



## **BTG plc: Preliminary Results**

**London, UK, 21 May 2010:** BTG plc (LSE: BGC), the specialty pharmaceuticals company, today announces its preliminary results for the year ended 31 March 2010.

### **Financial highlights**

- Revenue increased by 16.2% to £98.5m (08/09: £84.8m))
- Profit before tax £9.1m (08/09: loss of £11.3m)
- Cash and equivalents at year end of £82.6m (08/09: 78.2m)

### **Operating highlights**

- US commercial operations in place in preparation for selling CroFab™ and DigiFab™ from 1 October 2010
- Varisolve® US Phase III trials to commence H2 2010; BTG to commercialise Varisolve® in the US reimbursed sector
- Integration of Protherics and reorganisation of business processes almost completed
- Voraxaze™ BLA being finalised; targeting end of 2010 for completing submission
- Pleneva™ Phase IIa study initiated in patients with multiple sclerosis

Louise Makin, BTG's chief executive officer, commented: "I am really encouraged by the strong financial and operating progress in the first full year of trading of the enlarged business. This enables us to invest in major opportunities such as Varisolve®, which is now gearing up to start Phase III trials following a successful recent meeting with the FDA. Having evaluated commercial options and made material progress with the programme, I am pleased to announce that we have decided to market Varisolve® ourselves in the US reimbursed sector.

"Our plans to start selling CroFab™ and DigiFab™ through our own sales force from October are now well advanced, and we will seek to further strengthen our portfolio as we continue to build BTG into a sustainably profitable specialty pharmaceuticals company."

### **For further information contact:**

#### **BTG**

Andy Burrows, Director of Investor Relations  
+44 (0)20 7575 1741; mobile: +44 (0)7990 530605  
Rolf Soderstrom, Chief Financial Officer  
+44 (0)20 7575 0000

#### **Financial Dynamics**

Ben Atwell  
+44 (0)20 7831 3113

### **About BTG**

BTG is an international specialty pharmaceuticals company that is developing and commercialising products targeting critical care, cancer, neurological and other disorders. The company is also seeking to acquire new products to develop and market to hospital specialists, and is building a sustainable business financed by revenues from sales of its critical care products and from royalties and milestone payments on partnered products. For further information, visit: [www.btgplc.com](http://www.btgplc.com).

## **Chairman's statement**

Since our last annual report to shareholders we have made good progress towards achieving our near-term objectives, while positioning the business to deliver sustainable growth over the long term.

We have almost completed the integration of the Protherics business, which we acquired in December 2008. The financial benefits of the acquisition are evident in our strong results for the year.

Revenue of £98.5m (08/09: £84.8m) generated a gross profit of £65.7m (08/09: £47.7m). The Group made a profit before tax of £9.1m, which compares with a loss before tax of £11.3m in the prior year. Cash and equivalents increased to £82.6m at 31 March 2010 from £78.2m at 31 March 2009.

The financial review describes the results for the year in detail and provides a financial outlook for the year ahead.

A key objective for the past year was the establishment of a sales and marketing capability in the US, which is core to our growth strategy. I am pleased to report that we have now put in place the key commercial operations required to enable us to begin marketing our own products in the US.

From October 2010, when the current distribution agreement ends, we will start selling our two approved products, CroFab™, an antivenom, and DigiFab™, for digoxin toxicity, in the US ourselves. These established, potentially life-saving products have limited competition and are well known by the specialists who administer them. These attributes make them ideal first products for our new US sales and marketing teams.

To deliver sustainable growth we must add products both to our development pipeline and to our marketed products portfolio. To this end, we continue to invest in our pipeline and to review suitable in-licensing and acquisition opportunities; for the latter, having a US sales capability increases our attractiveness as a partner.

We have made the decision to take Varisolve® forward ourselves. Completing the development of Varisolve® and marketing it in the US reimbursed sector is a big investment for BTG. It is also an investment that has the potential to deliver significant returns and is, we believe, in the best interests of shareholders.

In addition to Varisolve®, our pipeline comprises another programme we intend to take to market ourselves, which is Voraxaze™, for methotrexate toxicity, and four other programmes we intend to partner. Further details are provided in the pipeline update.

I am grateful to Professor Colin Blakemore, who will retire from the Board at this year's Annual General Meeting in July, for his significant contributions to the company's development during his three years as a director.

We look forward with excitement and confidence to the year ahead, in which we start selling our own products in the US and take the next step towards becoming a sustainably profitable specialty pharmaceuticals business.

**Dr John Brown**  
**Chairman**

## **TRADING UPDATE**

Revenue of £98.5m (08/09: £84.8m) comprised total royalty income of £64.2m (08/09: £71.4m) and marketed product revenues of £34.3m (08/09: £13.4m). Recurring royalties were £54.1m (08/09: £55.3m). Slightly higher sales of BeneFIX<sup>®</sup> and a positive impact from currency exchange were offset by reduced revenues from the three-part knee, for which the European patent expired, and lower sales of Campath<sup>®</sup>. Milestones and one-off income were £10.1m (08/09: £16.1m). Marketed product revenues from CroFab<sup>™</sup> were £24.2m (08/09: reported: £9.2m; pro forma £20.6m) and from DigiFab<sup>™</sup> were £5.4m (08/09: reported, £2.2m; pro forma, £5.5m). Further details are provided in the financial review.

## **PIPELINE UPDATE**

BTG has an internal development pipeline and a pipeline of licensed programmes.

### **Internal pipeline**

Our pipeline comprises six programmes in clinical development. Notable progress in 2009/10 included:

**Varisolve<sup>®</sup>**, being developed to treat moderate to severe varicose veins – end of Phase II clinical and CMC meetings held with the US FDA; Special Protocol Assessment (SPA) request made for two Phase III pivotal trials in the US. At a recent meeting, the FDA gave support to commence three planned Phase III trials. BTG plans to fund the Phase III trials in the US and to market the product in the US reimbursed sector while exploring options for partnering in the US aesthetic and rest-of-world markets. The Phase III trials are expected to commence in H2 2010, leading to a potential NDA submission in H2 2012.

**Voraxaze<sup>™</sup>** (glucarpidase), under development for the treatment of delayed methotrexate elimination – we continue to prepare submissions for completing the rolling Biologics Licence Application (BLA) in the US this year.

**OncoGel<sup>™</sup>**, a special formulation of paclitaxel targeting oesophageal cancer – a Phase IIb study continued patient enrolment; preliminary tumour response data are anticipated at the end of 2010, with survival data expected at the end of 2011.

**Pleneva<sup>™</sup>**, an oral compound under development for multiple sclerosis – a Phase IIa study was initiated in January 2010. Recruitment is on target, with 67 of 166 patients enrolled and 23 of 35 study sites initiated to date; data are anticipated in H1 2011.

