

5 July 2011

GW Pharmaceuticals

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
09/09	24.1	1.8	1.7	0.0	73.7	N/A
09/10	30.7	5.2	4.1	0.0	30.5	N/A
09/11e	28.9	1.2	1.1	0.0	N/A	N/A
09/12e	27.0	(4.3)	(3.3)	0.0	N/A	N/A

Note: *PBT and EPS exclude intangible amortisation and share-based payments.

Investment summary: German launch

GW Pharmaceuticals' European partner, Almirall, has launched Sativex for multiple sclerosis spasticity in Germany, Europe's largest MS market, triggering a £250,000 milestone. Germany is the third European country in which Sativex is commercially available, and further EU launches are anticipated in Denmark and Sweden before year-end. Progress is also being made with Sativex in other indications – with the second US Phase III cancer pain trial now underway – and the rest of the pipeline, with Phase IIa data from the exploratory metabolic disease studies expected soon.

Sativex: Europe and beyond

International commercialisation of Sativex is on track, with increasing global penetration expected over the next few years as additional regulatory submissions are filed, approvals granted, and launches occur. Near-term EU launches include Denmark and Sweden (2011), with launch in Italy, the Czech Republic and Austria expected next year. Novartis is also expected to file MAAs in 2011 with ex-EU approvals also possible in 2012, including Australia (already filed).

High MS prevalence in northern Europe

Germany and Scandinavia are important markets for Sativex as MS prevalence there is among the highest in Europe; Germany is also the largest MS market in Europe with more than 120,000 patients. GW's prelims in November should provide initial information on the first three months of Sativex's commercial sales in Germany.

Cancer pain: The US opportunity and label extension

Both Sativex Phase III cancer pain trials are now underway, with results expected in 2013. This is the lead indication in the US; and with the Novartis deal, the significant cancer pain opportunity also extends to non-US and non-EU regions. Sativex development in a third, undisclosed, indication is also under consideration.

Valuation: DCF-based valuation of £227m

Our base case DCF valuation of £227m includes forecast Sativex sales by Novartis. Edison acknowledges that significant upside opportunity remains associated with new indications/geographies for Sativex. Furthermore, this valuation does not include GW's earlier-stage R&D projects, which are coming increasingly into focus.

Price 125.25p
Market cap £165m

Share price graph



Share details

Code GWP
Listing AIM
Sector Pharmaceuticals & Biotechnology
Shares in issue 131.5m

Price

52-week High 130.0p Low 83.0p

Balance sheet as at 31 March 2011

Debt/equity (%) N/A
NAV per share (p) 12.6
Net cash (£m) 28.3

Business

GW Pharmaceuticals is a UK company focused on developing cannabinoids as pharmaceuticals. Its lead product, Sativex, is in development for the treatment of neuropathic pain and spasticity associated with MS, cancer pain, and peripheral neuropathic pain.

Valuation

	2010	2011e	2012e
P/E relative	290%	N/A	N/A
P/CF	N/A	N/A	N/A
EV/sales	4.5	4.9	5.5
ROE	42%	9%	N/A

Revenues by geography

	UK	Europe	US	Other
	4.2%	21.0%	60.9%	13.9%

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Exhibit 1: Sativex R&D summary

Indication	Trial design/notes
Spasticity in MS (approved)	Approved for this indication in the UK (launched June 2010), Spain (launched March 2011), Germany (launched July 2011), Canada (Bayer proceeding with reimbursement discussions), New Zealand (Novartis to confirm plans) and Czech Republic (launch in 2012). Further EU approvals sought under MRP (recommended for approval in six EU countries in March 2011, national approvals pending: Almirall anticipates launch in Denmark and Sweden by end-2011 with launches in Italy, Austria and the Czech Republic in 2012). Second MRP to expand EU approval to start H211. Regulatory submissions filed in Australia and Israel and planned in the Middle East and South Africa. Specific indication: symptomatic improvement in pts suffering from spasticity as a result of MS who do not have adequate relief with existing medication.
Cancer pain (Phase III)	Approved for this indication in Canada. Two Phase III studies for relief of persistent pain in advanced cancer ongoing: 380-pt trial (results: Dec 2013) and 380-pt SPRAY III trial (results: Dec 2013). Patients will then enrol in a 760-pt long-term open-label extension trial with sites in Europe, North and Latin America, and Asia (results: Aug 2014). Each of the Phase III trials will have five weeks on low-to-mid dose therapy (3-10 sprays/day) with primary endpoint of continuous-response percentage change from baseline. Possible third Phase III trial under consideration. Cancer pain is the US lead indication (US use patent granted April 2011): submission possible late 2013/early 2014. EU submissions, using the same data, expected at the same time. Prior 360-pt Phase IIb trial in opioid-refractory cancer pain showed sig. improvement ($p < 0.05$) for low-dose (1-4 sprays/day) and mid-dose (6-10 sprays/day) groups and both groups combined: full data should be published in peer reviewed journal in 2011. Likely indication: advanced cancer pts with pain not wholly alleviated with optimised opioid therapy.
Neuropathic pain (peripheral and due to MS)	Approved for neuropathic pain in MS in Canada. 66-patient Phase III demonstrated efficacy in reducing pain ($p = 0.005$) and sleep disturbance ($p = 0.003$) in neuropathic pain in MS. A 339-pt Phase III did not show statistical significance in primary endpoint (30% or greater improvement in VAS), but significant results were seen at equal dosing and in a randomised withdrawal extension study. Two of three Phase III trials in peripheral neuropathic pain completed with statistically significant results.

