

## BTG plc: Final Results

**London, UK, 17 May 2016:** BTG plc (LSE: BTG), the specialist healthcare company, today announces its final results for the year ended 31 March 2016.

### Financial summary

- Group revenue grew 22% to £447.5m (2014/15: £367.8m); underlying revenue growth at constant currency was 14%
- Operating profit before acquisition adjustments and reorganisation costs rose to £93.0m (2014/15: £67.9m)
- Profit before tax of £57.5m (2014/15: £26.7m) reflects underlying growth and cost discipline
- Adjusted earnings per share (excluding acquisition adjustments and reorganisation costs) were 39% higher at 21.9p (2014/15: 15.7p)
- Cash and cash equivalents were £140.4m at 31 March 2016 (£73.8m at 31 March 2015)

### Operating highlights

#### Interventional Medicine

##### *Oncology*

- Commenced direct sales of DC Bead<sup>®</sup> in Europe; good progress with DC Bead<sup>®</sup> and TheraSphere<sup>®</sup> in Asia
- LC Bead LUMI<sup>™</sup>, the only commercially available visible bead, approved and launched in the US
- Acquisition of Galil Medical, a leader in cryoablation of kidney tumours with significant pipeline opportunities, announced post year-end

##### *Vascular*

- Strong growth from EkoSonic<sup>®</sup> reflecting leadership in the treatment of pulmonary embolism (PE)
- Varithena<sup>®</sup> (polidocanol injectable foam) approved by Health Canada

##### *Pulmonology*

- RENEW pivotal US study of PneumRx<sup>®</sup> Coil successfully completed; presented at American Thoracic Society meeting and published in the Journal of the American Medical Association
- Reimbursement determination under way in France following successful completion of REVOLENS study

#### Specialty Pharmaceuticals

- Vistogard<sup>®</sup> (uridine triacetate), a treatment for 5-FU overdose, approved and launched in the US
- Successful study using CroFab<sup>®</sup> for the treatment of Copperhead snake envenomation

#### Licensing

- Strong growth from Lemtrada<sup>™</sup> (alemtuzumab) following US approval
- Continued strong performance from Zytiga<sup>®</sup> (abiraterone acetate)

Louise Makin, BTG's CEO, commented: "We are making good progress in implementing our growth strategy, investing in geographic expansion, product innovation and indication expansion to maximise the value of our portfolio. Our strategy is also to expand our portfolio through M&A, and the acquisition of Galil Medical cements our leadership in interventional oncology. Through consistent delivery of our operating goals and financial targets, we are well placed to maintain or develop leading positions in all our chosen market segments. With our portfolio, team, capabilities and resources, we have a scalable platform for long-term growth and sustained value creation for shareholders."

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### **About BTG**

BTG is a growing international specialist healthcare company bringing to market innovative products in specialist areas of medicine to better serve doctors and their patients. We have a portfolio of Interventional Medicine products to advance the treatment of liver tumours, severe blood clots, varicose veins and advanced emphysema, and Specialty Pharmaceuticals that help patients overexposed to certain medications or toxins. Inspired by patient and physician needs, BTG is investing to expand its portfolio to address some of today's most complex healthcare challenges. To learn more about BTG, please visit: [www.btgplc.com](http://www.btgplc.com).

## **Chairman's statement**

I am pleased to report a strong financial performance for the year, with double-digit growth in revenue and profitability. The continued delivery of our financial targets underpins the investments we are making now to deliver on our long term objectives.

We have made significant progress during the year in implementing our growth strategy. We commenced direct sales of DC Bead<sup>®</sup> in Europe and received approval in the US for LC Bead LUMI<sup>™</sup>, which is a significant innovation in the locoregional treatment of liver cancer. After year-end, we announced the acquisition of Galil Medical and its portfolio of cryoablation products, expanding our interventional oncology offering into kidney and other cancers and bringing further potential growth opportunities.

Market adoption of the varicose veins treatment, Varithena<sup>®</sup>, has been slower than we had anticipated in the US. However, feedback from customers on the product's clinical performance continues to be positive, and reimbursement coverage is gradually expanding.

We have completed the integration of PneumRx, Inc., the interventional pulmonology business we acquired last year. The successful completion of two clinical studies during the year supports our expansion plans in the EU and US.

The FDA approval of Vistogard<sup>®</sup> (uridine triacetate) added a fourth product to our Specialty Pharmaceuticals business, highlighting our commitment to, and leadership in, important antidote therapies.

There is real momentum in our business. We have the right strategy, the talent and the resources to enable us to achieve our long term goals. Most importantly, we are in a privileged position to help our customers improve the treatment of their patients and, ultimately, that is what drives everyone at BTG.

**Garry Watts**  
Chairman

## OPERATING REVIEW

Over the past decade BTG has successfully transformed from an intellectual property commercialisation company to a fast growing, specialist healthcare business. We have built a company that now develops, manufactures and sells its own unique products to specialist physicians through small, efficient sales teams.

Underpinning our transformation is the solid foundation that we have established through our highly cash generative Specialty Pharmaceuticals and Licensing businesses. Our strategy is to reinvest the cash generated by these businesses into our Interventional Medicine portfolio. Here we are building a portfolio of differentiated, minimally invasive therapies that have the potential to deliver efficacy and safety benefits to patients while reducing hospital stays and overall healthcare costs.

Interventional Oncology is the most advanced demonstration of our Interventional Medicine strategy. Double-digit revenue growth this year reflects a strong performance by TheraSphere<sup>®</sup> and the continued growth of our Beads business, for which we commenced direct sales in European markets in April 2015. We hired our first sales representatives in Canada, where we are now also selling both products directly.

We made good progress in key Asian markets. Our partner in China, SciClone Pharmaceuticals, Inc., won its first provincial tenders and the first patients were treated with DC Bead<sup>®</sup>. TheraSphere<sup>®</sup> received approval in the growing markets of Singapore and South Korea whilst in Japan our partner Eisai Co., Ltd received expanded approval for DC Bead<sup>®</sup>.

During the year we received US approval for LC Bead LUMI<sup>™</sup>, a radiopaque bead developed in collaboration with the imaging specialist Royal Philips. We anticipate EU approval in due course. We are also exploring other options outside of the liver with the development of our biodegradable bead, where we see potential to enter new markets for benign tumours.

After year-end we announced the acquisition of Galil Medical, a leader in cryoablation. This highly complementary, bolt-on acquisition enhances our offering to interventional oncologists with a suite of cryoablation products that are used for the treatment and palliative care of kidney and other cancers. Additional indications in treating lung and bone metastases could result from two studies that are nearing completion. Importantly, cryoablation is a platform technology and we have the opportunity to invest to expand its use into new indications and market segments. In particular, we will explore the potential crossover in call points with our PneumRx and EKOS businesses.

The treatment of cancer continues to evolve. More effective treatments mean that more people are living longer with their cancer, and that the management of an individual's cancer is likely to involve multiple treatments at different stages of disease. Interventional oncologists are exploring the potential role of locoregional approaches including cryoablation and radiation therapy alongside existing and developing treatment modalities, such as immuno-oncology. BTG's unique position as a provider of multiple interventional therapies means we are well placed to take advantage of these trends.

In Interventional Vascular, the EkoSonic<sup>®</sup> blood clot treatment device continues to deliver strong growth. There is an increasing recognition of the benefits of treating blood clots interventionally and the annual number of procedures in the US is growing strongly - from about 95,000 when we bought this business in 2013 to about 140,000 today. Over this time we have increased penetration into US hospitals, helped by the FDA clearance we received in 2014 for the treatment of life-threatening pulmonary embolism (PE).

Our plans are to build on this leadership position in the US and expand our presence in Europe and other territories. We are also developing a new control unit that will enable bilateral treatment of PE and deep vein thrombosis (DVT) and we are adding to the clinical evidence with two studies, for which we expect to complete patient enrolment this financial year.

As we approach two years since launching Varithena<sup>®</sup> in the US reimbursed sector, physician interest remains high, with 792 physicians now enrolled in the training programme, up from 573 in November 2015, and we continue to receive positive feedback on its clinical performance. Despite a slower start than we had originally anticipated, reimbursement for Varithena<sup>®</sup> is gradually improving. Approximately 161 million US lives (of 320 million total US insured lives) are now covered by payers who have Varithena<sup>®</sup> on policy, with approximately 91 million lives covered by insurers who have also paid claims at appropriate rates. Further progress is anticipated during the current financial year.

