BTG

FY15 results

Right time, right place

Pharma & biotech

BTG's FY15 results demonstrate the strength of its strategy and growth prospects. It is becoming a leader in the growing interventional medicine (IM) market, with a portfolio spanning oncology, vascular and pulmonary products, targeting sales of >$1.25bn in 2021. The investment in the IM franchise is being supported by the strong cash flow from specialty pharmaceutical sales and licensing revenues. We have increased our valuation from $5.06bn to $5.36bn ($14.04/share).

Year end	Revenue ($m)	PTP* ($m)	EPADR ($)	DPADR ($)	P/E (x)	Gross yield (%)
03/14	444.4	117.2	0.29	0.0	38.3	N/A
03/15	562.7	105.0	0.31	0.0	35.9	N/A
03/16e	659.3	138.3	0.30	0.0	37.1	N/A
03/17e	727.8	158.4	0.32	0.0	34.8	N/A

Note: Converted at £0.65/US$. Dividend yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

Strong growth in FY15, with more to come

BTG delivered revenue growth of 27% in FY15. This was boosted by the full year of revenues from last year's acquisitions of Ekos and TheraSphere, but the underlying growth rate was still 21%. This reflects the favorable market dynamics of the IM market and strong execution by BTG. The company has successfully integrated recent acquisitions and continues to penetrate and expand the IM market.

Interventional medicine: A fast-growing niche

Interventional medicine combines medical device and drug technologies to deliver targeted therapies. The markets are relatively small, but fast-growing and with limited competition as they are yet to attract the attention of major pharmaceutical companies. This means that BTG is well placed to benefit from the trend towards more targeted and less invasive therapies.

Investing for the future

BTG's underlying operating margin fell to 18% in FY15 from 23%, even with the benefits of the high-margin specialty pharma division (65%) and royalty streams from its licensed products (30% margin after central costs). This is because BTG is investing heavily in its IM franchises, with a focus on maximizing the long-term value of its product lines, rather than short-term considerations. This is illustrated by the careful launch of Varithena for varicose veins, with BTG ensuring patients and physicians have a good experience with the product.

Valuation: DCF valuation of $5.36bn, $14.04/share

We have increased our sum-of-the-parts DCF valuation by 6% to $5.36bn ($14.04/share) after updating our model with the FY15 results. Our valuation increases to $16.83/share if we raise our estimated peak sales for Varithena from $340m to $500m in line with BTG's target. The company also remains in a strong capital position and able to conduct bolt-on acquisitions as opportunities arise.

28 May 2015

Price	**$11.12**
Market cap	**$4,246m**

*underlying £ price converted at US$1.53 ADR/Ord conversion ratio 1/1

Net cash ($m) at 31 March 2015	112.9
ADRs in issue	381.8
ADR Code	BTGYY
ADR exchange	OTC
Underlying exchange	LSE
Depository	JP Morgan

ADR price performance

Business description

BTG is a UK-based specialist healthcare company with a direct commercial presence with its interventional medicine portfolio and in US acute care medicine. It also received royalties from a number licensing agreements.

Next events

AGM	15 July 2015
H116 results	10 November 2015

Analysts

Dr Mick Cooper	+44 (0)20 3077 5734
Christian Glennie	+44 (0)20 3077 5728
Dr Philippa Gardner	+44 (0)20 3681 2521

healthcare@edisongroup.com

Edison profile page

Update: Right time, right place

In FY15 BTG delivered underlying revenue growth of 21% (at constant currency and adjusted for pro forma 12-month sales of acquired products). This reflects the strength of its strategy and operational execution, including the integration of acquisitions. This provides us with confidence that the company will be able to maintain this strong growth and be able to grow revenues at a CAGR of 14.3% and underlying operating profit by 25.8% over the next six years, as per our forecasts.

The area of interventional medicine is a relatively new area of medicine, which has developed from the demand for more effective and less invasive procedures. The therapies often have the complexity of combining drugs and medical devices in the same product, adding barriers to entry. This is particularly the case as products require the clinical data, which pharmaceutical companies are used to producing, but the sales techniques of medical device companies with reps providing procedural support.

IM is a market that major pharmaceutical companies are yet to focus on, probably because the market is still relatively small compared to those for pharmaceutical products and the different marketing approach, which would probably affect margins. Medical device companies are more interested in IM, but again they only really focus on the major markets, such as interventional cardiology where the market for drug-eluting stents is >$5bn – an area that BTG is not targeting. It does face competition in some areas from companies such as Covidien, but the field of IM is sufficiently new and BTG's products have sufficiently innovative for the company to be able to compete successfully in the fields of oncology, vascular and pulmonary IM (Exhibit 1).

