

GW Pharmaceuticals

2015 outlook

High hopes for cannabinoids

Pharma & biotech

10 February 2015

Price **\$74.80**
Market cap **\$1.48bn**

ADR/Ord conversion ratio 1:12

Net cash (\$m) at 31 Dec 2014 238

ADRs in issue 19.7m

ADR Code GWPH

ADR exchange NASDAQ

Underlying exchange LSE

Depository CITI

The expansion of GW Pharmaceuticals' (GW's) cannabinoid portfolio beyond Sativex continues to gather momentum. At the forefront is Epidiolex, poised to enter an extensive Phase III clinical program for two refractory childhood epilepsies, Dravet Syndrome and Lennox-Gastaut Syndrome. With results from one of these studies now due by end-2015, the clinical development timeline of Epidiolex has exceeded our expectations, while also moving ahead of potential competition. Our DCF now stands at \$1.75bn (\$88.51/ADR), ahead of further catalysts in 2015.

Year end	Revenue (US\$m)	PTP* (US\$m)	EPADR (\$)	DPADR (\$)	P/E (x)	Gross Yield (%)
09/13	41.5	(14.8)	(0.47)	0.0	N/A	N/A
09/14	45.7	(27.9)	(1.16)	0.0	N/A	N/A
09/15e	37.5	(65.6)	(2.77)	0.0	N/A	N/A
09/16e	36.6	(64.3)	(2.76)	0.0	N/A	N/A

Note: Converted at £1/US\$1.52 for the table above and throughout the note.

Rapid clinical development with Epidiolex...

GW's primary focus is on the development, and potential commercialization, of Epidiolex (cannabidiol) for Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS), refractory forms of childhood epilepsy that represent an unmet medical need and significant commercial opportunity (\$800m peak sales). With part A of a Phase II/III study design in 34 patients (only two withdrawals) with DS just completed, four Phase III trials of Epidiolex (two in each of DS and LGS) should start by end-Q115. Potential competitor candidates (Insys/Zogenix) will not enter Phase III until H215.

...supported by compelling physician-led data...

The acceleration of Epidiolex's clinical development has come on the back of highly encouraging results from the physician-led, IND treatment program in the US that has so far treated 235 children at 13 clinical sites (many of which will participate in the Phase III studies). Data from 58 patients suffering multiple types of epilepsy (not just DS/LGS), show substantial reductions in seizure frequencies with high responder rates, at least comparable to approved anti-epileptic drugs.

...backed up by fresh opportunities

Further key development milestones for GW's other cannabinoid-based products in 2015 include: Sativex for cancer pain (first Phase III missed primary endpoint but further Phase III data due in H215), GWP42003 for schizophrenia (Phase IIa data by end-2015), and CBDV for adult epilepsy (Phase IIa study initiation in Q115).

Valuation: \$1.75bn (\$88.51/ADR), ahead of catalysts

Our DCF valuation now stands at \$1.75bn or \$88.51/ADR (vs \$1.3bn, \$73/ADR), primarily after increasing the probability of success for Epidiolex to 50% from 20%, as a result of the compelling physician-led data, and acceleration of the clinical program (potential launch now in 2017 vs 2018/19 previously). We note that our \$1.75bn valuation represents fair value, ahead of further potential catalysts in 2015, most notably Phase III results with Epidiolex by the end of the year.

ADR price performance



52-week high/low \$41.9 \$109.0

Business description

GW Pharmaceuticals is a UK-based speciality pharma focused on cannabinoids. Sativex is marketed in various European countries for multiple sclerosis spasticity, and is in Phase III for cancer pain. Lead pipeline candidate is Epidiolex for refractory childhood epilepsy, now entering multiple Phase III studies.