The number of physicians who are regularly reordering whilst small is increasing, with clinics in geographies where there is good insurance coverage and clinics that specialise in treating advanced venous disease, such as leg ulcers, being more likely to reorder. We look forward to launching Varithena<sup>®</sup> in Canada during 2017 and we are continuing to progress plans to develop related products to treat cosmetic leg veins and other venous disorders.

PneumRx is at an early stage of its commercial development. Our medium term goals for this business are to expand European market adoption and reimbursement, using emerging clinical data to provide physicians and payers with confidence in patient selection, and to secure US approval. We have made good progress since completing the acquisition and continue to be excited by the large commercial potential of PneumRx and for Interventional Pulmonology overall.

In May 2015 the REVOLENS study, a trial sponsored by the French Ministry of Health, met its primary endpoint. We are now seeking national reimbursement for the PneumRx<sup>®</sup> Coils in France and anticipate a decision during the 2017 calendar year. A decision on national reimbursement in Germany is also anticipated during 2017.

In December 2015 we announced positive top line data from the US RENEW trial, one of the largest randomised controlled clinical trials of a medical device in patients with severe emphysema. Full data were presented at the American Thoracic Society meeting in May 2016 and published in the Journal of the American Medical Association. The full data analysis shows that patients with heterogeneous or homogeneous emphysema and a higher degree of lung over-inflation showed the greatest improvements in quality of life and exercise capacity versus control patients. This provides a good basis for the development of this therapy, as it will help physicians identify those patients who are most suitable for treatment with the coils.

We are now finalising the clinical module of our rolling US regulatory submission in the US. As a result of ongoing dialogue with the FDA, we are adding additional usability testing data to a previously submitted module, and we now anticipate completing our rolling Pre-market Approval (PMA) submission at the end of 2016.

Specialty Pharmaceuticals, which comprises a portfolio of unique rescue therapies, is an established business that delivers on average mid-to-high single digit annual revenue growth. In the period our partner Wellstat Therapeutics Corporation received FDA approval for Vistogard<sup>®</sup> (uridine triacetate), the only drug to treat patients following an overdose of the common chemotherapy drug 5-fluorouracil (5-FU), and first sales were achieved in the launch month of March 2016. We have created two dedicated field forces in order to serve our customers more effectively, one focusing on the emergency room products CroFab<sup>®</sup> and DigiFab<sup>®</sup> and the other on the oncology antidote products Voraxaze<sup>®</sup> and Vistogard<sup>®</sup>.

Royalties from our Licensing segment provide strong cash flows to help fund our investments in other parts of the business. A continued strong performance from Johnson & Johnson's Zytiga<sup>®</sup> (abiraterone acetate) was supplemented by strong growth in Sanofi/Genzyme's multiple sclerosis treatment Lemtrada<sup>™</sup> (alemtuzumab).

## FINANCIAL REVIEW

BTG has reported another year of strong financial growth. This performance reflects our increasing financial maturity and supports the execution of our strategy to achieve sustained profitable growth.

### Revenue

Group revenue increased by 22% to £447.5m (2014/15: £367.8m) and by 14% at constant currency. Given the high proportion of US\$ denominated revenues, movements in the US\$ to sterling exchange rate influence reported revenues. The average rate for the year was \$1.51 compared to \$1.61 in the prior year. A five cent movement in the dollar exchange rate results in an approximate £13m change in Group revenues. In the table on page 6 we show reported product sales and Licensing revenues, together with growth rates at constant currency.

Interventional Medicine revenues were 33% higher at £150.2m (2014/15: £112.7m), a 27% increase at constant currency.

Our Interventional Medicine portfolio comprises different products at varying stages of their lifecycle. Within this segment the most advanced franchise is Interventional Oncology, which generated sales of £91.4m (2014/15: £75.5m), representing growth of 16% at constant currency in line with our annual average growth guidance. TheraSphere<sup>®</sup> continued to grow strongly, while EU Beads revenue growth was impacted by channel disruption following the transition from a distribution arrangement to direct sales in April 2015. We expect to realise the full benefits of selling Beads directly in Europe in the current financial year.

Interventional Vascular revenues increased to £46.4m (2014/15: £34.9m), representing 24% growth at constant currency, driven by another strong performance from the EkoSonic<sup>®</sup> blood clot treatment device. Receiving FDA clearance for use in the treatment of pulmonary embolism in 2014 has enabled us to increase sales significantly in this indication and to continue to increase penetration into US hospitals. Sales of our varicose veins treatment Varithena<sup>®</sup> were flat as we continue to establish a smooth reimbursement process. We anticipate an increase in physician reordering leading to sales growth sometime during our 2016/17 financial year.

The first full year of revenue from the PneumRx<sup>®</sup> Coil, our Interventional Pulmonology treatment for advanced emphysema, was £12.4m, in line with revenue in the prior 12 months. This primarily reflects a flat performance in Germany, which accounts for ~80% of sales and where we currently have interim reimbursement.

Specialty Pharmaceuticals revenue increased to £133.1m (2014/15: £121.1m), growing by 3% at constancy currency. Sales of the snake bite antivenin CroFab<sup>®</sup> and the digoxin toxicity treatment DigiFab<sup>®</sup> were steady and there was double-digit growth from Voraxaze<sup>®</sup>, the treatment for high-dose methotrexate toxicity. At the end of the period we also recorded our first US sales of Vistogard<sup>®</sup>.

Licensing revenues grew to £164.2m (2014/15: £134.0m), a 14% increase at constant currency. Royalties from the largest contributor, Johnson & Johnson's treatment for advanced prostate cancer Zytiga<sup>®</sup> (abiraterone acetate), grew to £118.9m and were enhanced by a one-off back payment of £8.5m during the year. Zytiga<sup>®</sup> royalties would be impacted if generic products are launched; we believe the earliest date for generic entry in the US could be in our 2018/19 financial year. Royalties from Lemtrada<sup>™</sup> grew strongly to £19.8m following US approval last year. Our royalties on Lemtrada<sup>™</sup> will cease during our 2017/18 financial year on patent expiry. Other royalty contributors generated £25.5m in total and included our final royalties on the MRC patents, which amounted to £8.4m.

		2015/16 (£m)	2014/15 (£m)	Change (%)	Change at CC* (%)
<b>Interventional Medicine</b>					
<i>Interventional Oncology</i>	Beads/TheraSphere <sup>®</sup>	91.4	75.5	21	16
	<i>Total Interventional Oncology</i>	91.4	75.5	21	16
<i>Interventional Vascular</i>	EkoSonic <sup>®</sup>	45.4	33.9	34	25
	Varithena <sup>®</sup>	1.0	1.0	-	-
	<i>Total Interventional Vascular</i>	46.4	34.9	33	24
<i>Interventional Pulmonology</i>	PneumRx <sup>®</sup> Coil	12.4	2.3	nm	nm
	<b>Total Interventional Medicine</b>	<b>150.2</b>	<b>112.7</b>	<b>33</b>	<b>27</b>
<b>Specialty Pharmaceuticals</b>					
	CroFab <sup>®</sup>	67.9	61.8	10	2
	DigiFab <sup>®</sup>	47.0	44.7	5	(1)
	Voraxaze <sup>®</sup>	16.6	14.3	16	11
	Vistogard <sup>®</sup>	1.3	0.2	nm	nm
	Other	0.3	0.1	nm	nm
	<b>Total Specialty Pharmaceuticals</b>	<b>133.1</b>	<b>121.1</b>	<b>10</b>	<b>3</b>
<b>Licensing</b>					
	Zytiga <sup>®</sup>	118.9	105.2	13	5
	Lemtrada <sup>™</sup>	19.8	4.9	nm	nm
	Two-Part Hip Cup	13.7	13.8	(1)	(9)
	Others	11.8	10.1	17	12
	<b>Total Licensing</b>	<b>164.2</b>	<b>134.0</b>	<b>23</b>	<b>14</b>
<b>Total revenue</b>		<b>447.5</b>	<b>367.8</b>	<b>22</b>	<b>14</b>

\*At constant currency GBP vs USD (1.51 vs 1.61 in prior year)  
nm – not meaningful

## Gross profit

Gross profit rose by 21% to £306.7m (2014/15: £253.1m) giving a gross margin of 69% (2014/15: 69%). The blended Group gross margin is expected to remain steady at around 70% in the medium term.

