EDISON

BTG

Outlook post-IMS

Catalysts and core growth

Pharma & biotech

BTG is entering a critical 12-month period marked by multiple catalysts involving its lead internal programmes (Varisolve, Beads) and partnered drugs (Lemtrada). Key near-term catalysts include FY13 results (20 May) and EU (Q213) and US (H213) regulatory decisions on Lemtrada. Continued growth in core direct sales (Specialty Pharma, Interventional Medicine) and Zytiga royalties suggests FY14 revenues of £235m; it also supports our DCF-derived valuation of £1.3bn, or 398p per share, implying 11% upside.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/12	197.0	57.2	14.8	0.0	23.6	N/A
03/13e	229.6	71.4	19.0	0.0	18.4	N/A
03/14e	235.3	62.1	13.0	0.0	26.9	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

Updated model reflects strong core business

BTG's recent pre-close update guided to FY13 revenues of c £230m (prev. £215m) driven by growth in core business activities and one-off effects. We believe c 30% of the £15m guidance uplift came from increased Zytiga royalties, strong sales of Specialty Pharma drugs (c 20%), a CytoFab final payment (c 25%) and favourable FX movements (c 25%). We now forecast FY13 revenues of £229.6m, underlying diluted EPS of 19.7p and period-end cash of £151m. Looking forward, continued growth in Specialty Pharma (+7% y-o-y), Interventional Medicine (+12%) and Zytiga royalties (+38%) suggests FY14 revenues of £235m and underlying EPS of 16.2p.

Zytiga – multiple growth drivers in mCRPC

We expect BTG to receive Zytiga royalties of c £42m in FY13 on sales of $1.1bn by partner J&J. The Q113 uptick in US sales and script growth allays, in our view, concerns about new competition from Medivation/Astellas' Xtandi. We expect the expanded label and ongoing ex-US roll-out to drive continued sales growth in 2013.

Lemtrada – upcoming regulatory catalysts

A positive EU regulatory opinion for Lemtrada in relapsing multiple sclerosis (RMS) in Q213 could lead to EU approval and launch by partner Sanofi in Q313. An FDA decision is expected H213. Phase III extension data reinforce our positive view on Lemtrada's efficacy. However, we continue to believe that a positive benefit-risk decision by the EU regulator hinges on the risk (safety) side of the equation.

Valuation: Fair value of 398p per share

We value BTG at £1.31bn, or 398p per share, based on a DCF analysis of revenues/royalties on marketed products (£737m), probability adjusted estimates for Varisolve (£270m) and Lemtrada (£147m), plus end-FY13 cash of £153m. We continue to view BTG as an attractive investment proposition, with the current share price offering c 11% upside to a valuation underpinned by its core cash-generative business segments and a low-risk profile by biotech standards.

2 May 2013

Price	**350.0p**
Market cap	**£1,149m**
Net debt/cash (£m)	£151m
Shares in issue	328.3m
Free float	68%
Code	BTG
Primary exchange	LSE

Share price performance

%	1m	3m	12m
Abs	(2.1)	4.5	(7.2)
Rel (local)	(2.7)	2.2	(17.6)

52-week high/low 423.0p 300.3p

Business description

BTG is a UK-based biopharmaceutical company with a direct commercial presence in US acute care medicine and interventional oncology. It has a number of internal and partnered R&D programmes.

Next events

FY13 results	20 May 2013
Lemtrada EU regulatory opinion	Q213
PRECISION bead HDE filing	Mid-2013
Lemtrada EU potential approval	Q313

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Edison profile page

Investment summary

Company description

BTG is a UK-based specialty healthcare company with a fast-growing US market presence in specialty pharmaceuticals and interventional oncology, as well as significant and growing royalty interests in developmental-stage and marketed products. The company is organised into three business areas: Specialty Pharmaceuticals (critical care products – antivenoms and antidotes), Interventional Medicine (drug-eluting bead and brachytherapy products) and Licensing & Biotechnology (interests in approved and developmental products, licensed to partners). BTG was formed by the merger of three companies: the pre-2008 BTG, Protherics (acquired in December 2008) and Biocompatibles (acquired in January 2011). It employs c 580 people across sites in the UK, US, Germany and Australia.

Valuation: DCF value of £1.3bn or 398p/share

We value BTG at £1.31bn, or 398p per share, based on a DCF analysis of revenues and royalties on marketed products (£737m), probability adjusted estimates for Varisolve (£270m) and Lemtrada (£147m), plus end-FY13 cash of £153m. We continue to view BTG as an attractive investment proposition, with the current share price offering c 11% upside to a valuation underpinned by its core cash-generative business segments and a low-risk profile by biotech standards.

Sensitivities

BTG is subject to sensitivities common to most specialist healthcare companies, such as potential clinical or regulatory failure of delay, commercialisation risks (launch, uptake, pricing, reimbursement, competition) and reliance on partners. The key stock-specific sensitivities include: (1) potential competition to directly marketed products: CroFab (snake antivenom) may face new competition in the form of Bioclon's Antivipmyn; Drug-eluting beads may face increasing competition from Sirtex's radiation-emitting microspheres; (2) Varisolve is currently under FDA review and failure to secure US approval would negatively affect our valuation; (3) Lemtrada may not be approved in the US and/or Europe, which would reduce our valuation, (4) Zytiga faces increased competition from Medivation's Xtandi and, potentially, Takeda's Orteronal, which could lead to us reducing our revenue/royalty forecasts for the drug; and (5) pipeline products (ie uridine triacetate) may fail in clinical trials or be rebuffed by the regulators.