Next events

Epidiolex: start Part B of Phase II/III study in Dravet Syndrome March 2015

Epidiolex: start Phase III studies in DS (1x) and LGS (2x) Q115

Q215 results May 2015

Sativex (cancer pain): results from second Phase III study H215

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Investment summary

Company description: Cannabinoid medicines specialist

Founded in 1998, GW Pharmaceuticals is a UK-based biopharmaceutical company that discovers, develops and commercializes proprietary cannabinoid medicines for a broad range of diseases. Cannabinoids are diverse chemical compounds that GW extracts from different cannabis plant varieties (chemotypes) it has bred. GW's cannabinoid platform generated the world's first plant-derived cannabinoid therapeutic, Sativex, for the treatment of spasticity due to multiple sclerosis (MS), sold by multiple global partners. GW is also developing a broad pipeline of cannabinoid medicines targeting cancer, diabetes and central nervous system (CNS) disorders including epilepsy; the lead – and most valuable – pipeline program is Epidiolex (cannabidiol), which is entering a pivotal Phase III clinical program for Dravet Syndrome (DS) and Lennox-Gastaut Syndrome (LGS), refractory forms of childhood epilepsy. GW listed on AIM in 2001 and the NASDAQ exchange in 2013, where offerings of American depositary shares (ADSs) have raised gross proceeds of approximately \$300m. GW employs approximately 300 staff.

Valuation: \$1.75bn or \$88.51/ADR, ahead of 2015 catalysts

Our DCF-based valuation of GW now stands at \$1.75bn or \$88.51/ADR (previously \$1.3bn or \$73/ADR). This increase results from a number of updates we have made to our model, most importantly increasing our probability of success for Epidiolex in DS and LGS to 50% from 20%, as a result of the compelling expanded access program data, and acceleration of the clinical timeline (potential launch in 2017 vs 2018/19 previously). The bulk of our valuation is now attributable to Epidiolex and is mirrored by investor expectations that have seen GW's stock rise +130% since the program was formally announced in November 2013. We also note that our \$1.75bn (\$88.51/ADR) valuation represents fair value for the stock today, ahead of further potential catalysts in 2015, most notably Phase III results with Epidiolex. For illustration, increasing the probability of success to 65% on positive outcomes from the first Epidiolex study would raise our overall valuation to approximately \$2.17bn or \$110/ADR. Epidiolex also holds wider potential in other refractory forms of childhood epilepsy that we do not currently capture in our model.

Sensitivities: Clinical, regulatory and commercial

GW Pharma is subject to sensitivities common to most biopharmaceutical companies, such as potential clinical or regulatory failure or delay, commercialization risks (launch, uptake, pricing, reimbursement, competition) and reliance on partners. With Sativex launched for MS spasticity in a number of European and international markets, GW is a commercial-stage business and hence a lower-risk investment proposition. However, with funds raised during 2014, GW has renewed its focus on pipeline development, in particular the advancement of Epidiolex as well as investment into various exploratory studies in other indications. The clinical progress with Epidiolex (with initial Phase III data by end-2015) is a key near-term sensitivity.

Financials: Fully funded to execute clinical/commercial plans

GW ended Q115 (31 December 2014) with \$238m in cash, boosted by net proceeds of approximately \$210m from equity financings in 2014. This mainly comprised two separate offerings of ADSs on the NASDAQ exchange (1.96m ADRs sold at \$86.83/ADR in June 2014, and 2.8m ADRs sold at \$36.00/ADR in January 2014). This should provide GW with the resources to fully execute its clinical, manufacturing and commercialization plans for Epidiolex, the primary reason why cash burn is expected to significantly increase in FY15e. GW has guided to total cash outflow in FY15e of \$109m, comprised of c \$76m in operating expenses and \$33m in capex, to support the expansion of manufacturing facilities and capabilities. Cash burn should decrease in FY16e

Outlook: High hopes for cannabinoid pipeline

GW's pipeline breadth was highlighted at its R&D day in October 2014, which also provided an opportunity to update the market on the available clinical data for the refractory childhood epilepsy program, Epidiolex. Epidiolex, a formulation of cannabidiol (CBD), is entering an extensive Phase III clinical trial program in Q115, with four pivotal studies planned in DS and LGS.

