

3 June 2010

GW Pharmaceuticals

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
09/08	11.8	(9.5)	(6.2)	0.0	N/A	N/A
09/09	24.1	1.8	1.7	0.0	71.8	N/A
09/10e	27.6	4.2	3.2	0.0	38.1	N/A
09/11e	27.7	2.3	1.7	0.0	71.8	N/A

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

Investment summary: Cannabinoid potential

First European approval and launch of GW Pharmaceuticals' lead product, Sativex, is anticipated in the UK by end-Q210, and in Spain shortly after in multiple sclerosis spasticity. In the US, Sativex Phase III trials in cancer pain with partner Otsuka are expected to initiate later this year. While it is widely expected that GW will run trials to support future Sativex label extensions, the progress and potential of the earlier stage pipeline is less well appreciated. This may soon change as a Phase IIa study in Type 2 diabetes is planned for H210, and new data from the Otsuka research collaboration, supportive of cannabinoid use in glioma, has been presented.

Sativex MS approvals expected in Q2

UK and Spanish approvals should materialise in Q2, with an immediate UK launch by Bayer. Launch in Spain is subject to pricing decisions. Further EU approvals will be sought under the MRP in H210, with approvals likely in H111. A decision on the Canadian submission for MS spasticity is also expected in H210.

FDA meeting for cancer pain

An end-of-Phase II FDA meeting is scheduled for H210. This will finalise the protocols for the Phase III programme in opioid-refractory cancer pain, expected to start in 2010. The registration programme is likely to comprise two 370-pt trials.

Wider cannabinoid opportunity

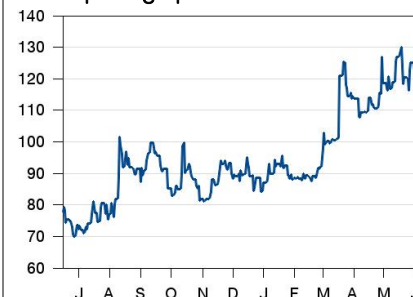
GW will run Phase IIa trials of THC/CBD combinations in metabolic disease; the first trial in Type 2 diabetes will start in Q3, with a second by year-end. Also, preclinical data suggests low dose Sativex with temozolomide could be efficacious in glioma.

Valuation: DCF-based valuation of £197m

Our base case DCF valuation (including cash) is £197m. This applies a 65% development risk to potential cancer pain revenues in the US, and assumes 7% peak market share. Further upside is possible based on greater than expected market share/market growth/price and new indications/geographies for Sativex. This valuation also does not yet include GW's other early-stage R&D projects.

Price 122p
Market cap £158m

Share price graph



Share details

Code GWP
Listing AIM
Sector Pharmaceuticals & Biotechnology
Shares in issue 129.6m

Price

52 week High 130p Low 70p

Balance sheet as at 31 March 2010

Debt/equity (%) N/A
NAV per share (p) 15.7
Net cash (£m) 20.4

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

	2009	2010e	2011e
P/E relative	673%	368%	807%
P/CF	N/A	N/A	N/A
EV/sales	5.5	5.0	5.0
ROE	32%	30%	14%

Revenues by geography

UK	Europe	US	Other
4.7%	5.0%	71.5%	18.8%

Analysts

Robin Davison 020 3077 5737
Lala Gregorek 020 3077 5736
healthcare@edisoninvestmentresearch.co.uk

Investment summary: New indications for Sativex

Company description: Cannabinoid-focused biotech

GW Pharmaceuticals is a UK company entirely focused on R&D into plant-based cannabinoids as pharmaceutical products. Its lead project, Sativex, is awaiting final approval in the UK and Spain for spasticity associated with multiple sclerosis (and has completed its regulatory review). Sativex is also expected to enter Phase III studies in the US for the treatment of opioid-refractory cancer pain.

GW has amassed a considerable body of clinical trial data supporting Sativex. This consists of 10 Phase III studies (four in MS spasticity, one in each central neuropathic pain and bladder symptoms of MS, three in peripheral neuropathic pain and two in cancer pain), multiple Phase II (including a large Phase IIb in cancer pain) and other studies (eg randomised withdrawal). GW has commercial partnerships with Bayer HealthCare, Almirall and Otsuka, which in aggregate have provided c \$60m in signature and milestone fees, with some \$365m in future milestones (largely approval and sales-related) and effective royalties at 20-30%. The company has raised a total of £60m in equity since listing on AIM in 2001 and has tax losses of £43.7m.