**ATV** (Angiotensin Therapeutic Vaccine), a novel approach to treating hypertension – a Phase I dose ranging study was completed with BTG's novel proprietary adjuvant to explore suitable doses to take into further clinical studies. BTG is exploring partnering options while preparing ATV for a new Phase IIa study.

**BGC20-1531**, a novel EP4 receptor antagonist targeted at a number of indications in pain and inflammation – formulation development continued and several studies were performed in models of pain and inflammation.

In November 2009, BTG licensed its exclusive worldwide rights for **Acadra<sup>™</sup>** (acadesine) back to Advancell S.A., in exchange for an undisclosed potential future milestone payment and a royalty on any future sales. Acadra<sup>™</sup> is progressing through a Phase I/II study in patients with B-cell chronic lymphocytic leukaemia.

A Phase IIa study of **Prolarix™** in primary liver cancer was discontinued following BTG's decision to seek a specialist oncology partner that can potentially progress the compound through a number of cancer indications.

### **Licensed pipeline**

BTG has an economic interest in a number of programmes it has licensed to industry partners. The milestones and royalties payable to BTG on successful development and commercialisation vary from product to product. Milestones tend to increase as products progress towards regulatory approvals; on average, BTG receives mid-to-high single digit royalties on product sales and retains low-to-mid single digit royalties after revenue sharing.

Progress in 2009/10 was made in several programmes.

**Campath®** (alemtuzumab), licensed to Genzyme Corporation, is approved as a treatment for chronic lymphocytic leukaemia and in Phase III development for multiple sclerosis. Recruitment has been completed in two pivotal Phase III trials of patients with multiple sclerosis. A four-year review of a Phase II study, presented at the American Academy of Neurology annual meeting, showed that an estimated 71% of alemtuzumab-treated patients were free of clinically-active disease, compared to 35% of patients taking Rebif® (interferon beta-1a). Data from the Phase III trials are anticipated in 2011, with a potential approval in multiple sclerosis in 2012.

**Otelixizumab** (formerly TRX4), licensed to Tolerx, Inc, is a targeted T-cell immunomodulator in Phase III development for the treatment of type 1 diabetes. Tolerx has partnered with GlaxoSmithKline to develop otelixizumab in a range of autoimmune disorders. In January 2010, the DEFEND-1 Phase III study completed enrolment of 240 patients, aged 12-45 years, with newly diagnosed autoimmune type 1 diabetes. This triggered a milestone payment to BTG of \$2.5m. A second Phase III trial has commenced recruiting patients.

**Abiraterone acetate**, licensed to Cougar Biotechnology, Inc, which was acquired by Johnson & Johnson in July 2009, is in Phase III development for treating prostate cancer. The first Phase III trial is testing abiraterone acetate in patients with metastatic, castration-resistant prostate cancer who have progressed after docetaxel-based chemotherapy has failed. The second Phase III trial is studying abiraterone acetate in patients with metastatic, castration-resistant prostate cancer who have yet to receive chemotherapy.

**CytoFab™**, licensed to AstraZeneca, is being developed to treat severe sepsis. BTG manufactures CytoFab™, which is based on the same polyclonal antibody platform as CroFab™ and DigiFab™. AstraZeneca successfully completed a Phase IIa study of CytoFab™ in 70 patients and is preparing to initiate a Phase IIb study in around 300 patients.

**ONX 0801**, licensed to Onyx Pharmaceuticals, Inc, is a novel compound under development for treating a range of solid tumours. In September 2009, Onyx initiated a Phase I open-label, dose-finding study to evaluate the safety and pharmacokinetics of ONX 0801 in patients with advanced solid tumours. Approval to commence this study triggered a \$7m milestone payment to BTG.

### **FINANCIAL REVIEW**

BTG's financial performance in 2009/10 was pleasing, particularly in relation to progress made in achieving cost reductions and synergies following the acquisition of Protherics PLC in December 2008.

Prior year figures in the financial statements include the results of the Protherics business from 4 December 2008 to 31 March 2009. We include as an appendix to the accounts, for comparative purposes only, an unaudited pro forma consolidated income statement for the prior year combining the results of BTG plc and Protherics PLC and based on extracts from the books and records of both companies.

### **Revenue**

Reported revenue increased by 16.2% to £98.5m (08/09: £84.8m). Total royalty income of £64.2m (08/09: £71.4m) included recurring royalties of £54.1m, which were slightly lower than in the prior year (08/09: £55.3m), when growth had been 30.4%, and milestones/one-off income of £10.1m (08/09: £16.1m). Key contributors to recurring royalties included BeneFIX™, the haemophilia B treatment marketed by Wyeth, at £26.6m (08/09: £24.7m) and the two-part hip cup, licensed to all major hip manufacturers, which generated £10.8m (08/09: £10.3m).

Marketed product revenues increased to £34.3m (08/09: £13.4m) and compare favourably to pro forma 08/09 revenues of £29.7m. CroFab™ sales generated £24.2m (08/09: £9.2m), with reductions in volumes offset by price increases. DigiFab™ sales were £5.4m (08/09: £2.2m) and Voraxaze™ generated £3.4m (08/09: £1.0m) from cost recovery in the US and named patient sales in other territories. From the pro forma accounts, in the full year to March 31 2009, CroFab™ sales were £20.6m, DigiFab™ sales were £5.5m and Voraxaze™ generated £2.9m.

Non-recurring revenues of £10.1m (08/09: £16.1m) included a £4.2m milestone from Onyx Pharmaceuticals, Inc. on approval to initiate a Phase I clinical study of ONX 0801 and £2.0m revenue recognition of milestones received in prior period ends under the CytoFab™ contract. The balance mainly comprised a milestone from Tolerx, Inc. on completion of enrolment to a Phase III study of orelizumab in type 1 diabetes and an upfront payment from licensing exclusive worldwide rights to Allergan to develop products for diseases and conditions of the eye using BTG's ReGel® drug delivery system.

### **Gross profit**

Gross profit increased to £65.7m (08/09: £47.7m) and delivered a gross margin of 66.7% (08/09: 56.3%). The components of gross profit are royalties, which include recurring and non-recurring income, and marketed products. Revenue sharing on recurring royalties was £16.1m (08/09: £23.2m), giving a gross margin of 70.2% (08/09: 58.0%). The increase in margin resulted primarily from reduced revenue-sharing obligations relating to the Factor IX licence. On non-recurring royalties, revenue sharing was £1.5m (08/09: £5.1m). The cost of sales relating to marketed products was £15.2m and included a non-cash fair value adjustment of £0.3m relating to profit in stock on acquisition. This compared with a cost of sales in the prior year of £8.8m on sales between 4 December 2008 and 31 March 2009 of £13.4m, including a non-cash fair value adjustment of £2.3m. Gross margin on marketed products increased to 55.7% (08/09: reported, 34.3%; pro forma, 50.5%).