Headline data from one of these studies (most likely the already underway Phase II/III trial in DS) are expected by the end of 2015 and will be a key focus for investors this year. Epidiolex is a key near-term valuation driver and positive study outcomes would add upside to our current \$1.75bn valuation. Our model currently only reflects the opportunity within DS and LGS, but we acknowledge that experience from the US Expanded Access Program, where Epidiolex has been used in multiple other types of epilepsies (eg tuberous sclerosis-related epilepsy; febrile infection-related epilepsy syndrome or 'FIREs'), suggests Epidiolex has potential across a spectrum of orphan childhood epilepsies. We look forward to further program updates in 2015, with the prospect that GW will also expand its Epidiolex development plans beyond DS and LGS.

Beyond Epidiolex, key milestones for other pipeline opportunities are also expected in 2015, most notably with: results from the second and third Sativex Phase III studies in cancer pain (first trial missed the primary endpoint); and Phase IIa data from GWP42003 in schizophrenia. We present GW's product portfolio and anticipated pipeline news flow in Exhibit 1.

Exhibit 1: GW Pharmaceuticals' pipeline and expected newsflow

Product	Indication	Cannabinoids (ratio)	Stage	Next news
Sativex	Cancer pain	THC/CBD (1:1)	Phase III	H215: results from 2nd Phase III study (1 st Phase III missed 1ry endpoint). Q415: results from 3rd Phase III study ('enriched' design, >15% responders).
	MS spasticity	THC/CBD (1:1)	US (Phase III); ex-US (marketed)	Q115: FDA grant of SPA for US Phase III study. H215: potential start of US Phase III study (SPA-dependent).
Orphan diseases				
Epidiolex (GWP42003-P)	Dravet syndrome	CBD	Phase II/III	Q115: start part B (n=80) efficacy phase of Phase II/III trial; part A (n=34) dosing/safety cohort complete (two withdrawals); DSMB to determine dose; data expected by end-2015. Q115: initiate 2nd Phase III trial (n=120); data likely in H116.
Epidiolex (GWP42003-P)	Lennox-Gastaut Syndrome	CBD	Phase III-ready	Q115: start two Phase III studies (n=80 + n=120); data likely in H116.
Epidiolex	Childhood epilepsy syndromes (DS + LGS + others)		Expanded access, physician-led, IND treatment program (~400 patients); 235 children treated at 13 clinical sites; data from 58 patients so far; further data expected in 2015 (eg possible additional data from ~100 patients to be presented at the AAN meeting in April 2015).	
GWP42002 / GWP42003	Refractory glioma	THC/CBD (1:1)	Phase Ib/IIa	Phase Ib safety cohort complete; Phase IIa (n=20) efficacy cohort ongoing; recruitment to complete in 2015, results in 2016.
GWP42003 (IV)	Neonatal hypoxic ischemic encephalopathy (NHIE)	CBD	Pre-clinical	Pending application for orphan drug designation.
Non-orphan diseases				
GWP42004	Type II diabetes	THCV	Phase IIb	H216: results from 200-pt dose-ranging Phase IIb study.
GWP42003 (extract)	Ulcerative colitis	CBD/THC (20:1)	Phase IIa	Phase IIa study (n=60) complete: primary endpoint (% remission ≤2 Mayo score) not met; analysis ongoing; next steps to be determined
GWP42003	Schizophrenia	CBD	Phase IIa	H215: results from Phase IIa (n=80) study.
GWP42006	Adult epilepsy	CBDV	Phase IIa-ready	Q115: start Phase IIa trial (n=130).

Source: GW Pharmaceuticals, Edison Investment Research. Notes: THC = tetrahydrocannabinol; CBD = cannabidiol; THCV = tetrahydrocannabivarin; CBDV = cannabidivarin.