Valuation

We indicate a base case valuation of £197m based on a DCF model with 12.5% cost of capital, and including FY10e cash. We acknowledge that this base case valuation may be conservative: we currently assume a 65% development risk to potential cancer pain revenues in the US, and have a current peak market share assumption of 7% in 2020. Pricing is a key sensitivity and we assume Sativex is priced at similar levels to the current named patient basis (Canada C\$125, UK £44 and Spain €75 per 5ml vial), except in the US, where a higher price is assumed. There is upside if GW's partners achieve higher pricing post approval (as is likely), garner higher market share than our current assumption, if other indications are pursued and/or other R&D projects progress.

Sensitivities

GW's business is subject to many of the usual risks associated with biotech companies, particularly product development and regulatory risk, and there is a high single-product risk associated with Sativex. However, the effective completion of the UK/Spanish regulatory process removes the immediate risk of Sativex not gaining approval in the EU, leaving only the commercial risks associated with pricing of Sativex and its uptake (both for approved and off-label) and development of additional indications. The potential of Sativex in indications outside MS and cancer pain (eg glioma) and the value from other early-stage R&D programmes is not included in the valuation.

Financials

GW reported H101 revenue of £11.4m, of which £9.5m related to R&D fees from Otsuka, £0.93m from Sativex sales and £0.95m from the release of signature fees from Sativex partners. The bulk of GW's R&D spend was partner funded, with £2.6m of R&D spending on its own account. This, coupled with lower admin expenses of £1.4m, translated to a £2.7m operating loss and loss after tax. GW's cash balance at the end of the period was £20.4m, and we expect the company to end FY10 with cash of c £21m, following receipt of a £10m milestone from Bayer in H210.

Update: Insight into wider cannabinoid opportunities

In addition to presenting interim results, GW Pharmaceuticals' highlighted expected news flow for the rest of 2010, confirming both timelines for the anticipated first European approvals for Sativex for multiple sclerosis spasticity and that partners were gearing up for launch, also provides additional insights into plans for Sativex beyond MS and the wider cannabinoid pipeline.

GW's lead compound, Sativex, is primarily composed two cannabinoids, THC (delta 9 tetrahydrocannabinol) and CBD (cannabidiol) and is administered as a metered-dose oromucosal spray; each 100µl spray contains 2.7mg of THC and 2.5mg of CBD. These components bind to cannabinoid receptors distributed throughout the central nervous system and in immune cells.

Exhibit 1 summarises the current status of Sativex's development in various indications and the other programmes in GW's R&D portfolio, with GW's licensing arrangements detailed in Exhibit 2.

Exhibit 1: R&D/clinical trial summary

Product/indication	Trial design/notes
Sativex – spasticity in multiple sclerosis	EU filing in UK (reference member state) and Spain (concerned member state): Day 210 Final Assessment Report issued recommending approval. Formal approval should be finalised in Q210 in the UK, with Spain following shortly thereafter, allowing approvals to be sought under mutual recognition procedure (MRP) in other EU countries in H210. MRP approvals expected H111. Also filed in Canada (Nov 2009) and New Zealand, with approval decisions expected H210. Post-UK approval, further submissions expected to be filed (Middle East, Latin America, Africa and Asia). Indication is likely to be for symptomatic improvement in patients suffering from spasticity as a result of MS who do not have adequate relief with existing medications.
Sativex – cancer pain	360-pt Phase IIb trial in opioid-refractory cancer pain shows significant improvement in various measures of pain. End-of Phase II meeting with FDA in H210 to confirm design of studies required for approval. Two Phase III studies of c 370-pts each (five weeks on low-to-mid dose therapy ie 4-10 sprays/day) with primary endpoint of continuous response percentage change from baseline envisaged; these should start recruitment in H210. US submission possible in 2012. EU submissions, using the same data, at the same time. Indication is likely to be for advanced cancer patients with pain not wholly alleviated with optimised opioid therapy.
Sativex – neuropathic pain in MS	66-pt Phase III demonstrated efficacy in reducing pain (p=0.005) and sleep disturbance (p=0.003). 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.
Sativex – peripheral neuropathic pain	Two of three Phase III trials completed with statistically significant results. Two Phase III studies planned after first EU approval for MS spasticity.
THCV: CBD – metabolic syndrome, type 2 diabetes	Multiple-dose, three month 48-pt Phase IIa study (testing THCV and CBD combined at different ratios) in Type 2 diabetics with residual pancreatic function planned for H210. Primary endpoint to concern measures of blood and liver lipid levels. Single-dose Phase I study completed in 12 healthy volunteers, with no tolerability at relevant doses. Preclinical models suggest that THCV: CBD reduces fasting insulin, leptin and body fat, increases energy expenditure, reduces total cholesterol and increases HDL. Second Phase IIa to start H210.
CBD, CBDV, CBC, CBG, THCA, THCV, CBN and others, incl. combinations	Drug candidates under evaluation in collaboration with Otsuka for CNS (anti-psychotic, anti-depressant, anti-epileptic and anxiolytic) and anticancer (antiproliferative, antiangiogenic, proapoptotic, antimigratory) properties. Three-year deal (signed July 2007). First candidate (possibly in a psychiatry indication or epilepsy) could enter clinical trials in 2010. Sativex has shown a synergistic benefit with temozolomide in an <i>in vivo</i> model of glioma and further preclinical studies in other <i>in vivo</i> cancer models (prostate, breast, lung) are currently underway.

