

BTG plc: Final Results

Strong financial performance enabling continued investment in growth strategy

London, UK, 20 May 2013: BTG plc (LSE: BTG), the specialist healthcare company, today announces its final results for the year ended 31 March 2013.

Financial highlights

- Revenue increased by 19% to £233.7m (11/12: £197.0m)
- Underlying operating profit before acquisition adjustments and reorganisation costs of £69.0m (11/12: £54.0m); reported operating profit of £25.7m (11/12: £19.9m)
- Profit after tax of £16.4m (11/12: £14.6m)
- £46.8m of cash generated, with cash and cash equivalents, together with cash on fixed term deposits, of £158.7m at 31 March 2013 (£111.9m at 31 March 2012)

Operating highlights

- **Strong performance from Specialty Pharmaceuticals**
 - CroFab[®] (crotalidae polyvalent immune fab (ovine)) sales benefitted from normalisation of wholesaler inventories
 - DigiFab[®] (digoxin immune fab (ovine)) performance helped by continued geographic expansion
 - Strong US launch for Voraxaze[®] (glucarpidase)
- **Interventional Medicine growth plans on track**
 - Varisolve[®] (polidocanol endovenous microfoam (PEM)) US NDA accepted for review
 - Transition to direct US sales of LC Bead[™] delivering increased revenues, margins and contribution
 - Beads indication expansion, geographic expansion and innovation activities progressing well
- **Licensing & Biotechnology**
 - Strong growth in royalties from Johnson & Johnson's Zytiga[®] (abiraterone acetate)
 - Sanofi/Genzyme's Lemtrada[™] (alemtuzumab) under review in the US and EU for multiple sclerosis

Louise Makin, BTG's Chief Executive Officer, commented: "We have delivered strong financial results which reflect the successful transition of our business into a commercially focused, specialist healthcare company that makes and markets its own products. We are on track with our growth strategy, and are investing in our Beads business, preparing for a potential H1 2014 US approval and launch of Varisolve[®] and actively seeking opportunities to add new products and programmes. Overall, we have the financial resources and capabilities to continue to build the business and deliver our growth strategy."

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About BTG

BTG is an international specialist healthcare company that is developing and commercialising products targeting critical care, cancer and varicose veins. 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.

Chairman's statement

I am pleased to report that our business has performed very well during 2012/13. Revenues, underlying profitability and cash generation all increased substantially and we made good progress with the operating priorities we set for the year.

The strong growth in revenue reflects a robust performance in our Specialty Pharmaceuticals business, the impact of the transition to direct sales of our interventional oncology products in the US and increased royalties from licensed products. Operating achievements during the year include the submission of a new drug application for Varisolve[®] PEM in the US and the US launch of Voraxaze[®] (glucarpidase) by our acute care team.

To deliver further growth, we continue to pursue our strategy of investing in and expanding our portfolio of specialist healthcare products. Our strong cash reserves and increasing cash generation enable us to invest both in internal development activities and in the acquisition of complementary products and late-stage development programmes. During the year, we outlined a planned programme of studies to expand the approved uses of our interventional oncology products. In addition, we continue to review a number of acquisition opportunities that arose during the year.

These focused investments give us the platform to create a leading international specialist healthcare business that makes a real difference to physicians and patients alike, that delivers significant value to our stakeholders and that creates fulfilling careers for our employees.

Our key challenge is to grow in a sustainable way. For us, sustainability means combining the right strategy with strong execution, financial discipline, a culture of continuous improvement, strong governance and good corporate citizenship.

BTG has made excellent progress in recent years. We have the financial resources, capabilities and opportunities to continue to build the business and deliver sustainable growth.

Garry Watts

Chairman

OPERATING REVIEW

BTG has three business segments: Specialty Pharmaceuticals, Interventional Medicine and Licensing & Biotechnology. Each already generates revenues from marketed products or royalties and has ongoing development programmes which, if successful, would lead to new revenue streams. Our Specialty Pharmaceuticals and Interventional Medicine businesses have opportunities for further growth through acquisition, development and geographic expansion activities.

Specialty Pharmaceuticals

In the US we now sell three marketed products, CroFab[®], DigiFab[®] and Voraxaze[®], through our acute care field force of 19 representatives. Whereas CroFab[®] is only sold in the US, DigiFab[®] and Voraxaze[®] are sold through partners in other countries where approved or available on a named patient basis.

Revenues in this segment grew from £76.7m to £97.2m. A strong CroFab[®] performance was enhanced by wholesalers rebuilding inventory from the comparatively low levels held in the previous year. DigiFab[®] sales continue to grow, in part due to continued geographic expansion and a price increase. Voraxaze[®] sales were significantly higher than in the previous year following US approval and the US nationwide launch in April 2012.

All of these products address markets bounded by the number of toxic events. In the case of CroFab[®], there are on average 5,500 treated envenomations per annum in the US; our goal is to ensure every bite that needs treating is treated optimally in terms of initial dosing and maintenance.

DigiFab[®] is used when life-threatening toxicity or overdose occur following digoxin administration. The number of global digoxin prescriptions is fairly static from year to year at around 16 million globally, with between 1% and 4% of patients experiencing toxicity. Through educational activities, we aim to ensure that physicians are aware of the signs of life-threatening digoxin toxicity and that it is treated when detected. We are also seeking to extend the geographical approvals of the product, or to make it available on a named patient basis where achieving regulatory approval is not practical.

Voraxaze[®] is approved in the US to treat life-threatening toxicity following treatment with the chemotherapeutic high-dose methotrexate, which we estimate affects around 200-300 patients in the US each year. We are exploring additional regulatory approvals in other geographies and seek to make the product available on a named patient basis where appropriate.

Specialty Pharmaceuticals is a highly cash-generative business segment. We anticipate that revenue from the current product portfolio has the potential to grow annually at a rate of mid-to-high single digits on average. Revenue growth above this level would reflect the addition of new products, which would also be expected to enhance commercial operating efficiency.

We currently have one late-stage product in the pipeline: uridine triacetate, which is being developed by Wellstat Therapeutics Corporation. This is another antidote, a potential treatment for life-threatening toxicity following administration of the chemotherapeutic 5-fluorouracil. If the US New Drug Application (NDA) is submitted as expected around mid-2014, with a priority review this could result in approval and launch by the end of 2014.

Interventional Medicine

In the US we now sell our embolising Bead products, which are used to treat liver tumours, and Brachytherapy products, which are used to treat early-stage prostate cancer, directly through a team of 20 account managers. The US business is supported by 12 medical science liaisons. The products are sold in other territories through distribution partners; we are seeking to expand their geographical availability by pursuing additional regulatory approvals in key markets such as Asia, working with appropriate local partners.

Interventional Medicine revenues increased from £28.7m to £36.1m. The switch to direct sales of LC Bead[™] in the US has gone well. Product that was in the supply chain from the previous distribution arrangement has now been depleted, and ordering patterns from customers have normalised.