Exhibit 1: BTG's interventional medicine franchises

Business unit	Product	Indication	Notes
Interventional oncology	LC/DC beads	Primary (HCC) and metastatic liver tumours	Embolic drug-eluting polymer bead for transarterial chemoembolization (TACE) treatment of primary liver cancer (hepatocellular cancer, HCC) and liver metastases. Sold direct in the US, Taiwan and Europe (from April 2015), via distributors elsewhere.
	TheraSphere	HCC and metastatic liver tumours	Embolic radioactive (yttrium-90) glass microspheres (20-30 micrometer diameter) for intra-arterial treatment of inoperable HCC and metastatic liver tumors. FDA approval under HDE as radiation therapy for HCC. EU and Canadian approval for HCC and metastatic liver cancer. Marketed direct in the US, Canada and certain EU territories; sold via distributors in some other territories (product currently used in c 200 centers in 15 countries).
Interventional Vascular medicine	EkoSonic	Severe thrombus	EkoSonic Endovascular Device is used to treat severe thrombus (blood clots) including DVT (deep vein thrombosis), PE (pulmonary embolism) and PAO (peripheral arterial occlusion). Combines locoregional approach (controlled and selective infusion of thrombolytics) with ultrasound acceleration (to loosen clot and allow greater penetration of thrombolytic). Marketed directly in US by distributors in Europe and elsewhere.
	Varithena	Varicose veins	FDA approval (November 2013) to treat patients with varicose veins (incompetent veins and visible varicosities of the great saphenous vein system); first commercial patient treated August 2014 under two-phase controlled launch. Potential for indication expansion: aesthetic leg veins, new venous indication. Marketed directly in the US only.
Interventional pulmonary medicine	RePneu	Emphysema	CE mark approved in Europe since 2010, generating sales of c $25m in CY15. A pivotal trial is ongoing in the US, which is fully recruited, and could allow for approval in 2016. Marketed directly in Europe.

Source: BTG, Edison Investment Research

BTG's first foray into IM was into oncology IM with the acquisition on Biocompatibles in January 2011 and was expanded with the purchase TheraSphere in July 2013. Consequently, it is BTG's most established IM franchise and accounts for 67% of total IM revenues in FY15. The combination of the TheraSphere products with the Beads has also meant that it can differentiate itself better from Sirtex, which sells yttrium-90 polymer spheres that compete with TheraSphere. BTG changed its marketing approach last year from being product-centric to being more patient-centric, with the

advantages of the Beads and TheraSphere sold in parallel so that oncologists are better able to select the most appropriate product for their patients. BTG reports that it has started to see the benefit of this approach in the US, although the financial impact has been masked by short-term sales channel disruption in Europe. BTG took over the European marketing of DC Bead and Bead Block from distributors in April 2015, and is now selling them together with TheraSphere, as it does in the US. BTG has also had DC Beads approved in China and commercial plans are underway with its partner SciClone Pharmaceuticals.

BTG entered vascular IM with the acquisition of Ekos at the same time as TheraSphere in July 2013, and launched its internally-developed Varithena for August 2014 (first patient treated). The EkoSonic device, which enables thrombolytic drugs to better penetrate thromboses, remains the main revenue generator in this IM franchise, as BTG is using a two-phase controlled launch for Varithena. This is despite our forecast that in FY21 EkoSonic sales will be $120m (£80m) compared to $331m (£221) for Varithena. The controlled initial phase of the launch is being adopted to ensure that all patients and physicians have a good experience, including with reimbursement. To this end, BTG has established a Varithena Solutions Center; so far 16% of the population has full insurance coverage for the procedure, with temporary drug (J code) and procedure reimbursement (CPT) codes. BTG reports that the product is being well received by patients and physicians, although reimbursement issues are currently slowing adoption as was expected. By the beginning of 2017, BTG hopes to have permanent codes in place with the majority of people covered, at which stage the launch will enter the second phase with revenue growth accelerating; we forecast that Varithena revenues will increase from $61m in FY17 to $136m in FY18.

The company entered the field of interventional pulmonology with the acquisition of PneumRx in January 2015, and now sells RePneu for the treatment of severe emphysema in Europe. The ongoing US trial could result in the product being launched in the US in 2016. The recent results of a French study in 100 patients bode well for the US trial and adoption of RePneu, because the proportion of patients showing an improvement of ≥54m in the six-minute walk test (6MWT) at six months was 36% in the RePneu arm compared to 18% in the standard-of-care group. As with the other indications, BTG only needs a small salesforce (10 reps currently) to sell RePneu to the c 400 interventional pulmonologists in Europe.