### **Operating expenses**

Operating expenses increased to £38.4m (08/09: £23.6m), reflecting the full-year impact of employees and expanded activities following the Protherics acquisition. Within operating expenses, acquisition adjustments and reorganisation costs relating to amortisation and impairment of acquired intangibles were £9.1m (08/09: £3.0m).

Other operating expenses of £25.3m (08/09: £19.7m) included one-off expenditure of £1.9m for legal activity and advisory services primarily relating to the Multi-level Cell

litigations. Selling costs increased to £3.8m (08/09: £0.5m) as preparations continued to establish US commercial operations and compare to pro forma costs in 2008/09 of £2.9m. G&A costs of £19.6m (08/09: £19.2m) compare favourably to pro forma G&A expenses of £26.5m in 2008/09.

Research and development (R&D) costs of £27.0m (08/09: £21.6m) compared with costs of £36.0m from the pro forma accounts for the 2008/09 year.

BTG set a target of reducing G&A costs by £10m and R&D expenses by £10m by the end of the 2010/11 financial year. Reductions to date of £6.9m in G&A costs and £9.0m in R&D expenses compared with the pro forma 2008/09 results show that the Group is making excellent progress.

Approximately 80% of the Group's recurring revenue is denominated in US\$. The average £:US\$ rate during 2009/10 was £1:\$1.60 compared to an average rate of £1:\$1.69 in 2008/09. There was a positive impact due to the movement of the US\$ on reported revenue of approximately £2.8m when compared to the prior year. The Group has a policy to hedge between 80% and 90% of surplus US\$ cash flows for the forthcoming 12 months. This results in realised gains and losses as contracts expire. In 2009/10, settlement of forward contracts and other \$-denominated transactions resulted in losses of £4.0m (08/09: £0.9m). In addition, unrealised foreign exchange gains and losses are recognised at year end on the mark to market of forward contracts. At 31 March 2010, the total effect of mark-to-market adjustments was a gain of £6.5m (08/09: loss of £4.9m). These movements in fair value are reflected in net financing.

The Group made a profit on sale of investments and intangible assets of £1.1m (08/09: £2.6m).

#### **Acquisition adjustments and reorganisation costs**

Acquisition adjustments and reorganisation costs relating to the acquisition of Protherics were £8.7m (08/09: £16.2m).

A charge of £9.1m is included in operating expenses of which £8.3m (08/09: £3.0m) is amortisation of intangible assets acquired with Protherics and £0.8m is an impairment charge following the decision to discontinue development of Prolarix™.

A non-cash fair value adjustment of £0.3m (08/09: £2.3m) has been charged to cost of sales within marketed products following the sale of inventory acquired with Protherics, which had been valued to reflect profit accrued up to the stage of production at the time of the transaction.

In the results for the 2008/09 year, reorganisation costs relating to redundancies, site closure costs and impairment charges were £10.9m. In the current year, operating expenses have benefited from a net credit of £0.7m in relation to reorganisation costs, which arose following successful exits from leased premises, allowing the release of previously provided amounts, offset by other reorganisation costs.

#### **Operating profit**

BTG made an operating profit of £10.8m (08/09: £7.0m) before acquisition adjustments and reorganisation costs. The pro forma 2008/09 results showed an operating loss of £1.1m.

**Financial income and costs**

The net financial income was £7.0m (08/09: net financial expense of £2.1m). Financial income of £7.1m included interest on cash held of £0.6m and a fair value gain of £6.5m on marking to market BTG's forward contracts to sell US dollars.

**Profit after tax**

Taxation charges and adjustments in respect of prior years, together with movements in deferred tax assets and liabilities, produced a tax credit of £2.2m, resulting in a profit after tax of £11.3m (08/09: loss of £13.1m).

To assist with the understanding of underlying trading performance and earnings trends, BTG has included an underlying earnings and earnings per share calculation. This adjusts for the impact of acquisition adjustments and reorganisation costs. The underlying profit for the financial year was £17.7m (08/09: £2.1m).

**Earnings per Share**

In our first full year of trading following the acquisition of Protherics we are pleased to report our earnings per share of 4.4p which marks a significant improvement from the reported loss per share 7.1p in 2008/09. The underlying earnings per share was 6.9p (08/09: 1.1p).

**Non-current assets**

Non-current assets decreased from £211.1m to £197.9m. The majority of the decrease relates to amortisation of the intangible assets acquired with Protherics. The net book value of the Group's property, plant and equipment decreased by £0.5m owing to depreciation of manufacturing assets and equipment offset by additions.

**Current assets, current and non-current liabilities**

Inventory of raw material, work in progress and finished goods of CroFab™ and DigiFab™ decreased to £9.6m (08/09: £10.5m). Trade and other receivables decreased from £29.2m to £20.4m following receipt of one-off accrued royalties at the prior year-end.

Current liabilities decreased from £69.7m to £43.4m. Trade and other payables reduced from £52.0m to £40.8m as a result of the release of deferred income relating to advance payments received from Nycomed and due to the payment of accrued revenue sharing amounts on one-off income included at 31 March 2009. Derivative instruments reduced from £7.3m to £0.8m as a result of the movement in the fair value of forward contracts to sell US dollars.

Non-current liabilities increased from £47.1m to £52.4m. The major movements are an increase of £9.2m relating to the BTG defined benefit pension plan and a reduction of £1.8m in the provision for deferred taxation on the valuation of the intangible assets acquired with Protherics.

**Cash**

Net cash and equivalents increased from £78.2m at 31 March 2009 to £82.6m at 31 March 2010. BTG has no debt financing and considers the existing cash balances together with the cash generated from operations sufficient to meet its current operational requirements.

**Outlook**

We exceeded our financial goals in 2009/10. By driving through our integration and cost saving initiatives we delivered a profitable and cash-generative business. This is the

important first step in our growth strategy. Having established a resilient financial platform we are now able to move forward to invest for future growth.

2010/11 is a milestone year for BTG as we will for the first time sell our own products in the US. To manage this transition requires investment in sales force, marketing and working capital as we unwind existing relationships with Nycomed, build our capabilities and establish launch stock to sell ourselves. In 2011/12 we will enjoy a full year of selling CroFab™ and DigiFab™ ourselves and see the benefits of that investment flow through in increased sales, gross margin and earnings.

We have also confirmed that we will take Varisolve® forward in phase III trials for the US reimbursed market. We estimate the investment required will be approximately \$55m to achieve product approval. This will be spread over three years. Varisolve® will potentially deliver significant revenue and earnings growth.