Source: Edison Investment Research

Exhibit 2: GW Pharmaceutical licensing arrangements

Partner	Product	Financial terms
Bayer HealthCare	Sativex in UK and Canada	£32m total milestones payable, of which £8m have been received to date. £10m payable on first UK approval (Q210). Transfer price less manufacturing cost results in a c 30% effective royalty on sales.
Almirall	Sativex in Europe (excluding UK)	£12m signature fee plus milestones payments of £30m. £8m paid on EU filing, with £2.5m payable on first EU approval (Spain, on completion of pricing negotiations, assumed Q310). Transfer price less manufacturing cost results in a c 25% effective royalty.
Otsuka	Sativex in US	\$18m signature fee, plus \$255m in milestone payments. 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.
Otsuka	Global cannabinoid R&D collaboration	Otsuka funds evaluation of cannabinoids as drug candidates in cancer and CNS for an initial three-year term. The research agreement reaches the end of its initial three-year term in July 2010, although it is likely to be extended. Initial \$9m of funding to cover GW operating costs and external collaborations. Additional >\$6m committed to specific research activities.

Source: Edison Investment Research

Upcoming, and perhaps under-appreciated, catalysts

GW's shares have performed well since the March announcement that Day 150 of the regulatory process for Sativex in MS spasticity had been reached with no major issues requiring resolution, and the subsequent positive Phase IIb cancer pain results.¹ Investor focus has been on the upcoming approvals and launches for Sativex in the UK and Spain, which trigger £12.5m in combined milestones; however, there are also various additional events taking place during 2010 which could represent further upside, some of which had not previously been disclosed.

Sativex: MS spasticity

The UK approval of Sativex in Q210 should permit GW and European partner Almirall to apply for approval in other European countries via the MRP in H210, with these approvals expected to come though in H111. However, equally importantly, UK approval may also prompt regulatory filings in currently unlicensed territories (including Australia, Latin America, Middle East, South Africa – we highlight that the latter regions effectively recognise a UK approval as sufficient), followed by potential licensing deals for these regions with either new or existing partners (Bayer or Otsuka).

Post-European approval, GW also intends to explore and evaluate the commercial opportunities for Sativex in additional indications, including other symptoms of MS and pain indications.

Sativex: Cancer pain

A post-Phase II FDA meeting has been scheduled for H210, which will allow finalisation of the Phase III protocols for the Sativex cancer pain programme ahead of an anticipated start shortly thereafter. This programme will be run by GW but funded by Otsuka, and it is expected that it will involve two 370-patient dose-ranging trials.

In the completed Phase IIa cancer pain trial, results were analysed according to three methodologies: (1) mean absolute change in Numerical Rating Scale² (NRS) from baseline, (2) the percentage of patients achieving a 30% change from baseline (30% responder analysis), and (3) continuous response analysis. The latter (where all responders are characterised by percentage improvement) has been the key efficacy parameter in the product labelling of several recently approved medicines for pain in the US, and will be the primary endpoint in the Phase III studies.

Given the less favourable tolerability (gastrointestinal and CNS side-effects) seen in the high-dose arm of the Phase IIa study, low-to-mid doses of Sativex (4-10 sprays/day) are likely to be studied in the Phase III trials, with patients finding their own dose.