Over the near to medium term, we expect underlying low double-digit annual growth for our Bead products. This is expected to result from the general increasing trend towards using locoregional therapies to treat liver tumours and from the continued generation of clinical data supporting the use of transarterial

chemoembolisation (TACE) in patients with liver cancer. TACE is currently included as the standard of care for intermediate-stage patients in guidelines such as the Barcelona Centre Liver Cancer staging system for hepatocellular carcinoma (HCC), the most common form of primary liver cancer.

Investing to build the Beads business

During the year, we outlined a planned series of investments designed to expand further the indicated uses of the Beads.

We aim to seek Humanitarian Device Exemptions (HDEs) in the US for PRECISION Bead[®] and PARAGON Bead[®], which are novel drug-device combination products that are pre-loaded with appropriate chemotherapeutics, for treating patients with uveal melanoma metastases and intrahepatic cholangiocarcinoma, respectively. HDE approvals are based on demonstrated safety and probable clinical benefit demonstrated in exploratory studies in niche indications where there is currently no treatment option. Subject to ongoing dialogue with the FDA, the HDE submissions, which have 75 day review cycles, are expected during H2 2013.

We will continue to fund investigator-led studies to explore use in different patient populations with primary or metastatic liver cancer. In addition to proposing certain studies ourselves, we also invite physicians to submit proposals to us for funding to conduct studies, which are intended to inform our future development strategy. We also intend to generate data from larger-scale randomised, controlled clinical trials which, if successful, would support expanded approvals such as pre-market approvals (PMAs) in specific indications.

In primary liver cancer we are planning studies in earlier-stage patients to maintain their eligibility for transplant, and in later-stage patients to explore the use of the Beads in combination with sorafenib, the current standard of care chemotherapeutic for advanced-stage primary liver cancer. We are finalising the designs of appropriate studies and aim to start one study, subject to regulatory approvals, by the end of 2013. Expanding the use of our Beads from intermediate-stage patients to earlier- and later-stage patients could approximately double the addressable patient population.

In secondary liver cancer, we recently completed the PARAGON II study in patients with metastatic colorectal cancer (mCRC) to assess the safety of PARAGON Bead[®] in surgical resection. We are also reviewing data from a US phase II study using our Beads loaded with irinotecan in combination with systemic chemotherapy (FOLFOX-DEBIRI) in patients with mCRC. TACE is not currently indicated for use in patients with mCRC and success in this study would open up a significant new opportunity for further development of the Beads.

Sales of our Brachytherapy products were slightly lower than in the previous year, which was a good performance in a challenging market that declined by around 20%. We believe that US healthcare reform has resulted in fewer men receiving prostate specific antigen (PSA) tests with fewer subsequent referrals for treatment.

During the year we completed a review of options for CellMed, which we acquired with Biocompatibles. Having reviewed manufacturing options for our novel pre-loaded Bead products, we have decided to refocus CellMed (renamed as BTG International Germany GmbH) primarily to support the development and manufacturing of these products.

Progress with Varisolve[®] (PEM)

There was good progress during the year with Varisolve[®] (PEM), which is under development to treat varicose veins. Full data from the pivotal US Phase III trials, in which all endpoints were met, were presented at the American College of Phlebology's annual meeting in November 2012. A NDA seeking approval of PEM as a comprehensive treatment to improve the symptoms and appearance of varicose veins was submitted in February 2013 and accepted for full review in April 2013. We anticipate potential US approval and product launch in H1 2014. If approved, PEM will be the only approved comprehensive treatment for the symptoms and appearance of varicose veins in patients with great saphenous vein incompetence.

Secondary manufacturing was successfully transferred to our Farnham site, where we are constructing a dedicated facility.

Commercial activities are progressing ahead of the anticipated US approval. These include pricing and reimbursement research, physician research and planning for the recruitment of a dedicated PEM sales team. There are approximately 1,000 private vein clinics in the US, which we estimate can be served by a sales team of around 40 people.

We estimate the global peak sales potential of PEM to be \$500m. Around half of this is represented by the US reimbursed sector, which will be our first target market following approval. The balance relates to self-pay markets in the US and in other countries where there are established self-pay markets for healthcare products.

Licensing & Biotechnology

Revenue in the Licensing & Biotechnology segment results principally from royalties relating to sales of products that are subject to intellectual property and technology licence agreements between BTG and various partners. BTG has no role in or influence over those sales. Royalties vary but on average are around mid-to-high single digit percentages of partners' sales revenues; the gross royalty amounts received by BTG are usually shared on a 50:50 basis with originators of the relevant intellectual property or technology.

Revenue in this segment increased from £91.6m to £100.4m. The continued growth of Johnson & Johnson's Zytiga[®] (abiraterone acetate), used for treating patients with metastatic castration-resistant prostate cancer, was the chief driver of higher royalties.

Over the medium term, the performance of this business segment will be strongly influenced by Zytiga[®] royalties and the potential 2013 EU and US approvals of Sanofi's Lemtrada[™] (alemtuzumab), which is under review as a treatment for patients with multiple sclerosis.

Attrition rates are high in drug development and, during the year, an experimental treatment for severe sepsis, AZD9773 (CytoFab[™]), did not achieve the endpoints in a Phase II study being conducted by AstraZeneca. Development and the associated licence agreement were terminated.

FINANCIAL REVIEW

BTG has continued with its track record of delivering strong financial results. Revenue has grown by 19% to £233.7m reflecting the transition to direct sales of LC Bead[™] in the US, the growth of the Zytiga[®] royalty stream and another successful year from the Specialty Pharmaceuticals products.

Gross margin of 71% is in line with prior year as the positive impact of selling LC Bead[™] directly in the US is offset by a reduction in margin from Licensing & Biotechnology following the receipt of final royalties from BeneFIX[®].

Operating profit of £25.7m compares to £19.9m in the prior year. Operating profit excluding acquisition adjustments and reorganisation costs has grown by 28% to £69.0m.

The Group generated £46.8m of cash, resulting in cash and cash equivalents, together with cash on fixed term deposits, of £158.7m at 31 March 2013 (31 March 2012: £111.9m).

Specialty Pharmaceuticals

The Specialty Pharmaceuticals operating segment has delivered a strong trading performance during the year. Revenue of £97.2m is 27% above the prior year total of £76.7m. This is principally due to a first full year of commercial sales from Voraxaze[®] and to strong performances from both CroFab[®] and DigiFab[®], with the latter benefitting from geographic expansion and a price increase.

Gross margin at 78% (11/12: 76%), which is broadly in line with prior year and with our ongoing expectations for this operating segment, generated £75.6m of gross profit (11/12: £58.0m). After deducting selling, general and administrative (SG&A) expenses of £20.2m (11/12: £18.6m) this segment generates a profit contribution of £55.4m (11/12: £39.4m) reflecting a 57% operating margin (11/12: 51%).