The Interventional Medicine gross margin of 71% (2014/15: 70%) reflects a fixed manufacturing cost base for the early stage Varithena<sup>®</sup> and PneumRx products, and is expected to increase over time as revenues from these products build. In Specialty Pharmaceuticals the gross margin rose to 89% (2014/15: 86%) driven by product mix and manufacturing efficiencies. Gross margin in Licensing was lower at 50% (2014/15: 52%) as a result of increased revenues from lower margin licensing streams.

## Contribution

We define contribution as gross profit less selling, general and administrative (SG&A) expenditure, which broadly reflects the cash generated by the business before any investment in research & development (R&D) or capital activities.

In line with our commercial expansion strategy, SG&A increased over the year to £141.4m (2014/15: £124.8m). Contribution increased to £165.3m (2014/15: £128.3m) and the Group contribution margin increased to 37% (2014/15: 35%).

The increase in SG&A reflects the full year costs associated with the acquisition of PneumRx and increased investment in the commercial capabilities of the rest of the Interventional Medicine segment. Investments include costs associated with the US launch of Varithena<sup>®</sup>, for which the US sales force was increased, and the commercial expansion of our Interventional Oncology products in Europe and Asia.

The more established Specialty Pharmaceuticals and Licensing segments have both delivered increased contribution margins of 69% (2014/15: 65%) and 38% (2014/15: 30%) respectively. Whilst making investments to support the launch of Vistogard<sup>®</sup>, we continue to seek operating efficiencies in these businesses to maximise cash generation and support our investments to deliver high growth in the Interventional Medicine business. We anticipate that the current Interventional Medicine contribution margin of 7% (2014/15: 8%) will increase over time as revenues across the portfolio increase.

## Research and development

Research and development investments increased to £77.2m (2014/15: £68.3m) in line with the expanded innovation and development activities, primarily within Interventional Medicine, and reflecting a full year of PneumRx activities.

Patient enrolment continues into our EPOCH and STOP-HCC TheraSphere<sup>®</sup> Phase III trials, which are designed to support PMA submissions in the US; we took the decision in March 2016 to terminate the YES-P trial and to reallocate investment into the TheraSphere<sup>®</sup> PMA trials. We are developing a new control unit and software upgrade for EkoSonic<sup>®</sup> and we have made investments in the OPTALYSE and ACCESS PTS studies to support further indication expansion for this product.

Investment continues into indication expansion and product innovation for Varithena<sup>®</sup>, and we continue to invest in the RENEW study and other activities designed to support US approval of the PneumRx<sup>®</sup> Coil. In addition to innovation and development, we invest in providing ongoing regulatory, clinical and medical affairs support for the expanded portfolio of marketed products.

We will continue to invest in research and development to support pipeline opportunities arising from our expanding portfolio.

## Operating profit

Operating profit before acquisition adjustments and reorganisation costs was £93.0m (2014/15: £67.9m) reflecting higher revenue growth partially offset by increased investment in selling capabilities and research and development.

Operating profit includes the impact of foreign exchange. The £:\$ exchange rate moved from \$1.48 at the beginning of the year to \$1.44 at the end of the year. BTG's exposure to US\$ assets and liabilities resulted in a net foreign exchange gain of £4.4m (2014/15: £6.7m).

Acquisition adjustments include the release of the fair value uplift of inventory acquired with PneumRx of £1.5m (2014/15: £0.9m) and amortisation of acquired intangible assets of £35.0m (2014/15: £28.4m), which has increased as a result of the acquisition of PneumRx in January 2015.

Operating profit after acquisition adjustments and reorganisation costs was £56.5m (2014/15: £34.9m).

## Financial expense/income

Net financial income was £1.0m (2014/15: net financial expense of £8.2m). Included within this are fair value adjustments to contingent considerations, resulting in an overall income of £1.4m (2014/15: charge of £1.0m). This comprises a £12.0m (\$20m) credit relating to the non-payment of the first PneumRx acquisition milestone. This was offset by a £10.6m charge relating to fair value adjustments to other contingent considerations, including a £9.0m charge relating to increasing the probability of payment of the US approval milestone for PneumRx following the successful completion of the RENEW trial. In addition there was a gain on the mark-to-market of foreign exchange forward contracts of £1.2m (2014/15: loss of £6.2m).

## Profit before tax and taxation

Profit before tax for the year is £57.5m (2014/15: £26.7m). Group profits arise in the UK, the United States and other overseas territories and as a consequence the effective tax rate is a blend of the varying tax rates in different jurisdictions.

In the period the Group has recognised a tax credit of £3.0m (2014/15: credit of £6.9m) due principally to the recognition of historic tax losses relating to EKOS, Voraxaze<sup>®</sup> and PneumRx, plus the deferred tax impact of the amortisation of intangible assets. The Group's anticipated effective tax rate is expected to move toward 27% over the medium term once tax losses have been fully recognised.

## Earnings per share

Basic earnings per share were 15.8p (2014/15: 9.1p) on a profit after tax of £60.5m (2014/15: 33.6m). The adjusted earnings per share excluding acquisition adjustments and reorganisation costs were 21.9p (2014/15: 15.7p) on an adjusted profit after tax of £83.6m (2014/15: £57.8m).

	2015/16	2014/15
	£m	£m
Profit for year	60.5	33.6
Add back <sup>1</sup> :		
Fair value adjustment on acquired inventory	0.9	0.6
Amortisation of acquired intangible fixed assets	23.6	19.5
Acquisition and reorganisation costs	-	3.1
Fair value changes on contingent consideration	(1.4)	1.0
Underlying earnings	83.6	57.8
Underlying profit per share (p)	21.9	15.7

<sup>1</sup>Adjustments shown post tax impact

## Balance sheet

### Non-current assets

Non-current assets comprise goodwill, intangible assets, property, plant and equipment, other investments, deferred tax assets, employee benefits and derivative financial instruments. Non-current assets have increased to £851.3m from £838.3m as at 31 March 2015. The most significant element of non-current assets is intangible assets of £599.2m (2014/15: £597.9m). Changes in the year reflect an increase of £23.0m relating to the purchase of the residual financial interest in Varithena<sup>®</sup> and changes in foreign currency of £15.0m, offset by intangible asset amortisation of £38.0m.

The Group's defined benefit pension scheme as measured under IAS19 Revised – Employee Benefits increased to an asset of £19.3m at 31 March 2016 from £13.2m at 31 March 2015 principally due to an increase in the discount rate used to value the defined benefit obligation.

### Current assets

Current assets comprise inventories, trade and other receivables, corporation tax receivable, derivative financial instruments, cash and cash equivalents. Current assets have increased to £297.5m from £207.6m at 31 March 2015. Cash and cash equivalents have increased from £73.8m to £140.4m as a result of strong cash generation from the businesses. Inventory increased to £46.5m (31 March 2015: £40.5m) and receivables increased to £106.5m (31 March 2015: £91.9m) as a result of underlying business growth.

### Non-current liabilities

Non-current liabilities comprise trade and other payables, deferred tax liabilities and provisions. Non-current liabilities increased to £176.1m (31 March 2015: £171.7m). This is a result of an increase in the PneumRx FDA contingent milestone due to an increased probability of payment, partially offset by a decrease in the deferred tax liability position, due to recognising tax losses relating to Voraxaze<sup>®</sup>, EKOS and PneumRx.

### Current liabilities

Current liabilities comprise trade and other payables, corporation tax payable, provisions and derivative instruments. In current liabilities, trade and other payables increased to £114.8m (31 March 2015: £111.0m), reflecting the underlying growth of the business.

