

## BTG plc: Final Results

Transformational year creating a leader in Interventional Medicine

Strong financial performance, enabling investment in multiple growth opportunities

**London, UK, 20 May 2014:** BTG plc (LSE: BTG), the specialist healthcare company, today announces its final results for the year ended 31 March 2014.

### Financial summary

- Reported revenue including the impact of acquisitions was 24% higher at £290.5m (12/13: £233.7m); underlying<sup>1</sup> revenue grew 20% to £244.8m (12/13: £203.8m)
- Profit before tax 38% higher at £33.3m (12/13: £24.1m) reflects higher revenues and reduced impairment charges offset by increased investment in R&D and the Varithena™ launch
- Basic EPS 36% higher at 6.8p (12/13: 5.0p)
- Cash and equivalents of £38.2m at 31/3/14 (£158.7m at 31/3/13) post acquisitions and equity issue

### Operating highlights

#### Interventional Medicine

- Revenue increased to £79.1m from £36.1m reflecting 16% growth in Beads and £45.0m new revenues from acquisitions
- Varithena™ (polidocanol injectable foam) 1% approved in the US; controlled launch progressing well and first commercial treatments anticipated in Q3 2014
- Acquisitions of TheraSphere® and EKOS Corporation completed; both businesses integrated and performing strongly in line with expectations
- Increasing investment in R&D to accelerate TheraSphere® Phase III trials and deliver pipeline of product innovations for Beads, EKOS and Varithena™
- Geographic expansion progressing: US sales force expanded; direct sales force being established in the EU, initially focusing on TheraSphere®; Asian hub established in Hong Kong

#### Specialty Pharmaceuticals

- 5% revenue growth to £102.3m in line with expectations following strong growth in prior period
- Uridine triacetate progressing towards US New Drug Application; first EU named-patient sales made

#### Licensing

- 40% growth in underlying revenues to £109.1m driven by higher Zytiga® (abiraterone acetate) royalties
- Lemtrada™ (alemtuzumab) approved in the EU for multiple sclerosis; US sBLA to be re-submitted

Louise Makin, BTG's CEO, commented: "2013/14 was a transformational year for BTG. With the approval of Varithena™ and the acquisitions of TheraSphere® and EKOS, we are now a leader in interventional medicine with vision to build a \$1bn+ business by 2021. We have the resources and capabilities to invest in multiple growth opportunities to unlock the full value of our portfolio and pipeline, while in parallel seeking additional acquisition opportunities in both Interventional Medicine and Specialty Pharmaceuticals."

<sup>1</sup>Excluding acquisitions from the current period and non-recurring revenue (BeneFIX®, brachytherapy, AZD9773) from both periods

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**About BTG**

BTG is an international specialist healthcare company that is developing and commercialising products targeting acute care, cancer and vascular diseases. The company has diversified revenues from sales of its own marketed products and from royalties on partnered products, and is seeking to acquire new programmes and products to develop and market to specialist physicians. For further information about BTG, please visit our website at [www.btgplc.com](http://www.btgplc.com).

## **OPERATING REVIEW**

### **Chairman's statement**

BTG has had an exceptional year transforming our business into a leading player in interventional medicine. We have delivered a strong financial performance, expanded our portfolio of marketed products and development opportunities and enhanced our capacity and capabilities to enable the business to continue to deliver sustainable growth.

Our strong financial performance reflects good organic growth and a positive contribution from acquisitions. In July 2013, we acquired TheraSphere<sup>®</sup> and EKOS Corporation, adding two highly complementary products to our business, and then in November 2013 we received US approval for Varithena<sup>™</sup>, our novel treatment for varicose veins. This enlarged portfolio means that we now have a leading Interventional Medicine business and that we are a significant partner for interventional clinicians.

To position the business for sustained growth, we have enhanced our capacity and capabilities in key functions including commercial, regulatory, medical, manufacturing and quality. We have also reorganised our Innovation and Development functions and enhanced Quality, Compliance and Environmental Health and Safety systems and processes, to improve our controls, operating efficiency and effectiveness.

We now have a diversified product portfolio providing significant organic growth opportunities, particularly in our Interventional Medicine business. We have also broadened the number and scope of our development and innovation projects which provide additional growth potential. We have the financial and organisational capability to expand our portfolio further through acquisition, and we intend to explore opportunities in both interventional medicine and specialty pharmaceuticals.

Over the past several years our business has expanded significantly, evidenced by increased revenue, profitability and investment, an expanded portfolio of marketed products, development programmes, more employees and share price appreciation.

We have built a great platform. We now anticipate a period of sustainable, profitable growth combined with ongoing investment to expand the indicated uses and geographic availability of our products.

**Garry Watts**  
Chairman

## OPERATING REVIEW

Through the growth of our Bead products, the acquisitions of TheraSphere<sup>®</sup> and EKOS Corporation and the US approval of Varithena<sup>™</sup>, BTG has become a leader in Interventional Medicine.

We have built our portfolio with innovative products that target under-served patient populations and that are valued by clinicians and payers based on their clinical profiles. We believe that this focus on unmet need, innovation and investment to demonstrate clinical benefit is the right strategy in a changing healthcare environment and will enable us to build sustainable competitive advantage in our markets.

Our goal is to increase our Interventional Medicine revenues from approximately \$150m on an annualised basis at present to \$1bn+ by our 2020/21 financial year. This is based on increasing sales of our oncology products from approximately \$110m annualised to \$300m - \$400m; growing revenues from the EKOS family of ultrasound blood clot treatment products from approximately \$40m annualised to \$100m - \$200m; and building Varithena<sup>™</sup> into a \$500m+ franchise.

These growth targets are underpinned by activities that are already under way relating to product innovation, which has created a pipeline of new products in development, commercial activities to expand their geographical availability and development activities intended to expand the approved uses of the products.

### Multiple organic growth drivers

The US approval of Varithena<sup>™</sup> in late November 2013 was a significant achievement for the company and represents an opportunity for significant value creation.

It is a patient-centred treatment and the first product to be approved based on randomised trials showing clinically meaningful improvements in both the symptoms and appearance of varicose veins.

To realise its full potential we are following a controlled launch strategy in the US. This is designed to ensure optimum clinician and patient experience from the start. As a comprehensive treatment that may be used in place of two or more existing procedures, Varithena<sup>™</sup> represents a versatile and minimally invasive experience for physicians and patients. We aim to equip vein clinicians with the clinical training and market access support to fully integrate Varithena<sup>™</sup> into their practices.

Our first market is the US reimbursed sector for great saphenous vein (GSV) incompetence. Here, approximately 750,000 procedures are conducted annually by circa 1,000 vein specialists. We completed recruitment of a US sales force of 24 representatives in February 2014 and commenced physician outreach in March, focusing initially on well-established vein clinicians. Clinicians are required to complete online training and will be supported by a BTG medic during the first patient procedures. We expect that commercial patient treatments will commence in the US in Q3 2014.

We are finalising plans to seek approval to extend use of Varithena<sup>™</sup> into treatment of aesthetic leg veins. Treatment of these smaller veins may not be reimbursed in the US hence this is likely to be predominantly a self-pay segment. In addition, we intend to seek approval to market Varithena<sup>™</sup> in several other geographic markets.

We see multiple organic growth opportunities for our other interventional products.

Use of the EKOS blood clot treatment products is continuing to grow in the US driven by greater awareness of the potential benefits of interventional treatment over standard anticoagulation therapy. Our US sales force now calls on 600 US hospitals, and we are expanding our sales efforts in selected other geographies including the EU.

Based on positive clinical data from studies exploring the use of EKOS in treating patients with pulmonary embolism, we have applied for 510k clearance to expand use into this patient population in the US. We are also studying the use of our product for treating patients with chronic deep vein thrombosis (the ACCESS clinical study).

Within interventional oncology, we have combined and expanded the US sales forces for TheraSphere<sup>®</sup> and the Beads, significantly increasing the number of hospitals detailed with TheraSphere<sup>®</sup> and

expanding coverage for the Beads over the year from 480 to 600 hospitals. We are also expanding our commercial presence in other geographies. In Europe we are building small direct sales forces in the five major markets, initially to focus on TheraSphere<sup>®</sup> and to a more limited extent EKOS. In Asia, we are creating a regional hub in Hong Kong to serve as a local centre of excellence for regulatory and medical affairs, supporting direct sales operations (we are finalising our plans for direct sales in Taiwan) or distributors.

DC Bead<sup>®</sup> is already approved in a number of Asian markets including Japan, South Korea and Taiwan and is under review in China, although it is likely that we will need to supplement the data package to gain marketing approval. We are developing a regulatory strategy for TheraSphere<sup>®</sup> in Asian markets including China. We are also accelerating the three Phase III trials of TheraSphere<sup>®</sup>, two of which are intended to gain pre-market approvals (PMAs) in the US for treating patients with unresectable hepatocellular carcinoma (HCC) and as a second-line treatment for patients with metastatic tumours in the liver resulting from colorectal cancer (mCRC).

Our Innovation team is working on a number of pipeline projects including an imageable Bead product for identifying potential areas of under-treatment and a bioresorbable Bead product for use in non-malignant tumours such as uterine fibroids, and is exploring the potential of a proprietary Bead product pre-loaded with a targeted oncology drug that may offer improved anti-tumour activity.

### **Good progress in Specialty Pharmaceuticals and Licensing**

Our Specialty Pharmaceuticals business continues to contribute strong cash flows. Although the bounded nature of the markets for these antidote products means revenue growth is not of the same order as in Interventional Medicine, we nevertheless anticipate average annual growth in the mid-to-high single digit range for the segment.

We anticipate submission of a New Drug Application in the US by Wellstat Therapeutics Corporation by the end of 2014 for uridine triacetate, for which we recorded our first European named-patient sales during the year.