Financials

Our updated financial model reflects the recent FY13 pre-close update (revenue guidance c £230m), various one-off items (ie foreign exchange movements, CytoFab final payment and release of deferred income) and expected Zytiga royalties (following J&J's reported Q113 sales). For FY13, we forecast revenues of £229.6m (previously £201m), normalised pre-tax profit of £71.4m (previously £49.4m) and underlying diluted EPS of 19.0p (previously 12.5p). Expected end-FY13 cash is £152.5m. For FY14, we project revenues of £235.3m, normalised PBT of £62.1m, and underlying EPS of 13.0p. Projected end-FY14 cash is £182.8m.

BTG datasheet

Exhibit 1: Business segment/principal products

Business unit	Product	Indication	Notes
Specialty Pharma	CroFab	Antivenom	Approved in US, c 8,000 North American pit viper snake bites pa in US, of which c 5000 treated in US emergency departments annually.
	DigiFab	Digoxin antidote	Approved (US, Switz, Canada and 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 $15m/year in the US, $25m globally.
	Uridine triacetate	5-FU toxicity	NDA filing expected mid-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.
Interventional medicine	LC/DC beads	Transarterial chemoembolisation (TACE)	US Humanitarian Device Exemption (HDE) submission planned for PRECISION (doxorubicin bead) in uveal melanoma liver metastases in mid-2013. Targeted US HDE filing in H213 for PARAGON (irinotecan bead) for intrahepatic cholangiocarcinoma (ICC). Potential HDE approval for both PRECISION and PARAGON by year-end 2013. Sold direct in US, via distributors elsewhere: Termuno (EU), Transmedic (SE Asia); Eisai (Japan, filed), Device Technologies (Aus/NZ); SciClone (China, filed Q412). Ten ongoing investigator-led studies of PRECISION in hepatocellular carcinoma (HCC). Two key investigator-led studies of PARAGON for liver metastases from colorectal cancer (mCRC): Paragon II as neoadjuvant therapy (pre-surgery) fully recruited; Paragon Louisville as first-line therapy with systemic chemotherapy (FOLFOX-6 + Avastin) recruitment completed. Planned PRECISION Phase III trial in HCC (downstage for surgery/resection or combination with sorafenib) in Q413. Planned PARAGON Phase III in first-line metastatic colorectal cancer (mCRC) with FOLFOX + Avastin in H114.
	Brachytherapy	Prostate cancer	Radioactive seed implants. Various devices (AnchorSeed, EchoStrand, VariStrand) and radio-isotope (Iodine-125, Palladium-103, Cesium-131) combinations.
	Varisolve	Varicose veins	FDA filing in Feb 2013, accepted for review April 2013, potential US approval and launch H114.
Licensing and biotech	Zytiga	mCRPC	Initial US (April 2011) and EU (September 2011) approvals for chemo-refractory mCRPC patients. Additional approval in US (December 2012) and EU (January 2013) to include chemo-naïve patients. Partner: Johnson & Johnson.
	Lemtrada	MS	EU filing for relapsing multiple sclerosis (RMS) in June 2012, accepted for review in Q312, CHMP regulatory opinion expected Q213. FDA refuse to file letter in August 2012, re-filing accepted in January 2013. Partner: Sanofi.

Source: Edison Investment Research

Exhibit 2: Licensing and biotechnology programmes

Drug/indication	Licensee	Development/notes
Zytiga (abiraterone), mCRPC	J&J	Approved US/EU for chemo-naïve and chemo-refractory metastatic castration-resistant prostate cancer (mCRPC). Patents to 2026.
Lemtrada (alemtuzumab), RRMS	Sanofi	US and EU filings for RMS under review. Originally approved as Campath for B-CLL Patent to 2017.
Two-part hip cup	Various	Prosthetic hip that allows an improved range of motion, helping to avoid dislocation. Licensees include Zimmer, Stryker, Smith & Nephew and Biomet. Patent to 2019.
MRC IP	Various	Multiple partners. Patents (on antibody humanisation) to 2015.
ONYX 0801	Onyx	60-pt Phase I study in pts with advanced solid tumours (completed). Onyx now seeking sub-licensee.
Otelixizumab/ GSK2136525	GSK	30-pt Phase II trial for thyroid eye disease (results: Q213); 40-pt Phase I study in rheumatoid arthritis (results: July 2014). Ongoing 33-pt Phase I study of subcutaneous formulation for Type I diabetes (results: H215).
Nexvax2	ImmusanT	34-pt Phase I study in coeliac disease completed.