### Contingent liabilities

In July 2014, BTG announced that it had received a subpoena from the US Department of Justice, seeking documents in relation to an investigation regarding LC Bead<sup>®</sup>. The investigation covers the period from 2003. BTG continues to



cooperate fully with this investigation. As at 31 March 2016, the possibility that a material outflow of funds will be required to settle or otherwise resolve the investigation was more than remote. It was not, however, possible to make a reliable estimate of the amount that may be required to be paid.

	<b>31 March 2016</b>	31 March 2015
	<b>£m</b>	£m
Non-current assets	<b>851.3</b>	838.3
Current assets	<b>297.5</b>	207.6
Non-current liabilities	<b>(176.1)</b>	(171.7)
Current liabilities	<b>(125.0)</b>	(115.6)
<b>Net assets</b>	<b><u>847.7</u></b>	<u>758.6</u>

## Cash flow

Cash and cash equivalents were £140.4m. The business generated £101.8m from operating activities (2014/15: £62.7m), reflecting good cash generation in the business and working capital movements. Cash outflow of £29.9m from investing activities includes £23.0m for the purchase of the residual financial interest of Varithena<sup>®</sup> and continued investment in manufacturing facilities. The prior period cash generation reflects both the acquisition of the PneumRx for a net cash outflow of £147.7m and the proceeds of a share issue for a cash inflow of £147.2m.

In November 2015 the Group signed a new £100m multi-currency revolving credit facility with an option to extend by a further £100m. This facility has a three year term that can be extended up to five years and replaced the previous £60m facility.

	<b>2015/16</b>	2014/15
	<b>£m</b>	£m
<b>Opening cash and cash equivalents</b>	<b>73.8</b>	<b>38.2</b>
Operating cash flow before working capital	108.0	73.2
Movement in working capital	<u>(6.2)</u>	<u>(10.5)</u>
<b>Cash generation from operations</b>	<b>101.8</b>	<b>62.7</b>
Investing activities	(29.9)	(158.9)
Financing, Tax paid and others	(5.3)	131.8
<b>Net change in cash</b>	<b>66.6</b>	<b>35.6</b>
<b>Closing cash and cash equivalents</b>	<b>140.4</b>	<b>73.8</b>

## Summary and financial outlook

Our financial strategy is to deliver double digit compound annual revenue growth, while maintaining cost discipline, to enable reinvestment in our capabilities and in pipeline opportunities to underpin our long-term growth. Our results for the year show strong delivery against all these objectives, which provides the foundations to achieve our goal of delivering revenues of ~\$1.5bn in our 2021/22 financial year and sustained growth thereafter.

For the 2016/17 financial year, we expect revenues to be in the range £485m to £515m, SG&A costs to be £160m to £170m and research and development investment to be £85m to £95m.

## CONSOLIDATED INCOME STATEMENT

	Note	Year ended 31 March 2016			Year ended 31 March 2015		
		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>447.5</b>	-	<b>447.5</b>	367.8	-	367.8
Cost of sales		(139.3)	(1.5)	(140.8)	(113.8)	(0.9)	(114.7)
<b>Gross profit</b>	2	<b>308.2</b>	(1.5)	<b>306.7</b>	254.0	(0.9)	253.1
<i>Operating expenses:</i>							
Amortisation of acquired intangible assets	7	-	(35.0)	(35.0)	-	(28.4)	(28.4)
Foreign exchange gains		4.4	-	4.4	6.7	-	6.7
Selling, general and administrative expenses		(141.4)	-	(141.4)	(124.8)	-	(124.8)
Operating expenses: total		(137.0)	(35.0)	(172.0)	(118.1)	(28.4)	(146.5)
Research and development		(77.2)	-	(77.2)	(68.3)	-	(68.3)
Profit on disposal of property, plant and equipment and intangible assets		-	-	-	0.3	-	0.3
Other operating expenses		(1.0)	-	(1.0)	-	-	-
Acquisition and reorganisation costs		-	-	-	-	(3.7)	(3.7)
<b>Operating profit</b>		<b>93.0</b>	(36.5)	<b>56.5</b>	67.9	(33.0)	34.9
Financial income	3	1.4	3.0	4.4	0.1	-	0.1
Financial expense	3	(1.8)	(1.6)	(3.4)	(7.3)	(1.0)	(8.3)
<b>Profit before tax</b>		<b>92.6</b>	(35.1)	<b>57.5</b>	60.7	(34.0)	26.7
Tax credit	4			3.0			6.9
<b>Profit for the year</b>				<b>60.5</b>			33.6
<b>Basic earnings per share</b>	5			<b>15.8p</b>			9.1p
<b>Diluted earnings per share</b>	5			<b>15.6p</b>			9.0p

All activity arose from continuing operations.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
<b>Profit for the year</b>	<b>60.5</b>	33.6
<b>Other comprehensive income</b>		
<i>Items that may be reclassified subsequently to profit or loss</i>		
Foreign exchange translation differences	18.7	41.6
<i>Items that will not be reclassified subsequently to profit or loss</i>		
Remeasurements of the net defined benefit liability asset	3.3	2.2
Deferred tax on defined benefit pension scheme asset	(1.1)	(1.8)
<b>Other comprehensive income for the year</b>	<b>20.9</b>	42.0
<b>Total comprehensive income for the year</b>	<b>81.4</b>	75.6

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Note	31 March 2016 £m	31 March 2015 £m
<b>ASSETS</b>			
<b>Non-current assets</b>			
Goodwill	6	187.9	183.8
Intangible assets	7	599.2	597.9
Property, plant and equipment		35.7	35.5
Other investments		1.4	3.0
Deferred tax asset	4	6.8	4.9
Employee benefits		19.3	13.2
Derivative financial instruments		1.0	-
		<b>851.3</b>	<b>838.3</b>
<b>Current assets</b>			
Inventories		46.5	40.5
Trade and other receivables		106.5	91.9
Corporation tax receivable	4	1.8	1.4
Derivative financial instruments		2.3	-
Cash and cash equivalents		140.4	73.8
		<b>297.5</b>	<b>207.6</b>
<b>Total assets</b>		<b>1,148.8</b>	<b>1,045.9</b>
<b>EQUITY</b>			
Share capital		38.3	38.2
Share premium account		434.8	433.8
Merger reserve		317.8	317.8
Other reserves		28.1	9.4
Retained earnings		28.7	(40.6)
<b>Total equity attributable to equity holders of the parent</b>		<b>847.7</b>	<b>758.6</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Trade and other payables		27.5	17.9
Deferred tax liabilities	4	147.0	152.4
Provisions		1.6	1.4
		<b>176.1</b>	<b>171.7</b>
<b>Current liabilities</b>			
Trade and other payables		114.8	111.0
Derivative financial instruments		3.0	0.9
Corporation tax payable	4	5.8	3.2
Provisions		1.4	0.5
		<b>125.0</b>	<b>115.6</b>
<b>Total liabilities</b>		<b>301.1</b>	<b>287.3</b>
<b>Total equity and liabilities</b>		<b>1,148.8</b>	<b>1,045.9</b>

## CONSOLIDATED STATEMENT OF CASH FLOWS

	Note	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
<b>Profit after tax for the year</b>		<b>60.5</b>	33.6
Tax credit	4	(3.0)	(6.9)
Financial income	3	(4.4)	(0.1)
Financial expense	3	3.4	8.3
<b>Operating profit</b>		<b>56.5</b>	34.9
Adjustments for:			
Profit on disposal of property, plant and equipment and intangible assets		-	(0.3)
Amounts written off investments		1.6	-
Amortisation of intangible assets	7	38.0	29.5
Depreciation and impairment on property, plant and equipment		6.6	5.5
Share-based payments		6.7	5.6
Pension scheme funding		(2.9)	(2.9)
Fair value adjustments		1.5	0.9
<b>Cash from operations before movements in working capital</b>		<b>108.0</b>	73.2
Increase in inventories		(7.6)	(11.4)
Increase in trade and other receivables		(14.4)	(14.9)
Increase in trade and other payables		14.7	14.8
Increase in provisions		1.1	1.0
<b>Cash from operations</b>		<b>101.8</b>	62.7
Corporation tax paid		(6.2)	(15.2)
<b>Net cash inflow from operating activities</b>		<b>95.6</b>	47.5
<b>Investing activities</b>			
Interest paid		-	(0.1)
Purchases of intangible assets	7	(24.3)	(1.4)
Purchases of property, plant and equipment		(6.2)	(9.8)
Acquisition of businesses net of cash acquired		-	(147.7)
Other		0.6	-
Net proceeds from disposal of property, plant and equipment and intangible assets		-	0.1
<b>Net cash outflow from investing activities</b>		<b>(29.9)</b>	(158.9)
<b>Cash flows from financing activities</b>			
Proceeds of share issues		1.1	147.2
Other financing activities		(1.1)	(1.0)
<b>Net cash inflow from financing activities</b>		<b>-</b>	146.2
Increase in cash and cash equivalents		65.7	34.8
Cash and cash equivalents at start of year		73.8	38.2
Effect of exchange rate fluctuations on cash held		0.9	0.8
<b>Cash and cash equivalents at end of year</b>		<b>140.4</b>	73.8