Source: Edison Investment Research

Exhibit 2: Sativex licensing arrangements

Partner/territory	Financial terms
Bayer HealthCare UK/Canada	£32m total milestones payable, of which £20m has been triggered to date. Transfer price less the manufacturing cost results in a c 30% effective royalty on sales.
Almirall/Europe (ex-UK)	£12m signing fee plus milestones of £30m. £22.5m received (£8m paid on Phase III MS data, £2.5m on first EU launch Spain: £250k due on German launch). Transfer price less manufacturing cost results in a c 25% effective royalty.
Otsuka/US	\$18m signing fee plus \$255m in milestones (\$22m received). Transfer price less manufacturing cost results in a c 20% effective royalty. Otsuka funds all development for cancer pain, additional indications and in any future formulations. Joint oversight of all US clinical development and regulatory activities. GW responsible for clinical development in cancer pain indication, with costs reimbursed. Otsuka has responsibility for all subsequent indications.
Novartis Australia/NZ, Asia (ex-Japan, China/HK), Middle East (ex-Israel/Palestine) and Africa	\$5m upfront payment, plus additional approval and commercial milestones of up to \$28.75m and royalties (Edison assumes mid-teens) on net sales. Novartis holds exclusive commercialisation rights (all indications) and responsibility for regulatory filings. GW responsible for manufacture and supply (structured as COGS plus margin).

Source: Edison Investment Research

Exhibit 3: GW Pharmaceuticals non-Sativex R&D summary

Product/indication	Trial design/notes
GWP42003/GWP42004 THCv:CBD – metabolic syndrome, T2D/NAFLD/anti-psychotic-induced dyslipidaemia	Programme of three exploratory Phase II studies. Two trials ongoing: 50-pt Phase IIa (GWMD1092) exploring activity of 1:1 and 20:1 ratios of GWP42003:GWP42004, and GWP42003 and GWP42004 as single agents in Type 2 diabetes and dyslipidaemia (results: Oct 2011), and 24-pt Phase IIa (GWMD09112) of CBD alone in non-alcoholic fatty liver disease, NAFLD (results: mid-2011). 60-pt Phase II (GWMD09126) trial to start Q411 in antipsychotic-induced dyslipidaemia (in schizophrenic pts). Preclinical models indicate THCv:CBD reduces fasting insulin, leptin and body fat, reduces total cholesterol, and increases energy expenditure and HDL.
Undisclosed oral cannabinoid/inflammation	At least one Phase IIa study planned in inflammation; indication to be confirmed. Positive data in several <i>in vivo</i> models (inhibition of neutrophil chemotaxis, chemically and immunologically induced inflammation, in colon pre-neoplasms) and mouse DNBS induced colitis model. Pilot study with cannabinoid showed improvement on Crohn's disease activity index (36.8% vs 3.5% placebo). 58-pt study of Sativex in rheumatoid arthritis showed significant analgesic effect and reduction in disease activity (Blake et al, 2006).
GWP42006/epilepsy	Covered by Otsuka R&D collaboration. Lead compound selected (GWP2006): IND possible later-2011. Preclinical studies suggest similar efficacy to valproate. Extensive preclinical evaluation ongoing.
THC:CBD/glioma	Covered by Otsuka R&D collaboration. Preclinical studies show synergistic activity of low-dose Sativex with temozolomide in U87MG model, and when orally administered in orthotopic graft models. Mechanism of action: interference with mTOR-mediated suppression of apoptosis.
Cannabinoids (incl. combinations)/other CNS/anti-cancer indications	Covered by Otsuka R&D collaboration. Various cannabinoids (including CBD, CBDV, CBC, CBG, THCA, THCv, CBN) under evaluation as single agents and in combination for other CNS (anti-psychotic, anti-depressant and anxiolytic) and anti-cancer indications. Preclinical studies in various <i>in vivo</i> cancer models (prostate, breast, lung) underway. Preclinical studies in various <i>in vivo</i> cancer models (prostate, breast, lung) underway; positive effects seen in hormone sensitive and triple negative breast cancer.

Source: Edison Investment Research

Valuation

Edison continues to ascribe a base-case valuation of £227m, based on a DCF model to 2020 with a 12.5% cost of capital. More details regarding our valuation and methodology can be found in the Edison Review note '[On a roll](#)' published 23 May 2011.