Source: Edison Investment Research

Exhibit 3: BTG key catalysts next 12 months (including competitor products)

Date	Product/event	Comment
20 May	BTG FY13 results	Update on company and divisional performance, pipeline programmes and FY14 guidance.
Q213	Lemtrada EU regulatory opinion	CHMP regulatory opinion is expected Q213.
Mid-2013	PRECISION bead HDE filing	US HDE submission for indication of uveal melanoma metastases
H213	PARAGON bead HDE filing	US HDE submission for indication of ICC
Q313	Lemtrada EU potential approval	Positive CHMP opinion in Q213 could lead to EU approval and launch in Q313.
Q313	Xtandi EU potential approval	Positive CHMP in late-April 2013 should trigger EU approval and Launch by Astellas in Q313.
Q413	Lemtrada potential US approval	FDA refuse to file letter in August 2012, re-filing accepted in January 2013, potential FDA approval in H213.
Q413	PRECISION Phase III start in HCC	Planned initiation of one Phase III study in hepatocellular carcinoma (HCC).
Q413	PARAGON and PRECISION HDEs	Potential US HDE approvals for PARAGON and PRECISION beads in ICC and melanoma liver metastases.
Q413	DC Bead Chinese approval	DC Bead submission accepted for SFDA review in October 2012, potential approval by end-2013.
H213	Takeda's Orteronel Phase III data	Potential Phase III results for orteronel in chemo-naïve and chemo-refractory mCRPC.
Q114	Varisolve US approval	Regulatory filing in February 2013, accepted by FDA for review in April 2013, potential US approval in Q114.
Mid-2014	Uridine triacetate US filing.	Targeting NDA submission mid-2014.
H114	PARAGON Phase III start in mCRC	Planned initiation of Phase III study in combination with systemic chemotherapy in unresectable patients.

Source: Edison Investment Research

Update: Catalyst-driven 12 months ahead

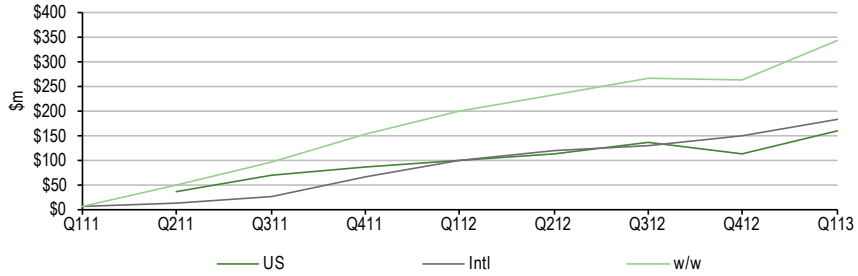
BTG is entering a critical 12-month period marked by multiple catalysts involving its lead internal programme (Varisolve) and partnered products (Lemtrada). The US Varisolve filing is under review with potential approval and launch in H114. Nearer term, potential value inflection points include US HDE approvals for PARAGON and PRECISION Beads plus EU/US regulatory decisions on Lemtrada. As discussed below, we continue to believe that positive benefit-risk decisions by the regulators hinge on the risk (safety) side of the equation. Separately, we highlight Zytiga as an important driver for BTG, with recent label expansions and ongoing ex-US roll-out expected to drive continued sales growth.

Zytiga – multiple growth drivers

US sales dip in Q4 due to stocking effects

J&J's Zytiga (abiraterone acetate), in which BTG holds a c 6% gross (c 3% net) royalty, has posted the most successful oral oncology drug launch in history. As a reminder, Zytiga is a treatment for metastatic castration-resistant prostate cancer (mCRPC) that decreases levels of testosterone (which stimulates tumour growth) by inhibiting the CYP17 enzyme in the testes, adrenal glands and tumour. During 2012, in its first full year on the market, the drug garnered $961m in global revenues (US $463m, ex-US $498m). While ex-US sales have shown continued sequential quarterly growth, US sales declined to $114m in Q412, but rebounded strongly to $161m in Q113 (Exhibit 1).

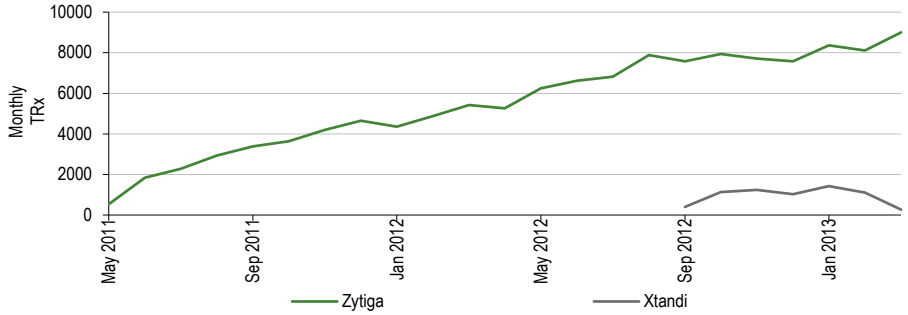
Exhibit 4: Zytiga quarterly sales ($m)



Source: Edison Investment Research, Johnson & Johnson

Medivation/Astella's competing drug, Xtandi, was launched in the US in late-Q3 and delivered Q4 sales of $57m. While it is tempting to ascribe the Q4 sales dip to this new competition, underlying Zytiga prescription data show continued script growth (Exhibit 5). According to J&J, the apparent disconnect between Zytiga US sales and script growth in Q412 (and rebound in Q113) related to replenishment of wholesaler stocks during the quarter (Source: J&J Q113 analyst call).

Exhibit 5: Zytiga and Xtandi total US monthly prescriptions (TRx)



Source: Bloomberg Industries, Symphony Health Solutions. Note: Xtandi prescription data are incomplete and do not provide a representative TRx number.