Interventional Medicine

The Interventional Medicine operating segment represents the portfolio of Beads and Brachytherapy products.

Revenue of £36.1m (11/12: £28.7m) reflects the first full year of selling LC Bead™ directly in the US. This generated gross profit of £30.5m (11/12: £20.1m), an increase of 52% on the prior year. The gross margin was 84% (11/12: 70%). Prior year cost of sales includes the final release of a fair value uplift adjustment to inventory recognised upon acquisition of £2.1m. Excluding this adjustment, the prior year gross margin was 77%.

The increase in SG&A to £17.5m (11/12: £13.3m) reflects the full year run-rate of having the direct sales force in the US.

Overall profit contribution margin from this operating segment has increased to 36% (11/12: 24%; 31% excluding fair value acquisition adjustments).

Licensing & Biotechnology

The Licensing & Biotechnology operating segment principally includes revenues from the Group's licensed portfolio of intellectual property. Revenue is split between recurring income from royalties from products already being sold by licensees and one-off income relating to milestones.

£m	2013	2012
Recurring revenue	91.8	80.5
Milestones and one-offs	8.6	11.1
	<u>100.4</u>	<u>91.6</u>

Recurring revenue includes royalties from Zytiga® of £49.9m (11/12: £18.6m), the Two-Part Hip-Cup of £13.3m (11/12: £13.0m) and BeneFIX® of £14.0m (11/12: £29.4m).

The final Factor IX patent relating to BeneFIX® expired in March 2011 and BTG continued to receive royalties on sales of inventory held by Pfizer at the patent expiry date. The receipt of £14.0m in the current year represents the final royalty payment from Pfizer.

Milestones and one-offs in the year relate to AZD9773. The release of deferred income of £6.1m (11/12: £1.5m) was supplemented by a £2.5m payment from AstraZeneca following termination of the licence. In the prior year, in addition to the release of deferred income in relation to AZD9773, the approval of Zytiga® triggered two milestones payments and deferred income was also released in respect the GLP-1 licence that was terminated by AstraZeneca in that year.

Gross margin at 60% is below the prior year comparative of 68% due principally to the lower level of income from BeneFIX®, which had a 90% margin. Typically royalty streams have onerous obligations to the original inventors of the product and the relative mix of income between products influences gross margin. This is expected to reduce further next financial year as there will be no income from BeneFIX®.

SG&A includes the overheads specific to the management of the royalty business but also most centrally managed support functions and corporate costs. This has shown an increase over the prior year due to selected investments in central support functions to ensure that the business is well positioned for sustainable growth.

The overall contribution of this business was £40.1m (11/12: 45.6m) reflecting a margin of 40% (11/12: 50%).

Research and development

The Group's investment in research and development activities during the year was £41.2m, slightly above the prior year total of £39.7m. Activities during the year have continued to focus on PEM, with the NDA submission and Chemistry, Manufacturing and Controls activities being the major work streams, and the continued investment in relation to the Bead products to support investigator-led studies and the progression of our novel pre-loaded Beads towards regulatory submissions.

Operating profit

Before acquisition adjustments and reorganisation costs the Group delivered a 28% increase in underlying operating profit from £54.0m to £69.0m. The key driver of this improvement in operational performance is an additional £16.7m of profit contribution from the three operating segments as described above.

Foreign exchange gains of £3.1m were recorded in the year compared to gains of £2.6m in the prior year. Asset impairment charges of £1.8m were recognised against fixed assets used in the manufacture of AZD9773 during the year following termination of the licence agreement by AstraZeneca. In the prior year, impairment charges of £3.0m were recognised against the carrying value of fixed assets used in the manufacture of Novabel[®] following termination of the licence agreement by Merz.

Acquisition adjustments and reorganisation costs were £43.3m (11/12: £34.1m). These include underlying amortisation of acquired intangible assets of £14.4m (11/12: £18.3m), a charge of £22.5m (11/12: nil) relating to impairment of the carrying value of the AZD9773 contract with AstraZeneca that was terminated during the year, and other impairment charges totalling £6.5m (11/12: £12.4m). In the prior year impairment charges were taken against the Group's carrying values of GLP-1 and Novabel[®], two assets acquired with Biocompatibles.

Net financial expense

Net financial expense of £1.6m (11/12: income of £3.1m) includes interest receivable on cash deposits of £1.1m (11/12: £0.7m) and a loss on the mark-to-market of foreign exchange forward contracts of £2.6m (11/12: £1.5m). Also included in the prior year comparative is net financial income of £2.9m relating to the write-back of a loan from Merz in relation to Novabel[®] manufacturing fixed assets and the write-back of £1.1m in relation to the Contingent Value Notes (CVNs) issued to certain Biocompatibles shareholders upon acquisition which was not payable.

Profit before tax

The Group's profit before tax, which increased by £1.1m to £24.1m (11/12: £23.0m), was adversely impacted by the impairment charge taken against AZD9773.

Tax

The tax charge for the year is £7.7m (11/12: £8.4m). This reflects an effective tax rate of 32% (11/12: 37%). Current tax is £4.1m (11/12: £3.9m) and deferred tax is £3.6m (11/12: £4.5m). Current tax principally arises in the UK, where the Group has incurred corporation tax of £3.6m during the year. The deferred tax charge reflects the utilisation of tax losses recognised on the balance sheet offset by a deferred tax credit arising from the amortisation and impairment of intangible assets.

Earnings per share

Basic earnings per share was 5.0p (11/12: 4.5p) on profit after tax of £16.4m (11/12: £14.6m). Adjusted earnings per share, excluding acquisition adjustments and restructuring costs, increased by 3.1p to 14.5p.

Balance sheet

Non-current assets have reduced from £331.5m at 31 March 2012 to £302.4m at 31 March 2013. Amortisation, depreciation and impairment charges total £50.0m in the year to 31 March 2013, including the impairment charges recognised in relation to AZD9773 (£22.5m within intangible assets and £1.8m within property, plant and equipment). Additions to non-current assets were £10.2m, including £3.0m in relation to our Farnham manufacturing site. The retranslation of assets denominated in foreign currencies added a net £6.4m to the carrying value in the balance sheet.

The Group's defined benefit pension scheme, as measured under IAS19 'Employee Benefits', has changed from a £0.1m liability at 31 March 2012 to an asset of £4.7m at 31 March 2013, which has been recorded within non-current assets. The movements in this position are due to company contributions during the year of £5.1m plus an actuarial gain of £0.1m offset by an income statement charge of £0.4m. The actuarial deficit at 31 March 2010, the date of the last formal actuarial valuation and measured in accordance with guidelines set by the Pensions Regulator, was £13.9m. The next formal actuarial valuation will be measured as at 31 March 2013. The results of this valuation exercise, undertaken by the Trustees of the scheme, are expected in 2014.