Significant growth in recurring royalty revenues in the Licensing segment was a result of the continued growth of Johnson & Johnson's Zytiga<sup>®</sup>, which is now tracking to annual global sales approaching \$2bn. We anticipate the commencement of royalties from Sanofi's Lemtrada<sup>™</sup> (alemtuzumab), which was approved in the EU in September 2013 and received a complete response letter for the US regulator in December. Sanofi expects to re-submit the US Biologics Licence Application during Q2 2014.

### **Growth through M&A activities**

Our vision to build a \$1bn+ Interventional Medicine business is based on organic growth in the existing portfolio and pipeline. However, we have created a scalable platform for growth, underpinned by strong cash flows and enhanced organisational capabilities and capacity, and we are seeking opportunities to expand our portfolio to drive additional growth. We see opportunities to further enhance our Interventional Medicine business and are actively seeking new products to expand and grow our Specialty Pharmaceuticals business.

## **FINANCIAL REVIEW**

The Group has delivered a strong financial performance that reflects good organic revenue growth, the impact of acquisitions during the year and ongoing clinical and commercial investments to drive future performance.

The results include the impact of approximately 9 months of contribution from the acquisitions completed in July 2013.

### **Revenue**

Reported revenue grew by 24% to £290.5m (12/13: £233.7m). This reflected underlying revenue growth of 20% to £244.8m (12/13: £203.8m). Acquisitions added revenue of £45.0m (12/13: nil) and non-recurring items were £0.7m (12/13: £29.9m).

We saw revenue growth across each of our operating segments. In Interventional Medicine reported revenues of £79.1m (12/13: £36.1m) included a 16% increase in revenue from our embolic beads to

£33.4m (12/13: £28.8m) plus revenues of £24.7m (12/13: nil) from TheraSphere® and £20.3m (12/13: nil) from EKOS. During the year we disposed of our Brachytherapy business which contributed revenues of £0.7m (12/13: £7.3m)

In Specialty Pharmaceuticals we saw growth of 5% to £102.3m (12/13: £97.2m) which reflects the established nature of the two major products, CroFab® and DigiFab®. It is pleasing to see Voraxaze® delivering double digit growth in its second year since launch.

The Licensing segment revenues increased to £109.1m (12/13: £100.4m). We have seen strong Zytiga® revenues of £83.8m (12/13: £49.9m) which has more than offset the lack of non-recurring revenues from BeneFix® following patent expiry and from AZD9773 following termination of that programme (12/13: £22.6m)

		2013/14 (£m)	2012/13 (£m)	Change (%)
<b>Specialty Pharmaceuticals</b>	<i>CroFab®</i>	<b>62.7</b>	62.7	-
	<i>DigiFab®</i>	<b>27.3</b>	23.8	<b>+15</b>
	<i>Voraxaze®/other</i>	<b>12.0</b>	10.7	<b>+12</b>
	<i>Uridine triacetate</i>	<b>0.3</b>	-	
	Total	<b>102.3</b>	<u>97.2</u>	<b>+5</b>
<b>Interventional Medicine</b>	<i>Embolic beads</i>	<b>33.4</b>	<u>28.8</u>	<b>+16</b>
	Total	<b>33.4</b>	<u>28.8</u>	<b>+16</b>
<b>Licensing</b>	<i>Zytiga®</i>	<b>83.8</b>	49.9	<b>+68</b>
	<i>Two-part hip cup</i>	<b>13.0</b>	13.3	<b>-2</b>
	<i>Others</i>	<b>12.3</b>	<u>14.6</u>	<b>-16</b>
	Total	<b>109.1</b>	<u>77.8</u>	<b>+40</b>
<b>Total</b>	Total underlying revenues	<b>244.8</b>	<u>203.8</u>	<b>+20</b>
<b>Acquisitions</b>	<i>TheraSphere®</i>	<b>24.7</b>	-	
	<i>EKOS</i>	<b>20.3</b>	-	
<b>Non-recurring</b> (Brachytherapy, BeneFix®, AZD9773)		<b>0.7</b>	<u>29.9</u>	
<b>Total</b>		<b>290.5</b>	<u>233.7</u>	<b>+24</b>

## Gross Profit

Reported gross margin reduced to 67% from 71%. This reflects the expected reduction in the Licensing segment gross margin to 53% (12/13: 60%) following the loss of high margin contributions from BeneFix® and AZD9773 in the prior year. In Interventional Medicine gross margins have been impacted by both acquisition adjustments and lower gross margin products from acquisitions. Excluding the impact of acquisition adjustments of £1.9m (12/13: nil), gross margins were 74% (12/13: 84%). In Specialty Pharmaceuticals margins have increased to 80% (12/13: 78%). We expect BTG gross margins to return to around the 70% level as we see higher margin revenue growth drive further efficiencies.

## Contribution

SG&A expenses have increased from £58.0m to £84.0m. The majority of this increase has occurred in the Interventional Medicine segment and comprises the incremental cost base associated with 9 months ownership of EKOS and TheraSphere®, the commercial preparations for the US launch of Varithena™ and investment in the underlying embolic Bead business.

The group monitors segmental contribution (gross profit less SG&A). In total this has increased to £111.5m (12/13: £108.5m), however contribution margin has dropped to 38% (12/13: 46%). This is due to the lower gross margins from the Licensing segment plus the impact of acquisitions and investments in the Interventional Medicine segment. As we look forward we would expect the contribution to move back above the 40% level as we see growth from the Interventional Medicine segment.

In Interventional Medicine, the contribution grew 6% to £13.8m (12/13: £13.0m) and the contribution margin decreased to 17% from 36% as a result of the lower gross margin and increased SG&A investment. The contribution in Specialty Pharmaceuticals increased to £58.7m (12/13: £55.4m) and the contribution margin was 57% as in the prior year. The Licensing segment profit contribution decreased to £39.0m (12/13: £40.1m) and the contribution margin fell from 40% to 36%, predominantly as a result of the lower gross margin.

### **Operating Profit**

Operating profit is calculated as contribution less: amortisation and impairments of acquired intangible assets; foreign exchange gains/losses; research and development; amounts written off or profit on disposal of intangible assets and property plant and equipment; and acquisition and reorganisation costs.

Amortisation and impairment of acquired intangible assets has reduced to £23.3m (12/13: £43.4m). Whilst amortisation has increased during the year to £23.3m (12/13: £14.4m) due to the acquisitions of EKOS and TheraSphere<sup>®</sup>, there were no impairments in the current year (12/13: £29.0m).

The \$/£ exchange rate moved by approximately 10% from \$1.50/£ at the beginning of the year to \$1.66/£ at the end of the year. BTG's exposure to US\$ denominated revenue and costs has resulted in the recognition of foreign exchange losses of £5.0m (12/13: £3.1m gain).

Investment in research and development activities grew to £47.2m (12/13: £41.2m). The main areas of expenditure were activities to progress the US approval and launch of Varithena<sup>™</sup>, studies and innovation projects associated with the Beads platform, activities to support marketed products and new expenditure associated with clinical development of the acquired TheraSphere<sup>®</sup> and EKOS products. A review of the Interventional Oncology research and development strategy has been completed and is expected to result in increased R&D expenditure in the near term as the Group accelerates the ongoing Phase III trials of TheraSphere<sup>®</sup> and continues to support a number of innovation programmes and other studies associated with marketed products.

Acquisition and reorganisation costs of £9.8m (12/13: £0.1m credit) related to the acquisitions of EKOS and TheraSphere<sup>®</sup> during the year.

Operating profit before acquisition adjustments and reorganisation costs was £62.3m (12/13: £69.0m). The net decrease is principally due to the inclusion in 2012/13 of non-recurring, high-margin Licensing revenues relating to BeneFix<sup>®</sup> and AZD9773, which contributed £21.2m to operating profit in that year. After accounting for acquisition adjustments and reorganisation costs, reported operating profit was £27.3m (12/13: £25.7m) the increase being a result of lower acquisition and reorganisation charges of £35.0m (12/13: £43.3m).

### **Financial income and expense**

Financial income of £8.2m (12/13: £1.1m) included a gain on mark-to-market of foreign exchange forward contracts of £7.5m (12/13: loss of £2.6m). This offsets the foreign exchange loss of £5.0m (12/13: gain of £3.1m) included within operating profit. Financial expense of £2.2m (12/13: £2.7m) relates principally to an adjustment of £1.4m (12/13: nil) related to the contingent milestones for the acquisition of EKOS.

### **Profit before tax and taxation**

The Group's profit before tax was £33.3m (12/13: £24.1m). The Group profits arise in the UK, the United States and other overseas territories. As a consequence the effective tax rate is a combination of a blend of the varying tax rates in the differing countries. In the UK, the BTG has benefited from the Patent Box legislation which allows for lower tax charges on income from qualifying assets. The effective tax rate for the Group this year is 27% (12/13: 32%) which has resulted in a tax charge of £9.0m for the year (12/13: £7.7m) which comprises a current tax charge of £13.7m offset by a deferred tax credit of £4.7m.

## Earnings per share

Basic earnings per share was 6.8p (12/13: 5.0p) on profit after tax of £24.3m (12/13: £16.4m). Underlying earnings per share, excluding acquisition adjustments and restructuring was 14.5p on underlying profit after tax of £51.5m (12/13: 14.5p on underlying profit after tax of £47.4m).

## Balance Sheet

### *Non-current assets*

Non-current assets have increased significantly at 31 March 2014 to £565.5m (31 March 2013: £308.0m). The main reasons for the growth in assets are the acquisitions of EKOS and TheraSphere® and investment in manufacturing facilities, primarily relating to Varithena™.

The acquisitions have resulted in gross additions to goodwill of £71.1m and intangible assets of £245.5m which have been offset by amortisation, disposals and foreign exchange to result in net increases of £64.4m in goodwill and £188.7m in intangible assets.