## 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 2014	36.1	288.7	317.8	(32.2)	(80.0)	530.4
Profit for the year	-	-	-	-	33.6	33.6
Foreign exchange translation differences	-	-	-	41.6	-	41.6
Remeasurements of the net defined benefit liability asset	-	-	-	-	2.2	2.2
Deferred tax on defined benefit pension scheme asset	-	-	-	-	(1.8)	(1.8)
Total comprehensive income for the year	-	-	-	41.6	34.0	75.6
<b>Transactions with owners:</b>						
Issue of BTG plc ordinary shares	2.1	145.1	-	-	-	147.2
Movement in shares held by the Trust	-	-	-	-	(0.2)	(0.2)
Share-based payments	-	-	-	-	5.6	5.6
<b>At 31 March 2015</b>	<b>38.2</b>	<b>433.8</b>	<b>317.8</b>	<b>9.4</b>	<b>(40.6)</b>	<b>758.6</b>

	Share capital £m	Share premium £m	Merger reserve £m	Other reserves £m	Retained earnings £m	Total equity £m
At 1 April 2015	38.2	433.8	317.8	9.4	(40.6)	758.6
Profit for the year	-	-	-	-	60.5	60.5
Foreign exchange translation differences	-	-	-	18.7	-	18.7
Remeasurements of the net defined benefit liability asset	-	-	-	-	3.3	3.3
Deferred tax on defined benefit pension scheme asset	-	-	-	-	(1.1)	(1.1)
Total comprehensive income for the year	-	-	-	18.7	62.7	81.4
<b>Transactions with owners:</b>						
Issue of BTG plc ordinary shares	0.1	1.0	-	-	-	1.1
Movement in shares held by the Trust	-	-	-	-	(0.1)	(0.1)
Share-based payments	-	-	-	-	6.7	6.7
<b>At 31 March 2016</b>	<b>38.3</b>	<b>434.8</b>	<b>317.8</b>	<b>28.1</b>	<b>28.7</b>	<b>847.7</b>

# Notes to the consolidated financial statements

## 1. General information

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 2016 ("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 11.

BTG's 2016 Annual Report will be posted to shareholders on 14 June 2016. The financial information set out herein does not constitute the Group's statutory accounts for the year ended 31 March 2016 but is derived from those accounts and the accompanying directors' report. Statutory accounts for 2016 will be delivered to the Registrar of Companies following the Company's Annual General Meeting which will be held at 10.30am on 14 July 2016. The auditor has 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 2015 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 auditor and delivered to the Registrar of Companies. The report of the auditor was unqualified and did not contain statements under Section 495 (4)(b) of the Companies Act 2006. Interim and preliminary announcements notified to the London Stock Exchange are available on the internet at [www.btgplc.com](http://www.btgplc.com).

### Accounting standards adopted in the year

No standards and interpretations issued by the EU adopted in the year had a significant impact on the Group.

### Accounting standards issued but not yet effective

No standards and interpretations issued by the EU but not yet effective are expected to have a significant impact on the Group.

IFRS 15 'Revenue from Contracts with Customers' was issued by the IASB in May 2014, effective for accounting periods beginning on or after 1 January 2018. The Group is currently assessing the impact, if any, of IFRS 15 on the Group's consolidated financial statements.

IFRS 16 'Leases' was issued by the IASB in January 2016, effective for accounting periods beginning on or after 1 January 2019. The Group is currently assessing the impact, if any, of IFRS 16 on the Group's consolidated 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 next 12 months. 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;
- Many of the Group's products are life-saving in nature, providing some protection against an uncertain economic outlook; and
- In November 2015, the Group signed a £100m multi-currency revolving credit facility providing access to funds for a period of three years to November 2018 with the option to extend for a further two years. This facility remains undrawn.

### Acquisition adjustments and reorganisation costs

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

- PneumRx, Inc. in January 2015;
- EKOS Corporation in July 2013;
- Targeted Therapies Division of Nordion Inc. in July 2013;
- Biocompatibles International plc in January 2011; and
- Protherics PLC in December 2008.

The costs relate to the following:

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

## 2. Operating segments

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

In assessing performance and making resource allocation decisions, the Leadership Team (which is BTG's chief operating decision-making body) reviews contribution by segment. Contribution is defined as being gross profit less directly attributable selling, general and administrative costs (SG&A). The Licensing operating segment includes SG&A relating to the Group's centrally managed support functions and corporate overheads. This reflects the management structure and stewardship of the business. No allocation of central overheads is made across the Specialty Pharmaceuticals or Interventional Medicine operating segments. Research and development continues to be managed on a global basis, with investment decisions being made by the Leadership Team as a whole. It is not managed by reference to the Group's operating segments, though each programme within the pipeline would ultimately provide revenues for one of the operating segments if successful.

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

	Year ended 31 March 2016			Total £m
	Interventional Medicine <sup>1</sup> £m	Specialty Pharmaceuticals £m	Licensing £m	
<b>Revenue</b>	150.2	133.1	164.2	447.5
Cost of sales	(43.8)	(15.1)	(81.9)	(140.8)
<b>Gross profit</b>	106.4	118.0	82.3	306.7
Selling, general and administrative expenses	(96.2)	(25.5)	(19.7)	(141.4)
<b>Contribution</b>	10.2	92.5	62.6	165.3
Amortisation of acquired intangibles assets				(35.0)
Foreign exchange gains				4.4
Research and development				(77.2)
Profit on disposal of property, plant and equipment and intangible assets				-
Other operating expenses				(1.0)
Acquisition and reorganisation costs				-
<b>Operating profit</b>				56.5
Financial income				4.4
Financial expense				(3.4)
<b>Profit before tax</b>				57.5
Tax credit				3.0
<b>Profit for the year</b>				60.5
<b>Unallocated assets</b>				1,148.8

1) 2016 Cost of sales includes a £1.5m release of a fair value adjustment to inventory purchased on the acquisition of PneumRx Inc. on the 7 January 2015 within the Interventional Medicine segment. This represents the release of a fair value uplift applied to inventory purchased on acquisition recognised through the income statement as the product is sold.

	Interventional Medicine <sup>2</sup> £m	Specialty Pharmaceuticals £m	Licensing £m	Total £m
<b>Revenue</b>	112.7	121.1	134.0	367.8
Cost of sales	(33.5)	(17.1)	(64.1)	(114.7)
<b>Gross profit</b>	79.2	104.0	69.9	253.1
Selling, general and administrative expenses	(70.1)	(24.9)	(29.8)	(124.8)
<b>Contribution</b>	9.1	79.1	40.1	128.3
Amortisation of acquired intangibles assets				(28.4)
Foreign exchange losses				6.7
Research and development				(68.3)
Profit on disposal of property, plant and equipment and intangible assets				0.3
Acquisition and reorganisation costs				(3.7)
<b>Operating profit</b>				34.9
Financial income				0.1
Financial expense				(8.3)
<b>Profit before tax</b>				26.7
Tax credit				6.9
<b>Profit for the year</b>				33.6
<b>Unallocated assets</b>				1,045.9

2) 2015 Cost of sales includes a £0.9m release of a fair value adjustment to inventory purchased on the acquisition of PneumRx, Inc. on the 7 January 2015 within the Interventional Medicine segment. This represents the release of a fair value uplift applied to inventory purchased on acquisition recognised through the income statement as the product is 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 2016 £m	Year ended 31 March 2015 £m
USA	393.1	327.1
Europe	42.3	31.1
Other regions	12.1	9.6
	<b>447.5</b>	<b>367.8</b>

### Revenue from major products and services

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
Product sales	283.3	233.8
Royalties	164.2	134.0
	<b>447.5</b>	<b>367.8</b>

## Major customers

The Group's products are sold both directly and through distribution agreements in the USA, Europe and Asia Pacific region. No individual customer generated income in excess of 10% of the Group revenue during the year ended 31 March 2016 or 31 March 2015.