In-house pipeline: Diabetes/metabolic disease

GW is conducting proprietary research focusing on diabetes, obesity and metabolic syndrome. This has looked primarily at THCv (a neutral CB1 antagonist thought to decrease food intake and increase energy expenditure), CBD (a non-psychoactive compound believed to alter circulating lipid levels and control fat distribution) and combinations thereof. GW will be funding a small scale exploratory Phase IIa programme focused on lipid metabolism and distribution in patients with metabolic diseases. Two trials of THCv/CBD combined at different ratios are expected to start by year-end, the first being a three-month study in Type 2 diabetics with residual pancreatic function

¹ Please see our Update note: *Positive cancer pain data*, published on 25 March 2010, for detailed discussion.

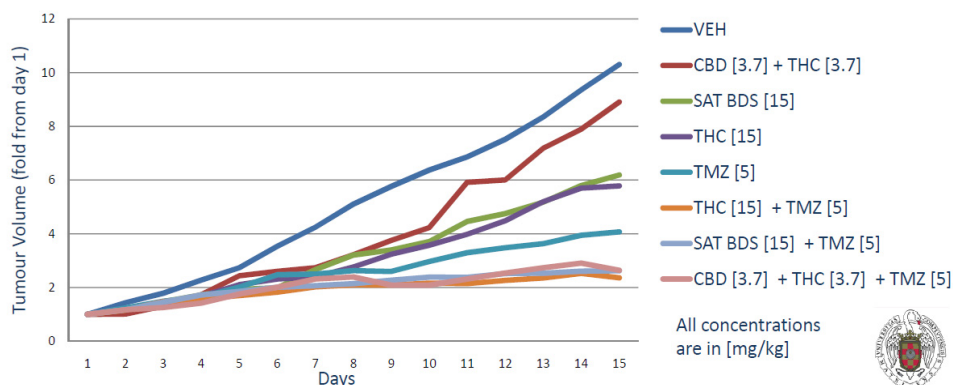
(targeted to start in Q310) exploring the effects of THCv:CBD on dyslipidaemia and fatty liver, with details of the second trial currently undisclosed.

Otsuka collaboration: Opportunities in cancer

GW's relationship with Otsuka covers US Sativex rights, but also a broader global R&D collaboration evaluating GW's library of cannabinoids (derived from its chemovars³) in cancer and CNS. This latter collaboration will likely be extended on reaching the end of the initial three-year term in July 2010. Preclinical *in vitro* and *in vivo* data on cannabinoids in glioma generated under this collaboration were presented at GW's interim results presentation. GW has previously presented data on efficacy of CBD and THCv in preclinical models of psychosis and epilepsy.

Promising *in vitro* glioma data has been confirmed by initial results of the efficacy of cannabinoids in U87MG xenografts (Exhibit 3). The *in vivo* studies support the development of Sativex in combination with temozolomide (TMZ), but also point to comparable efficacy of a lower dose combination of CBD and THC with temozolomide.

Exhibit 3: *In vivo* efficacy of various cannabinoids plus TMZ in a glioma xenograft model



Source: GW Pharmaceuticals, Edison Investment Research

These data provide some scientific rationale for Otsuka to move ahead with clinical development of Sativex in glioma which, as Sativex would be approved by this time, would potentially be a quick process and could add significant value to GW. However, we recognise that Otsuka may decide not to pursue this strategy for various commercial reasons.

In addition to glioma, management has previously disclosed that promising preclinical data regarding efficacy of CBD has been generated in prostate cancer and breast cancer models. Otsuka may pursue further development in any one (or more) of these indications. Under the terms of the Otsuka partnership, the selection of a candidate for full development by Otsuka would trigger a separate licensing deal, with specific terms agreed at the time of selection (presumably including the funding of further development and commercialisation and payment of licence fees, milestones and royalties to GW, as well as committing to a long-term commercial supply price). The first clinical trial under this collaboration could start in 2011-2012.

² The NRS is a well-validated scale, scored by the patient and universally accepted for clinical studies in pain. A score of 0 represents "no pain" while 10 is "worst pain imaginable".

