



**Underlying half year pre-tax profits up 12% at £10.9m, underlying EBITDA up 20% at £12.5m**

**Burton-on-Trent, UK – 26 February 2014** – Clinigen Group plc (AIM: CLIN, Clinigen or the Group), the global specialty pharmaceuticals and pharmaceutical services business, has today published its half year results for the six months ended 31 December 2013.

#### **Financial highlights**

- Group revenue of £61.8m (H1FY13: £61.0m); like for like\* sales up 6.5%
- Underlying\*\* EBITDA up 20% to £12.5m (H1FY13: £10.5m)
- Underlying\*\* pre-tax profit 12% higher at £10.9m (H1FY13: £9.7m)
- Reported pre-tax profit of £9.6m (H1FY13: £3.7m)
- Underlying earnings per share\*\*\* up 7.8% to 9.7p (H1FY13: 9.0p)
- Reported earnings per share of 8.7p (H1FY13: 3.5p)
- Interim dividend of 1.0p per share (H1FY13: 0.6p per share)
- Cash and cash equivalents of £16.8m at 31 December 2013 (30 June 2013: £11.3m)

#### **Business highlights**

- CTS: margins improved through better supplier terms. Post period end, exclusive agreement with Accord Healthcare extended to supply capecitabine in Europe
- GAP: large GAP programs running as planned, with new access programs signed up with Eisai for Fycompa® and a third program for BTG for uridine triacetate
- SP: integration of Cardioxane® and Vibativ® on track

\* H1FY13 included circa £3m of Foscavir stock fill for the US market which has been adjusted to give like-for-like sales

\*\* Underlying earnings excludes share based payments and one off exceptional costs in FY13 arising as a result of the IPO

\*\*\* Underlying EPS excludes share based payments and one off exceptional costs and is based on the weighted average number of shares in issue post IPO

**Peter George, Chief Executive Officer, said:**

“Our focus on value creation has resulted in another strong financial performance.

“We are particularly pleased with the gross profit improvement in the CTS business and that we continue to add new customers.

“GAP continues to go from strength to strength, and our growing reputation is attracting not only important new clients such as Eisai but also returning customers like BTG.

“In SP, the integration of our new products Cardioxane and Vibativ is going well with some of the commercial activities ahead of plan, and Foscavir sales, as expected, are levelling out. Acquisitions for SP are a priority and our activity in this area is high; we are confident we will add further to our portfolio in CY2014.

“In summary, a good start to FY14, with full year expectations on track.”

**-Ends-**

An analyst briefing will be held at 9:00am today at the Group’s London offices at 1 King Street, London EC2V 8AU.

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

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

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## **About Clinigen Group**

The Clinigen Group is a specialty global pharmaceutical company headquartered in the UK, with offices in the US and Japan. The Group, dedicated to delivering 'the right drug, to the right patient at the right time', has three operating businesses; Specialty Pharmaceuticals (Clinigen SP or SP), Clinical Trials Supply (Clinigen CTS or CTS), and Global Access Programs (Clinigen GAP or GAP). Clinigen SP focuses on acquiring and in licensing specialist, hospital only medicines worldwide and commercializing them within niche markets. Clinigen CTS sources commercial medical products for use in clinical studies only, including comparator drugs, adjuvant drugs and rescue therapies. Clinigen GAP specializes in the consultancy, development, management and implementation of programs providing access for patients and their clinicians to drugs not available in their markets. For more information, please visit [www.clinigengroup.com](http://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. Clinigen undertakes no obligation to update or revise (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events or other circumstances.*

## Overview

Clinigen remains focused on its key goals of becoming the global leader in clinical trial supply and global access programs, as well as fulfilling its ambition to significantly expand its specialty pharmaceutical business through acquiring five to seven more drugs over the next three to five years which are capable of being revitalised. Clinigen continues to set ambitious growth plans and remains on track to deliver on its three year strategy.

The Group saw like-for-like sales up 6.5% with underlying EBITDA improving by 20% to £12.5m (H1FY13: £10.5m). Underlying pre-tax profit was 12% higher at £10.9m (H1FY13: £9.7m) and underlying earnings per share increased by 7.8% to 9.7p (H1FY13: 9.0p).

Both Foscavir and Cardioxane have shown volume growth over the six month period and the integration of the acquired products remains on track. The focus on margin improvement in CTS has delivered and whilst business can be lumpy due to the size of the contracts, it is performing as expected.

GAP has seen one large early access program winding down during H1, which is expected as products are approved and commercialised. However, during H2FY14 other existing and new programs are expected to grow, such as ones with BTG and Eisai. Overall, GAP continues to grow at a fast rate and remains on target to meet full year expectations.

## Current trading and outlook

Clinigen has delivered a good H1 performance and remains on track to meet the Board's FY14 expectations. The business remains focused on realising its ambition of becoming the number one global provider of CTS and GAP services and a major global specialty pharmaceutical company.

