are not traded in an active market hence the fair value of the asset is determined using discounted cash flows which involves the Group using judgement and assumptions.

(d) Inventory provisioning

The 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.

(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 9 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 utilized. 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 recognized 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 recognizable at exercise is likely to differ to the one recognized 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) business were fully integrated into Clinigen Clinical Trial 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-licensed 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 Group has four main reportable segments, being the Group's operating businesses, performance is evaluated on the basis of gross profit or loss from operations.

Classes of business

	2015	2014
	£'000	£'000
Revenue arises from:		
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
	184,359	126,639
Gross profit arises from:		
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

	53,651	41,203
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)
Profit before tax	8,355	21,283

	2015	2014
	£'000	£'000
Breakdown of revenues by products and services:		
Products	168,818	118,449
Services	12,118	8,190
Royalties	3,423	—
	184,359	126,639

Geographical analysis

	2015	2014
	£'000	£'000
Revenue arises from the following locations:		
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
	184,359	126,639

Gross profit arises from the following locations:		
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
	53,651	41,203

Analysis of concentration of customers (based on customers contributing at least 10% of revenue):

Customer A – Clinical Trial Services	28,056	17,138
Other	156,303	109,501
	184,359	126,639

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

	2015			2014		
	Underlying	Non-	Total	Underlying	Non-	Total
	£'000	underlying	£'000	£'000	underlying	£'000

	£'000			£'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	(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. 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	(2,421)	—
	15,179	1,434

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.

5. Income tax

	2015	2014
	£'000	£'000
Current tax expense		
Current tax on profits of the year	2,854	5,262
Adjustment in respect of prior years	397	37
Total current tax expense	3,251	5,299
Deferred tax expense		
(Increase) / decrease in deferred tax assets (note 11)	(155)	(229)
Total deferred tax benefit	(155)	(229)
Income tax expense	3,096	5,070

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	2014
	£'000	£'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 amortization and impairment	376	22
Adjustments to tax charge in respect of prior years	397	(192)
Short-term timing differences	47	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)	—
Total tax expense	3,096	5,070

Amounts recognized 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	2014
	£'000	£'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)	—
	(1,733)	(1,024)

Tax losses:

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

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.

6. Earnings per share ("EPS")

	2015	2014
Profit	£'000	£'000
Profit used in calculating basic and diluted EPS	5,259	16,213
<hr/>		
Number of shares	Number	Number
	87,242,26	82,555,58
Weighted average number of shares for the purpose of basic EPS	9	5
Effect of:		
Employee share options	2,621,694	2,654,055
	89,863,96	85,209,64
Weighted average number of shares for the purpose of diluted EPS	3	0
<hr/>		
EPS	Pence	Pence
Basic	6.0	19.6
Diluted	5.9	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 28.0 pence (2014: 24.5 pence).

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

7. Intangible assets

	Brand £'000	Contract relationships £'000	Customer relationships and licences £'000	Trademarks £'000	Computer software £'000	Goodwill £'000	Total £'000
Cost							
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
Accumulated amortization							
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
Net book value							
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
Cost							
At 1 July 2014	—	—	—	48,261	1,212	8,742	58,215
Acquisition of subsidiary (note 13)	49,449	17,720	42,996	—	3,006	147,867	261,038
Additions	—	—	—	7,543	923	—	8,466
Disposals	—	—	—	—	(1,275)	—	(1,275)
At 30 June 2015	49,449	17,720	42,996	55,804	3,866	156,609	326,444
Accumulated amortization							
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
At 30 June 2015	412	1,026	692	15,356	736	—	18,222
Net book value							
At 30 June 2015	49,037	16,694	42,304	40,448	3,130	156,609	308,222

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 useful economic life is 20 years of which the remaining amortisation period is 19 years 10 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 useful economic life is 5 years of which the remaining amortisation period is 4 years 10 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, these are CTS 7 years (remaining 6 years 10 months), GA ranging from 7 years to 14 years (remaining ranging from 6 years 10 months to 13 years 10 months).

Trademarks and licences

On 18 August 2014, Clinigen Group plc acquired the intellectual property for the product Ethyol, this consisted of the trademarks, marketing authorizations and manufacturing dossier. The cost of the addition recognized 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-licenced 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, the total amortisation period ranges between 7 and 15 years with the average remaining amortisation period being 5 years 8 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 and associated hardware.

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.

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.

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	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%.

The below shows the changes that would cause If any one of the following changes were made the carrying amount and recoverable amount would to 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 12% 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	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%.	

The below shows the changes that would cause If any one of the following changes were made the carrying amount and recoverable amount would to 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%

GA

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

Key assumptions	Sales growth	(6.5)% per annum
	Profit margins	
	Discount rate	30%
	Terminal growth rate	12%
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%.	

The below shows the changes that would cause the carrying amount and recoverable amount to 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.

8. Inventories

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

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 recognized throughout the year.

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

9. Trade and other receivables

	2015	2014
	£'000	£'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
Total trade and other receivables	67,131	23,644

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
	8,949

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 £5.0m (2014: £8.9m) were past due but not impaired.

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	4,507	7,591
Three to six months	515	1,271
	5,022	8,862

10. Loans and borrowings

The book value of loans and borrowings are as follows:

	2015 £'000	2014 £'000
Non-current liability		
Bank borrowings	34,530	—
Current liability		
Bank borrowings	69,470	16,500
Total loans and borrowings	104,000	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	Unamortised costs	Net borrowings	Gross borrowings	Unamortised costs	Net borrowings
	£'000	£'000	£'000	£'000	£'000	£'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

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.

11. 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	—
	21,546	—

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

	Fair value gains
Deferred tax liabilities	
At 1 July 2013, 30 June 2014 and 1 July 2014	—
Acquisition of subsidiary	21,972
Credited to other comprehensive income	(426)
At 30 June 2015	21,546

	Unexercised share		Total
Deferred tax assets	options	Tax losses	
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
At 30 June 2015	2,475	1,368	3,843

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%).

12. 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.

Today, Clinigen 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 £100 million. Link is being acquired on a debt-free cash-free basis with an initial consideration of £44.5 million, payable at completion 50% in cash and 50% in shares. Additional deferred consideration of up to £55.5 million 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 after the Clinigen AGM.

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

13. 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)
Net assets acquired	51,607
Goodwill arising on acquisition	147,867
Total consideration	199,474

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 £5.0m over the same period. Had the transaction occurred on the first day of the financial year, then the estimated contribution to Group revenues would have been £200m and net profit of £1.3m before one-off items.