Expanded label, US market expansion and ongoing ex-US roll-out

Zytiga is currently approved in over 75 countries and was initially approved in the US (April 2011) and EU (September 2011) for mCRPC patients who progress following docetaxel chemotherapy (chemo-refractory setting). Label expansions to include chemo-naïve patients in the US (December 2012) and EU (January 2013) followed results of the 302 Study, where Zytiga delivered a 5.4-month increase in median overall survival versus placebo (HR 0.792, P=0.0151). Before the formal approval for chemo-naïve mCRPC, anecdotal reports suggested Zytiga was widely used "off-label" in this setting. In its Q113 analyst call, J&J attributed the continued growth in global sales to the chemo-naïve label and further ex-US launches, primarily the ongoing EU roll-out. Finally, the company also pointed to continued US market expansion, with over 80% of chemo-refractory patients now seeking treatment, up from 40% at the time of Zytiga's launch.

In April 2013, Germany's drug assessment agency (IQWiG) concluded that Zytiga provides "significant" additional benefit in chemo-naïve patients, paving the way for expanded reimbursement (chemo-refractory setting is already reimbursed) in Europe's largest pharmaceutical market. A final benefit decision from Germany's higher G-BA body is expected in early-July, which should trigger formal reimbursement for chemo-naïve use by the state health insurers (GKV-SV) in H213. We note that Zytiga is one of few drugs to have received a "significant" added benefit rating under Germany's new and challenging AMNOG drug pricing system.

Higher royalties contribute to increased FY13 guidance

BTG receives c 6% gross (c 3% net) royalty on global Zytiga sales for as long as a licensed patent remains in force, which could extend to 2026 (see below). For fiscal 2013 (year ended 31 March), we estimate that BTG will receive gross royalties of c £42m (£21m net) based on J&J's net global sales of $1.1bn over calendar Q213-Q113; this is slightly ahead of Edison's £40m (£20m net) estimate. As noted in BTG's pre-close update, increased Zytiga royalties contributed to the upward revision in FY13 revenue guidance to £230m from £215m.

Expecting further Zytiga sales growth in FY14 and FY15

Looking forward, we expect three major drivers – expanded label, further ex-US launches, US market expansion – to drive continued sequential quarterly growth in Zytiga global sales. Edison currently models Zytiga global net sales of $1.5bn over BTG's FY14 (ie CYQ213 to Q114) rising to $1.7bn in FY15. This translates into estimated FY14 and FY15 royalties of £58m (net £29m) and £65m (net £32m), respectively.

In the context of Zytiga growth drivers, we believe that Xtandi will have a limited impact on the Zytiga sales trajectory in 2013. While the Xtandi label has various advantages (ie once-daily dosing, lack of food effect, no need to co-administer steroids), it offers a comparable overall survival (OS) benefit in chemo-refractory patients (median OS: 4.8 vs 4.6mths, HR 0.63 vs. 0.74), but is priced at a significant premium ($7,450 vs $5,500 per month). In Europe, Xtandi received a positive regulatory opinion for chemo-refractory mCRPC in late-April, which points to European approval and launch in Q313. Finally, Xtandi Phase III PREVAIL data in chemo-naïve patients are still awaited. In April 2013, Medivation announced that the primary number of PFS events had been exceeded, meaning the PFS analysis (plus interim OS analysis) is expected in 2013. An expanded US label is, in our view, achievable by year end 2013 if positive PREVAIL data are delivered this quarter and the FDA grants priority review.

BTG's royalty interest could extend to 2025

BTG receives a royalty on worldwide Zytiga sales for as long as a licensed patent remains in force. These licensed patents include manufacturing process patents that run to 2026. While the key US composition of matter (COM) patent covering Zytiga expires in February 2014, the drug is covered by five-year data exclusivity to April 2016. However, comments by the US PTO suggest a patent

term extension, if granted, could expire in December 2016 (ie during BTG's FY17). J&J refused to comment on its patent extension strategies at the Q113 results, apart from "obviously our teams are working on that." It is, therefore, possible that US exclusivity could extend beyond 2017. In Europe, Zytiga is covered by granted patents, and, more importantly, by data exclusivity through to September 2021.

Lemtrada – upcoming regulatory catalysts

EU regulatory opinion in Q213

Partner Sanofi originally submitted US and EU regulatory filings for Lemtrada (alemtuzumab) to treat relapsing multiple sclerosis (RMS) in July 2012. The EMA accepted the Lemtrada filing and an EU regulatory opinion (from the CHMP) is expected in Q213, which points to potential approval in Q313. The FDA, in contrast, issued a refuse-to-file letter based on a technicality. Specifically, it asked Sanofi to reformat its submission, but critically, did not request further data or new studies. The re-filing was accepted by the FDA in January 2013, which suggests potential approval in H213. As discussed below, we continue to believe that a positive benefit-risk decision by both regulators hinges on the risk (safety) side of the equation.