CTS continues to be the main revenue generator with 64% of total sales in H1FY14 and margins have improved. GAP had significant growth in revenue and margin in H1FY13, driven by acceleration of Astellas' enzalutamide program and from other large programs such as those of Sanofi and BTG.

In SP, Foscavir continues to demonstrate volume growth across major markets. Price increases have been successfully applied in three key markets, although these have not yet fully impacted sales. For Cardioxane all European Marketing Authorisations (MAs) were successfully transferred in H1FY14 and manufacturing of Clinigen branded stock commenced in February 2014. The transfer plan in other key markets, South Korea and Latin America, is underway and on schedule. Vibativ did not impact H1FY14 sales, although the European GAP program went live in January 2014. Acquisitions remain a key priority, with the aim of acquiring a further five to seven products over the next three to five years whilst simultaneously ensuring proper integration of new products and new accounts.

The Directors aim to maintain the Group's growth momentum by continued focus on delivery on its key performance indicators (KPI).

## Financial Review

Reported Group revenues in the half year grew by 1.2% (H1FY13: £61.0m) to £61.8m, and gross profit grew by 16.4%.

Both sales and profit comparisons for CTS and SP are impacted by favourable transactions in the prior year as well as growth in the current period. In SP, the stock fill of Foscavir in the US (c.£3m) in H1FY13, as highlighted in the FY results last year, masked like-for-like Group sales growth of circa 6.5%. Adjusting for this stock fill, growth in SP was 22.2% (+£2.2m) enhanced by sales in Cardioxane which was acquired in March 2013.

In CTS, in H1FY13 there were high levels (£24m) of low margin anti-viral sales which have resulted in reported sales decline of 12.5% and a significant improvement in gross profit margin in H1FY14. Margins also benefitted from improved negotiated terms with suppliers.

Growth in GAP was driven by expansion in existing programs and the introduction of new ones with revenues and gross profit growing by 256% and 146% respectively.

Underlying EBITDA increased by 20% to £12.5m (H1FY13: £10.5m) as a result of gross profit growth from all three operating businesses of £2.8m, offset by overhead growth of £0.8m supporting the integration of acquisitions and organic growth.

Underlying pre-tax profit, which excludes share based payment charges of £1.3m increased by 12.4% to £10.9m (H1FY13: £9.7m). The Group reported a profit before tax of £9.6m (H1FY13: £3.7m).

Underlying earnings per share, excluding share based payment charges, is 9.7p (H1FY13: 9.0p). The reported earnings per share is 8.7p (H1FY13: 3.5p).

In line with the Group's stated dividend policy, it is paying an interim dividend of 1.0p per share (H1FY13: 0.6p). The dividend will be payable on 28 March 2014 to all shareholders on the register at 7 March 2014.

The Group is in a healthy cash position with cash and cash equivalents at £16.8m, up from £11.3m at 30 June 2013. It also has a £20m banking facility available. \$11m of deferred consideration for the acquisition of Cardioxane is due to be paid in March 2014. The Group is debt free at the period end and continues to operate a working capital-light business model.

The cash increase in the period of £5.5m was generated by cash from operations of £8.2m and tax received of £0.4m, offset by capital expenditure of £0.9m, purchase of own shares of £0.3m, dividend of £1.6m and financing costs and currency translations of £0.2m.

## Operational review

### Clinigen CTS

	H1FY14 £'000	H1FY13 £'000	% change
Sales	39,497	45,134	(12.5%)
Gross profit	6,523	5,804	12.4%
Gross profit margin	16.5%	12.9%	27.9%

CTS sales show a decline of 12.5% on prior year. However, gross profit is up 12.4% with a significantly improved gross profit percentage of 16.5% (H1FY13: 12.9%). This is partially due to prior year revenues benefitting from a number of large anti-viral study sales (£24m) at low margin, which pulled the gross profit percentage down. Over the past year the CTS team has improved supplier terms to support a higher gross profit percentage going forward. Gross profit margins are unlikely to be sustained for the full year. However, the aim is still to achieve margins of 13-15% on a longer term basis.

Clinigen continues to maintain a strong position in the CTS market with an estimated 8% market share, positioning the Group as number two globally; the market leader has circa 10% market share.

Year to date CTS has provided product to 56 customers, 12 of which generated sales of greater than £1m. Clinigen's offering continues to resonate with customers, generating further new business. The advantages of CTS being part of a larger pharmaceutical group have been highlighted with two recent project wins. Firstly, Clinigen is alone in being able to offer an import route to Europe for US product for use in a clinical trial. Secondly, having an MIA/IMP license enables the Group to import the product and the in-house Qualified Person (QP) service allows its release into the market for clinical trial use. This has enabled significant savings for two customers, one current and one new.

Clinigen's exclusive supply agreements continue with Astra Zeneca and have recently been extended with Accord to include the company's launch of a significant new product, capecitabine (generic Xeloda). Clinigen is in negotiations to potentially add a third exclusive agreement during H2FY14.