Within current assets, cash, cash equivalents and held to maturity financial assets (fixed-term cash deposits) have increased by £46.8m to £158.7m (31 March 2012: £111.9m) and trade and other receivables have increased by £14.4m to £54.5m (31 March 2012: £40.1m). The increase in receivables is principally due to higher royalty accruals at 31 March 2013 in relation to Zytiga[®] in particular and also due to the business's overall increase in sales leading to higher trade receivable balances than at 31 March 2012.

Subsequent to the year end, the Group signed a £60m multi-currency revolving credit facility providing access to funds for a period of three years to April 2016.

The Group's total liabilities have increased by £8.7m to £108.3m at 31 March 2013 (31 March 2012: £99.6m). There has been an increase in the net deferred tax liability of £6.6m as the rate of utilisation of tax losses (which reduces the amount of deferred tax asset that can be applied against the deferred tax liability recognised on business combination intangible assets) has been faster than the reduction in the deferred tax liability that occurs in line with the amortisation of intangible assets. Trade and other payables have increased by £1.7m, primarily representing additional revenue sharing accruals (due to higher levels of royalty income) offset by the release of deferred income on AZD9773. The fair value of the Group's forward contracts as at 31 March 2013 was a liability of £2.2m compared to an asset of £0.5m at 31 March 2012. Other movements within liabilities are a reduction in tax accruals of £0.9m due to payments made on account by the Group during the year and a reduction in provisions of £0.8m.

Cash flow

The Group has continued its track record of strong cash generation during the year, with closing cash and short-term deposits at 31 March 2013 of £158.7m, an increase of £46.8m over the prior year closing position of £111.9m.

Operating profit of £25.7m (11/12: £19.9m) has generated a net cash inflow from operating activities of £61.0m (11/12: £48.3m). The principal reconciling items are non-cash income statement charges of £54.6m (11/12: £40.7m); a net cash outflow from working capital balances of £14.7m (11/12: £7.5m) and contributions made to the Group's defined benefit pension fund of £4.6m (11/12: £4.8m).

The working capital outflow is principally due to an increase in royalty accruals relating to Zytiga®.

The Group has invested £10.2m (11/12: £9.7m) in capital expenditure, securing the building within which both the Bead products and PEM are manufactured and investing in the required equipment for the secondary manufacture of PEM. Also included within investing activities is the purchase of EU rights to Wellstat's UTA product for an initial payment of \$3.0m. In the prior year the Group purchased the US commercial rights to the same product for an initial payment of \$7.5m.

Tax payments of £5.5m (11/12: £1.1m) have been made, principally in the UK as profits in this jurisdiction have arisen in statutory entities where tax losses do not fully offset profits.

SUMMARY AND OUTLOOK

The Group delivered a strong financial performance during the year with revenues, underlying profitability and cash generation all increasing substantially. We also made significant progress with key operating goals of advancing our pipeline and building our capabilities.

Specifically, we intend to invest in a third specialist sales team to support our PEM product, which we anticipate could be approved and launched in the first half of 2014. We also plan to initiate a number of clinical studies to support expansion of the approved uses of our Bead products.

A core part of our strategy is to acquire products and programmes: we continue to review opportunities and we are in a strong position financially and in terms of capabilities to expand our portfolio with complementary products.

Overall, the business is in good shape: we have the financial resources, capabilities and opportunities to enable us to continue building value and to deliver further profitable growth.

CONSOLIDATED INCOME STATEMENT

	Note	Year ended 31 March 2013			Year ended 31 March 2012		
		Results before acquisition adjustments and reorganisation costs £m	Acquisition adjustments and reorganisation costs £m	Total £m	Results before acquisition adjustments and reorganisation costs £m	Acquisition adjustments and reorganisation costs £m	Total £m
Revenue		233.7	-	233.7	197.2	(0.2)	197.0
Cost of sales		(67.2)	-	(67.2)	(54.2)	(2.1)	(56.3)
Gross profit	2	166.5	-	166.5	143.0	(2.3)	140.7
<i>Operating expenses:</i>							
Amortisation and impairment of acquired intangible assets		-	(43.4)	(43.4)	-	(30.7)	(30.7)
Foreign exchange gains		3.1	-	3.1	2.6	-	2.6
Selling, general and administrative expenses		(58.0)	-	(58.0)	(48.9)	-	(48.9)
Operating expenses: total		(54.9)	(43.4)	(98.3)	(46.3)	(30.7)	(77.0)
Research and development		(41.2)	-	(41.2)	(39.7)	-	(39.7)
Profit on disposal of intangible assets and investments		0.4	-	0.4	0.2	-	0.2
Amounts written off property, plant and equipment		(1.8)	-	(1.8)	(3.0)	-	(3.0)
Acquisition and reorganisation costs		-	0.1	0.1	-	(1.1)	(1.1)
Amounts written off investments		-	-	-	(0.2)	-	(0.2)
Operating profit/(loss)		69.0	(43.3)	25.7	54.0	(34.1)	19.9
Financial income		1.1	-	1.1	3.6	1.1	4.7
Financial expense		(2.7)	-	(2.7)	(1.6)	-	(1.6)
Profit before tax				24.1			23.0
Tax	3			(7.7)			(8.4)
Profit for the period				16.4			14.6
Basic earnings per share	4			5.0p			4.5p
Diluted earnings per share	4			5.0p			4.4p

All activity arose from continuing operations.

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Year ended 31 March 2013 £m	Year ended 31 March 2012 £m
Profit for the period	16.4	14.6
Other comprehensive income		
Foreign exchange translation differences	4.2	(0.3)
Actuarial gain/(loss) on defined benefit pensions scheme	0.1	(2.9)
Deferred tax on defined benefit pension scheme asset	(1.6)	-
Other comprehensive income for the year	2.7	(3.2)
Total comprehensive income for the year	19.1	11.4

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Note	31 March 2013 £m	31 March 2012 £m
ASSETS			
Non-current assets			
Goodwill		59.2	59.2
Intangible assets	5	209.2	246.0
Property, plant and equipment		25.4	22.0
Other investments		3.0	3.0
Deferred tax asset		0.9	1.0
Employee benefits	6	4.7	-
Biological assets		-	0.3
		302.4	331.5
Current assets			
Inventories		23.3	21.8
Trade and other receivables		54.5	40.1
Taxation		0.4	-
Derivative instruments		-	0.5
Held to maturity financial assets		-	5.0
Cash and cash equivalents		158.7	106.9
		236.9	174.3
Total assets		539.3	505.8
EQUITY			
Share capital		32.8	32.7
Share premium account		188.6	188.3
Merger reserve		317.8	317.8
Other reserves		0.2	(4.0)
Retained earnings		(108.4)	(128.6)
Total equity attributable to equity holders of the parent		431.0	406.2
LIABILITIES			
Non-current liabilities			
Trade and other payables		0.5	5.0
Employee benefits	6	-	0.1
Deferred taxation	3	41.8	35.2
Provisions		0.4	1.0
		42.7	41.3
Current liabilities			
Trade and other payables		61.6	55.4
Derivative instruments		2.2	-
Taxation		1.2	2.1
Provisions		0.6	0.8
		65.6	58.3
Total liabilities		108.3	99.6
Total equity and liabilities		539.3	505.8