BTG is entitled to a c 6% gross (c 3% net) royalty on net global sales of Lemtrada, provided the drug successfully navigates the US and/or EU regulators. Edison has modelled a peak sales figure of $1.25bn/year in MS, which could be conservative, for valuation purposes. However, we also note that Sanofi could either price and/or market Lemtrada in such a way as to maximise the value of its overall MS franchise over the longer term. The recent presentation by David Meeker (Genzyme, CEO) suggests that Sanofi is positioning Aubagio (oral tablet) as a "platform" therapy for early-to-moderate MS patients, with Lemtrada (injected therapy) reserved for severe/highly active disease. This strategy could also have implications for BTG, which only receives royalties until 2017.

Filings based on CARE-MS I and II data

Lemtrada filings were based on results of two Phase III studies, which compared the drug to Rebif (interferon beta-1a) in therapy-naïve (CARE-MS I) and experienced patients (CARE-MS II) over two years. Results showed Lemtrada was superior to Rebif in reducing relapse rates (55% CARE-MS I, 49% CARE-MS II) and the risk of sustained accumulation of disability (42% in CARE-MS I). In both trials, Lemtrada was given at a dose of 12mg, via IV administration, eight times over the course, with the first treatment course given on five consecutive days and the second course on three consecutive days 12 months later. Rebif 44mcg was administered by sc injection three times a week throughout the two years of study. In CARE-MS II, a third group of patients received a higher dose of Lemtrada (24mg), given on the same dosing schedule as the lower dose. Key results of the pivotal studies are shown in Exhibit 6.

Exhibit 6: Phase III studies with Lemtrada

Study	Results
840-pt CARE-MS II Phase III trial in treatment-experienced relapsing-remitting MS (RRMS) active on prev. therapy,[1] Pts randomised to Lemtrada (12mg and 24mg) or high-dose Rebif (interferon beta-1a)	Stat. significant reductions in annualised relapse rate (ARR) and six months' sustained accumulation of disability (SAD). 49% reduction in ARR for the 12mg dose (p<0.0001) and a 42% reduction in the risk of SAD, as measured by expanded disability status scale (EDSS) (HR 0.58, p=0.0084). 29% of pts with alemtuzumab six-month showed a reduction in disability, meaning their level of disability improved, as compared to only 13% for Rebif (p=0.0002).
581-pt CARE-MS I Phase III trial in treatment-naive RRMS randomised 2:1 to alemtuzumab (12mg) or Rebif.	55% reduction in ARR at two years (p<0.0001). Not significant on other co-primary end point, time to six-month SAD (HR=0.70, p=0.22). This may reflect the relatively early-stage disease with only a small proportion (8% in alemtuzumab, 11% on Rebif) showing SAD at two years.

Source: Edison Investment Research

[1] Patients had to have experienced >2 relapses within two years of entering the trial, with>1 of these occurring within one year of relapsing remitting multiple sclerosis (RRMS) is the initial stage of the disease, characterised by unpredictable relapses followed by periods (lasting months to years) of remission. Deficits suffered relapses may either resolve or leave sequelae.

Extension data highlights strong efficacy…

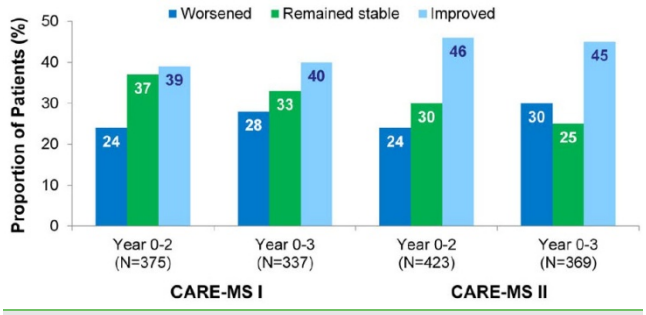
Further compelling efficacy data from the CARE MS extension study, which recruited >90% of patients completing CARE-MS I and II, were presented at the 2013 American Academy of Neurology (AAN) meeting. Patients entering the extension could receive Lemtrada 12mg IV as retreatment (existing Lemtrada patients) or as crossover therapy (former Rebif patients). Encouragingly, efficacy data for Lemtrada-treated patients during extension year 1 showed that: (1) relapse and disability rates remained low; (2) disability levels remained stable or improved; and (3) the majority (c 80%) of patients received no retreatment during year 3 (Exhibits 7 and 8). Efficacy data for Rebif crossovers will be reported after two courses of Lemtrada and two years' follow up.

Exhibit 7: Lemtrada three-year disease activity

	CARE-MS I n=376		CARE-MS II n=435	
	At Year 2	At Year 3	At Year 2	At Year 3
% Relapse-free	78	67	65	55
% Patients SAD-free	92	88	87	80

Source: Fox et al, AAN 2013. Note: SAD = sustained accumulation of disability.