General market dynamics remain strong for CTS, with increasing numbers of clinical trials being performed and those with a comparator arm are expected to increase 8% per annum over the next three years. Higher comparator drug prices are also predicted as more trials with more expensive biologics drugs impact and comparators are expected to take a higher percentage of overall trial cost than previously (15% from 5-10%). Increasing difficulty in sourcing comparator drugs for clinical trials was stated by customers as a major trend over the next five years, due to regulatory changes, which favours specialist suppliers like Clinigen.

There are several regulatory changes which will impact the comparator market in the near future, and which are expected to further strengthen Clinigen's market position. Temperature control of drugs in the supply chain is the main regulatory change to impact the comparator market in the near future. With Clinigen's extensive distribution network, this issue can be handled for customers. In addition,

regulatory changes to the EU Clinical Trials Directive are expected to benefit the comparator market, such as the potential for single approval for investigational products. Tighter EU regulations will reduce the threat of counterfeiting by requiring mandatory documentation and robust supply chains, which plays to Clinigen’s strong reputation of dealing directly with the drug manufacturers.

CTS is developing a new service offering, “direct to site”. Initially, two small projects have been used to demonstrate this competency; one where Clinigen stores bulk product and ships these co-therapies direct to clinical sites when required. Another project involves the sourcing of product and then the import, storage, QP certification and release and distribution to a single site of finished clinical kits, incorporating the sourced product. A new project involves the same service for finished clinical kits but now to multiple sites. This new service is in early phase but there appears to be demand for this type of value-add service.

Finally, CTS has identified a new site for its expanding US operations in the Philadelphia Navy Yard. This mixed office and new warehouse space should be ready for occupation by early CY15.

**Clinigen GAP**

	H1FY14 £'000	H1FY13 £'000	% change
Sales	9,934	2,790	256%
Gross profit	2,775	1,126	146%
Gross profit margin	27.9%	40.4%	(30.9)%

GAP sales grew over H1FY13 by 256%. This has been driven by significant accelerated growth in the Astellas enzalutamide program, and also from other large programs such as Sanofi’s and BTG’s programs. GAP accounted for 16.1% of total sales in H1FY14 up from 4.6% in the same period last year.

The enzalutamide early access program for advanced prostate cancer has been accelerated by a combination of a high unmet patient need and the effectiveness of the drug – in the UK it has been reported to cut the risk of death by one third. This has led to a fast track approval in many key markets, such as France and Germany. Approval has led to the access program in these territories coming to an end sooner than anticipated and current volumes are 20% of the peak seen in April through to October 2013. The French program in particular caused a reduction in gross profit percentage, as it was the only part of the program for which the drug was charged for and it was at low margin, diluting overall GAP margins. Since November, when the French program ceased, overall margins have returned to circa 40% levels.

Sanofi’s Campath, which is a long term withdrawal program, has also shown impressive growth compared to H1FY13, but it is likely that this has now reached its peak levels.

GAP is now running three programs for BTG. In July 2013, BTG added uridine triacetate (UTA) to Voraxase and Digifab in its extended access programs; again all are longer term programs. Overall BTG sales have shown steady growth over H1FY13.

Initial customer feedback to the newly launched Cliniport, Clinigen's on-line management and communication platform for GAP programs is excellent, and H2FY14 will see it extended to add value to further high volume programs.

Looking forward to other activities in H2FY14, the Directors expect to see continued strong performance from the high volume programs such as Sanofi and BTG. For example, the Eisai Fycompa program, announced in September, will start in Germany and it is expected to be a high volume program with good margins into FY15. In addition, unlicensed programs for Clinigen's own drugs remain key; 12.5% of sales from Foscovir have been in unlicensed markets year to date and the Vibativ and Cardioxane named patient programs will start. Whilst these sales are not recorded in GAP, they are an essential element of the synergies of the businesses.

Clinigen has completed extensive market research around the unlicensed supply market, albeit it is difficult to gather data in such a new and evolving market sector. However, it is clear that gaining access to unlicensed and yet to be licensed medicines is becoming an increasingly important tool for clinicians to treat their patients, and schemes are being set up to help them do this.

An example of this is the Cancer Drugs Fund in England which is providing an additional £200m each year for cancer patients to receive access to drugs not routinely available on the NHS or have not been approved or appraised by the National Institute for Health and Clinical Excellence (NICE). The Fund also provides fast track access to cancer drugs that are awaiting NICE guidance as well as access to drugs for less common cancers. This model, in various guises, is being adopted in many countries and is one of the key drivers underpinning Clinigen's GAP business.

### **Clinigen SP**

	H1FY14 £'000	H1FY13 £'000	% change
Sales	12,330	13,083	(5.8%)
Gross profit	10,623	10,183	4.3%
Gross profit margin	86.2%	77.8%	10.8%

Sales in SP have shown a 5.8% reduction over H1FY13, whilst gross profit has improved by 4.3%. However, reported sales are not comparable as H1FY13 included circa £3m of Foscovir stock fill for the US market, which is masking a 3% volume increase in Foscovir supply and some pricing benefits from several markets. Adjusted for this stock fill, growth in SP was 22.3% (+£2.2m) with the acquisition Cardioxane adding £1.8m and underlying Foscovir growth of £0.4m.