BTG is aiming to be a global leader in IM, not just in Europe and the US. To this end, in FY15 it opened an office in Hong Kong to support all commercial and regulatory activity in the Far East, and has a direct sales force in Taiwan.

BTG's other revenue streams – Specialty Pharma and Licensing (Exhibit 2) – are increasingly becoming non-core as the company targets IM revenues of >$1.25bn in 2021. However, the Specialty Pharma and Licensing divisions currently generate strong cash flows that BTG can invest in developing its IM division. The Speciality Pharma division is an efficiently-run standalone division with 19 reps and an operating margin of 65.3%, and the Licensing division has an operating margin of 29.9% after the originators of the licensed products receive their share of the royalties and central operating costs have been deducted.

Exhibit 2: BTG's Specialty Pharma and Licensing divisions

Business unit	Product	Indication	Notes
Specialty Pharma	CroFab	Antivenom	Approved in the US, c 8,000 North American pit viper snake bites pa in US, of which c 5,000 are treated in US emergency departments annually.
	DigiFab	Digoxin antidote	Approved (US, Switzerland, Canada, Australia, UK), c 16m scripts/year; c 1% of pts experience toxicity.
	Voraxaze (glucarpidase)	Treatment for MTX toxicity	Approved US/available elsewhere under named-patient/compassionate use protocols. Licensed to Ohara Pharmaceutical (Japan). Peak sales c US$15m/year in the US, US$25m globally.
	Uridine triacetate	5-FU toxicity	NDA filing expected end 2014. US marketing rights licensed from Wellstat in July 2011. Acquired EU named patient supply rights and option to EU marketing rights in May 2012.
Licensing	Zytiga	mCRPC	Approved for chemo-refractory mCRPC patients (US: April 2011; EU: September 2011) and chemo-naïve patients (US: December 2012; EU: January 2013). Partner: Johnson & Johnson.
	Lemtrada	Multiple sclerosis	EU approval (September 2013) for the treatment of relapsing-remitting MS. Approved in >40 countries. FDA AdCom (November 2013) backed approval for relapsing MS, but not as first-line therapy; FDA approval (November 2014) for relapsing MS in patients with an inadequate response to two or more MS drugs. Us availability will be through a restricted distribution REMS strategy. Originally approved as Campath for B-CLL. Partner: Sanofi.

Source: BTG, Edison Investment Research

Financials

In FY15, BTG's revenues increased by 27% to $562.7m, slightly ahead of our forecast of $545.4m, and with underlying growth of 21% (with pro forma 12-month revenues for acquired products: EkoSonic, TheraSphere and RePneu and at constant currency). This was driven by strong performance by all the divisions. Underlying IM sales grew by 21% to $172.4m, although Bead sales fell 7% because of destocking by distributors in Europe ahead of BTG selling directly. Speciality pharmaceutical sales increased by 22% to $185.3m, largely because of DigiFab sales growing by 65% to $68.4m due to price increases and geographic expansion. Finally, licensing revenues rose by 21% because of continued strong sales growth of Zytiga sales.

Of the three divisions, IM is the only one that we expect will continue to deliver sustained double-digit growth with a CAGR of 32.2% between FY15 and FY21. The specialty pharmaceuticals portfolio is maturing with only uridine triacetate for 5-fluorouracil toxicity expected to be launched in FY17; we forecast a CAGR of 5.7% during the same period; and licensing sales are expected to fall from FY17 as the key US patent covering Zytiga lapses on 13 December 2016.

BTG's underlying operating margin fell from 23% in FY14 to 18% in FY15 as the company invested in the launch of its IM products, prepared for marketing the Bead products in Europe and expanded its operations in Asia. We expect the margin to remain at this level for the next two years with the company continuing to invest in the IM portfolio, before the benefits of operational leverage start to flow through in FY18. We estimate that the operating margin will be 35% in FY21.

After updating our model with the FY15 results (long-term forecast $/£ exchange rate unaltered at $1.50/£), we have amended our estimates, as shown in Exhibit 3. There has been a change in revenue mix, which has led to sales forecasts staying almost unchanged in FY16 and to decrease by 3.4% in FY17; the main changes being lowering sales estimates for Beads by $17.9m to $54.3m in FY16 and by $21.0m to $65.6m in FY17 and increases in sales from DigiFab (by $16.4m to $71.1m and $15.0m to $72.5m in FY16 and FY17 respectively) and Zytiga royalties (by $11.3m in FY16, but a fall of $4.1m in FY17). We have also increased the level of R&D investment by $12.2m in FY16 and $4.3m in FY17 to reflect company guidance.