Sensitivities

With Sativex launched in the UK, Spain and now Germany (and recommended for approval in five other European countries), GW is a much lower-risk proposition than most biotech companies, although it remains subject to certain risks and uncertainties typically associated with drug development. Furthermore, the entirety of its value is currently associated with Sativex. The completion of the regulatory process in the EU removes EU regulatory risk, leaving only the commercial risks associated with pricing and usage of Sativex. The approval has also set a precedent and defined the regulatory pathway for approval of other plant-derived cannabinoid therapeutics in Europe. The key remaining regulatory risk relates to the timing of approval: this and the completion of country-specific pre-launch administrative requirements may affect the timing of launch, either positively or negatively. Various other assumptions have been made in our valuation model, which could vary on both the upside and downside, including the pricing of Sativex (and potentially other cannabinoid products), its market penetration, its use (approved and off-label) for additional indications and its future value from the early stage R&D portfolio, which is currently excluded from the valuation.

Financials

Management expects a small profit for FY11, on account of higher Sativex sales (due to German launch of Sativex), recognition of part of the Novartis upfront payment and lower GW-funded R&D spending (in line with FY10).

Edison's revenue expectations for FY11 include milestones of £5.35m (reflecting the milestones already received and a further £250,000 from the German launch), and £3.8m from the deferred recognition of signature fees (which includes £1.9m from the Novartis \$5m upfront payment). With further Sativex approvals and launches, we expect sales revenue from Sativex to be £3.7m in FY11 and £7.6m in FY12 (in-market sales will be 3-5x higher). Edison continues to expect that the largest single contributor to GW's revenue will be partner-funded R&D: we expect this to be higher than the FY10 figure of £14.8m to reflect the costs of conducting the cancer pain Phase III studies. In line with guidance, we have revised GW's own-funded R&D for FY11 to be in line with FY10 (£7m). Edison forecasts end-FY11 cash of c £23m.

Edison's financial model for GW is shown in Exhibit 4.

Exhibit 4: GW Pharmaceuticals financial model

Year end 30 September	£'000s	2008	2009	2010	2011e	2012e
		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		11,774	24,121	30,676	28,891	27,014
Cost of sales		(249)	(433)	(752)	(1,007)	(2,056)
Gross profit		11,525	23,688	29,924	27,884	24,959
EBITDA		(9,862)	2,114	5,868	1,777	(3,580)
Operating profit (before goodwill and except.)		(10,277)	1,658	5,142	1,077	(4,380)
Intangible amortisation		0	0	0	0	0
Exceptionals		0	0	0	0	0
Share-based payment		(726)	(634)	(630)	(630)	(630)
Operating profit		(11,003)	1,024	4,512	447	(5,010)
Net Interest		809	128	92	75	100
Profit before tax (norm)		(9,468)	1,786	5,234	1,152	(4,280)
Profit before tax (FRS 3)		(10,194)	1,152	4,604	522	(4,910)
Tax		1,974	353	37	221	0
Profit after tax (FRS 3)		(8,220)	1,505	4,641	743	(4,910)
Average number of shares outstanding (m)		120.5	125.0	129.5	130.6	131.5
EPS - normalised (p)		(6.2)	1.7	4.1	1.1	(3.3)
EPS - FRS 3 (p)		(6.8)	1.2	3.6	0.6	(3.7)
Dividend per share (p)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed assets		6,317	7,068	6,776	7,576	9,276
Intangible assets		5,210	5,210	5,210	5,210	5,210
Tangible assets		1,107	1,858	1,566	2,366	4,066
Investments		0	0	0	0	0
Current assets		17,129	22,323	27,216	25,233	18,621
Stocks		503	551	780	1,044	2,132
Debtors		2,572	1,171	1,217	1,235	1,359
Cash		14,054	20,601	25,219	22,953	15,130
Current liabilities		(9,774)	(9,125)	(9,714)	(6,848)	(7,413)
Creditors		(5,363)	(4,531)	(4,594)	(5,651)	(6,216)
Short-term borrowings		0	0	0	0	0
Deferred revenue & advance payments		(4,411)	(4,594)	(5,120)	(1,197)	(1,197)
Long-term liabilities		(15,399)	(13,544)	(11,644)	(10,917)	(9,720)
Long-term borrowings		0	0	0	0	0
Deferred revenue		(15,399)	(13,499)	(11,599)	(10,872)	(9,675)
Other long-term liabilities		0	(45)	(45)	(45)	(45)
Net assets		(1,727)	6,722	12,634	15,044	10,764
CASH FLOW						
Operating cash flow		(9,588)	(571)	3,935	(1,284)	(5,423)
Net interest		821	127	92	75	100
Tax		2,191	1,791	397	221	0
Capex		(440)	(1,061)	(434)	(1,500)	(2,500)
Expenditure on intangibles		0	0	0	0	0
Acquisitions/disposals		0	0	0	0	0
Financing		104	6,261	628	222	0
Dividends		0	0	0	0	0
Net cash flow		(6,912)	6,547	4,618	(2,266)	(7,823)
Opening net debt/(cash)		(20,966)	(14,054)	(20,601)	(25,219)	(22,953)
HP finance leases initiated		0	0	0	0	0
Other		0	0	0	0	0
Closing net debt/(cash)		(14,054)	(20,601)	(25,219)	(22,953)	(15,130)

Source: Edison Investment Research

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