**Foscavir® is an antiviral licensed for the treatment of Cytomegalovirus (CMV) in HIV and Hematopoietic stem cell transplantation (HSCT) patients and Herpes Simplex Virus (HSV) infections in immune-compromised patients**

Foscavir continues to demonstrate volume growth across all markets. Additional price increases have been successfully applied in three key markets although these have not yet fully impacted sales.

The bone marrow indication (HSCT) has now been approved for Foscavir in five countries; in the Netherlands as a first line treatment and Japan, Belgium, Hungary and Luxembourg as a second line treatment. There are on-going applications in US, France, Spain and Germany and the HSCT indication has received orphan status in South Korea and there is an application for license in this country.

Underlying volumes when viewed as a rolling 12 month average show 3% growth. Growth was slightly higher in Japan and US than RoW, driven by the new indication in Japan and the product being newly available in a licensed format in the US.

Foscavir sales volumes are expected to continue to increase in line with increases in HSCT procedures, which is between 1-3% per annum. There will also be an impact in H2FY14 from price increases. In the Directors' opinion Foscavir sales are now levelling out. New markets will continue to be developed in countries such as South Korea and others will be explored such as South America, although the latter are longer term opportunities as licensing can take three years or more.

**Cardioxane® is for the prevention of chronic cumulative cardiotoxicity caused by doxorubicin or epirubicin use in breast cancer patients**

Sales of Cardioxane were £1.8m. However most markets will continue to be supplied by Novartis until the product is fully transferred to Clinigen, expected to be the end of CY14. Underlying volumes for CY13 were as expected in that underlying sales were slightly in excess of \$11m.

All European Marketing Authorisations (MAs) were successfully transferred to Clinigen in H1FY14 and manufacturing of branded stock will commence in February 2014.

The transfer plan in other key markets, South Korea and Latin America is underway and on track.

**Vibativ® is an antibiotic active against gram-positive bacteria, including resistant pathogens such as MRSA**

Vibativ did not impact H1 sales, although the European GAP program went live in January 2014. The launch plan remains on track, the key being the lifting of the MA suspension. The Committee for Medicinal Products for Human Use (CHMP) is of the opinion that Clinigen has provided sufficient evidence to confirm that a suitable manufacturing site has been approved and therefore has recommended to the European Commission (EC) for the lifting of the suspension. The decision from the EC is expected by the end of March 2014.

Clinigen is now finalising manufacturing and packaging plans to facilitate commercial launch, which is expected in Q2 CY14.

**Future acquisitions**

Clinigen's acquisition pipeline remains healthy with more candidates being considered than at any other time, with the expectation that some will convert to Clinigen ownership in CY14.

**Clinigen Group plc**

**Interim consolidated condensed statement of comprehensive income  
for the six months ended 31 December 2013**

	Note	Unaudited 6 months ended 31 December 2013 £'000	Unaudited 6 months ended 31 December 2013 £'000 Non- underlying	Unaudited 6 months ended 31 December 2013 £'000 Total	Unaudited 6 months ended 31 December 2012 £'000 Underlying	Unaudited 6 months ended 31 December 2012 £'000 Non- underlying	Unaudited 6 months ended 31 December 2012 £'000 Total
<b>Revenue</b>	4	61,761	-	61,761	61,007	-	61,007
Cost of sales		(41,840)	-	(41,840)	(43,894)	-	(43,894)
<b>Gross profit</b>	4	19,921	-	19,921	17,113	-	17,113
Administrative expenses		(8,978)	(1,264)	(10,242)	(7,377)	(6,025)	(13,402)
Profit / (loss) from operations		10,943	(1,264)	9,679	9,736	(6,025)	3,711
Finance income		2	-	2	-	-	-
Finance expense		(79)	-	(79)	(56)	-	(56)
<b>Profit / (loss) before income tax</b>	4	10,866	(1,264)	9,602	9,680	(6,025)	3,655
Income tax (expense) / credit	6	(2,831)	415	(2,416)	(2,227)	900	(1,327)
<b>Profit / (loss) for the period attributable to the owners of the parent</b>		8,035	(849)	7,186	7,453	(5,125)	2,328
<b>Other</b>							

**comprehensive  
income**

**Items that may  
be reclassified  
to profit or loss**

Exchange gains  
arising in the  
period on  
translation of  
foreign  
operations

(131)                      -                      (131)                      -                      -                      -

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**Total  
comprehensive  
income /  
(expense)  
attributable to  
owners of the  
parent**

7,904                      (849)                      7,055                      7,453                      (5,125)                      2,328

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**Earnings per  
share for profit  
attributable to  
the owners of  
the parent  
during the  
period**

7

Basic (p)

8.7

3.5

Diluted (p)

8.4

2.9

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All amounts relate to continuing operations.