Exhibit 3: Summary of changes to financial model

	Revenue			PTP			EPADR		
	Old	New	% chg.	Old	New	% chg.	Old	New	% chg.
2016e	657.4	659.3	0.3	161.3	138.3	(14.2)	0.36	0.30	(17.4)
2017e	753.7	727.8	(3.4)	201.2	158.4	(21.3)	0.44	0.32	(26.9)

Source: Edison Investment Research. Note: Revenue and PTP are in $m, EPADR is in $.

BTG remains well capitalized with a cash position of $112.9m and debt-free at FY15. It also has an undrawn $92m RCF so is well placed to continue to conduct its bolt-on M&A strategy to enhance its growth further. The company's focus is increasingly in IM; however, a specialty pharmaceutical product acquisition is also possible. The key considerations are strategic fit and cost, and BTG's past acquisitions demonstrate that the company has a disciplined approach to M&A.

Valuation

As a result of the changes to our model and adjusting the discount factors to reflect the progression of time, we are increasing our valuation of BTG by 6% to $5.36bn or $14.04/share. We summarize our revised valuation in Exhibit 4.

The main upside to our valuation comes from BTG being able to deliver on its target of IM sales of >$1.25bn in FY21. We estimate that the division will generate sales of $902m in FY21, with the main difference between our forecasts and BTG's target being with Varithena ($330m vs >$500m), as we have conservatively excluded the products potential in the cosmetic, non-reimbursed US market and in other geographies. If we assume Varithena achieves peak sales of $500m, our valuation increases to $6.43bn ($16.83/share).

Exhibit 4: Summary of sum-of-the-parts DCF valuation of BTG

Product	DCF ($m)	Partner	Indication	Peak sales/Royalty ($m)	Prob. of success (%)
Specialty Pharma (SP)	**603**				
CroFab		-	Snake anti-venom	104	100%
DigiFab		-	Digoxin tocixity	77	100%
Voraxaze		-	Methotrexate toxicity	32	100%
Uridine triacetate		Wellstat	5-FU toxicity	44	60%
Interventional Medicine (IM)	**1,982**				
DC/LC Bead		Distributors ex-US & EU (from April 2015)	Liver tumours	117	100%
PRECISION Bead		-	Intermediate HCC (Asia)	23	60%
PARAGON bead		-	Third-line mCRC	36	60%
TheraSphere		Distributors ex-US & EU	Advanced HCC, Second-line mCRC	181	100% / 60%*
EkoSonic		Distributors ex-US	Severe blood clots	146	100%
RePneu		Distributors ex-US	Emphysema	210	100%
Varithena		-	Varicose veins - US reimbursed	347	100%
Licensing (LG)	**105**				
Zytiga		J&J	Prostate cancer	170	100%
Lemtrada		Sanofi/Genzyme	Multiple sclerosis	9	100% (EU & US)
Two-part hip cup		Various	Hip replacement	22	100%
Other recurring		Various	-	17	100%
Total DCF	**2,710**				
Terminal value	**3,259**				
R&D	(646)				
Capex	(75)				
Net cash	113				
Total value ($m)	**5,360**				
Value per share ($)	**14.04**				