The net increase of £5.9m in property, plant and equipment comprises gross additions of £11.7m relating mainly to Varithena™ manufacturing expansion offset by disposals relating to the brachytherapy business, depreciation and foreign exchange.

The Group's defined benefit pension scheme, as measured under IAS19 Revised – Employee Benefits has changed from an asset of £10.3m at 31 March 2013 to an asset of £8.0m at 31 March 2014. The movements in the period reflect Company contributions during the year of £3.6m and an income statement credit of £0.1m offset by an actuarial loss of £6.0m. A formal actuarial valuation was measured as at 31 March 2013 and it expected to be agreed with the Trustees shortly.

### *Current assets*

Cash and cash equivalents have reduced from £158.7m to £38.2m due to the acquisitions of EKOS and TheraSphere®. The Group did not draw on its £60m multi-currency revolving credit facility during the year.

Both inventory and trade and other receivables have increased as a result of acquisitions and underlying business growth in the year. Inventory has increased to £27.0m (31 March 2013: £23.3m) and receivables to £75.1m (31 March 2013: £54.5m). The fair value of forward contracts as at 31 March 2014 was an asset of £4.4m compared to a liability of £2.2m as at 31 March 2013.

## Total Liabilities

Non-current liabilities have increased to £93.5m (31 March 2013: £44.7m) mostly as a result of an increase in the net deferred tax position of £46.6m, predominantly arising as a result of the acquisitions.

Trade and other payables have increased to £79.9m (31 March 2013: £61.6m) reflecting the underlying growth of the business, the impact of the acquisitions including contingent consideration payable on the acquisition of EKOS, and increased Zytiga® revenue sharing accruals.

## Cash flow

It has been a year of both organic investment and acquisitions which has been funded through cash generation from the business and fund raising. The business generated £48.5m from operating activities which compares to £55.5m at 31 March 2013. The lower levels of cash generation reflect higher levels of working capital in the business and investment in SG&A and research and development. During the year we raised £103.1m which together with our existing cash balances was used to fund the purchase of EKOS and TheraSphere® for total consideration of £260.3m and investments in our manufacturing capabilities of £11.6m.

We ended the year with cash and cash equivalents of £38.2m.

## Summary and financial outlook

We have delivered a strong performance in the underlying business and added new revenue streams from the acquisitions, which have performed in line with our expectations since completion in July 2013. We anticipate continued top-line growth across the portfolio and as we see the full year impact of the acquisitions. Revenue for the year ending 31 March 2015 is anticipated to be in the range £330m to £345m.

We are investing in commercial activities to support the launch of Varithena™ in the US and to establish direct sales operations in Europe, initially to support expansion of TheraSphere®. We are also establishing a regional hub for regulatory and medical affairs together with satellite commercial offices in Asia, primarily to support our interventional oncology products. We intend to increase investment in development activities, in particular to continue the acceleration of the three Phase III trials of TheraSphere®, to progress a number of innovation programmes and clinical studies associated with the Bead products and with the EKOS products.

Based on a solid financial platform and with multiple opportunities to drive performance through commercial, geographic and development activities, we are confident that the business is capable of delivering sustainable long-term financial growth.

## CONSOLIDATED INCOME STATEMENT

	Note	Year ended 31 March 2014			Year ended 31 March 2013		
		Results before acquisition adjustments and reorganisation costs £m	Acquisition adjustments and reorganisation costs £m	Total £m	Results before acquisition adjustments and reorganisation costs <sup>1</sup> £m	Acquisition adjustments and reorganisation costs £m	Total <sup>1</sup> £m
Revenue	2	290.5	-	290.5	233.7	-	233.7
Cost of sales	2	(93.1)	(1.9)	(95.0)	(67.2)	-	(67.2)
<b>Gross profit</b>	2	<b>197.4</b>	<b>(1.9)</b>	<b>195.5</b>	166.5	-	166.5
<b>Operating Expenses:</b>							
Amortisation and impairment of acquired intangible assets	7,10	-	(23.3)	(23.3)	-	(43.4)	(43.4)
Foreign exchange (losses)/gains		(5.0)	-	(5.0)	3.1	-	3.1
Selling, general and administrative expenses	2	(84.0)	-	(84.0)	(58.0)	-	(58.0)
Operating expenses: total		(89.0)	(23.3)	(112.3)	(54.9)	(43.4)	(98.3)
Research and development		(47.2)	-	(47.2)	(41.2)	-	(41.2)
Profit on disposal of property, plant and equipment and intangible assets		1.1	-	1.1	0.4	-	0.4
Amounts written off property, plant and equipment		-	-	-	(1.8)	-	(1.8)
Acquisition and reorganisation costs		-	(9.8)	(9.8)	-	0.1	0.1
<b>Operating profit</b>		<b>62.3</b>	<b>(35.0)</b>	<b>27.3</b>	69.0	(43.3)	25.7
Financial income	3	8.2	-	8.2	1.1	-	1.1
Financial expense	3	(0.8)	(1.4)	(2.2)	(2.7)	-	(2.7)
<b>Profit before tax</b>		<b>69.7</b>	<b>(36.4)</b>	<b>33.3</b>	67.4	(43.3)	24.1
Tax	4			(9.0)			(7.7)
<b>Profit for the period</b>				<b>24.3</b>			16.4
<b>Earnings per share</b>							
Basic earnings per share	5			6.8p			5.0p
Diluted earnings per share	5			6.7p			5.0p

1) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

All activity arose from continuing operations.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Note	Year ended 31 March 2014 £m	Year ended 31 March 2013 <sup>1</sup> £m
<b>Profit for the period</b>		<b>24.3</b>	16.4
<b>Other comprehensive income</b>			
<b>Items that may be reclassified subsequently to profit or loss</b>			
Foreign exchange translation differences		(32.4)	4.2
<b>Items that will not be reclassified subsequently to profit or loss</b>			
Actuarial (loss)/gain on defined benefit pension scheme	8	(6.0)	0.5
Deferred tax on defined benefit pension scheme asset		0.8	(3.7)
<b>Other comprehensive income for the period</b>		<b>(37.6)</b>	1.0
<b>Total comprehensive income for the period</b>		<b>(13.3)</b>	17.4

1) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Note	31 March 2014 £m	31 March 2013 <sup>1</sup> £m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Goodwill	6,10	123.6	59.2
Intangible assets	7,10	397.9	209.2
Property, plant and equipment		31.3	25.4
Other investments		3.0	3.0
Deferred tax assets		0.8	0.9
Employee benefits	8	8.0	10.3
Derivative Financial instruments		0.9	-
		<b>565.5</b>	<b>308.0</b>
<b>Current assets</b>			
Inventories		27.0	23.3
Trade and other receivables		75.1	54.5
Corporation tax receivable		1.5	0.4
Derivative financial instruments		4.4	-
Cash and cash equivalents		38.2	158.7
		<b>146.2</b>	<b>236.9</b>
<b>Total assets</b>		<b>711.7</b>	<b>544.9</b>
<b>EQUITY</b>			
Share capital		36.1	32.8
Share premium account	11	288.7	188.6
Merger reserve		317.8	317.8
Other reserves		(32.2)	0.2
Retained earnings		(80.0)	(104.8)
<b>Total equity attributable to equity holders of the parent</b>		<b>530.4</b>	<b>434.6</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Trade and other payables		2.6	0.5
Deferred tax liabilities	4	90.4	43.8
Provisions		0.5	0.4
		<b>93.5</b>	<b>44.7</b>
<b>Current liabilities</b>			
Trade and other payables		79.9	61.6
Derivative financial instruments		-	2.2
Corporation tax payable		7.4	1.2
Provisions		0.5	0.6
		<b>87.8</b>	<b>65.6</b>
<b>Total liabilities</b>		<b>181.3</b>	<b>110.3</b>
<b>Total equity and liabilities</b>		<b>711.7</b>	<b>544.9</b>

1) The financial position as at 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

## CONSOLIDATED STATEMENT OF CASH FLOWS

	Note	Year ended 31 March 2014 £m	Year ended 31 March 2013 <sup>1</sup> £m
<b>Profit after tax for the period</b>		<b>24.3</b>	16.4
Tax	4	9.0	7.7
Financial income	3	(8.2)	(1.1)
Financial expense	3	2.2	2.7
Operating profit		27.3	25.7
Adjustments for:			
Profit on disposal of property, plant and equipment and intangible assets		(1.1)	(0.4)
Amortisation and impairment of intangible assets		24.3	45.1
Amounts written off property, plant and equipment		-	1.8
Depreciation on property, plant and equipment		3.4	3.1
Share-based payments		5.3	4.7
Pension scheme funding		(3.3)	(4.6)
Fair value adjustments		1.9	-
Other		-	0.3
Cash from operations before movements in working capital		57.8	75.7
Decrease in inventories		(0.5)	(1.5)
Increase in trade and other receivables		(12.6)	(14.4)
Increase in trade and other payables		10.9	2.0
Decrease in provisions		(0.1)	(0.8)
<b>Cash generated from operations</b>		<b>55.5</b>	61.0
Taxation paid		(7.0)	(5.5)
<b>Net cash inflow from operating activities</b>		<b>48.5</b>	55.5
<b>Investing activities</b>			
Interest received		0.2	0.7
Purchases of intangible assets		(0.9)	(2.6)
Purchases of property, plant & equipment		(11.6)	(7.6)
Acquisition of businesses net of cash acquired	10	(260.3)	-
Net proceeds from disposal of property, plant and equipment and intangible assets		3.2	-
Net inflow from held to maturity financial assets		-	5.0
<b>Net cash outflow from investing activities</b>		<b>(269.4)</b>	(4.5)
<b>Cash flows from financing activities</b>			
Repayment of obligations under finance leases		-	(0.2)
Proceeds from issue of shares	11	103.4	0.4
Other financing activities		(0.7)	-
<b>Net cash inflow from financing activities</b>		<b>102.7</b>	0.2
(Decrease)/increase in cash and cash equivalents		(118.2)	51.2
Cash and cash equivalents at start of period		158.7	106.9
Effect of exchange rate fluctuations on cash held		(2.3)	0.6
<b>Cash and cash equivalents at end of period</b>		<b>38.2</b>	158.7

1) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Share capital £m	Share premium £m	Merger reserve £m	Other reserves £m	Retained earnings <sup>1</sup> £m	Total equity <sup>1</sup> £m
At 1 April 2012 (previously reported)	32.7	188.3	317.8	(4.0)	(128.6)	406.2
Impact of changes in accounting policies	-	-	-	-	5.3	5.3
At 1 April 2012 (restated)	32.7	188.3	317.8	(4.0)	(123.3)	411.5
Profit for the period	-	-	-	-	16.4	16.4
Foreign exchange translation differences	-	-	-	4.2	-	4.2
Actuarial gain on defined benefit pension scheme	-	-	-	-	0.5	0.5
Deferred tax on defined benefit pension scheme asset	-	-	-	-	(3.7)	(3.7)
Total comprehensive income for the period	-	-	-	4.2	13.2	17.4
<b>Transactions with owners:</b>						
Issue of ordinary shares	0.1	0.3	-	-	-	0.4
Movement in shares held by the Trust	-	-	-	-	0.6	0.6
Share-based payments	-	-	-	-	4.7	4.7
At 31 March 2013	32.8	188.6	317.8	0.2	(104.8)	434.6

1) The 12 months ended 31 March 2012 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

	Note	Share capital £m	Share premium £m	Merger reserve £m	Other reserves £m	Retained earnings <sup>2</sup> £m	Total equity <sup>2</sup> £m
At 1 April 2013		32.8	188.6	317.8	0.2	(108.4)	431.0
Impact of changes in accounting policies		-	-	-	-	3.6	3.6
At 1 April 2013 (restated)		32.8	188.6	317.8	0.2	(104.8)	434.6
Profit for the period		-	-	-	-	24.3	24.3
Foreign exchange translation differences		-	-	-	(32.4)	-	(32.4)
Actuarial gain on defined benefit pension scheme		-	-	-	-	(6.0)	(6.0)
Deferred tax on defined benefit pension scheme asset		-	-	-	-	0.8	0.8
Total comprehensive income for the period		-	-	-	(32.4)	19.1	(13.3)
<b>Transactions with owners:</b>							
Issue of ordinary shares	11	3.3	100.1	-	-	-	103.4
Movement in shares held by the Trust		-	-	-	-	0.4	0.4
Share-based payments		-	-	-	-	5.3	5.3
At 31 March 2014		36.1	288.7	317.8	(32.2)	(80.0)	530.4

2) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## 1. Basis of preparation

In accordance with EU law (IAS Regulation EC 1606/2002), the final results have been prepared in accordance with International Financial Reporting Standards ("IFRS") adopted for use in the EU as at 31 March 2014 ("adopted IFRS"), International Financial Reporting Interpretations Committee ("IFRIC") interpretations and those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

The final statements have been prepared in accordance with the Group's accounting policies approved by the Board.

Details of principal business risks and uncertainties can be found in note 13.

BTG's 2014 Annual Report will be posted to shareholders on 13 June 2014. The financial information set out herein does not constitute the Group's statutory accounts for the year ended 31 March 2014 but is derived from those accounts and the accompanying directors' report. Statutory accounts for 2014 will be delivered to the Registrar of Companies following the Company's Annual General Meeting which will be held at 10.30am on 16 July 2014. The auditors have reported on those accounts; their report was unqualified and did not contain statements under Section 495 (4)(b) of the Companies Act 2006.

The comparative figures for the year ended 31 March 2013 are not the Group's statutory accounts for the financial year but are derived from those accounts which have been reported on by the Group's auditors and delivered to the Registrar of Companies. The report of the auditors was unqualified and did not contain statements under Section 495 (4)(b) of the Companies Act 2006.

Interim and preliminary announcements notified to the London Stock Exchange are available on the internet at [www.btgplc.com](http://www.btgplc.com).

### Accounting standards adopted in the year

The following new accounting standards and amendments to standards have been adopted by the Group in these consolidated financial statements for the year ended 31 March 2014, with a date of initial application of 1 April 2013.

- a. Presentation of Items of Other Comprehensive Income (Amendments to IAS 1)
- b. IAS 19 Employee Benefits (2011)
- c. IFRS 13 Fair Value Measurement

The effects of these changes are described below.

#### a. Presentation of Items of Other Comprehensive Income

As a result of amendments to IAS 1 'Presentation of Financial Statements', the Group has modified the presentation of items of other comprehensive income in its consolidated statement of comprehensive income, to present separately items that may be reclassified to profit or loss in the future from those that would not be. Comparative information has also been re-presented accordingly.

The adoption of the amendment to IAS 1 has no impact on the recognised assets, liabilities and comprehensive income of the Group.

#### b. Employee Benefits

The Group adopted the revised IAS 19 'Employee Benefits', with an initial date of application on 1 April 2013.

The Group now applies the liability discount rate to determine the net interest income/expense on the net defined benefit obligation and interest income on the scheme assets. Previously, the Group determined interest income on scheme assets on their long term rate of expected return. The effect on the income statement has an equal and opposite effect in other comprehensive income. This change does not impact the Group's net assets.

The Group has also removed the administrative expenses reserve from the defined benefit obligation. This change results in a one-off credit to opening reserves and a corresponding increase in net assets. It also changes the allowance for pension scheme administrative costs in the income statement, from the previous assumed amount within current service cost and interest cost, to the new approach of recognising the schemes costs when the related services are provided.

The new standard also changes a number of disclosure requirements for post-employment arrangements.

The adoption of the new standard has been applied retrospectively. The impact of the restatements to the prior year comparatives is shown in note 8.

### c. Fair Value Measurement

IFRS 13 establishes a single framework for measuring fair value and making disclosures about fair value measurements when such measurements are required or permitted by other IFRSs. It unifies the definition of fair values as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

### Other accounting standards adopted in the year

All other standards and interpretations recently adopted by the EU not discussed above did not have or are not expected to have a significant impact on the Group.

### Going concern and liquidity

After making enquiries, the directors have a reasonable expectation that the Group has adequate resources to continue in operational existence for the foreseeable future. Accordingly, they continue to adopt the going concern basis in preparing the Annual Report and Accounts.

This conclusion has been reached having considered the effect of liquidity risk on the Group's ability to operate effectively. Currently, liquidity risk is not considered a significant business risk to the Group given its level of net cash and cash flow projections. The Group does not currently require significant levels of debt financing to operate its business. The key liquidity risks faced by the Group are considered to be the failure of banks where funds are deposited and the failure of key licensees, distributors or insurers.

In addition to the liquidity risk considered above, the directors have also considered the following factors when reaching the conclusion to continue to adopt the going concern basis:

- The Group's principal licensees are global industry leaders in their respective fields and the Group's royalty-generating intellectual property covers a broad portfolio of both licensees and industries;
- Many of the Group's sales products are life-saving in nature, providing some protection against the current uncertain economic outlook; and
- In April 2013, the Group signed a £60m multi-currency revolving credit facility providing access to funds for a period of three years to April 2016. This facility remains undrawn.

### Acquisition adjustments and reorganisation costs

The consolidated income statement includes a separate column to disclose significant acquisition adjustments and reorganisation costs arising on corporate acquisitions. Adjustments relate to the acquisitions of:

- EKOS Corporation in July 2013;
- Targeted Therapies Division of Nordion Inc. in July 2013;
- Biocompatibles International plc in January 2011; and
- Protherics PLC in December 2008.

The costs relate to the following:

- The release of the fair value uplift of inventory acquired;
- Amortisation and impairment arising on intangible assets acquired;
- Transaction costs incurred with professional advisors in relation to the completion of corporate acquisitions; and
- Reorganisation costs comprising acquisition related integration costs, redundancy programmes, property costs and asset impairments.
- Fair value adjustments to contingent consideration on corporate acquisitions.

## 2. Operating segments

The Group is aligned behind three reportable segments, being Interventional Medicine, Specialty Pharmaceuticals and Licensing.

The acquisition of EKOS Corporation on 5 July 2013 and the Targeted Therapies division of Nordion Inc. on 13 July 2013 are included within the Interventional Medicine operating segment.

In assessing performance and making resource allocation decisions, the Leadership Team (which is BTG's chief operating decision-making body) reviews contribution by segment. Contribution is defined as being gross profit less directly attributable selling, general and administrative costs (SG&A). The Licensing operating segment includes SG&A relating to the Group's centrally managed support functions and corporate overheads. This reflects

the management structure and stewardship of the business. No allocation of central overheads is made across the Specialty Pharmaceuticals or Interventional Medicine operating segments. Research and development continues to be managed on a global basis, with investment decisions being made by the Leadership Team as a whole. It is not managed by reference to the Group's operating segments, though each programme within the pipeline would ultimately provide revenues for one of the operating segments if successful.