**Clinigen Group plc**

**Interim consolidated condensed statement of financial position  
as at 31 December 2013**

	Note	Unaudited 31 December 2013 £'000	Unaudited 31 December 2012 £'000	30 June 2013 £'000
<b>Non-current assets</b>				
Property, plant and equipment	9	1,015	527	748
Intangible assets		37,948	14,680	38,893
Deferred tax asset		1,543	5,094	1,983
		<b>40,506</b>	20,301	41,624
<b>Current assets</b>				
Inventories		3,934	1,721	3,151
Trade and other receivables		24,761	18,452	18,721
Corporation tax recoverable		2,236	-	3,932
Cash and cash equivalents		16,804	22,303	11,326
		<b>47,735</b>	42,476	37,130
<b>Total assets</b>		<b>88,241</b>	62,777	78,754
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		30,986	19,234	27,804
Provisions for liabilities and charges	10	-	912	-
		<b>30,986</b>	20,146	27,804
<b>NET ASSETS</b>		<b>57,255</b>	42,631	50,950

**Issued capital and reserves  
attributable to owners of  
the parent company**

Share capital	11	<b>83</b>	83	83
Share premium account		<b>8,660</b>	8,660	8,660
Own shares	12	<b>(340)</b>	-	-
Merger reserve		<b>5,413</b>	5,413	5,413
Foreign exchange reserve		<b>(22)</b>	48	109
Retained earnings		<b>43,461</b>	28,427	36,685
<b>TOTAL EQUITY</b>		<b>57,255</b>	42,631	50,950

Clinigen Group plc

Interim consolidated condensed statement of cash flows  
for the six months ended 31 December 2013

	Note	Unaudited 6 months ended 31 December 2013 £'000	Unaudited 6 months ended 31 December 2012 £'000	Year ended 30 June 2013 £'000
<b>Cash flows from operating activities</b>				
Profit for the period		7,186	2,328	11,332
<i>Adjustments for:</i>				
Depreciation of property, plant and equipment		90	60	130
Amortisation of intangible fixed assets		1,505	662	1,746
Interest receivable		(2)	-	(7)
Interest expense		79	56	95
Income tax expense		2,416	1,327	3,180
Loss on disposal of property, plant and equipment		8	-	18
Share based payment expense		592	2,061	2,323
		<b>11,874</b>	<b>6,494</b>	<b>18,817</b>
<b>Changes in working capital</b>				
(Increase) in trade and other receivables		<b>(6,040)</b>	<b>(1,229)</b>	<b>(4,157)</b>
(Increase)/ decrease in inventories		<b>(783)</b>	<b>1,071</b>	<b>(359)</b>
Increase in trade and other payables		<b>3,182</b>	<b>4,689</b>	<b>6,235</b>
(Decrease) in provisions		-	-	(912)
		<b>8,233</b>	<b>11,025</b>	<b>19,624</b>
<b>Cash generated from operations</b>				
Income taxes received / (paid)		<b>369</b>	<b>(775)</b>	<b>(1,301)</b>
		<b>8,602</b>	<b>10,250</b>	<b>18,323</b>
<b>Net cash flows from operating activities</b>				
<b>Cash flows from investing activities</b>				
Purchases of property, plant and equipment		<b>(545)</b>	<b>(155)</b>	<b>(467)</b>

Purchase of intangible fixed assets		(388)	-	(18,272)
Sale of property, plant & equipment		8	-	-
Purchase of own shares	11	(340)	-	-
Interest received		2	-	7
<b>Net cash used in investing activities</b>		<b>(1,263)</b>	<b>(155)</b>	<b>(18,732)</b>
<b>Cash flows from financing activities</b>				
Interest paid		(79)	(56)	(95)
Loan repayments		-	(1,626)	(1,626)
Proceeds from issue of shares		-	8,693	8,693
Dividends paid		(1,651)	-	(495)
<b>Net cash (used in) / generated from financing activities</b>		<b>(1,730)</b>	<b>7,011</b>	<b>6,477</b>
<b>Net increase in cash and cash equivalents</b>		<b>5,609</b>	<b>17,106</b>	<b>6,068</b>
<b>Cash and cash equivalents at beginning of period</b>		<b>11,326</b>	<b>5,197</b>	<b>5,197</b>
Exchange gains		(131)	-	61
<b>Cash and cash equivalents at end of period</b>		<b>16,804</b>	<b>22,303</b>	<b>11,326</b>