Exhibit 8: Lemtrada three-year disability



Source: Fox et al, AAN 2013

…and increased risk of thyroid disorders

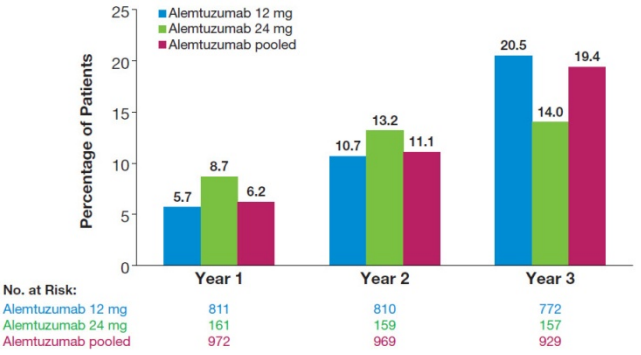
The interim extension data suggest, in our view, robust and durable efficacy for Lemtrada in RRMS. However, they also highlight the potential safety burden in the form of secondary autoimmunity (primarily thyroid disorders, and less frequently, immune thrombocytopenias and kidney disorders). While overall adverse event (AE) profile in the first extension year was similar to those in the core two-year studies, we note that the incidence of thyroid disorders increased from Year 1 to 3, with a cumulative incidence approaching 30% by the end of the third year (Exhibits 9 & 10). This finding mirrors results of the Phase II CAMMS223 study, which also showed delayed onset of thyroid AEs and peak incidence during the third year. The key caveat, however, is that four-year data to confirm this pattern are still awaited from CARE-MS.

Exhibit 9: Incidence of serious thyroid adverse events

System Organ Class Preferred Term	SC IFNB-1a 44 g N=389 n (%)	Alemtuzumab 12 mg N=811 n (%)	Alemtuzumab 24 mg N=161 n (%)	Alemtuzumab Pooled N=972 n (%)
Patients with events	0	6 (0.7)	2 (1.2)	8 (0.8)
Endocrine disorders	0	6 (0.7)	2 (1.2)	8 (0.8)
Hyperthyroidism[a]	0	2 (0.2)	0	2 (0.2)
Hypothyroidism[b]	0	2 (0.2)	1 (0.6)	3 (0.3)
Goiter	0	1 (0.1)	1 (0.6)	2 (0.2)
Thyrotoxic crisis	0	1 (0.1)	0	1 (0.1)
Laboratory investigations	0	1 (0.1)	0	1 (0.1)

Source: Miller et al, AAN 2013

Exhibit 10: Incidence of thyroid adverse events by year



Source: Miller et al, AAN 2013

The vast majority of thyroid disorders (>95%) were mild-to-moderate in severity and, hence, amenable to medical treatment. There were, however, eight serious thyroid AEs that required surgical intervention (thyroidectomy) in three cases and radioactive iodine ablation in two individuals. Given the relatively high incidence of thyroid autoimmunity and rare but potentially serious sequelae (requiring radical therapy), we expect thyroid safety to be a significant focus of the US and EU regulators.

MS competition intensifying…

Taken together, the risk-benefit profile of Lemtrada suggests it could be an effective treatment option for RRMS patients with active disease despite standard disease-modifying therapy. However, if approved, Lemtrada will be launched into an increasingly competitive and dynamic MS market. While established injectable therapies (interferons, Teva's Copaxone, Biogen's Tysabri) still dominate and continue to grow, the market is poised to be re-shaped by the new generation of oral therapies (Novartis's Gilenya, Sanofi's Aubagio, Biogen's Tecfidera).

Launched in Q410, Gilenya achieved blockbuster status in 2012 ($1.2bn) and continues to grow strongly (Q1 sales $421m, +70% q-o-q). However, the drug faces new competition from recently launched Aubagio (Q412) and Tecfidera (Q113). With the caveat that cross-trial comparisons are not scientifically valid, Phase III efficacy data suggest Lemtrada is competitive with the oral agents in terms of reducing relapses (Lemtrada 49-55%, Gilenya 52-54%, Tecfidera 44-54%, Aubagio 31%) and an edge in terms of reducing disability (Lemtrada 42%, Gilenya 25%, Tecfidera 39%, Aubagio 26%). However, whether MS patients would prefer Lemtrada's infrequent (annual) dosing versus a once- or twice-daily oral therapy remains unknown. Finally, it is worth noting that Biogen recently submitted (January 2013) regulatory applications to expand the Tysabri label to include first-line use in MS patients with negative JCV status. An expanded label could see Tysabri become a formidable front-line treatment option.

…and long-term safety is key

The long-term safety of all the new MS agents will be a critical determinant of success, as these drugs require chronic administration (with the possible exception of Lemtrada) to a relatively young population (average age of onset 34 years). All the new agents, including Lemtrada, have (or could have) rare but serious side effects that only materialise after widespread use. For example, Tysabri (2012 sales $1.6bn) is very effective – 67% ARR reduction, 42% reduction disability progression – but associated with an increased risk of progressive multifocal leukoencephalopathy (PML), a rare and potentially lethal brain infection by the JC virus (JCV). However, Biogen's restricted distribution programme and risk stratification (including a JCV test) have reduced the risk of PML.

The new oral therapies are associated with unique and potentially serious AEs. For example, Gilenya is associated with cardiovascular (heart conduction abnormalities), eye (macular oedema) and respiratory (decreased pulmonary function) side effects, which require pre- and post-dose monitoring. Tecfidera received US approval in March 2013 with the cleanest label among the oral MS drugs, with one safety warning (lymphopenia) and minimal monitoring (annual full blood count). However, two recent case reports of PML in European psoriasis patients taking dimethyl fumarate (the active compound in Tecfidera) could raise questions over its long-term safety in MS patients.