³ Chemovars are plant varieties whose chemical composition varies because of specific breeding and/or different environmental growing conditions. Each of GW's chemovars is responsible for expressing a different cannabinoid, eg, delta 9 THC, delta 8 THC, tetrahydrocannabinol (THCV), cannabidiol (CBD), cannabidivarinol, cannabidivarinic acid, cannabigerol, cannabichromene and others. The cannabinoids produced by each chemovar contribute to what is effectively a proprietary compound library, and this library is being used for early-stage research both in-house and through the Otsuka partnership.

Sensitivities

The approval of Sativex in the UK and Spain significantly reduces the risk associated with GW's investment case. It removes the immediate risk of Sativex not gaining approval in the EU, leaving only the commercial risks associated with pricing of Sativex and its uptake (both for approved and off-label) and development of additional indications. It also sets a precedent, and has defined the regulatory pathway for approval of other cannabinoid therapeutics in Europe.

Various assumptions have been made in our valuation model, which could vary on both the up and the down side, including the pricing of Sativex (and potentially other products); its market penetration; its use (both approved and off-label) for additional indications; and future value from the early stage R&D portfolio, which is currently excluded.

Valuation

We indicate a base case valuation of £197m based on a DCF model with 12.5% cost of capital, and including FY10e cash. We acknowledge that this base case valuation may be conservative: we currently assume a 65% development risk to potential cancer pain revenues in the US (previously 60%), and have a current peak market share assumption of 7% in 2020. Our base case Sativex revenue model is presented in Exhibit 4.

Clinical progress of Sativex in cancer pain in the US should increase our probability of success weighting, which would concomitantly increase our valuation. Clarity on other factors should also increase our valuation. Pricing is a key sensitivity; we assume Sativex is priced at similar levels to the current named patient basis (Canada C\$125, UK £44 and Spain €75 per 5ml vial), except in the US, where a higher price is assumed. Additional upside should arise if GW's partners achieve higher pricing post approval (as is likely), garner higher market share than our current assumption, off-label use is significant (especially within indication but for different symptoms) or if other indications are pursued and/or other R&D projects progress.

Exhibit 4: Base case Sativex revenue model

Note: *at each expected transfer price under each licensing deal; excludes GW's manufacturing cost.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Canada patients with MS spasticity	55,000	60,500	66,550	73,205	80,526	88,578	97,436	107,179	112,538	118,165	124,074
Sativex market share	2.0%	3.0%	5.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%
Cost per patient per year (£)	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353
Sativex sales (Canada; £'000)	2,589	4,271	7,831	12,059	13,265	14,591	16,051	17,656	18,538	19,465	20,439
GW revenue (Canada; £'000)*	1,035	1,708	3,132	4,824	5,306	5,837	6,420	7,062	7,415	7,786	8,175
US mod to sev cancer pain patients	710,667	739,093	768,657	799,403	831,379	864,635	899,220	935,189	972,596	1,011,500	1,051,960
Sativex market share	0.0%	0.0%	0.0%	0.5%	2.5%	5.0%	7.0%	7.0%	7.0%	7.0%	7.0%
Cost per patient per year (£)	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530
Sativex sales (US; £'000)	0	0	0	14,109	73,368	152,605	222,193	231,081	240,324	249,937	259,935
GW revenue (US; £'000)*	0	0	0	3,668	19,076	39,677	57,770	60,081	62,484	64,984	67,583
EU patients with MS spasticity	336,000	352,800	370,440	388,962	408,410	428,831	450,272	472,786	496,425	521,246	547,309
Sativex market share	1.0%	2.0%	3.0%	6.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%	7.0%
Cost per patient per year (£)	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825
Sativex sales (EU; £'000)	6,132	12,877	20,282	42,591	52,174	54,783	57,522	60,398	63,418	66,589	69,919
GW revenue (EU; £'000)*	2,146	4,507	7,099	14,907	18,261	19,174	20,133	21,139	22,196	23,306	24,472
EU cancer deaths per year	1,040,000	1,081,600	1,124,864	1,169,859	1,216,653	1,265,319	1,315,932	1,368,569	1,423,312	1,480,244	1,539,454
Sativex market share	0.0%	0.0%	0.0%	0.5%	2.5%	5.0%	7.0%	7.0%	7.0%	7.0%	7.0%
Cost per patient per year (£)	913	913	913	913	913	913	913	913	913	913	913
Sativex sales (EU; £'000)	0	0	0	5,337	27,755	57,730	84,055	87,417	90,914	94,551	98,333
GW revenue (EU; £'000)*	0	0	0	1,868	9,714	20,206	29,419	30,596	31,820	33,093	34,416
GW total Sativex revenue (£'000)*	3,182	6,216	10,231	25,267	52,357	84,894	113,743	118,879	123,916	129,169	134,646