	Year ended 31 March 2014			
	Interventional Medicine <sup>1</sup> £m	Specialty Pharmaceuticals £m	Licensing £m	Total £m
Revenue	79.1	102.3	109.1	290.5
Cost of Sales <sup>1</sup>	(22.5)	(20.9)	(51.6)	(95.0)
<b>Gross Profit</b>	<b>56.6</b>	<b>81.4</b>	<b>57.5</b>	<b>195.5</b>
Selling, general and administrative expenses	(42.8)	(22.7)	(18.5)	(84.0)
<b>Contribution</b>	<b>13.8</b>	<b>58.7</b>	<b>39.0</b>	<b>111.5</b>
Amortisation and impairment of acquired intangibles				(23.3)
Foreign exchange losses				(5.0)
Research and development				(47.2)
Profit on disposal of property, plant and equipment and intangible assets				1.1
Acquisition and reorganisation costs				(9.8)
<b>Operating profit</b>				<b>27.3</b>
Financial income				8.2
Financial expense				(2.2)
<b>Profit before tax</b>				<b>33.3</b>
Tax				(9.0)
<b>Profit for the period</b>				<b>24.3</b>
<b>Unallocated assets</b>				<b>711.7</b>

1) 2014 Cost of Sales includes a £1.9m release of a fair value adjustment to inventory purchased on the acquisition of EKOS on the 5 July 2013 within the Interventional Medicine segment. This release represents the reversal of a fair value uplift applied to inventory purchased on acquisition recognised through the income statement as the product is sold.

	Year ended 31 March 2013			
	Interventional Medicine <sup>2</sup> £m	Specialty Pharmaceuticals <sup>2</sup> £m	Licensing <sup>2</sup> £m	Total <sup>2</sup> £m
Revenue	36.1	97.2	100.4	233.7
Cost of Sales	(5.6)	(21.6)	(40.0)	(67.2)
<b>Gross Profit</b>	<b>30.5</b>	<b>75.6</b>	<b>60.4</b>	<b>166.5</b>
Selling, general and administrative expenses	(17.5)	(20.2)	(20.3)	(58.0)
<b>Contribution</b>	<b>13.0</b>	<b>55.4</b>	<b>40.1</b>	<b>108.5</b>
Amortisation and impairment of acquired intangibles				(43.4)
Foreign exchange gains				3.1
Research and development				(41.2)
Amounts written off property, plant and equipment				(1.8)
Profit on disposal of property, plant and equipment and intangible assets				0.4
Acquisition and reorganisation costs				0.1
<b>Operating profit</b>				<b>25.7</b>
Financial income				1.1
Financial expense				(2.7)
<b>Profit before tax</b>				<b>24.1</b>
Tax				(7.7)
<b>Profit for the period</b>				<b>16.4</b>
<b>Unallocated assets</b>				<b>544.9</b>

2) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

## Revenue analysis

An analysis of revenue, based on the geographical location of customers and the source of revenue is provided below:

Geographical analysis	Year ended 31 March 2014	Year ended 31 March 2013
	£m	£m
USA	256.1	202.8
UK	14.6	21.2
Europe (excluding UK)	11.9	5.3
Other regions	7.9	4.4
	<b>290.5</b>	<b>233.7</b>

Revenue from major products and services	Year ended 31 March 2014	Year ended 31 March 2013
	£m	£m
Product sales	180.1	134.3
Royalties	110.4	90.8
Other	-	8.6
	<b>290.5</b>	<b>233.7</b>

## Major customers

Products that utilise the Group's intellectual property rights are sold by licensees. Royalty income is derived from over 70 licences. One licence individually generated royalty income in excess of 10% of Group revenue of £83.8m (2013: One license generated £49.9m).

The Group's marketed products are sold both directly and through distribution agreements in the USA, Europe and Asia Pacific region. No individual customer generated income in excess of 10% of the Group revenue (2013: Two customers generated £25.2m and £24.8m respectively).

## 3. Financial income and expense

	Year ended 31 March 2014	Year ended 31 March 2013
	£m	£m
Interest receivable on money market and bank deposits	0.2	1.1
Fair value movement on foreign exchange forward contracts	7.5	-
Other	0.5	-
<b>Financial income</b>	<b>8.2</b>	<b>1.1</b>
Fair value movement on foreign exchange forward contracts	-	2.6
Fair value changes on contingent consideration	1.4	-
Other	0.8	0.1
<b>Financial expense</b>	<b>2.2</b>	<b>2.7</b>

Included within "Financial income" of £8.2m (12/13: included within "Financial expense": £2.7m) is £7.5m (12/13: £2.6m) which represents the movement in the fair value of the Group's foreign exchange forward contracts.

## 4. Tax

	Year ended 31 March 2014	Year ended 31 March 2013
	£m	£m
<b>Current tax</b>		
Current tax charge	13.7	4.1
<b>Deferred tax</b>		
(Decrease)/Increase in net deferred tax liability	(4.7)	3.6
<b>Total tax charge/(credit) for the year</b>	<b>9.0</b>	<b>7.7</b>

In addition to the tax charge in the income statement, a deferred tax credit of £0.8m has been recognised in the consolidated statement of other comprehensive income.

UK corporation tax is calculated at 23% (2013: 24%) of the estimated taxable profit for the year. Taxation for other jurisdictions is calculated at the rates prevailing in the respective jurisdictions.

## Deferred tax liability

The deferred tax liability of £90.4m (2013 restated for IAS19 Revised: £43.8m) represents the net position after taking into account the offset of deferred tax assets against deferred tax liabilities in each jurisdiction. Deferred tax liabilities of £109.2m arise on intangible assets recognised at fair value on acquisitions, £2.8m on pension fund surplus and £0.9m on short term timing differences. Deferred tax assets relate to brought forward trading losses. The table below summarises the gross and net position at each balance sheet date:

	Deferred tax assets £m	Deferred tax liabilities <sup>1</sup> £m	Net deferred tax liability £m
At 1 April 2012	37.9	(73.1)	(35.2)
Adjustments re prior years	1.3	-	1.3
Income statement (debit)/credit	(17.4)	12.5	(4.9)
Exchange differences	-	(1.6)	(1.6)
Other	0.5	(1.9)	(1.4)
At 1 April 2013	22.3	(64.1)	(41.8)
Impact of changes in accounting policies <sup>1</sup>	-	(2.0)	(2.0)
At 1 April 2013 (restated)	22.3	(66.1)	(43.8)
Adjustments re prior years	1.5	-	1.5
Acquisitions	7.0	(66.2)	(59.2)
Income statement (debit)/credit	(6.2)	9.4	3.2
Other comprehensive income	-	0.8	0.8
Offset against current tax payable	(1.1)	-	(1.1)
Exchange differences	(1.0)	9.2	8.2
<b>At 31 March 2013</b>	<b>22.5</b>	<b>(112.9)</b>	<b>(90.4)</b>

1) The financial position as at 31 March 2013 has been restated following the adoption of IAS 19 Revised.

Reductions in the rate of corporation tax to 21% from 1 April 2014 and to 20% from 1 April 2015 were substantively enacted on July 17 2013. This will reduce the company's future current tax charge accordingly. The UK deferred tax assets and liabilities at 31 March 2014 have been calculated based on the rate of 21% or 20% depending on when the timing difference is expected to reverse.

## 5. Earnings per share

The calculation of basic and diluted earnings per share is based on the following data:

	Year ended 31 March 2014	Year ended 31 March 2013 <sup>1</sup>
Profit for the period (£m)	24.3	16.4
Earnings per share (p)		
Basic	6.8	5.0
Diluted	6.7	5.0
Number of shares (m)		
Weighted average number of shares – basic	355.2	326.9
Effect of share options in issue	4.6	4.0
Weighted average number of shares – diluted	359.8	330.9

1) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

The calculation of basic and diluted earnings per share from underlying earnings is based on the following data:

	Year ended 31 March 2014	Year ended 31 March 2013 <sup>1</sup>
Profit for the period from operations (£m)	24.3	16.4
Add back:		
Fair value adjustment on acquired inventory <sup>a</sup>	1.2	-
Amortisation of acquired intangible fixed assets <sup>b</sup>	15.3	31.1
Acquisition and reorganisation costs <sup>c</sup>	9.3	(0.1)
Fair value changes on contingent consideration <sup>d</sup>	1.4	-
Underlying earnings	51.5	47.4
Profit per share (p)		
Basic	14.5	14.5
Diluted	14.3	14.3

1) The 12 months ended 31 March 2013 has been restated following the adoption of IAS 19 Revised. See accounting policies in note 1 and retirement benefit schemes in note 8 for further details.

Adjustments to profit are shown after taking into account the tax effect of such adjustments on the results as shown in the consolidated income statement as follows:

- In the year ended 31 March 2014 there was £0.7m tax impact on fair value adjustment of inventory acquired of £1.9m (2013: £nil)
- The release of deferred tax liability of £8.0m (2013: £12.3m) has been deducted from the amortisation and impairment of acquired intangible assets of £23.3m (2013: £43.4m) as shown in the consolidated income statement.
- In the year ended 31 March 2014 there was £0.5m tax impact on reorganisation credits of £9.8m. In the year ended 31 March 2013, £0.1m of tax effect of reorganisation costs was adjusted on the basis that the tax charge would have been £0.1m higher had it not been for deductions available against reorganisation costs paid in the financial year.
- No tax adjustment was required on the fair value changes on the contingent consideration.

## 6. Goodwill

Goodwill of £123.6m relates to the acquisitions of EKOS Corporation in July 2013 (see note 10), the Targeted Therapies Division of Nordion Inc. in July 2013 (see note 10), Biocompatibles International plc in January 2011 and Protherics PLC in December 2008 (12/13: £59.2m in relation to Biocompatibles International plc and Protherics PLC).