On 18 May 2010, we acquired the land in Australia on which we manage our sheep from Martindale Holdings Pty Ltd for A\$13.7m. This is a central part of our supply chain and an integral part of our FDA approved manufacturing process. This acquisition is not only an excellent opportunity to secure our supply chain, it will also drive further margin efficiency through cost savings.

We are able to make these investments with confidence built on the stable financial foundations we have created over the past year and look forward to seeing the benefits reflected in the future financial performance of BTG.

## CONSOLIDATED INCOME STATEMENT

	Note	Year ended 31 March 2010			Year ended 31 March 2009		
		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
<b>Revenue</b>	2	<b>98.5</b>	-	<b>98.5</b>	84.8	-	84.8
Cost of Sales		(32.5)	(0.3)	(32.8)	(34.8)	(2.3)	(37.1)
<b>Gross Profit</b>	2	<b>66.0</b>	<b>(0.3)</b>	<b>65.7</b>	50.0	(2.3)	47.7
<i>Operating expenses:</i>							
Amortisation and impairment of acquired intangible assets		-	(9.1)	(9.1)	-	(3.0)	(3.0)
Foreign exchange losses	4	(4.0)	-	(4.0)	(0.9)	-	(0.9)
Other		(25.3)	-	(25.3)	(19.7)	-	(19.7)
Operating expenses: total		(29.3)	(9.1)	(38.4)	(20.6)	(3.0)	(23.6)
Research and development		(27.0)	-	(27.0)	(21.6)	-	(21.6)
Profit on disposal of intangible assets and investments		1.1	-	1.1	2.6	-	2.6
Reorganisation costs	3	-	0.7	0.7	-	(10.9)	(10.9)
Amounts written off investments		-	-	-	(3.4)	-	(3.4)
<b>Operating profit/(loss)</b>		<b>10.8</b>	<b>(8.7)</b>	<b>2.1</b>	7.0	(16.2)	(9.2)
Financial income	4			7.1			2.9
Financial expense				(0.1)			(5.0)
<b>Profit/(loss) before tax</b>				<b>9.1</b>			<b>(11.3)</b>
Tax	5			2.2			(1.8)
<b>Profit/(loss) for the period</b>				<b>11.3</b>			<b>(13.1)</b>
<b>Basic and diluted earnings/(loss) per share</b>	6			<b>4.4p</b>			<b>(7.1)p</b>

All activity arose from continuing operations

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Note	Year ended 31 March 2010 £m	Year ended 31 March 2009 £m
<b>Profit/(loss) for the period</b>		<b>11.3</b>	<b>(13.1)</b>
<b>Other comprehensive income</b>			
Foreign exchange translation differences		(0.8)	0.8
Actuarial (loss)/gain on pension liabilities	8	(12.0)	0.8
Change in fair value of equity securities available-for-sale		-	0.5
<b>Other comprehensive income for the year</b>		<b>(12.8)</b>	<b>2.1</b>
<b>Total comprehensive income for the year</b>		<b>(1.5)</b>	<b>(11.0)</b>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Note	31 March 2010 £m	31 March 2009 £m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Goodwill	7	30.3	30.0
Intangible assets	7	152.7	165.8
Property, plant and equipment		10.6	11.1
Investments in associates		-	0.3
Other investments		3.7	3.2
Deferred tax asset		0.6	0.7
		<b>197.9</b>	<b>211.1</b>
<b>Current assets</b>			
Inventories		9.6	10.5
Trade and other receivables		20.4	29.2
Taxation		0.5	0.4
Cash and cash equivalents		82.6	78.2
		<b>113.1</b>	<b>118.3</b>
<b>Total assets</b>		<b>311.0</b>	<b>329.4</b>
<b>EQUITY</b>			
Share capital		25.8	25.5
Share premium account		188.1	187.3
Merger reserve		158.1	156.5
Other reserves		(0.9)	(0.1)
Retained earnings		(155.9)	(156.6)
<b>Total equity attributable to equity holders of the parent</b>		<b>215.2</b>	<b>212.6</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Trade and other payables		8.5	8.4
Obligations under finance leases		0.6	1.3
Employee benefits	8	9.2	-
Deferred taxation	5	33.4	35.2
Provisions	3	0.7	2.2
		<b>52.4</b>	<b>47.1</b>
<b>Current liabilities</b>			
Trade and other payables		40.8	52.0
Borrowings		-	0.2
Obligations under finance leases		0.7	0.8
Derivative instruments		0.8	7.3
Taxation		-	3.3
Provisions	3	1.1	6.1
		<b>43.4</b>	<b>69.7</b>
<b>Total liabilities</b>		<b>95.8</b>	<b>116.8</b>
<b>Total equity and liabilities</b>		<b>311.0</b>	<b>329.4</b>

## CONSOLIDATED STATEMENT OF CASH FLOWS

	Year ended 31 March 2010 £m	Year ended 31 March 2009 £m
<b>Profit/(loss) after tax for the year</b>	<b>11.3</b>	<b>(13.1)</b>
Tax	<b>(2.2)</b>	1.8
Financial income	<b>(7.1)</b>	(2.9)
Financial expense	<b>0.1</b>	5.0
Operating profit/(loss)	<b>2.1</b>	(9.2)
Adjustments for:		
Profit on disposal of intangible assets and investments	<b>(1.1)</b>	(2.2)
Amounts written off associates and investments	-	3.4
Amortisation and impairment of intangible assets	<b>9.9</b>	6.2
Depreciation on property, plant and equipment	<b>2.5</b>	1.5
Reorganisation – impairment of fixed assets	-	1.3
Share-based payments	<b>1.1</b>	1.3
Pension scheme funding	<b>(2.8)</b>	(3.8)
Other	<b>0.3</b>	(0.9)
Share of associates' losses	<b>0.3</b>	0.4
Cash from operations before movements in working capital	<b>12.3</b>	(2.0)
Decrease in inventories	<b>1.2</b>	3.4
Decrease/(increase) in trade and other receivables	<b>9.4</b>	(8.3)
Decrease in trade and other payables	<b>(8.5)</b>	(1.7)
(Decrease)/increase in provisions	<b>(6.1)</b>	7.0
<b>Cash from operations</b>	<b>8.3</b>	(1.6)
Interest expense	<b>(0.1)</b>	(0.1)
Taxation paid	<b>(2.4)</b>	(0.1)
<b>Net cash inflow/(outflow) from operating activities</b>	<b>5.8</b>	(1.8)
<b>Investing activities</b>		
Interest received	<b>0.6</b>	2.0
Purchases of intangible assets	<b>(1.2)</b>	(0.8)
Purchases of property, plant and equipment	<b>(1.5)</b>	(1.2)
Net proceeds from disposal of investments and intangible assets	<b>(0.3)</b>	3.2
Cash acquired with subsidiary, net of transaction costs	-	19.2
Net expenditure on investments	<b>(0.2)</b>	(0.6)
<b>Net cash (outflow)/inflow from investing activities</b>	<b>(2.6)</b>	21.8
<b>Cash flows from financing activities</b>		
Repayment of borrowings	<b>(0.2)</b>	-
Repayment of finance leases	<b>(0.8)</b>	-
Costs of issue of shares on acquisition of Protherics PLC	-	(0.4)
Proceeds of share issues	<b>2.4</b>	0.3
<b>Net cash from financing activities</b>	<b>1.4</b>	(0.1)
Increase in cash and cash equivalents	<b>4.6</b>	19.9
Cash and cash equivalents at start of year	<b>78.2</b>	57.0
Effect of exchange rate fluctuations on cash held	<b>(0.2)</b>	1.3
<b>Cash and cash equivalents at end of year</b>	<b>82.6</b>	78.2