Source: GW Pharmaceuticals, Edison Investment Research

We expect further guidance on pricing around the time of Sativex launch in the UK and Spain, and at that point we will revise our model if necessary. To illustrate the effect of market share on valuation, we detail a 'better case' revenue model in Exhibit 5. Under the better case, a peak market share assumption of 15% (dependent on geography and indication) would indicate a £427m DCF-based valuation (including cash). Again, we will look to revise our model once Sativex launch trajectories in various markets are established.

Exhibit 5: Better case Sativex revenue model

Note: *At each expected transfer price under each licensing deal; excludes GW's manufacturing cost.

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Canada patients with MS spasticity	55,000	60,500	66,550	73,205	80,526	88,578	97,436	107,179	112,538	118,165	124,074
Sativex market share	2.0%	3.0%	5.0%	7.5%	10.0%	12.5%	15.0%	15.0%	15.0%	15.0%	15.0%
Cost per patient per year (£)	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353	2,353
Sativex sales (Canada; £'000)	2,589	4,271	7,831	12,920	18,950	26,056	34,394	37,834	39,725	41,712	43,797
GW revenue (Canada; £'000)*	1,035	1,708	3,132	5,168	7,580	10,422	13,758	15,133	15,890	16,685	17,519
US mod to sev cancer pain patients	710,667	739,093	768,657	799,403	831,379	864,635	899,220	935,189	972,596	1,011,500	1,051,960
Sativex market share	0.0%	0.0%	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	13.0%	14.0%	15.0%
Cost per patient per year (£)	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530	3,530
Sativex sales (US; £'000)	0	0	0	70,546	146,736	228,908	317,419	412,644	446,316	499,874	557,003
GW revenue (US; £'000)*	0	0	0	18,342	38,151	59,516	82,529	107,288	116,042	129,967	144,821
EU patients with MS spasticity	336,000	352,800	370,440	388,962	408,410	428,831	450,272	472,786	496,425	521,246	547,309
Sativex market share	1.0%	2.5%	5.0%	7.5%	10.0%	12.5%	15.0%	15.0%	15.0%	15.0%	15.0%
Cost per patient per year (£)	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825	1,825
Sativex sales (EU; £'000)	6,132	16,097	33,803	53,239	74,535	97,827	123,262	129,425	135,896	142,691	149,826
GW revenue (EU; £'000)*	2,146	5,634	11,831	18,634	26,087	34,239	43,142	45,299	47,564	49,942	52,439
EU cancer deaths per year	1,040,000	1,081,600	1,124,864	1,169,859	1,216,653	1,265,319	1,315,932	1,368,569	1,423,312	1,480,244	1,539,454
Sativex market share	0.0%	0.0%	0.0%	2.5%	5.0%	7.5%	10.0%	12.5%	13.0%	14.0%	15.0%
Cost per patient per year (£)	913	913	913	913	913	913	913	913	913	913	913
Sativex sales (EU; £'000)	0	0	0	26,687	55,510	86,595	120,079	156,102	168,840	189,101	210,713
GW revenue (EU; £'000)*	0	0	0	9,341	19,428	30,308	42,028	54,636	59,094	66,185	73,749
GW total Sativex revenue (£'000)*	3,182	7,342	14,963	51,484	91,247	134,486	181,456	222,356	238,590	262,779	288,528

Source: GW Pharmaceuticals, Edison Investment Research

GW's current market cap suggests that the market also assumes c 7% peak Sativex market share. However, we highlight that there are currently a number of uncertainties due to the pre-launch stage of Sativex, and clarity on these may represent considerable upside for GW. For example, later in 2010, we would expect more information on timing of upcoming EU launches under the MRP, which could prompt us to upgrade our assumptions.