Products that utilise the Group's intellectual property rights are sold by licensees. Royalty income is derived from over 50 licences. One licence individually generated royalty income in excess of 10% of Group revenue of £118.9m (2015: £105.2m).



### 3. Financial income and expense

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
Interest receivable on money-market and bank deposits	0.2	0.1
Fair value changes of foreign exchange forward contracts	1.2	-
Fair value changes on contingent consideration	3.0	-
<b>Financial income</b>	<b>4.4</b>	<b>0.1</b>

Fair value changes on contingent consideration relates to the PneumRx acquisition and comprises a £12.0m credit relating to the non-payment of the first revenue milestone and a £9.0m charge relating to the US regulatory milestone.

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
Fair value changes of foreign exchange forward contracts	-	6.2
Fair value changes on contingent consideration	1.7	1.0
Others	1.7	1.1
<b>Financial expense</b>	<b>3.4</b>	<b>8.3</b>

The Group recognised a fair value expense of £1.6m related to the EKOS acquisition.

### 4. Tax

An analysis of the tax credit in the income statement for the year, all relating to current operations, is as follows:

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
<b>Current tax</b>		
UK corporation tax charge	-	-
Overseas corporate tax charge	11.7	12.2
Adjustments in respect of prior years	(2.2)	(1.2)
<b>Total current taxation</b>	<b>9.5</b>	<b>11.0</b>
<b>Deferred taxation</b>		
Deferred tax credit	(13.8)	(17.9)
Adjustment to tax rates	1.3	-
<b>Total deferred taxation</b>	<b>(12.5)</b>	<b>(17.9)</b>
<b>Total tax credit for the year</b>	<b>(3.0)</b>	<b>(6.9)</b>

In addition to the tax credit in the income statement, a deferred tax charge of £1.1m (2015: £1.8m charge) has been recognised in the consolidated statement of other comprehensive income relating to the deferred tax on the pension fund surplus.

UK corporation tax is calculated at 20% (2015: 21%) of the estimated taxable profit for the year. Taxation for other jurisdictions is calculated at the rates prevailing in the respective jurisdictions.

Reconciliation of the effective tax rate:

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
<b>Profit before tax</b>	<b>57.5</b>	<b>26.7</b>
Tax using UK corporation tax rate of 20% (2015: 21%)	11.5	5.6
Effect of overseas tax rates	4.2	2.2
Recognition of tax losses <sup>1</sup>	(15.2)	(8.2)
Change in unrecognised deferred tax assets	(0.4)	(3.4)
Non-deductible expenses	-	1.4
Effect of UK patent box deduction	(4.4)	(3.7)
Intra group transfer of subsidiary undertaking	2.4	-
Adjustment to tax rates	1.3	-
Adjustments in respect of prior years <sup>2</sup>	(2.4)	(0.8)
	<b>(3.0)</b>	<b>(6.9)</b>

- 1) The increased recognition of historic tax UK and US losses arises from sustained profitability of the related underlying businesses.  
2) The prior year adjustment arises mainly from a reassessment of prior year US tax liabilities.

An analysis of amounts included in the Consolidated statement of financial position in respect of income taxes is shown below:

	<b>31 March 2016 £m</b>	31 March 2015 £m
<b>Current assets</b>		
UK corporation tax receivable	<b>1.8</b>	1.4
	<b>1.8</b>	1.4
<b>Current liabilities</b>		
Overseas corporate tax payable	<b>5.8</b>	3.2
	<b>5.8</b>	3.2

### Deferred taxation

The movements in the deferred tax asset and liabilities (prior to the offsetting of balances within the same jurisdiction as permitted by IAS 12, Income Taxes) during the year are as shown below. The deferred tax asset and liabilities are only offset where there is a legally enforceable right of offset and there is an intention to settle the balance net.

#### Deferred tax asset

	<b>2016 £m</b>	2015 £m
Deferred tax asset recognised at 1 April	<b>4.9</b>	0.8
Income statement credit	<b>1.3</b>	4.2
Reclassification	<b>0.5</b>	-
Currency movements	<b>0.1</b>	(0.1)
Deferred tax asset recognised at 31 March	<b>6.8</b>	4.9

The deferred tax asset relates to tax losses in the UK and short term timing differences in the UK and Australia. The UK losses and timing differences have been recognised using a tax rate of 18-20% (2015: 20%) depending on when they will be used. The short term timing differences in Australia have been recognised using a tax rate of 30% (2015: 30%). The directors are of the opinion, based on recent and forecast trading, that the level of profits in the UK and Australia in the forthcoming years will lead to the realisation of the respective assets.

#### Deferred tax liability

	Liabilities Acquired intangibles £m	Liabilities Pension fund surplus £m	Liabilities Short term timing differences £m	Assets Tax losses £m	Assets Short term timing differences £m	Net deferred tax liability £m
At 1 April 2014	(109.2)	(2.8)	(0.9)	20.7	1.8	(90.4)
Adjustments re prior years	-	-	0.1	(0.6)	0.1	(0.4)
Acquisitions	(73.1)	-	(0.9)	11.0	-	(63.0)
Income statement credit	8.7	-	1.7	-	3.6	14.0
Other comprehensive income charge	-	(1.8)	-	-	-	(1.8)
R&D tax credits	-	-	-	-	0.3	0.3
Reclassification	-	-	(0.5)	-	0.5	-
Currency movements	(12.6)	-	-	-	1.5	(11.1)
<b>At 31 March 2015</b>	<b>(186.2)</b>	<b>(4.6)</b>	<b>(0.5)</b>	<b>31.1</b>	<b>7.8</b>	<b>(152.4)</b>
Adjustment re prior years	0.1	-	-	1.0	0.1	1.2
Income statement credit/(charge)	11.2	(1.0)	0.6	(1.9)	1.1	10.0
Other comprehensive income charge	-	(1.1)	-	-	-	(1.1)
R&D tax credits	-	-	-	-	0.2	0.2
Reclassification	-	-	-	-	(0.4)	(0.4)
Currency movements	(5.3)	-	-	0.5	0.3	(4.5)
<b>At 31 March 2016</b>	<b>(180.2)</b>	<b>(6.7)</b>	<b>0.1</b>	<b>30.7</b>	<b>9.1</b>	<b>(147.0)</b>

The deferred tax liability of £147.0m (2015: £152.4m) represents the net position after taking into account the offset of deferred tax assets against deferred tax liabilities in each jurisdiction.

The rate of 20% from 1 April 2016 was substantively enacted on 25 March 2015. The rate of 19% from 1 April 2017 and the rate of 18% from 1 April 2020 were substantively enacted on 26 October 2015. A proposed rate of 17% from 1 April 2020 was announced on 16 March 2016 but has not yet been substantively enacted. These will reduce the Company's future current tax charge accordingly. The UK deferred tax assets and liabilities at 31 March 2016 have been calculated based on the substantively enacted rates at which the timing differences are expected to unwind.

### Unrecognised tax losses

In addition to the losses on which a deferred tax asset has been recognised, the Group has additional tax losses and other timing differences which have arisen principally as a result of research and development. These losses and timing differences are shown below. UK tax losses can be carried forward indefinitely.

The US tax losses can be carried forward for 20 years and the first year in which they expire is 2018.

A deferred tax asset has not been recognised in respect of the losses and timing differences shown below as there is uncertainty as to whether such losses and timing differences can be used.