## 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 2008	15.1	187.0	-	(1.4)	(145.5)	55.2
Loss for the year	-	-	-	-	(13.1)	(13.1)
Other comprehensive income	-	-	-	1.3	0.8	2.1
Total comprehensive income for the year	-	-	-	1.3	(12.3)	(11.0)
<b>Transactions with owners:</b>						
Issue of BTG plc ordinary shares	10.4	0.3	156.5	-	-	167.2
Movement in shares held by the Trust	-	-	-	-	(0.1)	(0.1)
Share-based payments	-	-	-	-	1.3	1.3
<b>At 31 March 2009</b>	<b>25.5</b>	<b>187.3</b>	<b>156.5</b>	<b>(0.1)</b>	<b>(156.6)</b>	<b>212.6</b>

	Share capital £m	Share premium £m	Merger reserve £m	Other reserves £m	Retained earnings £m	Total equity £m
At 1 April 2009	25.5	187.3	156.5	(0.1)	(156.6)	212.6
Profit for the year	-	-	-	-	11.3	11.3
Other comprehensive income	-	-	-	(0.8)	(12.0)	(12.8)
Total comprehensive income for the year	-	-	-	(0.8)	(0.7)	(1.5)
<b>Transactions with owners:</b>						
Issue of BTG plc ordinary shares	0.3	0.8	1.6	-	-	2.7
Movement in shares held by the Trust	-	-	-	-	0.3	0.3
Share-based payments	-	-	-	-	1.1	1.1
<b>At 31 March 2010</b>	<b>25.8</b>	<b>188.1</b>	<b>158.1</b>	<b>(0.9)</b>	<b>(155.9)</b>	<b>215.2</b>

## **1. Basis of preparation**

In accordance with EU law (IAS Regulation EC 1606/2002), the preliminary results have been prepared in accordance with International Financial Reporting Standards ("IFRS") adopted for use in the EU as at 31 March 2010 ("adopted IFRS"), International Financial Reporting Interpretations Committee ("IFRIC") interpretations and those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

The preliminary 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 11.

The financial information for the years ended 31 March 2010 and 2009 set out above does not constitute statutory accounts within the meaning of sections 434 to 436 of the Companies Act 2006 ("the Act"). Statutory accounts for the year ended 31 March 2009 have been delivered to the Registrar of Companies, and the accounts for the year ended 31 March 2010 will be delivered to the Registrar of Companies following the Annual General Meeting. The auditors have reported on those accounts; their report was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report and (iii) did not contain a statement under section 498(2) or section 498(3) of the Companies Act 2006.

The annual report and accounts for the year ended 31 March 2010 will be posted to shareholders on 14 June 2010. The results for 2010 were approved by the Board of directors on 20 May 2010 and are audited. The Annual General Meeting will take place on 13 July 2010.

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 accounting standards have been adopted in the year:

#### *IFRS8 – Operating segments*

During the year, the Group has adopted IFRS8, which requires an entity to report financial and descriptive information about its reportable segments. Reportable segments are operating segments or aggregations of operating segments that meet specified criteria. In addressing these criteria, it was determined that the Group has two reportable segments, being Marketed Products and Royalties.

All significant decisions are made by the Leadership Team (which is BTG's chief operating decision-making body as defined by IFRS8), with implementation of that decision on a group-wide basis then being the responsibility of each member of the team or of cross-functional global teams where appropriate. The sales, manufacturing, business development, research and development and support functions are managed and operate on a global basis and are not dedicated to individual product, marketing or therapy areas.

In assessing performance and making resource allocation decisions, the Leadership Team reviews Gross Profit by segment, reflecting the two distinct routes available to it in realising commercial value from its assets. All other financial information, including assets, is presented on a consolidated basis for the Group as a whole, substantially in the form of, and on the same basis as, the Group's IFRS financial statements. Gross Profit is generated from marketed products, such as CroFab™ and DigiFab™, or from Royalty arrangements such as Factor IX, Campath® and Two-Part Hip-Cup. Royalty revenues are receivable on a broad portfolio of underlying intellectual property rights, covering amongst other things pharmaceutical products, medical devices and electronic components.

Research and development is an essential upstream activity of the Group, without which there could be no royalty or marketed product revenues. Research and development activities are managed on a consolidated, group-wide basis and are not managed by reference to the Group's operating segments.

#### *IAS1 – Presentation of Financial Statements (revised 2007)*

The adoption of IAS1 (revised 2007) has introduced a number of terminology changes (including titles for the consolidated financial statements) and has resulted in a number of changes in presentation and disclosure. The revised standard has had no impact on the reported results or financial position of the Group.

#### *IFRS7 revised – Financial instruments: Disclosures*

The adoption of IFRS7 revised has resulted in additional disclosure being given regarding the level of the fair value hierarchy within which the fair values of the Group's forward foreign exchange contracts are categorised and the maturity analysis required in relation to the timing of cash flows.

#### *Other accounting standards adopted in the year*

The following amendments and standards have also been adopted, but have had no significant effect on the reported results or financial position of the Group:

- IFRS2 – Amendment regarding Vesting Conditions and Cancellations
- IAS23 – Borrowing Costs (revised 2007)
- Amendments to IAS32 – Financial Instruments: Presentation
- IAS27 – Consolidated and Separate Financial Statements
- IFRIC14 – The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction

#### **Accounting standards issued but not yet effective**

The Group does not consider that any of the other standards or interpretations issued but as yet not effective will have a significant impact on the financial statements.

#### **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 financial statements.

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 cashflow 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 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 both licensees and industries; and
- The Group's Marketed Products are life-saving in nature, providing some protection against an uncertain economic outlook.