Financials

GW reported H110 revenue of £11.4m, of which £9.5m related to R&D fees from Otsuka, £0.93m from Sativex sales (which maintained their 74% margin) and £0.95m from the release of signature fees from Sativex partners. The bulk of GW's R&D spend was partner funded, with £2.6m of R&D spending on its own account; the company guided that total GW-funded R&D for the full year was likely to be in line with that of 2009 (ie c £6.8m). This, coupled with lower admin expenses of £1.4m, translated to a £2.7m operating loss and loss after tax. We note that GW does not expect to receive tax credits going forward, but due to significant unutilised tax losses (£43.7m available as of 30 September 2009); we do not expect tax to be paid until around 2014. GW's cash balance at the end of the period was £20.37m, and we expect the company to end the 2010 financial year with cash of c £21m, following receipt of a £10m milestone from Bayer in H210. We have moved our £2.5m Almirall into FY11 following company guidance. In addition, a \$5m milestone from Otsuka is payable on start of Phase III studies in cancer pain – likely in late 2010 (FY11).

Edison's financial model for GW is shown in Exhibit 6.

Exhibit 6: GW financials

Note: 2009 and 2010 revenue includes milestones received and expected under the Bayer and Almirall deals.

	£'000s	2007	2008	2009	2010e	2011e
Year end 30 September		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		5,677	11,774	24,121	27,614	27,660
Cost of sales		(254)	(249)	(433)	(816)	(1,554)
Gross profit		5,423	11,525	23,688	26,798	26,106
EBITDA		(12,059)	(9,862)	2,114	4,421	2,404
Intangible amortisation		0	0	0	0	0
Exceptionals		0	0	0	0	0
Share-based payment		(1,130)	(726)	(634)	(700)	(700)
Operating profit		(13,559)	(11,003)	1,024	3,321	1,304
Net Interest		958	809	128	150	250
Profit before tax (excl intangible amortisation and SBP)		(11,471)	(9,468)	1,786	4,171	2,254
Profit before tax (FRS 3)		(12,601)	(10,194)	1,152	3,471	1,554
Tax		2,015	1,974	353	0	0
Profit after tax (FRS 3)		(10,586)	(8,220)	1,505	3,471	1,554
Average number of shares outstanding (m)		120.1	120.5	125.0	129.5	129.6
EPS - excl intangible amortisation and SBP (p)		(7.9)	(6.2)	1.7	3.2	1.7
EPS - FRS 3 (p)		(8.8)	(6.8)	1.2	2.7	1.2
Dividend per share (p)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed assets		6,292	6,317	7,068	7,668	8,268
Intangible assets		5,210	5,210	5,210	5,210	5,210
Tangible assets		1,082	1,107	1,858	2,458	3,058
Investments		0	0	0	0	0
Current assets		24,316	17,129	22,323	25,003	25,276
Stocks		535	503	551	1,038	2,028
Debtors		2,815	2,572	1,171	2,888	3,177
Cash		20,966	14,054	20,601	21,077	20,071
Current liabilities		(7,646)	(9,774)	(9,125)	(7,087)	(7,606)
Creditors		(4,186)	(5,363)	(4,531)	(5,187)	(5,706)
Short-term borrowings		0	0	0	0	0
Deferred revenue & advance payments		(3,460)	(4,411)	(4,594)	(1,900)	(1,900)
Long-term liabilities		(17,299)	(15,399)	(13,544)	(11,644)	(9,744)
Long-term borrowings		0	0	0	0	0
Deferred revenue		(17,299)	(15,399)	(13,499)	(11,599)	(9,699)
Other long-term liabilities		0	0	(45)	(45)	(45)
Net assets		5,663	(1,727)	6,722	13,940	16,194
CASH FLOW						
Operating cash flow		(1,453)	(9,588)	(571)	973	(256)
Net interest		960	821	127	150	250
Tax		2,022	2,191	1,791	353	0
Capex		(500)	(440)	(1,061)	(1,000)	(1,000)
Expenditure on intangibles		0	0	0	0	0
Acquisitions/disposals		0	0	0	0	0
Financing		62	104	6,261	0	0
Dividends		0	0	0	0	0
Net cash flow		1,091	(6,912)	6,547	476	(1,006)
Opening net debt/(cash)		(19,875)	(20,966)	(14,054)	(20,601)	(21,077)
HP finance leases initiated		0	0	0	0	0
Other		0	0	0	(0)	0
Closing net debt/(cash)		(20,966)	(14,054)	(20,601)	(21,077)	(20,071)

Source: Edison Investment Research, GW Pharmaceuticals accounts

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Lincoln House, 296-302 High Holborn, London, WC1V 7JH ■ tel: +44 (0)20 3077 5700 ■ fax: +44 (0)20 3077 5750 ■ www.edisoninvestmentresearch.co.uk
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