**Clinigen Group plc**

**Interim consolidated condensed statement of changes in equity  
for the six months ended 31 December 2013**

	Share capital £'000	Share premium account £'000	Merger reserve £'000	Foreign exchange reserve £'000	Retained earnings £'000	Total equity £'000
<b>At 1 July 2012</b>	-	-	5,463	48	24,395	29,906
<b>Profit for the period</b>	-	-	-	-	2,328	2,328
<b>Other comprehensive income</b>	-	-	-	-	-	-
<b>Total comprehensive income</b>	-	-	-	-	2,328	2,328
Share based payment scheme	-	-	-	-	2,061	2,061
Deferred taxation on share based payment scheme	-	-	-	-	(9,126)	(9,126)
Tax credit in respect of tax losses arising on exercise of share options	-	-	-	-	8,769	8,769
Bonus issue of shares	50	-	(50)	-	-	-
Issue of new shares	33	10,221	-	-	-	10,254
Cost of new issue	-	(1,561)	-	-	-	(1,561)
<b>At 31 December 2012 and 1 January 2013</b>	83	8,660	5,413	48	28,427	42,631

	Share capital	Share premium account	Merger reserve	Own shares	Foreign exchange reserve	Retained earnings	Total equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000
<b>At 30 June 2013 and 1 July 2013</b>	<b>83</b>	<b>8,660</b>	<b>5,413</b>	<b>-</b>	<b>109</b>	<b>36,685</b>	<b>50,950</b>
<b>Profit for the period</b>	-	-	-	-	-	<b>7,186</b>	<b>7,186</b>
<b>Other comprehensive income</b>	-	-	-	-	<b>(131)</b>	-	<b>(131)</b>
<b>Total comprehensive income</b>	-	-	-	-	<b>(131)</b>	<b>7,186</b>	<b>7,055</b>
Share based payment scheme	-	-	-	-	-	<b>592</b>	<b>592</b>
Deferred taxation on share based payment scheme	-	-	-	-	-	<b>649</b>	<b>649</b>
Own shares acquired in the period	-	-	-	<b>(340)</b>	-	-	<b>(340)</b>
Dividend paid	-	-	-	-	-	<b>(1,651)</b>	<b>(1,651)</b>
<b>At 31 December 2013</b>	<b>83</b>	<b>8,660</b>	<b>5,413</b>	<b>(340)</b>	<b>(22)</b>	<b>43,461</b>	<b>57,255</b>

Included within retained earnings reserve as at 31 December 2013 is £858K (30 June 2013: £168K, 31 December 2012: £8,796K) that is non-distributable.

## Clinigen Group plc

### Notes forming part of the interim consolidated condensed financial statements for the six months ended 31 December 2013

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#### **1 Basis of preparation**

The Group have elected to prepare the interim consolidated financial statements in accordance with IAS34 Interim Financial Reporting as adopted by the EU. The interim financial information does not comprise statutory accounts within the meaning of S434 of the Companies Act 2006. They do not include all disclosures that would otherwise be required in a complete set of financial statements and should be read in conjunction with the consolidated financial statements of the Group for the year ended 30 June 2013.

The comparative figures for the financial year ended 30 June 2013 are not the Group's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and delivered to the registrar of companies. The report of the auditors was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention to by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498 of the Companies Act 2006.

The condensed consolidated interim financial statements have been prepared on a going concern basis, based on the Directors' opinion, after making reasonable enquiries, that the Group has adequate resources to continue in operational existence for the foreseeable future.

#### **2 Significant accounting policies**

The preparation of interim consolidated financial statements in compliance with IAS 34 requires the use of certain critical accounting estimates. It also requires Group management to exercise judgment in applying the Group's accounting policies. The areas where significant judgments and estimates have been made in preparing the financial statements and their effect are disclosed in the notes to the Group's statutory consolidated financial statements for the year ended 30 June 2013 and in the notes to these interim condensed consolidated financial statements.

Clinigen Group plc applies the same accounting policies and methods of computation in its interim consolidated financial statements as in its 2013 annual financial statements. None of the new standards, interpretations and amendments, effective for the first time from 1 July 2013, have had a material effect on the financial statements.

#### **3 Principal Risks and Uncertainties**

The principal risks and uncertainties associated with the Group's business can be divided into the following main areas:

- Competitive threat
- International trade and pharmaceutical regulations
- Counterfeit product
- Introduction of new products
- Foreign exchange

Information on these risks and how they are managed is given in the Annual Report. In the view of the Board these principal risks and uncertainties are as applicable to the remaining six months of the financial year as they were to the six months under review.

#### **4 Segment information**

The Group's reportable segments are strategic operating business units that provide different products and service offerings into different market environments. They are managed separately because each operational business focuses on different customer groups in relation to their product or service offering.

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 Board of Directors including the Chief Executive Officer and the Chief Financial Officer.

There has been no change in the nature of the operating segments or in the accounting policies applicable to these segments during the six months ended 31 December 2013.