Source: Edison Investment Research

Exhibit 5: Financial summary

$m	2013	2014	2015	2016e	2017e	2018e
Year-end 31 March	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	357.5	444.4	562.7	659.3	727.8	827.7
COGS/revenue sharing	(102.8)	(145.4)	(175.5)	(197.6)	(212.3)	(227.7)
Gross profit	254.7	299.1	387.2	461.7	515.5	600.0
R&D expenses	(63.0)	(72.2)	(104.5)	(118.7)	(129.0)	(130.8)
SG&A expenses	(88.7)	(128.5)	(190.9)	(221.7)	(248.9)	(290.1)
EBITDA	114.9	113.2	108.8	142.1	158.4	199.9
Op Profit (before amortization and except)	110.1	108.0	100.4	129.9	146.1	187.7
Amortization and impairment	(66.4)	(37.2)	(43.5)	(50.5)	(58.1)	(58.1)
Profit on disposals	0.6	1.7	0.5	0.0	0.0	0.0
Write-offs	(2.8)	0.0	0.0	0.0	0.0	0.0
Restructuring costs	4.9	(22.6)	3.2	0.0	0.0	0.0
Share based payments	(7.2)	(8.1)	(8.6)	(8.6)	(8.6)	(8.6)
Operating Profit	39.3	41.7	52.0	70.8	79.4	121.0
Net Interest	(2.4)	9.2	4.6	8.4	12.2	18.4
Profit Before Tax (norm)	107.7	117.2	105.0	138.3	158.4	206.0
Profit Before Tax (reported)	36.8	50.9	56.6	79.2	91.7	139.3
Tax	(11.8)	(13.8)	10.6	(14.3)	(21.1)	(36.2)
Profit After Tax (norm)	0.0	0.0	0.0	0.0	0.0	0.0
Profit After Tax (reported)	0.0	0.0	0.0	0.0	0.0	0.0
Average Number of Shares Outstanding (m)	326.9	355.2	367.9	381.8	381.8	381.8
EPS - normalized ($)	0.29	0.29	0.31	0.30	0.32	0.40
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	71.2	67.3	68.8	70.0	70.8	72.5
EBITDA Margin (%)	32.1	25.5	19.3	21.6	21.8	24.2
Operating Margin (before GW and except.) (%)	30.8	24.3	17.8	19.7	20.1	22.7
BALANCE SHEET						
Fixed assets	471.2	865.2	1,282.6	1,235.8	1,181.3	1,126.8
Intangible assets	320.1	608.8	914.8	866.4	810.4	754.4
Goodwill	90.6	189.1	281.2	281.2	281.2	281.2
Tangible assets	38.9	47.9	54.3	55.8	57.4	58.9
Investment in associates	21.7	19.4	32.3	32.3	32.3	32.3
Current assets	362.4	223.7	317.6	427.7	539.2	634.0
Stocks	35.6	41.3	62.0	66.8	82.3	106.3
Debtors	83.4	114.9	140.6	151.6	167.4	190.4
Cash	242.8	58.4	112.9	207.1	287.4	335.2
Other	0.6	9.0	2.1	2.1	2.1	2.1
Current liabilities	(100.4)	(134.3)	(176.9)	(171.9)	(189.0)	(214.0)
Creditors	(94.2)	(122.2)	(169.8)	(164.8)	(181.9)	(206.9)
Accruals/deferred income	0.0	0.0	0.0	0.0	0.0	0.0
Employees/provs/tax	(2.8)	(12.1)	(5.7)	(5.7)	(5.7)	(5.7)
Derivative instruments	(3.4)	0.0	(1.4)	(1.4)	(1.4)	(1.4)
Short-term borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Long-term liabilities	(68.4)	(143.1)	(262.7)	(262.7)	(262.7)	(262.7)
Long-term borrowings	0.0	0.0	0.0	0.0	0.0	0.0
Other long-term liabilities	(68.4)	(4.0)	(27.4)	(27.4)	(27.4)	(27.4)
Net assets	664.9	811.5	1,160.7	1,229.0	1,268.8	1,284.2
CASH FLOW						
Operating cash flow	93.3	84.9	95.9	126.2	105.0	122.9
Net interest	1.1	0.3	(0.2)	8.4	12.2	18.4
Tax	(8.4)	(10.7)	(23.3)	(14.3)	(21.1)	(36.2)
Acquisition/disposal of intangibles	(4.0)	3.5	(2.1)	(2.1)	(2.1)	(2.1)
Capital expenditure	(11.6)	(17.7)	(15.0)	(13.8)	(13.8)	(13.8)
Acquisitions/disposals	0.0	(398.3)	(226.0)	0.0	0.0	(41.3)
Financing	0.0	157.1	225.2	0.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.5	(3.5)	(0.3)	(10.2)	0.0	0.0
Net cash flow	70.8	(184.4)	54.3	94.2	80.3	47.8
Opening net debt/(cash)	(172.0)	(242.8)	(58.4)	(112.9)	(207.1)	(287.4)
HP finance leases initiated	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	(0.0)	(0.0)
Closing net debt/(cash)	(242.8)	(58.4)	(112.9)	(207.1)	(287.4)	(335.2)

Source: Edison Investment Research, company accounts

Solely for the convenience of the reader the financial summary table has been converted at a rate of US$1.53/£. BTG reports statutory accounts in pounds. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 9258 1161
Level 25, Aurora Place
88 Phillip St, Sydney
NSW 2000, Australia

Wellington +64 (0)48 948 555
Level 15, 171 Featherston St
Wellington 6011
New Zealand