#### **Acquisition adjustments and reorganisation costs**

The Consolidated Income Statement includes a separate column to disclose significant acquisition adjustments and reorganisation costs arising on the acquisition of Protherics PLC in December 2008. The costs relate to the following:

- The release of the fair value uplift of inventory acquired;
- Amortisation arising on intangible assets acquired; and
- Reorganisation costs comprising redundancy, property costs and asset impairments.

## 2. Operating segments

The Group has two operating segments (see note 1). Under IAS14, the Group previously reported its results within two operating segments, being "Life Sciences" and "Technology Commercialisation". Following the acquisition of Protherics PLC in December 2008 and the subsequent reorganisation of the management of the Group during the current financial year, these segments were no longer deemed representative of the way in which the Group manages its operations. There are no inter-segment transactions that are required to be eliminated on consolidation.

	Year ended 31 March 2010			Year ended 31 March 2009		
	Marketed products £m	Royalties £m	Total £m	Marketed products £m	Royalties £m	Total £m
<b>Revenue</b>	<b>34.3</b>	<b>64.2</b>	<b>98.5</b>	13.4	71.4	84.8
Cost of Sales*	(15.2)	(17.6)	(32.8)	(8.8)	(28.3)	(37.1)
<b>Gross Profit</b>	<b>19.1</b>	<b>46.6</b>	<b>65.7</b>	4.6	43.1	47.7
Operating expenses:						
Amortisation and impairment of acquired intangible assets			(9.1)			(3.0)
Foreign exchange losses			(4.0)			(0.9)
Other			(25.3)			(19.7)
Total operating expenses			(38.4)			(23.6)
Research and development			(27.0)			(21.6)
Profit on disposal of intangible assets and investments			1.1			2.6
Reorganisation costs			0.7			(10.9)
Amounts written off investments			-			(3.4)
<b>Operating profit/(loss)</b>			<b>2.1</b>			<b>(9.2)</b>
Financial income			7.1			2.9
Financial expense			(0.1)			(5.0)
<b>Profit/(loss) before tax</b>			<b>9.1</b>			<b>(11.3)</b>
Tax			2.2			(1.8)
<b>Profit/(loss) for the period</b>			<b>11.3</b>			<b>(13.1)</b>
<b>Unallocated assets</b>			<b>311.0</b>			<b>329.4</b>

\* Includes a release of £0.3m (2009: £2.3m) in marketed products representing the reversal of a fair value uplift of inventory purchased on acquisition of Protherics PLC on 4 December 2008, recognised through the income statement when the product was sold.

### Geographical revenue analysis

Geographical analysis of revenue, based on the geographical location of customers:

Year ended 31 March	2010 £m	2009 £m
USA	82.9	69.0
UK	8.3	9.9
Europe (excluding UK)	5.9	3.3
Other regions	1.4	2.6
	<b>98.5</b>	<b>84.8</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; being £26.6m (2009: 2 licensees generated £24.7m and £9.3m of revenue respectively, each representing more than 10% of Group revenue).

The Group's marketed products are sold through a distribution agreement with one distributor in the USA. Revenues in the period generated from that distribution agreement of £27.9m represent more than 10% of Group revenue (2009: £11.3m).

### 3. Reorganisation costs and provisions

	Year ended 31 March 2010 £m	Year ended 31 March 2009 £m
BTG plc and Protherics PLC reorganisation costs	<b>(0.7)</b>	10.9

The Group considers reorganisation costs to be those resulting from decisions to rationalise both operating sites and business operations.

Following the acquisition of Protherics on 4 December 2008, the Group undertook a restructuring to integrate and align the two businesses. The principal costs incurred relate to redundancy, property costs associated with onerous leases and impairment of assets made redundant as part of the restructuring. The majority of costs have been paid, however commitments on onerous leases extend for a further three years.

The credit to the income statement in the year ended 31 March 2010 represents the release of £1.5m of lease costs previously provided for following the completion of successful negotiations with the landlords of two of the Group's leased properties. This has allowed the Group to exit from the lease commitments below the amount originally provided. This is offset by other reorganisation costs incurred in the year.

The table below sets out the Group's provisions, which include amounts provided for reorganisation costs and onerous leases.

	2010	2010	Total	2009	2009	Total
	Leases £m	Reorganisation £m	£m	Leases £m	Reorganisation £m	£m
At 1 April	4.3	4.0	8.3	1.3	-	1.3
Provisions utilised during year	(1.6)	(3.2)	(4.8)	(0.6)	-	(0.6)
Provisions made during year	-	0.5	0.5	3.6	4.0	7.6
Provisions released during year	(1.5)	(0.3)	(1.8)	(0.1)	-	(0.1)
Difference on exchange	(0.1)	(0.3)	(0.4)	0.1	-	0.1
At 31 March	<b>1.1</b>	<b>0.7</b>	<b>1.8</b>	4.3	4.0	8.3
Balance due within one year	0.4	0.7	1.1	2.4	3.7	6.1
Balance due after more than one year	0.7	-	0.7	1.9	0.3	2.2
	<b>1.1</b>	<b>0.7</b>	<b>1.8</b>	4.3	4.0	8.3

Lease provisions relate to onerous leases and represent the net present value of future obligations and where relevant, not covered by income from tenants.

### 4. Foreign exchange gains and losses in the income statement

During the year ended 31 March 2010 the Group recognised foreign exchange losses of £4.0m (2009: losses of £0.9m) within operating profit. These arise from the retranslation of foreign currency balance sheet amounts, transactional exchange gains and losses in the period and the settlement of the Group's foreign exchange forward contracts during the period.

Included within "Financial income" of £7.1m is £6.5m which represents the movement in the fair value of the Group's foreign exchange forward contracts. In the period to March 2009 £4.9m is included within "Financial expense" in relation to the movement in the fair value of the Group's foreign exchange forward contracts in that period.

## 5. Tax

	Year ended 31 March 2010 £m	Year ended 31 March 2009 £m
<b>Current tax</b>		
UK corporation tax (credit)/charge	(0.6)	2.3
Overseas tax on royalties	0.1	0.2
Adjustments in respect of prior years:		
UK income tax	(0.5)	-
US income tax	-	0.4
Total current taxation	(1.0)	2.9
<b>Deferred taxation</b>		
Decrease/(increase) in estimate of recoverable deferred tax asset	0.2	(0.1)
Release of deferred tax liability	(1.4)	(1.0)
	(2.2)	1.8

The table below sets out the movements in the Group's deferred tax liability:

Deferred tax liability	Year ended 31 March 2010 £m	Year ended 31 March 2009 £m
At 1 April	35.2	-
Acquisitions	-	36.2
Released during the period	(2.8)	(1.0)
Decrease in tax losses available for offset	1.4	-
Exchange differences	(0.4)	-
At 31 March	33.4	35.2

The deferred tax liability of £33.4m (2009: £35.2m) arises as a result of the acquisition of Protherics PLC. Amounts released during the period of £2.8m (2009: £1.0m) represent the decrease of the deferred tax liability in line with amortisation charged against the carrying values of the associated assets. The decrease in tax losses available for offset of £1.4m (2009: nil) represents the decrease of Group tax losses during the period that are therefore no longer available to offset the deferred tax liability. No deferred tax has been recognised directly in equity.