Classes of business:	6 months ended 31 December 2013 £'000	6 months ended 31 December 2012 £'000	Year ended 30 June 2013 £'000
Revenue arises from:			
Clinical Trials Supply	39,497	45,134	87,753
Specialty Pharmaceuticals	12,330	13,083	24,342
Global Access Programs	9,934	2,790	10,485
	<hr/> 61,761	<hr/> 61,007	<hr/> 122,580
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
Gross profit arises from:			
Clinical Trials Supply	6,523	5,804	11,367
Specialty Pharmaceuticals	10,623	10,183	19,847
Global Access Programs	2,775	1,126	3,909
	<hr/> 19,921	<hr/> 17,113	<hr/> 35,123
Administrative expenses relating to underlying operations	(8,978)	(7,377)	(14,614)
Administrative expenses relating to non-underlying operations	-	(3,476)	(3,098)
Share based payment expense	(592)	(2,061)	(2,323)
Social security costs in respect of share based payments	(672)	(488)	(488)
Finance income	2	-	7
Finance expense	(79)	(56)	(95)
<b>Profit before tax</b>	<hr/> 9,602	<hr/> 3,655	<hr/> 10,252
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

All revenues arise from external customers.

## 5 Non-underlying items

The non-underlying items relate to a charge of £592K (H1FY13: £2,061K) in respect of share based payment schemes, corresponding social security costs of £672K (H1FY13: £488K) on options granted under 'unapproved' share option schemes and the deferred tax asset recognised on these transactions.

Non-equity IPO costs of £nil (H1FY13: £3,476K) are also disclosed as non-underlying administrative costs.

## 6 Taxation

The Group has recognised a tax charge in the income statement based on the current tax rate of 23%. The effective tax rate of 25.2% is higher than the standard rate due to the timing difference between accounting and corporation tax deduction of the share based payment charges. The corporation tax payable is reduced by losses brought forward which were generated in the previous year on the exercise of share options. As announced in the March 2013 Budget the UK corporation tax rate was reduced from 23% to 21% with effect from 1 April 2014, and a further reduction to 20% with effect from 1 April 2015 was substantially enacted in July 2013. The applicable tax rate for deferred tax is 20%, being the enacted rate from 1 April 2015. The impact of the change in applicable rate was to reduce the deferred tax asset by £94K.

## 7 Earnings per share ("EPS")

	<b>6 months ended 31 December 2013 £'000</b>	<b>6 months ended 31 December 2012 £'000</b>	<b>Year ended 30 June 2013 £'000</b>
<b>Profit</b>			
Profit used in calculating basic and diluted EPS	7,186	2,328	11,332
<b>Number of shares</b>	<b>Number</b>	<b>Number</b>	<b>Number</b>
Weighted average number of shares for the purpose of basic EPS	82,555,585	67,200,281	74,814,829
Effect of:			
Employee share options	2,513,102	13,306,460	7,511,178
Purchase of own shares	(39,750)	-	-
Weighted average number of shares for the purpose of diluted EPS	85,028,937	80,506,741	82,326,007
	<b>p</b>	<b>p</b>	<b>p</b>
<b>EPS</b>			
Basic	8.7	3.5	15.1
Diluted	8.4	2.9	13.8

Earnings per share is calculated based on the share capital of Clinigen Group plc and the earnings of the combined group. The number of shares used for the calculation for the period ended 31 December 2012 has been adjusted, retrospectively, to reflect the bonus issue of shares on 20 August 2012 and subdivision of shares on 29 August 2012.

Diluted earnings per share takes account of the weighted average number of outstanding share options being 2,513,102 and the purchase of own shares being 39,750.

The underlying basic earnings per share, based on the 82,555,585 shares in issue post IPO and the underlying earnings of the group as stated in the income statement for the six month period ended 31 December 2013 is 9.7p (2012: 9.0p). The underlying diluted earnings per share based on the total number of shares in issue and granted under employee share option schemes at 31 December 2013 of 85,212,972 is 9.4p (2012: 8.8p).

## 8 Dividends

A final dividend in relation to the year ended 30 June 2013 of 2.0p (2012: nil) per ordinary share was paid on 1 November 2013. This amounted to £1,651,112 (2012: nil).

An interim dividend of 1.0p (2012: 0.6p) per ordinary share is proposed. This amounts to £824,761 (2012: £495,334) and will be paid on 28 March 2014 to all shareholders on the register as at 7 March 2014.

## 9 Property, plant and equipment

During the period, £540K was spent on the expansion and refurbishment of the Group's Head Office. As part of the refurbishment, a number of fixtures and fittings were sold and replaced.

## 10 Provisions

	<b>£'000</b>
<b>Balance at 1 July 2012 and at 31 December 2012</b>	912
Utilised in the year	(529)
Released to the statement of comprehensive income	(383)
<b>Balance at 30 June 2013 and at 31 December 2013</b>	<hr/> <hr/> -

At 30 June 2012 at 31 December 2012, a provision for PAYE and NI payable in respect of payments made to the Remuneration Trust was made based on the best estimate of the economic outflow at that time. During the period to 30 June 2013, the amount payable was agreed with HMRC which resulted in a release to the statement of comprehensive income of £383k.