## 7. Intangible assets

The table below summarises the Group's Intangible Assets:

Group	Developed technology £m	Contractual relationships £m	In-process research and development £m	Computer software £m	Patents £m	Purchase of contractual rights £m	Total £m
<b>Cost</b>							
<b>At 1 April 2012</b>	<b>234.1</b>	<b>40.1</b>	<b>14.8</b>	<b>0.6</b>	<b>13.3</b>	<b>15.7</b>	<b>318.6</b>
Additions	-	-	-	0.2	0.7	1.8	2.7
Disposals	(4.8)	(0.2)	(8.9)	-	(0.6)	-	(14.5)
Currency movements	5.8	1.6	(0.1)	-	1.1	0.9	9.3
<b>At 1 April 2013</b>	<b>235.1</b>	<b>41.5</b>	<b>5.8</b>	<b>0.8</b>	<b>14.5</b>	<b>18.4</b>	<b>316.1</b>
Acquisitions	10	227.8	-	17.6	0.1	-	245.5
Additions	-	-	0.5	0.2	0.2	-	0.9
Disposals	(2.0)	-	-	-	-	-	(2.0)
Currency movements	(32.4)	(2.9)	(1.6)	-	(1.6)	(1.4)	(39.9)
<b>At 31 March 2014</b>	<b>428.5</b>	<b>38.6</b>	<b>22.3</b>	<b>1.1</b>	<b>13.1</b>	<b>17.0</b>	<b>520.6</b>
<b>Amortisation</b>							
<b>At 1 April 2012</b>	<b>29.1</b>	<b>13.5</b>	<b>9.7</b>	<b>0.1</b>	<b>10.6</b>	<b>9.6</b>	<b>72.6</b>
Provided during the year	12.5	2.0	-	0.1	0.8	0.4	15.8
Impairments	-	24.0	5.0	-	0.3	-	29.3
Writeback on disposals	(4.8)	(0.2)	(8.9)	-	(0.6)	-	(14.5)
Currency movements	0.8	1.3	-	-	1.0	0.6	3.7
<b>At 1 April 2013</b>	<b>37.6</b>	<b>40.6</b>	<b>5.8</b>	<b>0.2</b>	<b>12.1</b>	<b>10.6</b>	<b>106.9</b>
Provided during the year	22.8	0.5	-	0.2	0.4	0.4	24.3
Writeback on disposals	(0.5)	-	-	-	-	-	(0.5)
Currency movements	(2.5)	(2.8)	-	-	(1.7)	(1.0)	(8.0)
<b>At 31 March 2014</b>	<b>57.4</b>	<b>38.3</b>	<b>5.8</b>	<b>0.4</b>	<b>10.8</b>	<b>10.0</b>	<b>122.7</b>
<b>Net book value</b>							
<b>At 31 March 2014</b>	<b>371.1</b>	<b>0.3</b>	<b>16.5</b>	<b>0.7</b>	<b>2.3</b>	<b>7.0</b>	<b>397.9</b>
At 1 April 2013	197.5	0.9	-	0.6	2.4	7.8	209.2
At 1 April 2012	205.0	26.6	5.1	0.5	2.7	6.1	246.0

### (i) Developed technology, Contractual relationships and In-process research and development

Developed technology includes EkoSonic<sup>®</sup> acquired in EKOS Corporation (see note 10), TheraSphere<sup>®</sup> acquired in the Targeted Therapies Division of Nordion Inc. (see note 10), the antidote assets acquired in Protherics PLC comprising principally of the rights to CroFab<sup>®</sup> and DigiFab<sup>®</sup> and the bead assets acquired in Biocompatibles International plc comprising principally of the rights to the DC Bead<sup>®</sup> and LC Bead<sup>™</sup>. The carrying value of individually significant assets within developed technology is:

	31 March 2014 £m	31 March 2013 £m	Remaining amortisation period at 31 March 2014
EkoSonic®	105.8	-	14.3 years
TheraSphere®	90.3	-	14.3 years
CroFab®	63.3	73.1	19.7 years
DigiFab®	20.5	23.6	19.7 years
DC Bead® and LC Bead™	84.1	91.2	11.8 years

### In-process research and development

Additions to in-process research and development includes Targeted Therapies assets acquired in the Targeted Therapies Division of Nordion Inc. (see Note 10).

	31 March 2014 £m	31 March 2013 £m	Remaining amortisation period at 31 March 2014
Targeted Therapies Assets	15.9	-	-

In the prior year an impairment charge of £22.5m was recognised in amortisation and impairment of acquired intangibles in the acquisition adjustments and reorganisation costs column in the Income Statement in relation to AZD9773 (see note 9).

## 8. Defined benefit pension fund

The Group has recognised a net defined benefit asset of £8.0m on the Group's statement of financial position in accordance with IAS19 – *Employee benefits* in relation to the BTG Pension Fund (31 March 2013 restated: asset of £10.3m). The decrease of £2.3m since 31 March 2013 reflects £3.6m of Company contributions during the year, an income statement credit of £0.1m and an actuarial loss of £6.0m.

### IAS 19 (Revised)

As described in Note 1, the group has adopted IAS 19 Revised. The impacts are shown below:

#### Restatements to Condensed Consolidated Income Statement

There is no material impact on the consolidated income statement for the 12 months ending 31 March 2013.

#### Restatements to Consolidated Other Comprehensive Income

	Previously Published £m	Impact of IAS19 Revised £m	Restated £m
12 months ended 31 March 2013			
Foreign Exchange Differences	4.2	-	4.2
Actuarial gain on defined benefit pension scheme	0.1	0.4	0.5
Deferred tax on defined benefit pension scheme asset	(1.6)	(2.1)	(3.7)
<b>Other comprehensive income for the year</b>	<b>2.7</b>	<b>(1.7)</b>	<b>1.0</b>

#### Restatements to Consolidated Statement of Financial Position

	Previously Published £m	Impact of IAS19 Revised £m	Restated £m
31 March 2013			
<b>Assets</b>			
Employee Benefits	4.7	5.6	10.3
<b>Equity</b>			
Retained Earnings	(108.4)	3.6	(104.8)
<b>Liabilities</b>			
Deferred Taxation	41.8	2.0	43.8

## 9. AZD9773

In prior year, on 8 August 2012 BTG announced the top-line data from a Phase IIb study of AZD9773 in patients with severe sepsis and/or septic shock, conducted by AstraZeneca. The study failed to meet primary or secondary endpoints. AstraZeneca terminated its licence agreement and associated arrangement with BTG. BTG does not anticipate conducting any further development of AZD9773. Consequently the following transactions have been recognised in the 12 months ended 31 March 2013:

- The release of deferred income associated with previously received milestones from AstraZeneca in relation to AZD9773 work streams of £6.1m to the income statement within the Licensing segment;

- Revenue of £8.6m was recognised within milestones and one-off income in the Licensing operating segment. The components of this revenue were:
  - The release of deferred income associated with previous received milestones from AstraZeneca in relation to AZD9773 work streams totalling £6.1m; plus
  - Compensation for early contract termination of £2.5m.
- An impairment charge of £22.5m was recognised in amortisation and impairment of acquired intangibles in the acquisition adjustments and reorganisation costs column;
- Property, plant and equipment write-downs associated with assets used in the development of AZD9773 of £1.8m were recognised in the amounts written off property, plant and equipment.

## 10. Business Combinations

In July 2013, BTG completed the acquisitions of EKOS Corporation (EKOS) and the Targeted Therapies division from Nordion Inc.

### a) EKOS Corporation (EKOS)

BTG completed the acquisition of 100% of EKOS on 5 July 2013 for an initial cash consideration of £118.7m (\$178.8m) and up to \$40m in contingent consideration based upon future performance milestones. The contingent consideration has a carrying value equal to its fair value of £17.5m using acquisition date trading assumptions and forecasts to assess the likelihood of payments to be made. The purchase price allocation is the final determination of the fair values of assets acquired and liabilities assumed.

EKOS owns, manufactures and distributes the EkoSonic<sup>®</sup> Endovascular System (EkoSonic<sup>®</sup>), a differentiated interventional medicine product using a locoregional approach in the treatment of severe blood clots. EkoSonic<sup>®</sup> is cleared for use in the US and the EU. The acquisition is a complementary transaction in line with BTG's strategy of growing its Interventional Medicine business, following its acquisition of Biocompatibles International plc in 2011.

At acquisition, intangible assets principally comprised £123.2m relating to EkoSonic<sup>®</sup> developed technology. The fair value of this asset has been estimated using an income approach, using the excess earnings method. The estimated useful life of the technology is 15 years, and amortisation expense will be recorded on a straight-line basis. Goodwill arising of £47.8m, which is not deductible for tax purposes, has been assigned to the Interventional Medicine operating segment. Goodwill includes the values of tax impacts, assembled workforce and future potential indications for EkoSonic<sup>®</sup> which at the time of acquisition did not meet the criteria for recognition as separate intangible assets.

Under the terms of the acquisition agreement, BTG may be due to make further contingent payments dependent upon EKOS achieving certain revenue targets. This will comprise up to \$20m payable in respect of 2013 and up to \$20m payable in respect of 2014 and 2015 in aggregate. Total contingent payments will not exceed \$40m. During the year BTG paid the contingent payment in respect of 2013 of \$20.0m (£11.9m). The remaining contingent payment on the Statement of Financial Position is considered by management to be a level 3 financial instrument.

	Book Value £m	Fair Value Adjustment £m	Fair Value £m
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Intangible assets	0.1	123.2	123.3
Property, plant & equipment	1.4	-	1.4
<b>Current assets:</b>			
Inventories	2.7	1.9	4.6
Trade and other receivables	3.0	-	3.0
Cash and cash equivalents	3.1	-	3.1
<b>LIABILITIES</b>			
<b>Current liabilities:</b>			
Trade and other payables	(4.8)	-	(4.8)
<b>Non-current liabilities:</b>			
Trade and other payables	(0.4)	-	(0.4)
Deferred tax liabilities	-	(41.8)	(41.8)
Assets acquired	5.1	83.3	88.4
Goodwill			47.8
Total assets acquired			136.2
Cash consideration paid			118.7
Contingent consideration			17.5
<b>Total Consideration</b>			<b>136.2</b>
Cash and cash equivalents included in undertaking acquired			3.1
Cash consideration paid			(118.7)
<b>Net cash outflow arising on acquisition and in cash flow statement</b>			<b>(115.6)</b>

#### b) Targeted Therapies division of Nordion Inc.

On the 13 July 2013, BTG completed the acquisition of the Targeted Therapies Division of Nordion Inc. for a total cash consideration of £132.8m (US\$200.8m). The purchase price allocation is the final determination of the fair values of assets acquired and liabilities assumed.

