

BTG

EU nod for Lemtrada

The positive European regulatory opinion on Lemtrada (multiple sclerosis therapy) points to EU approval in Q313 and potential launch shortly thereafter. The recommended indication represents, in our view, a best case scenario for BTG and partner Sanofi. Separately, an FDA decision on Lemtrada is expected late-2013. With the positive EU opinion adding 10p to our risk-adjusted DCF, our new fair value for BTG is 510p.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
03/12	197.0	57.6	14.9	0.0	24.8	N/A
03/13	233.7	70.4	18.9	0.0	19.6	N/A
03/14e	281.2	63.2	15.7	0.0	23.5	N/A
03/15e	342.5	83.4	17.4	0.0	21.2	N/A

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

Positive EU regulatory opinion on Lemtrada...

The European regulator (CHMP) has recommended that Lemtrada should be approved to treat multiple sclerosis (MS). As a reminder, Lemtrada is partnered with Sanofi/Genzyme and, we estimate, BTG receives a c 6% gross (c 3% net) royalty on global sales until September 2017. The recommended indication 'adult patients with relapsing remitting MS (RRMS) with active disease defined by clinical of imaging features' and dosing 'two annual treatment courses' is consistent with Lemtrada's use in Phase III studies. This represents, in our view, a best case scenario given the lack of other restrictions to use in RRMS patients. Despite this, we expect initial Lemtrada use in more severe patients given the availability of other MS therapies and the potential side effects (autoimmune thyroid disorders).

...Should trigger formal approval in Q313

We anticipate formal EU approval in Q313 and potential launch shortly thereafter. Edison sees Lemtrada sales achieving \$750m (c 40% in EU) in 2016 (BTG's last full year of royalty entitlement) with BTG receiving gross royalties of £29m (£14.5m net) in FY17. However, the key unknown is pricing - Sanofi is faced with an unusual pricing issue given the drug's infrequent dosing (two courses only) rather than chronic use. Separately, the FDA recently extended the review cycle by 3 months, which means a US approval decision is expected late 2013.

Valuation: Fair value of 510p per share

Following the CHMP opinion, we have raised our probability of success on EU Lemtrada sales to 100% (from 80%). We now value BTG at £1.83bn, or 510p per share, based on a probability-weighted, sum-of-the-parts (SOTP) DCF analysis. We value the business segments at £2.06bn, deduct R&D (£208m) and capex (£43m) costs and add net cash (£28m) to arrive at our fair value. Our fair value of 510p per share offers c 40% upside to the current share price and, moreover, is underpinned by a value of 341p for marketed assets. This implies downside protection and potential if the pipeline fails to achieve key data and regulatory milestones.

Positive CHMP opinion

Pharma & biotech

1 July 2013

Price **369.5p**

Market cap **£1,332m**

US\$1.53/£

Net cash (£m) at end Mar 2013 159

Shares in issue 360.5m

Free float 71%

Code BTG

Primary exchange LSE

Share price performance



% 1m 3m 12m

Abs 3.9 3.9 (8.2)

Rel (local) 10.4 5.9 (20.4)

52-week high/low 423.00p 300.30p

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

TheraSphere transaction closes Mid-2013

Lemtrada EU approval Q313

PRECISION Bead HDE filing H213

PARAGON Bead HDE filing H213

Analysts

Dr Mike Aitkenhead +44 (0)20 3077 5736

Robin Davison +44 (0)20 3077 5737

healthcare@edisongroup.com

[Edison profile page](#)

