EDISON

BTG

Positive CHMP opinion

EU nod for Lemtrada

Pharma & biotech

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.

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

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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	Embolic 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: Termuno (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	Embolic 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	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, 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

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