## 11 Share capital

<b>Authorised</b>	<b>31 December 2013 Number</b>	<b>31 December 2012 Number</b>	<b>30 June 2013 Number</b>
Ordinary shares of 0.1p each	82,555,585	82,555,585	82,555,585
	<b>£'000</b>	<b>£'000</b>	<b>£'000</b>
Ordinary shares of 0.1p each	83	83	83
<b>Issued and fully paid</b>	<b>31 December 2013 Number</b>	<b>31 December 2012 Number</b>	<b>30 June 2013 Number</b>
Ordinary shares of 0.1p each	82,555,585	82,555,585	82,555,585
	<b>£'000</b>	<b>£'000</b>	<b>£'000</b>
Ordinary shares of 0.1p each	83	83	83

## 12 Own shares

	<b>£'000</b>
Balance at 1 July 2012, 31 December 2012 and 30 June 2013	-
Acquired during the period	340
Balance at 31 December 2013	<u>340</u>

The own shares reserve represents the cost of shares in Clinigen Group plc purchased in the market and held by the Clinigen Group Employee Benefit Trust to satisfy options under the Group's share options schemes (see note 13). The number of shares held by the Employee Benefit Trust at 31 December 2013 was 79,500 (2012: nil).

## 13 Share based payment

The Group operated seven equity-settled share based remuneration schemes: two UK tax authority approved schemes; two US schemes; and three unapproved schemes. Two of the schemes are for executive directors and certain senior management. The other five schemes are for all employees within the relevant country.

During the period there have been three grants, in addition to the one last year, under the unapproved Long Term Incentive Plan. The options under this scheme are subject to performance conditions and vest if the total shareholder return growth is greater than specified market criteria. All options under this scheme are for a three year period. If the individual leaves



earlier than the earliest vesting date, they may, if certain conditions are met, be still entitled to a proportion of the shares.

The Chairman has an option under an unapproved scheme. The option vests at the earliest of a change in control or 18 September 2015. 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. If the option remains unexercised for a period of ten years from the date of grant the option expires.

The Sharesave Plan is an HMRC approved scheme for all employees of the Group and directors, who are required to work for at least 25 hours per week. 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%. The vesting period is three years. If options remain unexercised after a period of six months from the vesting date the options expire. If monthly contributions are not made for more than six months over the three year period, the options lapse.

A US stock purchase plan was established during the period. Options granted under the scheme vest after two years and 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%.

The Group operates a Company Share Option Plan for certain employees who have invested in shares of the Company. The scheme grants share options to employees, matching the shares acquired by the employee. The options vest after three years if the employee still holds the shares acquired prior to the grant date or exercises their options through the Sharesave Plan. The approved Company Share Option Plan is only available to UK employees hence a US share scheme was put in place with the same conditions as the UK scheme.

Also, during the year a one year plan was established for all employees, the grant of awards was based on the length of service. The options vest on 1 October 2014.

	<b>6 months ended 31 December 2013 Weighted average exercise price (p)</b>	<b>6 months ended 31 December 2013 Number</b>	<b>6 months ended 31 December 2012 Weighted average exercise price (p)</b>	<b>6 months ended 31 December 2012 Number</b>
Outstanding at start of period	42.13	2,269,961	2,661	8,256
Granted during the period	-	-	5,800	938
	42.13	2,269,961	2,981	9,194
Adjusted options to reflect bonus issue of shares and subdivision	-	-	0.95	28,777,220
Granted during period	9.0	568,710	-	2,063,890
Cancellation of shares during period	-	-	0.95	(1,201,920)
Dilution on new share issue	-	-	0.95	(1,197,277)
Lapsed / surrendered during period	24.6	(99,284)	-	-
Exercised during period	-	(3,000)	0.96	(26,378,023)
Outstanding at end of period	35.9	2,736,387	-	2,063,890

The weighted average fair value of each option granted during the year was 320.9p (2012: 48.6p).

The share-based remuneration expense comprises of equity-settled schemes of £592k.

The Group did not enter into any share-based payment transactions with parties other than employees during the current or previous period.

During the year, the Chief Executive Officer and Chief Financial Officer surrendered share options over a total of 88,926 ordinary shares of 0.1p each granted under the Clinigen Group Long Term Incentive Plan.

At 31 December 2013, the Clinigen Group Employee Benefit Trust held 79,500 ordinary shares (2012: nil) for satisfying share options.

**14 Capital commitments**

At 31 December 2013, the group had committed expenditure of £523K (2012: nil) on the acquisition of software.

**15 Related party transactions**

In October 2013, a number of senior management partook in a management placing of shares. The Clinigen Group Employee Benefit Trust purchased 82,500 ordinary shares from this management placing.

**Responsibility statement**

The Directors confirm that this Interim Report has been prepared in accordance with IAS 34 and that the financial highlights, operational review and the interim financial information include a fair review of the information required by DTR 4.2.7R (indication of important events during the first six months and description of principal risks and uncertainties for the remaining six months of the year) and DTR 4.2.8R (disclosure of related party transactions and changes therein).

At the date of this statement, the directors are those listed in the Group's 2012/13 Annual Report and Accounts.

By order of the Board

**Peter George**

Group Chief Executive Officer

26 February 2014