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 5,000 are treated in US emergency departments annually.
	DigiFab	Digoxin antidote	Approved (US, Switzerland, 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 US\$15m/year in the US, 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	Primary (HCC) and metastatic liver tumours	Embolitic drug-eluting polymer bead for transarterial chemoembolisation (TACE) treatment of primary liver cancer (hepatocellular cancer, HCC) and liver metastases. Sold direct in US, via distributors elsewhere: Ternuno (EU), Transmedic (SE Asia); Eisai (Japan, approved Q213), Device Technologies (Aus/NZ); SciClone (China, filed Q412). US Humanitarian Device Exemption (HDE) submission planned for PRECISION (doxorubicin bead) in uveal melanoma liver metastases in H213. Planned US HDE filing for PARAGON (irinotecan bead) in intrahepatic cholangiocarcinoma (ICC) in H213. Potential HDE approvals for PRECISION and PARAGON by year-end 2013. 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) recently completed; Paragon Louisville as first-line therapy with systemic chemotherapy (FOLFOX-6 + Avastin) recruitment completed. Planned start of PRECISION Phase III trial in advanced HCC (combination with sorafenib) during H114. Applied for HUD (Humanitarian Use Device) for PRECISION as bridge to liver transplant and discussing HDE study design with FDA. Planned PARAGON Phase III in first-line metastatic colorectal cancer (mCRC) with systemic chemotherapy (FOLFOX + Avastin) in H114.
	TheraSphere	HCC and metastatic liver tumours	Embolitic radioactive (yttrium-90) glass microspheres (20-30 micrometre diameter) for intra-arterial treatment of inoperable HCC and metastatic liver tumours. FDA approval under HDE as radiation therapy for HCC. EU and Canadian approval for HCC and metastatic liver cancer. Marketed direct in US, Canada and certain EU territories; sold via distributors in some other territories (product currently used in c 200 centres in 15 countries). Three ongoing Phase III studies to seek PMA (pre-market approval) in US: (1) STOP-HCC – unresectable HCC (data H216), (2) EPOCH – colorectal cancer with liver metastases, in patients receiving second-line chemotherapy (data H216), and (3) YES-P – European study in patients with unresectable HCC and portal vein thrombosis (start H213).
	Brachytherapy	Prostate cancer	Radioactive seed implants. Various devices (AnchorSeed, EchoStrand, VariStrand) and radio-isotope (Iodine-125, Palladium-103, Cesium-131) combinations.
	EkoSonic	Severe thrombus	EkoSonic Endovascular Device is used to treat severe thrombus (blood clots) including deep vein thrombosis (DVT), pulmonary embolism (PE) and peripheral arterial occlusion (PAO). Combines locoregional approach (controlled and selective infusion of thrombolytics) with ultrasound acceleration (to loosen clot and allow greater penetration of thrombolytic). US approval (510k) for infusion of fluids (including thrombolytics) into peripheral vasculature and pulmonary artery. EU approval (CE Mark) for infusion of fluids (including thrombolytics) into peripheral vasculature and pulmonary artery (PE with clot burden ≥50% and right heart dysfunction).
	Varisolve	Varicose veins	FDA filing in Feb 2013, accepted for review April 2013, potential US approval and launch H114.
	Licensing and biotech	Zytiga	mCRPC
Lemtrada		MS	EU filing for relapsing multiple sclerosis (RMS) in June 2012, accepted for review in Q312, positive CHMP regulatory opinion in 28 June 2013. FDA refused 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 1: Financial summary