Targeted Therapies is a high growth business that is focused in utilising TheraSphere<sup>®</sup> for targeted interventional treatment of liver cancer. TheraSphere<sup>®</sup> is a product comprising radioactive glass beads which target the tumour from within the body with a high concentration of radiation, thereby limiting both damage to surrounding healthy tissue and side effects for the patient in comparison to externally delivered radiation. The acquisition is a complementary transaction in line with BTG's existing strategy of growing its Interventional Medicine business, following its acquisition of Biocompatibles International plc in 2011.

At acquisition, intangible assets comprised £104.6m relating to Targeted Therapies developed technology and £17.6m relating to in process research and development assets. The fair value of these assets has been estimated using an income approach, using the excess earnings method. The estimated useful life of the technology is 15 years, and amortisation expense will be recorded on a straight-line basis. Goodwill arising of £23.3m, which is not deductible for tax purposes, has been assigned to the Interventional Medicine operating segment. Goodwill includes the values of tax impacts and assembled workforce.

	Book Value £m	Fair Value Adjustment £m	Fair Value £m
<b>ASSETS</b>			
<b>Non-current assets:</b>			
Intangible assets	-	122.2	122.2
<b>Current assets:</b>			
Inventories	0.6	-	0.6
Trade and other receivables	5.8	-	5.8
<b>LIABILITIES</b>			
<b>Current liabilities:</b>			
Trade and other payables	(1.7)	-	(1.7)
<b>Non-current liabilities:</b>			
Deferred tax liabilities	-	(17.4)	(17.4)
Assets acquired	4.7	104.8	109.5
Goodwill			23.3
<b>Total consideration</b>			<b>132.8</b>
Cash paid			(132.8)
<b>Net cash outflow arising on acquisition and in cash flow statement</b>			<b>(132.8)</b>

#### Revenue and Profit Impact of acquisitions

EKOS contributed revenues of £20.3m and operating profit before acquisition adjustments and reorganisation costs of £2.3m in the period since acquisition. The Targeted Therapies Division of Nordion Inc. contributed revenues of £24.7m and operating profit before acquisition adjustments and reorganisation costs of £7.3m in the period since acquisition.

If both acquisitions had taken place on 1 April 2013, the first day of the reporting period under review, revenue and profit before tax and before acquisition adjustments and reorganisation costs of the combined group would have been £306.7m and £73.3m respectively.

#### 11. Share Placement

In May 2013, BTG completed a share placing for a total of 32,208,030 new ordinary shares at a price of 330p per placing share, raising proceeds of £106.3 million, being £103.1 million net of expenses.

#### 12. Related parties

Giles Kerr, a non-executive director of BTG plc, is also the Director of Finance for Oxford University and a director of Isis Innovations Limited, a wholly-owned subsidiary of Oxford University. Wholly owned subsidiaries of BTG plc entered into revenue sharing agreements with these organisations prior to Giles Kerr joining the BTG Board. The BTG Group has licensed the intellectual property covered by these agreements to third party companies that are developing and/or selling the licensed products. Under these licence agreements, BTG is entitled to receive milestone payments and/or a royalty on sales of the products made by the third party licensees. There were nil payments in the year ended 31 March 2014 (12/13: £1.5m) under these agreements and there were no amounts outstanding and payable at 31 March 2014 (12/13: £nil).

Under the various revenue sharing agreements, the BTG Group pays a share of any income it receives to Oxford University and Isis Innovations, depending on the specific technology that generated the income. As the revenue sharing agreements do not permit these organisations to have any input over the commercialisation of the licensed products or the amount payable under the relevant revenue sharing agreement, Giles Kerr is not able to influence the amounts received in his position outside BTG. Because he has no influence over any aspect of these agreements in his role outside the BTG Group, the Company considers that his independence in relation to the BTG Group is not compromised.

Within the BTG Group, to avoid any possible conflict of interest, it has been agreed that Giles Kerr will not participate in any discussions concerning the relevant agreements either within the Board meetings of BTG plc or in any other discussions or meetings with the executives of BTG plc and its subsidiaries. The Board has considered, and is satisfied with this safeguard through separation of duties.

### 13. Principal Risks and Uncertainties

Our performance and prospects may be affected by risks and uncertainties relating to our business and operating environment. Our internal controls include a risk management process to identify key risks and, where possible, manage the risks through systems and processes and by implementing specific mitigation strategies.

Here we describe the most significant risks that could materially affect the Group's ability to achieve its financial and operating objectives. Other risks are unknown or deemed less material at this time. Some risks are generic to the industry in which the group operates; others are specific to the Group. The Company considers all these risks relevant to any decision to invest in the Company.

#### **Risk: External supply chain**

**Impact:** We rely on third-party contractors for the supply of many key materials and services, such as supply of components and the filling and freeze-drying of end products in the Specialty Pharmaceuticals business. These processes inherently carry risks of failure and loss of product and are risks over which the Company has a lower degree of control. Problems at contractors' facilities such as technical issues, contamination and regulatory actions may lead to delays and disruptions or loss of supply or available capacity. Some materials and services may only be available from one source and regulatory requirements may make substitution costly, time-consuming or commercially unviable.

**Mitigation:** Rigorous monitoring of suppliers; maintenance of adequate product and component inventories; dual sourcing implemented or being investigated where practicable. In accordance with the risk rating the Company will continue to focus on this area to ensure market demand for products can continue to be met (as has historically been the case).

**Change in 2013/14:** The acquisition of TheraSphere<sup>®</sup> has increased our reliance on third party manufacturing (given our dependency on Nordion as the sole manufacturer of that product). We are assessing options to secure additional product capacity through the external supply chain.

#### **Internal Supply chain**

**Impact:** BTG relies on its single site in Wales for supply of manufactured antibody products, and a single site in Farnham, UK, for the manufacture of the Bead and Varithena<sup>™</sup> products with the consequent possibilities for disruption to or loss of supplies resulting from, for example, technical issues, contaminations or regulatory actions. BTG's polyclonal antibody products rely on serum produced from our sheep flocks in Australia, which could be subject to disease outbreaks or fire. BTG manufactures its EKOS products at a single site in Seattle, WA, USA, with the consequent possibilities for disruption to or loss of supply.

**Mitigation:** Dual sourcing is being investigated where practicable; inventories are being increased or maintained and monitored through a sales and operational planning process; production changes implemented where needed to ensure continued product supply; rigorous quality control procedures in place; regular checks made on sheep flock health; disaster recovery plans under regular review. In accordance with the risk rating the Company will continue to focus on this area to ensure market demand for products can continue to be met (as has historically been the case).

**Changes in 2013/14:** The acquisition of EKOS Corporation resulted in an additional significant BTG product line being dependent on an internal single manufacturing site (Seattle). The disposal of the brachytherapy business addressed an internal manufacturing risk that materialised during the year (receipt of an FDA warning letter relating to the brachytherapy Oxford, US site).

#### **Intellectual property, know-how, trade secrets**

**Impact:** BTG may be subject to challenges relating to the validity of its patents or alleging infringement by BTG of intellectual property rights of others, which might result in cessation of product sales, litigation and/or settlement costs and/or loss of earnings. BTG might elect to sue third-parties for their infringement of its patents in order to

protect product revenue streams. Litigation, especially in the US, involves significant costs and uncertainties. Failure by BTG to maintain or renew key patents might lead to losses of earnings and liabilities to licensees or licensors. BTG may not be able to secure the necessary intellectual property rights in relation to products in development, limiting the potential to generate value from these products and investments. Changes in patent laws and other intellectual property regulations in territories where BTG or its licensees conduct business that make it more difficult or time-consuming to obtain or enforce patents, or which reduce the available term of granted patents or periods of market exclusivity protection, could adversely impact the Group's financial performance.

Patent expiries can adversely impact the Group's revenues. Currently, BTG earns significant royalties from sales of Johnson & Johnson's Zytiga<sup>®</sup> (abiraterone acetate), which may be subject to generic competition in the US from our 2016/17 financial year when the US composition of matter patent expires, and in the EU from our 2020/21 financial year when the ten-year data post-approval exclusivity period ends.

BTG's patent portfolio is currently subject to several challenges.

Enforcement of third party patents against BTG may prevent BTG selling products or require BTG to pay royalties or other compensation to the patent holder. BTG may rely upon know-how and trade secrets to protect its products and maintain competitive advantage, which may be important where patent protection is limited or absent. BTG may have to sue third parties to protect its know-how and trade secrets; failure to maintain them could result in the loss of earnings.

**Mitigation:** Dedicated internal resource, supplemented by external expertise, monitors third-party patent portfolios and patent applications and intellectual property rights; development and implementation of BTG patent filing, defence and enforcement strategies; robust processes are in place to automate patent renewals; internal controls established to avoid disclosure of patentable material prior to filing patent applications and to protect know-how.

**Change in 2013/14:** IP management has been made more complex by the acquisitions of TheraSphere<sup>®</sup> and EKOS Corporation which are now overseen by the central IP group. The IP landscape is generally more complex in the Interventional Medicine market place rendering IP management more challenging. BTG is enforcing its patent rights and has initiated the commencement by the US International Trade Commission (ITC) of an investigation in relation to the importation of the Anavip<sup>®</sup> product into the US (as a potential competitor to CroFab<sup>®</sup>). The ITC will consider whether to exclude the importation of Anavip<sup>®</sup>.