Modelling peak sales of $1.25bn

Edison has modelled a peak sales figure of $1.25bn/year in MS, which it considers to be conservative, for valuation purposes. Lemtrada's sales potential may also hinge on its pricing relative to recently launched products (Gilenya $60k/year, Tecfidera $55k/year, Aubagio $45k/year). Sanofi is faced with an unusual pricing issue given the drug's infrequent dosing (two courses over two years) rather than chronic use.

Sanofi has already resolved one pricing issue by withdrawing Campath, which uses the same antibody for B-cell lymphocytic leukaemia (B-CLL), but at much higher doses than the MS indication ($60,000 pricing for B-CLL would translate into $6000 for MS). This will prevent off-label use of Campath for MS and allow Sanofi to command a higher price for the smaller MS dose.

Valuation

We value BTG at £1.31bn, or 398p per share, based on a DCF analysis of revenues/royalties on marketed products (£737m), probability adjusted estimates for Varisolve (£270m) and Lemtrada (£147m), plus end-FY13 cash of £151m. Late-stage pipeline product, uridine triacetate, represents pure upside to our valuation. We view BTG as an attractive investment proposition, with the current share price offering c 11% upside to a valuation that is underpinned by its core cash-generative business areas and a low-risk profile by biotech standards. Looking forward, potential regulatory milestones – Lemtrada approvals, PARAGON and PRECISION HDE approvals, Varisolve US approval – should narrow the discount between the current share price and our DCF valuation.

Exhibit 11: BTG valuation summary

Component	Value (£m)	Notes
Core business (Specialty Pharma/Interventional Medicine/ Licensing & Biotechnology)	737	DCF value with explicit forecast to 2016, terminal value based on 2017. 10% WACC, long-term growth 2%.
Varisolve	270	Assumes a 90% probability.
Lemtrada	147	Assumes 90% probability, peak sales of $1.25bn, 3% net royalty.
Cash	153	Projected fiscal FY13 cash figure.
Total	1,307	

Source: Edison Investment Research

Financials

Our updated model reflects BTG's revised FY13 revenue guidance of c £230m (previously £215m) due to growth in core business activities and one-off effects. We believe c 30% of the £15m revenue beat was due to increased Zytiga royalties, strong sales of Specialty Pharma products (c 20%), a CytoFab termination payment from AstraZeneca (c 25%) and favourable foreign exchange movements (c 25%). We estimate that one-off/non-repeating items contributed revenues of c £27m, which include a £14m final royalty payment from Pfizer on BeneFIX, £9m for the discontinued CytoFab programme (£5.4m release of deferred income, £4m termination payment from AstraZeneca) and £4m from favourable FX. For FY13, we forecast revenues of £229.6m (previously £201m), normalised pre-tax profit of £71.4m (previously £49.4m) and underlying diluted EPS of 19.0p (previously 12.5p). Expected FY13-end cash is £152.5m.

In FY14, we anticipate high-single digit growth (8%) in Specialty Pharma, continued double-digit (12%) growth in Interventional Medicine, and strong growth in Zytiga royalties (38%). As such, we project FY14 revenues of £235.3m, normalised PBT of £62.1m and underlying EPS of 13.0p. Projected end-FY14 cash is £182.8m.

Sensitivities

BTG derives revenue principally from direct product sales and royalty interests in marketed products, sold by third parties. Directly marketed products are primarily used in emergencies and are subject to little actual, or potential, competition. CroFab may face competition at some point and Varisolve, if approved, will have to compete with RF or laser ablation. Zytiga and Lemtrada (if approved, are both competing in highly dynamic markets that make forecasting sales longer term more uncertain. We have modelled what we consider to be a cautious base case, leaving significant potential for upside surprise. Principal risks relate to the success of commercialisation of products, both directly and by partners. The company is exposed to the normal drug development risks (ie the success or failure of clinical trials including those of competitors), regulatory risk and commercial decisions by partners and potential partners, although we consider these to be low by biotech standards.