CONSOLIDATED STATEMENT OF CASH FLOWS

	Year ended 31 March 2013 £m	Year ended 31 March 2012 £m
Profit after tax for the year	16.4	14.6
Tax	7.7	8.4
Financial income	(1.1)	(4.7)
Financial expense	2.7	1.6
Operating profit	25.7	19.9
Adjustments for:		
Profit on disposal of intangible assets and investments	(0.4)	(0.2)
Amounts written off investments	-	0.2
Amortisation and impairment of intangible assets	45.1	31.9
Amounts written off property, plant and equipment	1.8	3.0
Depreciation on property, plant and equipment	3.1	3.2
Share-based payments	4.7	2.4
Pension scheme funding	(4.6)	(4.8)
Other	0.3	0.2
Cash from operations before movements in working capital	75.7	55.8
Increase in inventories	(1.5)	(1.8)
Increase in trade and other receivables	(14.4)	(7.5)
Increase in trade and other payables	2.0	3.0
Decrease in provisions	(0.8)	(1.2)
Cash from operations	61.0	48.3
Taxation paid	(5.5)	(1.1)
Net cash inflow from operating activities	55.5	47.2
Investing activities		
Interest received	0.7	0.8
Purchases of intangible assets	(2.6)	(6.0)
Purchases of property, plant and equipment	(7.6)	(3.7)
Net proceeds from disposal of investments and intangible assets	-	0.3
Net expenditure on investments	-	(0.5)
Net inflow from held to maturity financial assets	5.0	5.2
Net cash outflow from investing activities	(4.5)	(3.9)
Cash flows from financing activities		
Repayment of finance leases	(0.2)	(0.3)
Proceeds of share issues	0.4	0.1
Net cash from financing activities	0.2	(0.2)
Increase in cash and cash equivalents	51.2	43.1
Cash and cash equivalents at start of year	106.9	63.7
Effect of exchange rate fluctuations on cash held	0.6	0.1
Cash and cash equivalents at end of year	158.7	106.9

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Share capital £m	Share premium £m	Merger reserve £m	Other reserves £m	Retained earnings £m	Total equity £m
At 1 April 2011	32.7	188.2	317.8	(3.7)	(142.7)	392.3
Profit for the year	-	-	-	-	14.6	14.6
Foreign exchange translation differences	-	-	-	(0.3)	-	(0.3)
Actuarial loss on defined benefit pension scheme	-	-	-	-	(2.9)	(2.9)
Total comprehensive income for the year	-	-	-	(0.3)	11.7	11.4
Transactions with owners:						
Issue of BTG plc ordinary shares	-	0.1	-	-	-	0.1
Share-based payments	-	-	-	-	2.4	2.4
At 31 March 2012	32.7	188.3	317.8	(4.0)	(128.6)	406.2

	Share capital £m	Share premium £m	Merger reserve £m	Other reserves £m	Retained earnings £m	Total equity £m
At 1 April 2012	32.7	188.3	317.8	(4.0)	(128.6)	406.2
Profit for the year	-	-	-	-	16.4	16.4
Foreign exchange translation differences	-	-	-	4.2	-	4.2
Actuarial loss on defined benefit pension scheme	-	-	-	-	0.1	0.1
Deferred tax on defined benefit pension scheme	-	-	-	-	(1.6)	(1.6)
Total comprehensive income for the year	-	-	-	4.2	14.9	19.1
Transactions with owners:						
Issue of BTG plc 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	(108.4)	431.0

Notes

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 2013 ("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 9.

BTG's 2013 Annual Report will be posted to shareholders on 14 June 2013. The financial information set out herein does not constitute the Group's statutory accounts for the year ended 31 March 2013 but is derived from those accounts and the accompanying directors' report. Statutory accounts for 2013 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 2013. 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 2012 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.

Accounting standards adopted in the year

No accounting standards adopted in the year have had a significant effect on the financial statements. Other amendments and standards have been adopted, but have had no significant effect on the reported results or financial position of the Group.

Accounting standards issued but not yet effective

IAS 19 (Amended): Employee benefits changes a number of disclosure requirements for post-employment arrangements and restricts the options currently available on how to account for defined benefit pension plans. The amendment requires the expected returns on pension plan assets, currently calculated based on management's estimate of expected returns, to be replaced by a gain on the pension plan assets calculated at the liability discount rate. In future years, this change is expected to result in a decrease in finance income on pension scheme assets, recognised in the income statement, and an equal and opposite increase in the actual returns less expected returns on pension scheme assets credited to other comprehensive income. The Group does not expect this change to impact the Group's net assets. The amendment also removes the option to include an expense reserve in pension scheme liabilities. This change is expected to result in a one-off credit to other comprehensive income, a one-off credit to opening reserves and a corresponding increase in net assets in 2013 comparatives in the year ending 31 March 2014, to release the expense reserves previously recognised within pension scheme liabilities.

The amendment to IAS 19 is effective 1 January 2013 and will be adopted by the Group in the accounting year beginning 1 April 2013.

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 basis

After making enquiries, the directors have a reasonable expectation that the Company and the Group have 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, distribution partners, wholesalers or insurers.

In addition to the liquidity risks 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 consists of a broad portfolio of licensees;
- The Group does not have a significant exposure to the Eurozone;
- The Group's marketed products are life-saving in nature, providing some protection against an uncertain economic outlook;
- The Group remains in a cash generative position for the year with cash and cash equivalents totalling £158.7m as at 31 March 2013; and
- Subsequent to the year end, the Group signed a £60m multi-currency revolving credit facility providing access to funds for a period of three years to April 2016.

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:

- 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 advisers in relation to the completion of the acquisition;
- Reorganisation costs comprising acquisition related redundancy programmes, property costs, and asset impairments; and
- Fair value adjustments to contingent consideration on corporate acquisitions.

2. Operating segments

Following the acquisition of Biocompatibles International plc on 27 January 2011, the Group aligned behind three reportable segments, being Specialty Pharmaceuticals, Interventional Medicine and Licensing & Biotechnology.

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 & Biotechnology 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.

There are no inter-segment transactions that are required to be eliminated on consolidation.