The total amount of tax losses and timing differences not recognised is shown below:

	Year ended 31 March 2016 £m	Year ended 31 March 2015 £m
UK tax losses	59.4	84.1
US tax losses	22.4	37.3
Deductible temporary differences	27.0	21.6
	<b>108.8</b>	<b>143.0</b>

## 5. Earnings per share

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

	Year ended 31 March 2016	Year ended 31 March 2015
Profit for the financial year (£m)	60.5	33.6
Profit per share (p)		
Basic	15.8	9.1
Diluted	15.6	9.0
Number of shares (m)		
Weighted average number of shares – basic	382.6	367.9
Effect of share options on issue	5.7	5.4
Weighted average number of shares – diluted	388.3	373.3

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

	Year ended 31 March 2016	Year ended 31 March 2015
Profit for the financial year (£m)	60.5	33.6
Add back:		
Fair value adjustment on acquired inventory <sup>(a)</sup>	0.9	0.6
Amortisation of acquired intangible fixed assets <sup>(b)</sup>	23.6	19.5
Acquisition and reorganisation costs <sup>(c)</sup>	-	3.1
Fair values changes on contingent consideration <sup>(d)</sup>	(1.4)	1.0
Underlying earnings	83.6	57.8
Underlying profit per share (p)		
Basic	21.9	15.7
Diluted	21.5	15.4

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:

- a. In the year ended 31 March 2016 there was £0.6m tax impact (2015: £0.3m) on fair value adjustment of inventory acquired of £1.5m (2015: £0.9m).
- b. The release of deferred tax liability of £11.4m (2015: £8.9m) has been deducted from the amortisation and impairment of acquired intangible assets of £35.0m (2015: £28.4m) as shown in the consolidated income statement.
- c. In the year ended 31 March 2015 there was £0.6m tax impact on reorganisation costs of £3.7m.
- d. There was no tax impact (2015: nil) on the contingent consideration fair value gain of £3.0m or the fair value loss of £1.6m (2015: fair value loss of £1.0m).

## 6. Goodwill

Goodwill of £187.9m relates to the acquisitions of PneumRx, Inc. in January 2015, EKOS Corporation in July 2013, the Targeted Therapies Division of Nordion Inc. in July 2013, Biocompatibles International plc in January 2011 and Protherics PLC in December 2008 (2015: £183.8m).

## 7. Intangible assets

Group	Note	Developed technology £m	Contractual relationships £m	In-process research and development £m	Computer software £m	Patents £m	Purchase of contractual rights £m	Total £m
<b>Cost</b>								
At 1 April 2014		<b>428.5</b>	<b>38.6</b>	<b>22.3</b>	<b>1.1</b>	<b>13.1</b>	<b>17.0</b>	<b>520.6</b>
Acquisitions		109.2	-	80.4	-	0.3	-	189.9
Additions		-	-	-	0.2	1.2	-	1.4
Disposals		-	-	-	-	-	(9.5)	(9.5)
Currency movements		40.1	3.5	3.1	0.1	2.0	1.0	49.8
At 31 March 2015		<b>577.8</b>	<b>42.1</b>	<b>105.8</b>	<b>1.4</b>	<b>16.6</b>	<b>8.5</b>	<b>752.2</b>
Additions		-	-	-	0.4	0.9	23.0	24.3
Disposals		(0.3)	(1.0)	-	-	-	-	(1.3)
Currency movements		15.1	1.0	3.2	-	0.7	0.2	20.2
<b>At 31 March 2016</b>		<b>592.6</b>	<b>42.1</b>	<b>109.0</b>	<b>1.8</b>	<b>18.2</b>	<b>31.7</b>	<b>795.4</b>
<b>Amortisation</b>								
At 1 April 2014		<b>57.4</b>	<b>38.3</b>	<b>5.8</b>	<b>0.4</b>	<b>10.8</b>	<b>10.0</b>	<b>122.7</b>
Provided during the year		28.4	-	-	0.3	0.6	0.2	29.5
Write back on disposals		-	-	-	-	-	(9.5)	(9.5)
Currency movements		5.8	3.5	-	-	2.0	0.3	11.6
At 31 March 2015		<b>91.6</b>	<b>41.8</b>	<b>5.8</b>	<b>0.7</b>	<b>13.4</b>	<b>1.0</b>	<b>154.3</b>
Provided during the year		34.7	0.4	-	0.3	0.3	2.3	38.0
Write back on disposals		(0.3)	(1.0)	-	-	-	-	(1.3)
Currency movements		3.3	0.9	-	-	1.0	-	5.2
<b>At 31 March 2016</b>		<b>129.3</b>	<b>42.1</b>	<b>5.8</b>	<b>1.0</b>	<b>14.7</b>	<b>3.3</b>	<b>196.2</b>
<b>Net book value</b>								
<b>At 31 March 2016</b>		<b>463.3</b>	<b>-</b>	<b>103.2</b>	<b>0.8</b>	<b>3.5</b>	<b>28.4</b>	<b>599.2</b>
At 31 March 2015		486.2	0.3	100.0	0.7	3.2	7.5	597.9
At 1 April 2014		371.1	0.3	16.5	0.7	2.3	7.0	397.9

Amortisation relating to acquired intangibles of £35.0m (2015: £28.4m) is shown on the face of the income statement within Amortisation of acquired intangibles. Other amortisation is shown within Cost of sales, Selling, general and administrative expenses or Research and development.

## Developed technology

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

	31 March 2016 £m	31 March 2015 £m	Remaining amortisation period at 31 March 2016
PneumRx <sup>®</sup> Coil (Europe)	104.9	108.9	13.8 years
EkoSonic <sup>®</sup>	105.5	110.5	12.3 years
TheraSphere <sup>®</sup>	90.1	94.4	12.3 years
CroFab <sup>®</sup>	66.0	67.5	17.7 years
DigiFab <sup>®</sup>	21.3	21.8	17.7 years
DC Bead <sup>®</sup> and LC Bead <sup>®</sup>	69.9	77.0	9.8 years

## In-process research and development

Acquisition increases to in-process research and development includes the PneumRx<sup>®</sup> Coil (US) acquired in PneumRx, Inc. in the year ended 31 March 2015.

	31 March 2016 £m	31 March 2015 £m
PneumRx <sup>®</sup> Coil (US)	84.2	81.5
Targeted Therapies Assets	18.4	17.8

## Purchase of contractual rights

In May 2015, BTG purchased the residual financial interest of the originator of the Varithena<sup>®</sup> foam sclerotherapy technology for a one-off cash payment of £23m, ensuring that the business retains 100% of the future value of Varithena<sup>®</sup>. This addition has been included in *purchase of contractual rights* and the asset is being amortised through Cost of sales.

	31 March 2016 £m	31 March 2015 £m	Remaining amortisation period at 31 March 2016
Varithena <sup>®</sup>	21.0	-	9.6 years

## 8. Contingent liability

In July 2014, BTG announced that it had received a subpoena from the US Department of Justice, seeking documents in relation to an investigation regarding LC Bead<sup>®</sup>. The investigation covers the period from 2003. BTG continues to cooperate fully with this investigation. As at 31 March 2016, the possibility that a material outflow of funds will be required to settle or otherwise resolve the investigation was more than remote. It was not, however, possible to make a reliable estimate of the amount that may be required to be paid.

## 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. During the year, BTG payments to Oxford University and Isis Innovations Ltd under the relevant license agreements were £24,000 for the year ended 31 March 2016 (£5,000 during the year ended 31 March 2015). There are no amounts still outstanding and payable by BTG under these agreements as at 31 March 2016 (2015: nil).

## 10. Post balance sheets events

On 6 May 2016 the Group announced that it had entered into an agreement to acquire Galil Medical for an initial cash consideration of US\$84.5m and up to US\$25.5m in future regulatory and commercial milestone payments in respect of the period to 31 December 2018.

## 11. Principal risks and uncertainties

BTG's 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 material principal risks are described below. Although not exhaustive we describe what we believe to be the most significant risks that could materially affect the Group's ability to achieve its financial goals, operating and strategic objectives. While other risks are deemed less material at this time, given the nature of the Company's business, risks continually change.

#### **Risk: securing adequate reimbursement for BTG's products**

**Details:** BTG may not be able to sell its products profitably if reimbursement by third-party payers, including government and private health insurers, is limited or unavailable. The Group may be subject to price limits on reimbursement of products which are outside of its control, reducing product sales volume or prices, negatively impacting Group revenues. This is particularly the case in the US where a significant proportion of the Group's revenues are derived, and in light of the ongoing US healthcare reforms, requiring increased rebates or discounts to be provided. Third-party payers are increasingly attempting to contain healthcare costs through measures that are likely to impact the products that BTG is developing.