## 6. Earnings per share

Basic earnings per share is calculated by dividing the profit attributable to ordinary shareholders of £11.3m (2009: loss of £13.1m) by the weighted average of ordinary shares outstanding during the period of 255.9m (2009: 183.4m). Diluted earnings per share is calculated using a weighted average of ordinary shares outstanding during the period, adjusted for outstanding share options, of 257.8m (2009: 184.5m).

The weighted average number of ordinary shares outstanding used in the calculations excludes the shares held by the BTG Employee Share Trust.

	2010	2009
Profit attributable to ordinary shareholders (£m)	11.3	(13.1)
Earnings per share (p)		
Basic & diluted	4.4	(7.1)
Number of shares (m)		
Weighted average number of shares – basic	255.9	183.4
Effect of share options in issue	1.9	1.1
Weighted average number of shares – diluted	257.8	184.5

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

	Year ended 31 March 2010	Year ended 31 March 2009
Profit/(loss) for the financial year (£m)	11.3	(13.1)
Add back:		
Fair value adjustment on acquired inventory	0.3	2.3
Amortisation of acquired intangible fixed assets	7.7	2.0
Reorganisation costs	(1.6)	10.9
<b>Underlying earnings</b>	<b>17.7</b>	<b>2.1</b>
Profit per share (p)		
Basic and diluted	<b>6.9</b>	1.1

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:

- No tax adjustment is required on the fair value of acquired inventory
- The release of deferred tax liability of £1.4m (2009: £1.0m) as shown in note 5 has been deducted from the amortisation and impairment of acquired intangible assets of £9.1m as shown in note 7
- A reorganisation cost credit of £0.7m in the Consolidated Income Statement has been increased by £0.9m tax effect, being the amount by which the Group's deferred tax charge would have been affected had there been no tax deduction available for reorganisation costs. The Group's tax charge would have been the same in the prior year if there had been no reorganisation costs.

## 7. Goodwill and intangible assets

Goodwill of £30.3m relates to the acquisition of Protherics PLC on 4 December 2008.

The table below sets out the Group's Intangible assets:

	Developed technology £m	Contractual relation- ships £m	In-process research and development £m	Computer software £m	Patents £m	Total £m
<b>Cost</b>						
At 1 April 2009	120.3	36.1	7.7	0.5	14.7	179.3
Additions	-	-	-	-	1.2	1.2
Disposals	-	-	-	(0.5)	(2.8)	(3.3)
Currency movements	(2.9)	(0.9)	-	-	(0.1)	(3.9)
<b>At 31 March 2010</b>	<b>117.4</b>	<b>35.2</b>	<b>7.7</b>	<b>-</b>	<b>13.0</b>	<b>173.3</b>
<b>Amortisation</b>						
At 1 April 2009	1.6	1.4	-	0.5	10.0	13.5
Provided during the year	4.5	3.8	-	-	0.8	9.1
Impairments	-	-	0.8	-	-	0.8
Writeback on disposals	-	-	-	(0.5)	(2.5)	(3.0)
Currency movements	0.2	0.2	-	-	(0.2)	0.2
<b>At 31 March 2010</b>	<b>6.3</b>	<b>5.4</b>	<b>0.8</b>	<b>-</b>	<b>8.1</b>	<b>20.6</b>
<b>Net book value</b>						
<b>At 31 March 2010</b>	<b>111.1</b>	<b>29.8</b>	<b>6.9</b>	<b>-</b>	<b>4.9</b>	<b>152.7</b>
At 1 April 2009	118.7	34.7	7.7	-	4.7	165.8

Developed technology, Contractual relationships and In-process research and development intangible assets relate to assets acquired on purchase of Protherics PLC in December 2008. Amortisation and impairment charges of £9.1m have been charged in relation to these assets during the period. The balance of the movement relates to the retranslation of the US-based assets at the closing exchange rate at 31 March 2010.

The balance of intangible assets of £4.9m (2009: £4.7m) comprises computer software and patents.

## **8. Defined benefit pension fund liability**

The liability recognised on the Group's balance sheet in accordance with IAS19 – *Employee benefits* in relation to the BTG Pension Fund is £9.2m (08/09: £nil). The increase in the liability since 31 March 2009 relates principally to actuarial gains and losses, which are recognised in the Consolidated Statement of Comprehensive Income. The movement in the discount rate applied to the fund liabilities from 6.9% to 5.5% and an increase in the inflation assumption from 3.2% to 3.9% has increased the deficit by £22.4m, offset by higher than expected returns on assets of £10.4m and employer contributions in excess of the charge to the Consolidated Income Statement of £2.8m which have reduced the deficit.

## **9. 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 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 in the year ended 31 March under these agreements were £1.2m and amounts still outstanding and payable at 31 March 2010 were £1.0m.

## **10. Post Balance Sheet Event**

On 18 May 2010 BTG completed the purchase of the land in Australia on which the Group manages its sheep and serum production for CroFab™, DigiFab™ and CytoFab™. This is a central part of the Group's supply chain and an integral part of the FDA approved manufacturing process. The purchase price was A\$13.7m.

## **11. Principal risks and uncertainties**

BTG's performance and prospects may be affected by risks and uncertainties relating to its business and to the environment in which it operates. The Group's internal controls include a risk management process to identify key risks and, where possible, manage the risks through its 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 below. Other risks are unknown or deemed immaterial.

### **Interruption of product supply**

BTG relies on third-party contractors for the supply of 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 and time-consuming. BTG's polyclonal antibody products rely on serum produced from our sheep flocks in Australia, which could be subject to disease outbreaks. BTG relies on its single site in Wales for supply of manufactured product, with the consequent possibilities for disruption to supplies.

#### *Controls and mitigating actions:*

Rigorous monitoring of suppliers; dual sourcing implemented wherever possible; inventories monitored through sales and operational planning process and production changes implemented where needed to ensure continued product supply; regular checks made on sheep flock health; disaster recovery plans in place.