Exhibit 12: Financial summary

£m	2011	2012	2013e	2014e
Year end 31 March	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	111.4	197.0	229.6	235.3
COGS/revenue sharing	(34.1)	(56.3)	(65.0)	(69.8)
Gross profit	77.3	140.7	164.6	165.5
EBITDA	16.0	57.3	71.4	61.6
Op Profit (before amortisation and except)	13.6	54.1	68.4	58.6
Amortisation and impairment	(19.6)	(30.7)	(43.5)	(17.0)
Profit on disposals	1.5	0.2	0.0	0.0
Write-offs	(1.4)	(0.2)	0.0	0.0
Restructuring costs	(7.3)	(1.1)	0.0	0.0
Share based payments	(0.6)	(2.4)	(2.4)	(2.4)
Operating Profit	(13.8)	19.9	22.5	39.2
Net Interest	3.0	3.1	3.0	3.5
Profit Before Tax (norm)	16.6	57.2	71.4	62.1
Profit Before Tax (reported)	(10.8)	23.0	25.5	42.7
Tax	20.0	(8.4)	(8.4)	(19.0)
Profit After Tax (norm)	36.6	48.8	63.0	43.1
Profit After Tax (reported)	9.2	14.6	17.1	23.7
Average Number of Shares Outstanding (m)	269.0	327.0	328.2	328.3
EPS - normalised (p)	13.6	14.9	19.2	13.1
EPS - normalised and fully diluted (p)	13.5	14.8	19.0	13.0
EPS - reported (p)	3.4	4.5	5.2	7.2
Dividend per share (p)	0.0	0.0	0.0	0.0
Gross Margin (%)	69.4	71.4	71.7	70.3
EBITDA Margin (%)	14.4	29.1	31.1	26.2
Operating Margin (before GW and except.) (%)	12.2	27.5	29.8	24.9
BALANCE SHEET				
Fixed assets	358.9	331.5	295.0	285.0
Intangible assets	271.0	246.0	205.5	191.5
Goodwill	59.2	59.2	59.2	59.2
Tangible assets	24.8	22.0	26.0	30.0
Investment in associates	3.9	4.3	4.3	4.3
Current assets	129.6	174.3	227.1	260.7
Stocks	20.0	21.8	27.9	30.1
Debtors	32.7	40.1	46.7	47.9
Cash	73.9	112.4	152.5	182.8
Other	3.0	0.0	0.0	0.0
Current liabilities	(52.3)	(58.3)	(71.8)	(73.5)
Creditors	(32.2)	(55.4)	(71.8)	(73.5)
Accruals/deferred income	(18.0)	0.0	0.0	0.0
Employees/provs/tax	(2.1)	(2.9)	(2.9)	(2.9)
Derivative instruments	0.0	0.0	0.0	0.0
Short-term borrowings	0.0	0.0	0.0	0.0
Long-term liabilities	(43.9)	(41.3)	(47.9)	(47.9)
Long-term borrowings	(2.9)	0.0	0.0	0.0
Other long-term liabilities	(41.0)	(41.3)	(47.9)	(5.1)
Net assets	392.3	406.2	402.4	424.3
CASH FLOW				
Operating cash flow	(10.7)	48.3	48.3	55.7
Net interest	0.4	0.6	3.0	3.5
Tax	(1.3)	(1.1)	(1.2)	(19.0)
Acquisition/disposal of intangibles	0.2	(6.0)	(3.0)	(3.0)
Capital expenditure	(10.2)	(3.7)	(7.0)	(7.0)
Acquisitions/disposals	14.4	0.0	0.0	0.0
Financing	0.0	0.1	0.0	0.0
Dividends	0.0	0.0	0.0	0.0
Other	(4.0)	0.0	0.0	0.0
Net cash flow	(11.2)	38.2	40.1	30.2
Opening net debt/(cash)	(81.9)	(71.0)	(112.6)	(152.5)
HP finance leases initiated	0.0	0.0	0.0	0.0
Other	0.3	3.4	(0.2)	0.1
Closing net debt/(cash)	(71.0)	(112.6)	(152.5)	(182.8)

Source: BTG, Edison Investment Research

Contact details	Revenue by geography
5 Fleet Place, London EC4M 7RD United Kingdom +44 (207) 575 0000 www.btgplc.com	N/A

CAGR metrics		Profitability metrics		Balance sheet metrics		Sensitivities evaluation	
EPS 10-14e	13%	ROCE 13	N/A	Gearing 13e	N/A	Litigation/regulatory	●
EPS 12-14e	-3%	Avg ROCE 10-14e	N/A	Interest cover 13e	N/A	Pensions	◖
EBITDA 10-14e	45%	ROE 13e	7%	CA/CL 13e	3.2	Currency	◖
EBITDA 12-14e	2%	Gross margin 13e	71.7%	Stock days 13e	44	Stock overhang	○
Sales 10-14e	24%	Operating margin 13e	29.8%	Debtor days 13e	74	Interest rates	○
Sales 12-14e	5%	Gr mgn / Op mgn 13e	2.4	Creditor days 13e	80	Oil/commodity prices	○

Management team

CEO: Dr Louise Makin	CFO: Rolf Soderstrom
CEO since October 2004. Previously at Baxter Healthcare, including as president, biopharmaceuticals Europe (2001-04). Director of Global Ceramics at English China Clays (1998-2000) at ICI (1985-98). Holds an MA in natural sciences and PhD in metallurgy (University of Cambridge) and MBA.	CFO (and board director) since December 2008. Joined as FD of Protherics in August 2007. Previously divisional FD at Cobham (2004-07), director of corporate finance at Cable & Wireless and at PWC.
Chairman: Gary Watts	**EVP, US: Matthew Gantz**
Chairman since January 2012. Also chairman of Spire Healthcare, director of Stagecoach Group and Coca-Cola Enterprises. Formerly CEO of SSL International (2003-10), former NED of Medeva, Celltech and Protherics.	Joined BTG in 2009. Previous experience includes founder/CEO of Acureon Pharmaceuticals, president/CEO of Hydrabiosciences, VP Europe for Chiron's Biopharmaceutical Division (2000-2003), GM for PathoGenesis Europe. NED of Swedish Orphan Biovitrum.

Principal shareholders	(%)
Invesco	29.3%
M&G	12.3%
Axa Framlington	4.6%
Legal & General	3.5%
Standard Life	3.4%

Companies named in this report

Johnson & Johnson (NYSE:JNJ), AstraZeneca (AZN.L), Sanofi (SAN.PA), Astellas (Tokyo: 4503), Medivation (Nasdaq:MDVN), GlaxoSmithKline (GSK.L)

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