	£m	2012	2013	2014e	2015e
Year end 31 March		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		197.0	233.7	281.2	342.5
COGS/revenue sharing		(56.3)	(67.2)	(87.8)	(104.9)
Gross profit		140.7	166.5	193.4	237.6
R&D expenses		(39.7)	(41.2)	(50.8)	(59.7)
SG&A expenses		(48.9)	(58.0)	(85.1)	(99.5)
EBITDA		57.7	75.1	65.3	86.0
Op Profit (before amortisation and except)		54.5	72.0	62.3	83.0
Amortisation and impairment		(30.7)	(43.4)	(25.0)	(29.0)
Profit on disposals		0.2	0.4	0.0	0.0
Write-offs		(3.0)	(1.8)	0.0	0.0
Restructuring costs		1.3	3.2	(9.0)	0.0
Share based payments		(2.4)	(4.7)	(4.7)	(4.7)
Operating Profit		19.9	25.7	23.6	49.3
Net Interest		3.1	(1.6)	0.9	0.4
Profit Before Tax (norm)		57.6	70.4	63.2	83.4
Profit Before Tax (reported)		23.0	24.1	24.5	49.7
Tax		(8.4)	(7.7)	(7.4)	(20.0)
Profit After Tax (norm)		49.2	62.7	55.9	63.4
Profit After Tax (reported)		14.6	16.4	17.2	29.7
Average Number of Shares Outstanding (m)		327.0	328.2	352.4	360.5
EPS - normalised (p)		15.1	19.1	15.8	17.6
EPS - normalised and fully diluted (p)		14.9	18.9	15.7	17.4
EPS - basic (p)		4.5	5.0	4.9	8.2
EPS - fully diluted (p)		4.4	4.9	4.8	8.2
Dividend per share (p)		0.0	0.0	0.0	0.0
Gross Margin (%)		71.4	71.2	68.8	69.4
EBITDA Margin (%)		29.3	32.1	23.2	25.1
Operating Margin (before GW and except.) (%)		27.7	30.8	22.1	24.2
BALANCE SHEET					
Fixed assets		331.5	302.4	540.0	520.6
Intangible assets		246.0	209.2	439.8	413.4
Goodwill		59.2	59.2	59.2	59.2
Tangible assets		22.0	25.4	32.4	39.4
Investment in associates		4.3	8.6	8.6	8.6
Current assets		174.3	236.9	119.8	155.0
Stocks		21.8	23.3	26.2	28.0
Debtors		40.1	54.5	64.7	78.8
Cash		112.4	158.7	28.5	47.9
Other		0.0	0.0	0.4	0.4
Current liabilities		(58.3)	(65.6)	(68.7)	(82.8)
Creditors		(55.4)	(63.4)	(66.5)	(80.6)
Accruals/deferred income		0.0	0.0	0.0	0.0
Employees/provs/tax		(2.9)	(1.8)	(1.8)	(1.8)
Derivative instruments		0.0	(2.2)	(2.2)	(2.2)
Short-term borrowings		0.0	0.0	0.0	0.0
Long-term liabilities		(41.3)	(47.9)	(47.9)	(47.9)
Long-term borrowings		0.0	0.0	0.0	0.0
Other long-term liabilities		(41.3)	(47.9)	(5.1)	(5.1)
Net assets		406.2	425.8	543.2	545.0
CASH FLOW					
Operating cash flow		48.3	61.0	35.5	51.5
Net interest		0.8	0.7	0.9	0.4
Tax		(1.1)	(5.5)	(7.4)	(20.0)
Acquisition/disposal of intangibles		(6.0)	(2.6)	(2.6)	(2.6)
Capital expenditure		(3.7)	(7.6)	(10.0)	(10.0)
Acquisitions/disposals		0.0	0.0	(253.0)	0.0
Financing		0.1	0.0	106.3	0.0
Dividends		0.0	0.0	0.0	0.0
Other		0.0	0.3	0.0	0.0
Net cash flow		38.4	46.3	(130.2)	19.3
Opening net debt/(cash)		(71.0)	(112.6)	(158.7)	(28.5)
HP finance leases initiated		0.0	0.0	0.0	0.0
Other		3.2	(0.2)	0.0	0.1
Closing net debt/(cash)		(112.6)	(158.7)	(28.5)	(47.9)

Source: Edison Investment Research, company accounts

Edison, the investment intelligence firm, is the future of investor interaction with corporates. Our team of over 100 analysts and investment professionals work with leading companies, fund managers and investment banks worldwide to support their capital markets activity. We provide services to more than 400 retained corporate and investor clients from our offices in London, New York, Berlin, Sydney and Wellington. Edison is authorised and regulated by the Financial Services Authority (www.fsa.gov.uk/register/firmBasicDetails.do?sid=181584). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is not regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244] www.edisongroup.com

DISCLAIMER

Copyright 2013 Edison Investment Research Limited. All rights reserved. This report has been commissioned by BTG and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is not registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE [2013]. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.