### **Patent validity, patent infringement litigation and changes in patent laws**

In common with all patents, BTG's patents can be subject to challenge at any time. Challenges can relate to the validity of patents or to alleged infringement of others' intellectual property, 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. Failure by BTG to maintain or renew key patents might lead to loss of earnings and liability to suit from both the licensee and licensor. 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 regulations in territories where BTG conducts its business that make it more difficult or time-consuming to prosecute patents, or which reduce the exclusivity period for granted patents, could adversely

impact the Group's financial performance. BTG's patent portfolio is currently subject to several challenges.

*Controls and mitigating actions:*

Dedicated internal resource supplemented by external expertise monitors patent portfolio and third-party patent applications; processes in place to automate patent renewals; internal controls established to avoid disclosure of patentable material prior to filing patent applications.

**Patent expiries, product supply, safety or compliance issues, or competition may reduce revenues**

BTG's key current royalty-generating products are expected to continue to provide royalty revenues until their patents or licence agreements expire. A number of patent expiries will occur in 2011, including those relating to BeneFIX<sup>®</sup>, the current largest revenue earner and the only approved recombinant Factor IX treatment for the bleeding disorder haemophilia B. Others are expected to continue to generate royalties including the MRC humanisation IP (2015), Campath<sup>®</sup> (2017) and the two-part hip cup (2019). Any unforeseen patent loss, supply, safety or compliance issues with these products could result in premature cessation of the revenues.

BTG also earns revenues from sales of its critical care products including CroFab<sup>™</sup> and DigiFab<sup>™</sup>. Both have patent protection and are also protected by significant know-how and complex manufacturing processes, and BTG expects to continue earning revenues following patent expirations. However, future competition cannot be ruled out and competing products could materially adversely impact BTG's financial results.

*Controls and mitigating actions:*

New royalty streams may emerge from, for example, abiraterone acetate if approved as a treatment for prostate cancer, Campath<sup>®</sup> if approved to treat multiple sclerosis, orelizumab if approved to treat type 1 diabetes and CytoFab<sup>™</sup> if approved to treat severe sepsis.

**Failure to comply with regulations may result in prosecutions**

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. This is particularly true in the US, from which the Group derives most of its revenues and where the Group is establishing its own sales and marketing operations. Regulatory regimes are complex and dynamic, and alterations to the regulations may result in delays in product development or in the products becoming non-approvable. Ensuring compliance with such regulations necessitates allocation of significant financial and operating resources.

Failure to comply with relevant 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.

*Controls and mitigating actions:*

New Code of Conduct for employees established with ongoing training programme; compliance systems established to ensure sales and marketing activities comply with US regulations, and US head of compliance being recruited – all activities to be completed by October 2010 when BTG begins marketing CroFab<sup>™</sup> and DigiFab<sup>™</sup>; standard operating procedures in place to ensure compliance with good clinical and manufacturing practice, monitored through quality control systems.

**Inability to access new products and programmes may limit future growth**

BTG does not conduct 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.

*Controls and mitigating actions:*

Dedicated, experienced product acquisition team in place; strategy is to focus on niche opportunities that leverage BTG's US commercial operations and may be a better fit with BTG than with other organisations.

**The success of development activities is uncertain**

BTG may not be able to access the later-stage development opportunities it seeks. The development of medical products is inherently uncertain and the timelines and costs to approval may vary significantly from budget or expectation. The product may not demonstrate the expected efficacy or safety benefits and may not be approved by the regulatory bodies, such as the US Food and Drug Administration. Manufacturing difficulties or patent litigation may cause programmes to be delayed or halted. Failure of a late-stage programme such as Varisolve® would materially adversely impact the Group's financial performance.

*Controls and mitigating actions:*

Experienced development team in place; focus is on acquiring later-stage programmes that have already demonstrated proof of concept and potentially have lower-risk development pathways; development programmes monitored by Pharmaceutical Management Committee to identify risks and challenges and recommend mitigating and corrective actions.

**Competition may erode revenues**

The Group operates in highly 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.

*Controls and mitigating actions:*

BTG focuses on niche opportunities addressing specialist markets where there is limited competition and high barriers to entry; CroFab™ has no current competitor and BTG estimates DigiFab™ has about 80% market share; both products are complex to manufacture.

**Pricing and reimbursement pressures are increasing**

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 Medicare and Medicaid. 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 CroFab™ and DigiFab™ products treat acute conditions and the impact on healthcare reform on current Group revenues is expected to be immaterial. If BTG acquires products in the future that are more impacted by the 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.

*Controls and mitigating actions:*

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

**Currency and treasury effects can adversely impact results**

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

### **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 business review 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

20 May 2010

### **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.

**Appendix 1 – Unaudited pro forma financial information**  
**Unaudited pro forma Consolidated Income Statement**  
**For the year ended 31 March 2010**

	Year ended 31 March 2010 £m	Year ended 31 March 2009 £m
Royalties	<b>64.2</b>	74.0
Marketed products	<b>34.3</b>	29.7
<b>Revenue</b>	<b>98.5</b>	103.7
Cost of sales: royalties	<b>(17.6)</b>	(28.3)
Cost of sales: marketed products	<b>(14.9)</b>	(14.7)
<b>Gross Profit</b>	<b>66.0</b>	60.7
Operating expenses: foreign exchange (losses)/gains	<b>(4.0)</b>	4.4
Operating expense : other	<b>(25.3)</b>	(29.4)
Operating expenses: total	<b>(29.3)</b>	(25.0)
Research and development	<b>(27.0)</b>	(36.0)
Profit on disposal of assets and investments	<b>1.1</b>	2.6
Amounts written off associates and investments	<b>-</b>	(3.4)
<b>Operating profit/(loss)</b>	<b>10.8</b>	(1.1)
Financial income	<b>7.1</b>	3.8
Financial expense	<b>(0.1)</b>	(7.0)
<b>Profit/(loss) before tax</b>	<b>17.8</b>	(4.3)
Tax	<b>0.8</b>	0.1
<b>Profit/(loss) for the year</b>	<b>18.6</b>	(4.2)
<b>Basic earnings per share</b>	<b>7.3p</b>	(1.6p)
<b>Diluted earnings per share</b>	<b>7.2p</b>	(1.6p)

All activity arose from continuing operations

**Basis of preparation**

The financial information contained in this appendix is pro forma and does not constitute full statutory accounts within the meaning of section 240 of the Companies Act 1985. The information has been extracted from the records of BTG plc and Protherics PLC combining the results for both companies for the years ended 31 March 2010 and 31 March 2009. The information has been prepared using the accounting policies and basis of preparation set out in note 2 to the Group financial statements, except that, for comparative purposes, the following items have been excluded from the pro forma information.

- Amortisation of business combination intangibles
- Effect of fair value adjustments on inventory arising from IFRS 3 – Business Combinations
- One-off transaction related expenses and reorganisation costs