	Year ended 31 March 2013			Total £m
	Specialty Pharmaceuticals £m	Interventional Medicine £m	Licensing & Biotechnology £m	
Revenue	97.2	36.1	100.4	233.7
Cost of sales	(21.6)	(5.6)	(40.0)	(67.2)
Gross profit	75.6	30.5	60.4	166.5
Selling, general and administrative expenses	(20.2)	(17.5)	(20.3)	(58.0)
Contribution	55.4	13.0	40.1	108.5
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 intangible assets and investments				0.4
Acquisition and reorganisation costs				0.1
Operating profit				25.7
Financial income				1.1
Financial expense				(2.7)
Profit before tax				24.1
Tax				(7.7)
Profit for the year				16.4
Unallocated assets				539.3

	Year ended 31 March 2012			Total £m
	Specialty Pharmaceuticals £m	Interventional Medicine £m	Licensing & Biotechnology £m	
Revenue	76.7	28.7	91.6	197.0
Cost of sales*	(18.7)	(8.6)	(29.0)	(56.3)
Gross profit	58.0	20.1	62.6	140.7
Selling, general and administrative expenses	(18.6)	(13.3)	(17.0)	(48.9)
Contribution	39.4	6.8	45.6	91.8
Amortisation and impairment of acquired intangibles				(30.7)
Foreign exchange gains				2.6
Research and development				(39.7)
Amounts written off property, plant and equipment				(3.0)
Profit on disposal of intangible assets and investments				0.2
Acquisition and reorganisation costs				(1.1)
Amounts written off investments				(0.2)
Operating profit				19.9
Financial income				4.7
Financial expense				(1.6)
Profit before tax				23.0
Tax				(8.4)
Profit for the year				14.6
Unallocated assets				505.8

*2012 includes a £2.1m release of the fair value uplift of inventory purchased on the acquisition of Biocompatibles International plc in January 2011 within the Interventional Medicine segment representing the reversal of a fair value uplift of inventory purchased on acquisition recognised through the income statement when the product was sold.

Revenue analysis

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

Geographical analysis

	Year ended 31 March 2013 £m	Year ended 31 March 2012 £m
USA	202.8	168.1
UK	21.2	10.0
Europe (excluding UK)	5.3	15.1
Other regions	4.4	3.8
	233.7	197.0

Revenue from major products and services

	Year ended 31 March 2013 £m	Year ended 31 March 2012 £m
Product sales	134.3	106.7
Royalties	90.8	79.2
Other	8.6	11.1
	233.7	197.0

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 £49.9m (2012: Two licences generated £29.4m and £24.4m respectively).

The Group's marketed products are sold both directly and through distribution agreements in the USA, Europe and Asia Pacific region. Two customers individually generated income in excess of 10% of Group revenue, being £25.2m and £24.8m respectively (2012: Two customers generated £22.3m and £21.9m respectively).

3. Tax

An analysis of the tax charge for the year, all relating to current operations, is as follows:

	Year ended 31 March 2013 £m	Year ended 31 March 2012 £m
Current tax		
UK corporation tax charge	3.6	2.8
Overseas corporate tax charge	2.6	0.9
Adjustments in respect of prior years	(2.1)	0.2
Total current taxation	4.1	3.9
Deferred taxation		
Deferred tax	1.8	5.3
Adjustment to tax rates	1.8	(0.8)
Total tax charge for the year	7.7	8.4

In addition to the tax charge in the income statement, a deferred tax charge of £1.6m has been recognised in the consolidated statement of other comprehensive income.

UK corporation tax is calculated at 24% (2012: 26%) 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 £41.8m (2012: £35.2m) 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 £62.4m arise on intangible assets recognised at fair value on acquisitions, £1.6m on pension fund surplus and £0.1m on accelerated capital allowances. 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 £m	Net deferred tax liability £m
At 1 April 2011	55.4	(86.1)	(30.7)
Adjustments re prior years	(1.4)	2.8	1.4
Income statement (debit)/credit	(16.2)	9.9	(6.3)
Exchange differences	0.1	(0.1)	-
Other	-	0.4	0.4
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)
Other comprehensive income (debit)	-	(1.6)	(1.6)
Exchange differences	0.5	(1.9)	(1.4)
At 31 March 2013	22.3	(64.1)	(41.8)

The 2013 Budget on 20 March 2013 announced that the UK corporation tax rate will reduce to 20% by 2015. A reduction in the rate from 24% to 23% (effective from 1 April 2013) was substantively enacted on 3 July 2012. The further reductions to 21% from 1 April 2014 and to 20% from 1 April 2015 have not yet been substantively enacted. This will reduce the company's future current tax charge accordingly. The UK deferred tax assets and

liabilities at 31 March 2013 have been calculated based on the rate of 23% substantively enacted at the balance sheet date. It has not yet been possible to quantify the full anticipated effect of the announced further 3% rate reduction, although this will further reduce the company's future current tax charge and reduce the company's deferred tax asset and liability accordingly.

4. Earnings per share

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

	Year ended 31 March 2013	Year ended 31 March 2012
Profit for the financial year (£m)	16.4	14.6
Profit per share (p)		
Basic	5.0	4.5
Diluted	5.0	4.4
Number of shares (m)		
Weighted average number of shares – basic	326.9	325.9
Effect of share options on issue	4.0	3.4
Weighted average number of shares – diluted	330.9	329.3

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

	Year ended 31 March 2013	Year ended 31 March 2012
Profit for the financial year (£m)	16.4	14.6
Add back:		
Fair value adjustment on acquired inventory ¹	-	2.1
Fair value adjustment on royalty income	-	0.1
Amortisation of acquired intangible fixed assets ²	31.1	19.3
Acquisition and reorganisation costs including CVN write-back ³	(0.1)	(0.1)
Reorganisation of US corporate structure ⁴	-	1.0
Underlying earnings	47.4	37.0
Underlying profit per share (p)		
Basic	14.5	11.4
Diluted	14.3	11.2

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:

1. No tax adjustment was required on the fair value of acquired inventory in the prior year.
2. The release of deferred tax liability of £12.3m (2012: £11.4m) has been deducted from the amortisation and impairment of acquired intangible assets of £43.4m (2012: £30.7m) as shown in the consolidated income statement.
3. In the year ended 31 March 2013 there was nil tax impact on reorganisation credits of £0.1m. In the year ended 31 March 2012, £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.
4. An adjustment was made for the deferred tax credit recognised at 31 March 2011 as a result of the completion of a tax-free reorganisation and subsequent review of such items in the year ended 31 March 2012.

5. 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
Cost							
At 1 April 2011	230.2	40.0	18.8	0.3	13.2	9.5	312.0
Additions	-	-	-	0.3	0.3	6.1	6.7
Transfers	3.9	-	(3.9)	-	-	-	-
Disposals	-	-	-	-	(0.2)	-	(0.2)
Currency movements	-	0.1	(0.1)	-	-	0.1	0.1
At 1 April 2012	234.1	40.1	14.8	0.6	13.3	15.7	318.6
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
At 31 March 2013	235.1	41.5	5.8	0.8	14.5	18.4	316.1
Amortisation							
At 1 April 2011	12.0	8.8	0.9	-	9.8	9.5	41.0
Provided during the year	12.3	4.7	-	0.1	0.6	0.1	17.8
Impairments	5.0	-	8.8	-	0.3	-	14.1
Writeback on disposals	-	-	-	-	(0.2)	-	(0.2)
Currency movements	(0.2)	-	-	-	0.1	-	(0.1)
At 1 April 2012	29.1	13.5	9.7	0.1	10.6	9.6	72.6
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
At 31 March 2013	37.6	40.6	5.8	0.2	12.1	10.6	106.9
Net book value							
At 31 March 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
At 1 April 2011	218.2	31.2	17.9	0.3	3.4	-	271.0

Amortisation relating to acquired intangibles is shown on the face of the income statement within 'Amortisation of acquired intangibles'. All other amortisation and impairment is shown within 'Selling, general and administrative expenses' in 'Operating expenses'.