**General mitigation strategy:** Ensuring effective advocacy with payers based on accurate data and analysis to inform reimbursement decisions. Ensuring accurate and complete submissions. BTG is seeking to utilise its expanding expertise across the portfolio, both within and outside the US. R&D plans increasingly seek to create the data likely to be required to secure the desired level of reimbursement for the applicable products after commercial launch.

**Change in 2015/16:** The Company continues to strengthen its global market access (reimbursement) capabilities with an ongoing focus on Varithena<sup>®</sup>. Adequate levels of reimbursement continue to be secured for Varithena<sup>®</sup>. In the US, that process has been materially slower than originally envisaged and is not yet universal, adversely impacting revenue growth. Progress continues to be made based on learnings to date. Acceptable progress continues to secure appropriate reimbursement for other products across the portfolio. A future focus will be on supporting appropriate reimbursement levels for the PneumRx Coil<sup>®</sup> both in EU and in US following approval. Notwithstanding progress to date, in light of the ongoing specific challenges relating to Varithena<sup>®</sup> and more challenging external environment in the industry generally, the overall risk is assessed to have increased.

#### **Risk: Obtaining/ maintaining product regulatory approvals**

**Details:** An inability to meet existing or new regulations or regulatory guidance. This may result in delays or failures in bringing products to market, additional material costs of development or the imposition of restrictions on approval or the sale of a product or its manufacture or distribution, including the possible withdrawal of a product from the market or narrowing of its approval or indicated uses. This is particularly the case for drug-eluting beads or other combination products in respect of which the regulatory requirements may be less clear in certain territories.

The pharmaceutical and device industries are highly regulated in relation to the development, approval, manufacturing and sale of its products.

**General mitigation strategy:** The Company has expert internal teams dedicated to ensuring compliance in each of these areas, defining regulatory strategies and supporting product approvals and maintenance of existing product licences. The process is supported by the governance systems and monthly monitoring of performance against goals and of changes in the regulatory landscape. The use of external resources such as contract clinical research organisations (CROs) is being more effectively leveraged.

**Change in 2015/16:** The Regulatory Affairs group was further strengthened and restructured during the year. Discussions with the UK MHRA and BSi continue with respect to the reclassification of the DC Bead<sup>®</sup> product in the EU which, if not resolved, could reduce the scope of the indicated uses of the product, adversely impacting the Group. Successful outcomes from the PneumRx RENEW study and CroFab<sup>®</sup> Copperhead snake studies. There has been a focus during the year on preparing the PMA submission to seek US approval of the PneumRx<sup>®</sup> Coil. That is expected to be submitted by the end of 2016. Vistogard<sup>®</sup> was approved and commercially launched in US. FDA has granted 510k clearance for and the Company has commercially launched a new product in US, LC Bead LUMI<sup>™</sup>.

While progress has been made in a number of areas, the overall level of risk is deemed equivalent to the prior year.

#### **Risk: IP / Legal challenges**

**Details:** BTG may be subject to challenges relating to the validity of its patents or alleging infringement by BTG of intellectual property (IP) rights of others, which might result in cessation of BTG product sales, litigation and/or settlement costs and/or loss of earnings. BTG might elect to sue third parties for their infringement of BTG's IP in order to protect current or future product revenue streams. Litigation involves significant costs and uncertainties. BTG may not be able to secure or maintain the necessary IP in relation to products acquired or in development, limiting the potential to generate value from these products and investments. Patent expiries can adversely impact the Group's revenues due to a resultant increase in competition.

**General mitigation strategy:** Maintenance of the IP group as a core capability of the Group, supplemented by external expertise, which monitors third-party patent portfolios and patent applications and IP rights. Development and implementation of BTG patent filing, defence and enforcement strategies, pursuing litigation or settlement strategies where appropriate. Robust processes are in place to automate patent renewals; internal controls established to avoid disclosure of patentable material prior to filing patent applications and to protect know-how.

**Change in 2015/16:** Currently, BTG earns significant royalties from sales of Johnson & Johnson's Zytiga<sup>®</sup>, which is subject to multiple challenges by manufacturers of generic versions seeking to enter the US and other markets. A third party inter partes review challenge

of one of the core patents protecting Zytiga<sup>®</sup> has also been commenced in the US. In light of the above, generic competition in the US may occur as early as the 2018/19 financial year in US and 2020/21 financial year in EU when the ten-year post-approval data exclusivity period ends. In each case generic competition would substantially reduce the value of Zytiga<sup>®</sup> and the level of royalties received by BTG.

BTG successfully defended the CroFab<sup>®</sup> patent against third party challenge. The commercial exploitation of Varithena<sup>®</sup> may lead to further IP challenges or competition requiring the Group to initiate litigation (for example against potential generic competitors).

Based on the progress of multiple IP strategies the overall risk in this area is assessed to have reduced in aggregate over the year.

### **Risk: Competition**

**Details:** BTG's products may face competition from products that have superior attributes, including better efficacy or side effect profiles, cost less to produce or be offered at a lower price than BTG's products.

The Interventional Medicine bead products compete with products from Merit Medical Limited and CeloNova Biosciences, Inc. (acquired by Boston Scientific in 2015) and TheraSphere<sup>®</sup> competes with a product from Sirtex Medical Limited. Varithena<sup>®</sup> competes with other treatment modalities including heat ablation, vein stripping and physician-compounded sclerosing foam. EkoSonic<sup>®</sup> competes with other interventional clot treatment products from US companies like Boston Scientific Corporation. There is a competitor to PneumRx in the form of the Pulmonx, Inc. valve.

There are currently no competitive products to CroFab<sup>®</sup>, DigiFab<sup>®</sup>, Voraxaze<sup>®</sup> or Vistogard<sup>®</sup> but Instituto Bioclon may launch a competitor product to CroFab<sup>®</sup> around October 2018.

In Licensing, Zytiga<sup>®</sup> competes with a number of other treatments for prostate cancer including Xtandi<sup>®</sup> (enzalutamide).

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

**Change in 2015/16:** We expanded our interventional oncology business into parts of Asia (with direct sales in Taiwan and Hong Kong) including China (via SciClone Pharmaceuticals, Inc.). In Interventional Oncology our previous EU distributor of DC Bead<sup>®</sup> (Terumo) has launched a competing chemoembolization bead product in EU, LifePearl<sup>®</sup>. Our previous US distributor (AngioDynamics) has also announced plans to launch an embolic bead of their own in US.

### **Risk: Healthcare law compliance**

**Details:** Extensive laws and regulations relate to how BTG markets its products and interacts with its customers and payers. Failure to meet applicable requirements may result in criminal or civil proceedings against the Group, exclusion for sale of products in certain territories and material financial penalties or other sanctions against the Group (or their commercial partners, or their respective employees or directors). Defending actual or alleged violations may require significant management time and financial commitment, even if not proven. In July 2014, BTG announced that it had received a subpoena from the US Department of Justice, seeking documents in relation to an investigation regarding LC Bead<sup>®</sup>, covering the period since 2003.

**General mitigation strategy:** A comprehensive compliance programme is in place as referred to above. Ongoing monitoring and auditing is undertaken to seek to ensure any material failures are identified where possible and remediated. The programme is continually reviewed and improved to reflect ongoing learnings and changes to the external environment.

**Change in 2015/16:** PneumRx commercial and other activities have been incorporated into BTG's global compliance programme. BTG continues to enhance its compliance programme. Monitoring data indicates that overall the risk is reducing (but not sufficiently to change overall risk rating), excluding the potential outcome of the US Department of Justice (DOJ) investigation with respect to LC Bead<sup>®</sup> in the US. BTG continues to fully cooperate with the DOJ in relation to the investigation. At this time it is not possible to determine the outcome which could potentially include restrictions on how BTG conducts its business and the imposition of material financial penalties. There can be no guarantee that equivalent investigations will not arise with respect to other parts of the Group or that existing compliance policies and procedures will be accepted as adequate by investigating agencies.