## Competition

**Impact:** The Group operates in competitive markets. The products on which BTG currently earns revenues, or from which it anticipates earning revenues once on the market, face competition from other products that are already approved or in development. Competing products may have superior efficacy or side effect profiles, cost less to produce or be offered at a lower price than BTG's products; such competition could materially adversely impact Group revenues.

There are currently no competitors to the Specialty Pharmaceuticals products CroFab<sup>®</sup>, DigiFab<sup>®</sup> or Voraxaze<sup>®</sup>. However, future competition is likely in some cases and competing products could materially adversely impact BTG's financial results. We believe Instituto Bioclon has submitted a Biological Licence Application to seek US approval for a potential competitor product (Anavip<sup>®</sup>) to CroFab<sup>®</sup>. That product may be launched in the US. Within Interventional Medicine, the Beads products compete with products from US companies Merit Medical and CeloNova; TheraSphere<sup>®</sup> competes globally with a product from Australian company SirTex; Varithena<sup>™</sup> competes with other treatment modalities including heat ablation, vein stripping and physician-compounded sclerosing foam; EKOS competes with other interventional clot treatment products from US companies Covidien, Bayer MedRad and others. In Licensing, Zytiga<sup>®</sup> (abiraterone acetate) competes with a number of recently approved treatments for advanced prostate cancer including Xtandi<sup>®</sup> (enzalutamide).

**Mitigation:** BTG focuses on niche opportunities, addressing specialist segment where there are high barriers to entry, for example, relating to the development and manufacturing processes, or to the need to generate significant supportive clinical data to gain approval and commercial acceptance. We seek to differentiate our products by demonstrating in clinical trials safety and efficacy benefits, or greater patient acceptance.

**Change in 2013/14:** Following the acquisition of EKOS and TheraSphere<sup>®</sup> and the approval of Varithena<sup>™</sup>, we now assess the competitive landscape separately for Specialty Pharmaceuticals and within Interventional Medicine, the Interventional Oncology (TheraSphere<sup>®</sup> and Beads) and Interventional Vascular (Varithena<sup>™</sup> and EkoSonic<sup>®</sup>) businesses. The sectors in which the Group operate remain competitive.

## Research and development execution

**Impact:** Failure to implement our research and development strategy could result in an inability to deliver new products and new indications for existing products, which would have a material detrimental effect on the sustainability of the business and on its medium to long term growth prospects. Failure of the programmes could result from lack of organisational resource or capability deficiencies, from not aligning R&D programmes with

commercial objectives or from changes in the regulatory landscape making it more difficult to conduct the planned R&D programmes or to achieve the desired clinical results and approval.

**Mitigation:** Capabilities and organisational capacity enhanced through recruitment; monthly monitoring of performance against goals; monitoring of regulatory landscape; use of external resources such as contract clinical research organisations (CROs) are being more effectively leveraged; active development of R&D and regulatory strategies and delivery plans. However, notwithstanding our mitigation activities, the inherent risks in pharmaceutical and medical device R&D remain material and difficult to mitigate.

**Change in 2013/14:** we have reorganised our research and development function and processes to ensure full alignment with manufacturing and commercial functions. The acquisitions of TheraSphere<sup>®</sup> and EKOS Corporation have significantly increased the portfolio of R&D projects and clinical trials to be executed to deliver on the Company's strategy. Specific plans are being implemented to accelerate delivery of those studies, including revising how the Company works with CROs to support these efforts and increasing the number of sites participating in the relevant clinical studies.

Given the increase in number and complexity of studies and the additional focus of the Group's strategy on R&D investment this risk is assessed to have increased in comparison to last year.

### **Quality & regulatory, process documentation**

**Impact:** Our quality systems and regulatory processes and documentation (including those relating to Good Manufacturing Practice and Good Clinical Practice) are regularly audited by regulators such as the US FDA. Any inadequacies identified can result in observations, major findings and/or warnings, which would need to be addressed through remedial actions but if not addressed adequately, could lead to regulatory action such as product recalls, an inability to release manufactured product, loss of manufacturing or product licences or forced temporary or permanent shutdown of facilities and the consequential disruption to product supply.

**Mitigation:** We have invested in upgrading our processes, capabilities and people capacity to ensure appropriate resources are available to support all required control measures. A Global Quality System has been established and implementation across the Group is nearing completion.

**Change in 2013/14:** EKOS and TheraSphere<sup>®</sup> were acquired during the year and continuing improvements are being made to the applicable quality systems to bring them into full conformation with the Company's Global Quality System as it continues to develop. As establishment of that system is nearing completion, overall, the risk is assessed as having decreased in comparison with the prior year and will continue to be assessed in light of the results of future external audits.

### **Commercial Compliance**

**Impact:** The pharmaceutical and device industries are highly regulated and, in addition to the broad range of regulations relating to the development, approval and manufacturing of its products, the Group must comply with many regulations relating to the marketing of its products. This is true in the US, from which the Group derives most of its revenues and where the Group has established its own direct sales and marketing operations. Ensuring compliance with such regulations necessitates allocation of significant financial and operating resources. Failure by BTG (or its commercial partners where BTG has a liability) to comply with certain rules, laws and regulations, including the US False Claims Act, Anti-Kickback Statute and the US Foreign and Corrupt Practices Act among others, for alleged improper conduct, including corrupt payments to medical professionals, off-label marketing of products, or the submission of false claims for reimbursement by the federal government may result in criminal and civil proceedings against the Group. Significant breaches could result in large financial penalties and injunctive or administrative actions against the Group which could materially adversely impact the Group's financial performance and prospects or result in the loss of product licences or exclusion from sale of certain products.

**Mitigation:** A Code of Conduct has been established, supported by a mandatory training programme. Robust and extensive compliance systems are in place to ensure sales and marketing and other activities comply with applicable regulations in the US and other territories in which the group operates. Internal expertise, procedures, monitoring and training is maintained and provided to seek to manage these risks. Notwithstanding the significant efforts made in this area, given the significant potential fines and other penalties related to any compliance failures, the risk rating remains high, reflecting the Company's continuing vigilance in this area.

**Change in 2013/14:** Enhanced compliance processes and monitoring and auditing programmes have been established. EKOS and TheraSphere<sup>®</sup> marketing and other activities have been incorporated into BTG's global compliance programme.

Given the anticipated continued geographic expansion of the group (with direct sales in the EU for TheraSphere<sup>®</sup> and Taiwan for DC Bead<sup>®</sup>) the remit for the compliance system has increased accordingly, including with respect to the Group's anti-bribery and anti-corruption controls and management processes.

## Organisational capabilities

**Impact:** Inability to implement growth and delivery plans through inadequate capabilities, capacity and processes would adversely affect the long-term sustainability and growth prospects of the business. BTG is subject to intense competition for key staff with the necessary skills and expertise. Given the industry in which the group operates a significant proportion of the group's staff are technical in nature. BTG's business and the scope of its activities have been transformed in recent years through organic growth and acquisitions. BTG's growth is being driven by numerous factors including new product launches and entering new markets. In parallel, the external environment has become more challenging as a result of increased regulation, pricing pressures and competition. To continue with its growth plans and be able to meet the external challenges, BTG must continue to enhance its capabilities through recruitment of key experienced personnel and training and development while delivering its financial targets.

**Mitigation:** Processes are in place to identify capability and resource gaps, and to identify and recruit key personnel to address those requirements. Training development and incentive plans are used to attract, motivate and retain staff.

**Change in 2013/14:** Initiatives introduced to promote BTG as an employer of choice. HR initiatives extended to include new employees associated with TheraSphere<sup>®</sup> and EkoSonic<sup>®</sup>. Continuing enhancement of BTG learning and development and leadership programmes.

## Product Liability

**Impact:** The manufacturing, clinical testing, marketing and sale of BTG's products involve significant potential product liability if our mitigation efforts fail. As the developer, manufacturer and/or seller of certain products, BTG may be held liable for death or personal injury to persons receiving the products during development or after the product is approved. BTG may be exposed to substantial product liability claims that could result in fines, damage awards to injured parties and legal or other material sanctions. Adverse events may also result in product recalls or suspension or loss of product licences adversely impacting BTG's revenues.

**Mitigation:** BTG conducts robust and well-designed and monitored clinical trial development plans to seek to ensure the safety of its products. BTG operates comprehensive quality systems relating to the manufacture of its products and a pharmacovigilance system to monitor and rapidly respond to safety events arising with respect to products sold or used. BTG maintains product liability insurance but it may not be commercially viable to adequately insure against the occurrence of this key risk. Notwithstanding the efforts made, quality and other systems may fail. Even in the absence of failure, significant product liability events may occur.

**Change in 2013/14:** The expanding operations in the US (from organic growth and acquisitions of EKOS Corporation and TheraSphere<sup>®</sup>) potentially increase liability risks.

## Non-IP-related litigation

**Impact:** As BTG grows and sells more products, particularly in the US, the likelihood of litigation increases. Defending against litigation brought by others, or pursuing litigation against others, requires substantial financial and human resources. Successful litigation against BTG could result in loss of rights, and the ability to commercialise products, substantial fines and damages, injunctive or administrative remedies that could materially impact the Group's performance and prospects. The range of types of actions and outcomes is broad: including employment claims, contract disputes, regulatory litigation and tax disputes.

**Mitigation:** Control procedures are in place to minimise litigation relating to the development, manufacturing and sale of the Group's products; legal oversight of contractual arrangements with third parties. Appropriate use of external advisors and dispute avoidance or resolution strategies.

**Change in 2013/14:** The operations of the Group have expanded through the acquisitions and Varithena<sup>™</sup> approval, though all internal controls have been applied across the businesses and portfolios.