Developed technology

Developed technology relates to both the antidote assets acquired in Protherics PLC comprising principally of the rights to CroFab[®] and DigiFab[®] and the Bead assets acquired in Biocompatibles International plc comprising principally of the rights to the DC Bead[®] and LC Bead[™].

Contractual relationships

Contractual relationships relates to the contracts acquired in Protherics PLC and Biocompatibles International plc. An impairment charge of £22.5m has been 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 7).

Purchase of contractual rights

In May 2012, BTG signed an agreement with Wellstat Therapeutics Corporation to acquire the rights to distribute uridine triacetate on a name patient supply basis in Europe for an upfront payment of \$3.0m, together with an option to market uridine triacetate following EU regulatory approval, under pre-agreed financial terms including a multi-million dollar exercise fee.

On 6 July 2011 BTG signed an agreement with Wellstat Therapeutics Corporation to acquire the US commercial rights to product candidate uridine triacetate. BTG paid Wellstat an upfront fee of \$7.5 million and will make milestone payments upon NDA acceptance and approval and inventory purchase payments based on manufacturing costs and a significant percentage of net sales.

6. Defined benefit pension liability

The Group's defined benefit pension fund asset, as measured under IAS19 – Employee Benefits, has reduced from a liability of £0.1m at 31 March 2012 to an asset of £4.7m at 31 March 2013. The principal movements are total contributions by the company of £5.1m and an actuarial gain of £0.1m offset by an income statement charge of £0.4m. The actuarial deficit at 31 March 2010, the date of the last formal valuation and measured in accordance with guidelines set by the Pensions Regulator, was £13.9m.

7. AZD9773

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 has terminated its licence agreement and associated arrangement with BTG and has handed back the asset to BTG. BTG does not anticipate conducting any further development of AZD9773. Consequently the following transactions have been recognised:

- Revenue of £8.6m has been recognised within milestones and one-off income in the Licensing & Biotechnology operating segment. The components of this revenue are:
 - 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 has been recognised in amortisation and impairment of acquired intangibles in the acquisition adjustments and reorganisation costs column; and
- Property, plant and equipment write-downs associated with assets used in the development of AZD9773 of £1.8m have been recognised in the amounts written off property, plant and equipment.

8. Related parties

Giles Kerr, a non-executive director of BTG plc is also the Director of Finance for Oxford University and a director of its wholly owned subsidiary, Isis Innovations Ltd. Wholly owned subsidiaries of BTG plc have pre-existing licence agreements with Oxford University and Isis Innovations under which they are obliged to pay royalties on amounts received from commercialising certain Intellectual Property. Payments made by BTG to Oxford University and Isis Innovations Ltd under the relevant licence agreements were £1.5m during the year ended 31 March 2013. There were no amounts still outstanding and payable by BTG under these agreements as at 31 March 2013.

9. 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.

The most significant risks identified in an annual update of the Group's risk register that could materially affect the Group's ability to achieve its financial and operating objectives are summarised in this section. Other risks are unknown or deemed less material.

Risk: Interruption to product supply

Impact: BTG relies on third-party contractors for the supply of many key materials and services, such as filling and freeze-drying of end products. These processes carry risks of failure and loss of product. Problems at contractors' facilities may lead to delays and disruptions in supplies. Some materials and services may be available from one source only and regulatory requirements make substitution costly, time-consuming or commercially unviable. 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 relies on its single site in Wales for supply of manufactured antibody products, with the consequent possibilities for disruption to supplies. BTG manufactures its own Bead and Brachytherapy products at single sites in Farnham, UK, and Oxford, CT, USA, respectively, with the consequent possibilities for disruption to supplies.

BTG plans to undertake the manufacture of PEM at its Farnham site, requiring completion of new manufacturing facilities to meet the requirements of Good Manufacturing Practice. This site will require regulatory approval and a licence to support the commercialisation of PEM. Any delay in completion of this facility or obtaining the necessary manufacturing licences may result in a delay in the approval of PEM reducing future earning potential. The continuity of potential PEM revenues will also be subject to single source risk.

Mitigation: Rigorous monitoring of suppliers; dual sourcing implemented where practicable; inventories maintained and monitored through sales and operational planning process and 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.

Change in 2012/13: PEM has been transferred to our Farnham site with a successful UK regulatory inspection completed.

Risk: Patent invalidity, patent infringement litigation and changes in patent laws

Impact: BTG can be subject to patent challenge at any time. Challenges can relate to the validity of BTG's patents or to alleged infringement by BTG of intellectual property rights of others, which might result in litigation costs and/or loss of earnings. BTG might be obliged to sue third parties for their infringement of its patents in order to protect revenue

streams. 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. 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 prosecute patents, or which reduce the available term of granted patents or periods of market exclusivity protection, could adversely impact the Group's financial performance.

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

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

Change in 2012/13: None

Risk: Patent expiry, competition may reduce current revenues

Impact: BTG's key current royalty-generating products are expected to continue to provide royalty revenues until their patents or licence agreements expire. Any unforeseen patent loss, supply, safety or compliance issues with these products could result in premature cessation of the revenues. BTG earns revenues from sales of its acute care products CroFab[®], DigiFab[®] and Voraxaze[®]. CroFab[®] is patent protected but DigiFab[®] and Voraxaze[®] have no patent protection at this time; CroFab[®] and DigiFab[®] are protected by significant know-how and complex manufacturing processes and BTG expects revenues to continue regardless of patent protection. However, future competition cannot be ruled out and competing products could materially adversely impact BTG's financial results. Instituto Bioclon has announced the completion of a Phase III clinical trial of a potential competitor product to CroFab[®]. BTG also earns revenues from sales of its Bead and Brachytherapy products, all of which are subject to competition. While these medical devices benefit from patent protection certain patents are subject to challenge.

Mitigation: New royalty streams may emerge. For example, following expanded regulatory approval in the US and elsewhere of Zytiga[®] as a treatment for men with advanced prostate cancer during 2012, this has become BTG's largest royalty stream; additional future royalty streams would result if alemtuzumab is approved to treat multiple sclerosis. Mitigations with respect to the Bead products include product development, geographic expansion, appropriate IP lifecycle management and the conduct of clinical studies to expand their indicated uses and sales.

Change in 2012/13: Zytiga[®] received approvals to treat chemo-naïve prostate cancer patients and royalty revenue increased significantly, offsetting the final royalties received on BeneFIX[®].

Risk: Failure to comply with regulations may result in product delays, failures, regulatory actions and financial penalties

Impact: The pharmaceutical industry is highly regulated and the Group must comply with a broad range of regulations relating to the development, approval, manufacturing and marketing of its products. Complex rules regulate product marketing activities. In each case this is particularly true in the US, from which the Group derives most of its revenues and where the Group has established its own sales and marketing operations. Specific requirements relating to quality assurance apply to the Group's manufacture of products, particularly in the pharmaceutical area. Regulatory regimes are complex and dynamic, and alterations to the regulations may result in delays in product development, approval or withdrawal. Ensuring compliance with such regulations necessitates allocation of significant financial and operating resources. Failure to comply with certain rules, laws and regulations may result in criminal and civil proceedings against the Group. Significant breaches could result in large financial penalties, which could materially adversely impact the Group's financial performance and prospects. Moreover, failure by BTG or a BTG partner company to comply with regulations may result in a product being withdrawn from the market with a subsequent loss of revenues.

Mitigation: A Code of Conduct has been established, supported by a mandatory training programme; robust compliance systems are in place to ensure sales and marketing activities comply with regulations in the US and other territories; standard operating procedures are in place to ensure compliance with good clinical and manufacturing practice and to manage pharmacovigilance requirements, monitored through quality control systems. Internal expertise is maintained to manage these risks.

Change in 2012/13: The Group had several regulatory inspections at its various sites during the year which have resulted in the Group needing to conduct assessments and undertake remedial actions in relation to findings.

Risk: Product liability and other key risks may not be capable of being adequately insured

Impact: The manufacturing, testing, marketing and sale of BTG's products involve significant product liability. 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.

Mitigation: BTG maintains product liability insurance and operates quality systems relating to the manufacture of its products and a pharmacovigilance system to monitor safety events arising with respect to products sold. It may not be commercially viable to adequately insure against the occurrence of other key risks.

Change in 2012/13: None

Risk: Inability to access new products and programmes may limit future growth

Impact: BTG conducts limited fundamental research to generate its own development programmes but instead seeks to acquire new products and late-stage development programmes from other organisations. There is significant competition from other companies also seeking to acquire new products and programmes who may have greater financial resources and sales and marketing reach than BTG. BTG may not be able to acquire suitable products and programmes, which will materially adversely impact the Group's financial future performance and growth prospects.

Mitigation: Dedicated product acquisition team in place; strategy is to focus on niche opportunities that leverage BTG's US commercial operations and those that may be a better fit with BTG than with other organisations. Development teams working to develop follow-on products from existing technology platforms such as embolisation Beads.

Change in 2012/13: Strategy to expand the approved uses of Bead products outlined during the year.

Risk: The success of development activities and market acceptance is uncertain

Impact: The development of medical products and medical devices is inherently uncertain and the timelines and costs to approval may vary significantly from budget or expectation. The product may not demonstrate the expected safety and efficacy benefits and may not be approved by regulatory bodies, such as the US Food and Drug Administration. Manufacturing difficulties or patent litigation may cause programmes to be delayed or halted or products withdrawn. Failure of a late-stage programme such as PEM would materially adversely impact the Group's financial prospects. Regulatory approval requirements may change, resulting in further uncertainty. Even if a product is approved that is no assurance of commercial success.

Mitigation: Experienced development team in place; focus is on acquiring late-stage programmes that have already demonstrated proof of concept and potentially have lower-risk development pathways; development programmes monitored to identify risks and challenges and recommend mitigating and corrective actions. Certain products are licensed to other companies who may have greater resources to support product development. Regulatory team in place, consultation undertaken with applicable regulatory authorities.

Change in 2012/13: None

Risk: Competition may erode revenues

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 and 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.

Mitigation: BTG focuses on niche opportunities addressing specialist markets where there is limited competition and high barriers to entry; CroFab[®] and DigiFab[®] have no current competitors; both products are complex to manufacture. We seek to differentiate the embolisation and drug-eluting Bead products by supporting a range of clinical studies to generate safety and efficacy data to expand their indicated uses.

Change in 2012/13: None.

Risk: Pricing and reimbursement pressures are increasing

Impact: There is increasing pressure on healthcare budgets causing payers to demand increasing treatment and economic benefits before agreeing to reimburse product suppliers at all or at appropriate prices. In March 2010, healthcare reform legislation was adopted in the US, requiring manufacturers to increase the rebates or discounts they give on products reimbursed or paid for by public payers, including Medicaid and Medicare. The purpose of the reform is to increase healthcare coverage in the US population and to manage treatment of chronic conditions efficiently and cost effectively. Management of acute conditions is generally not affected. BTG's acute care and interventional oncology products treat serious medical conditions and the impact of existing healthcare reform on current Group revenues is not expected to be material to the Group's financial position. If BTG acquires products in future that are more impacted by healthcare reforms, revenue expectations could be lower. Failure of a product to qualify for government or health insurance reimbursement or the failure to achieve an appropriate sales price could adversely impact the Group's financial performance. Future healthcare reforms may become more onerous and may have a negative impact on Group revenues.

Mitigation: BTG focuses primarily on niche products that address serious unmet needs; early on in a product's development, the Group conducts pricing and reimbursement studies; the assessments of potential new products will include an assessment of healthcare reforms on pricing and reimbursement.

Change in 2012/13: None

Risk: Currency and treasury effects can adversely impact results

Impact: Many of BTG's revenues and receipts are denominated in US dollars and movements in foreign exchange rates could adversely impact results.

Mitigation: BTG actively manages its exchange risks where feasible, using short-term hedging transactions guided by market expectations and economic forecasts to seek to match actual receipts and payments over a rolling 12-month period to those forecast. This policy can result in both exchange gains and losses but provides a level of certainty over cash receipts.

Change in 2012/13: None

Statement of Directors' responsibilities pursuant to disclosure and transparency rules

Each of the Directors, whose names and functions are listed below, confirms that, to the best of his or her knowledge:

- The financial statements, which have been prepared in accordance with the applicable set of accounting standards, give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and the undertakings included in the consolidation taken as a whole.
- The Directors' Report includes a fair review of the development and performance of the business and the position of the Company and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

Dr Louise Makin Chief Executive Officer
Rolf Soderstrom Chief Financial Officer

17 May 2013

Cautionary note regarding forward-looking statements

This results announcement contains certain forward-looking statements with respect to BTG's business, performance and prospects. Statements and other information included in this report that are not historical facts are forward-looking statements. Words such as 'expects', 'anticipates', 'intends', 'plans', 'believes', 'seeks', 'estimates' and 'potential', variations of these words and similar expressions are intended to identify forward-looking statements. These statements are based on current expectations and involve risk and uncertainty because they relate to events and depend upon circumstances which 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. Current principal risks and uncertainties are described above. 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. BTG undertakes no obligation to update publicly any forward-looking statement, whether as a result of new information, future events or otherwise.