Epidiolex – breakthrough potential

The development of Epidiolex, a liquid formulation of highly purified CBD extract, has been rapid and a clear example of the inherent potential within GW's cannabinoid technology platform. This has resulted in the investment case advancing well beyond Sativex, for many years the only significant valuation driver for the stock. In 2014, GW received Orphan Drug and Fast Track designations from the FDA for Epidiolex in the treatment of DS, as well as Orphan Designation from the EMA in Europe. Also in 2014, GW received Orphan Drug designation from the FDA for Epidiolex

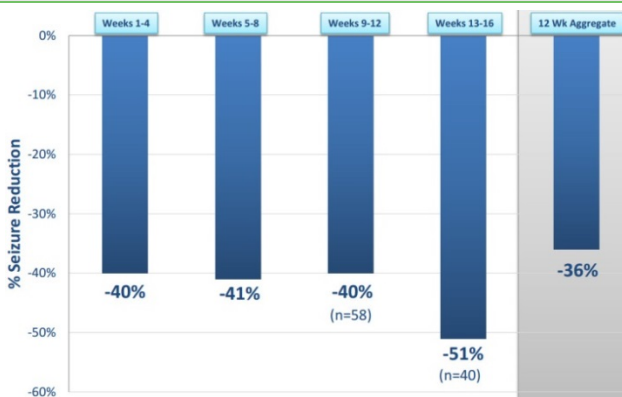
to treat LGS. These designations, coupled with highly encouraging data from an expanded access program in the US (235 children treated across 13 clinical sites), have led to the design of an extensive pivotal clinical study program for Epidiolex in DS and LGS. These trials are all expected to commence in Q115.

Expanded Access Program lends support

The FDA grants expanded access investigational new drug (IND) applications to allow physicians to treat patients with unapproved drugs for indications with a particularly high unmet medical need. Refractory childhood epilepsy is one such setting, and so far the FDA has awarded 20 expanded access INDs to allow physicians to use Epidiolex to treat approximately 410 children (at 17 clinical sites). To date, 235 children have received treatment with Epidiolex across 13 clinical sites in the US. While the data generated from this program are typically classified as anecdotal (when compared to the rigorous assessment of a randomized controlled clinical trial), they do provide an insight into a drug's efficacy and safety.

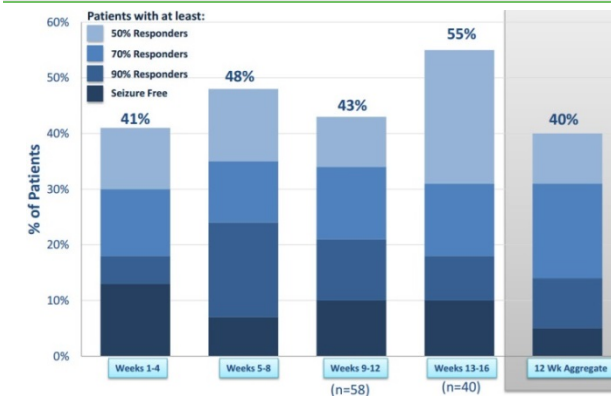
At GW's R&D day in October 2014, the company presented data for all 58 patients that had completed at least 12 weeks of continuous treatment. These patients came from three clinical sites at UCSF (nine patients), NYU (26) and Boston (23). Of these, 40 patients had gone on to complete 16 weeks of continuous treatment, the results for which were also presented. Across all patients (suffering a range of treatment-resistant epilepsies, including extreme and rare forms, eg major congenital structural brain abnormalities) there was a 36% reduction in median seizure frequency, when comparing the four-week average across all 12 weeks with the four-week average at baseline (Exhibit 2). This analysis included all seizures, whether convulsive or non-convulsive. The data were also presented as a responder analysis, showing the proportion of patients achieving responses of greater than or equal to 50%, 70%, 90% or seizure-free (Exhibit 3). A 50% responder would have had at least a 50% reduction in seizure frequency compared to baseline. This responder analysis showed that across all 12 weeks of treatment, 40% of patients (23 of 58) had at least a 50% reduction in seizures.

Exhibit 2: Median % reduction in total seizures (n=58)



Source: GW R&D Day (October 2014); all-patient analysis

Exhibit 3: Responder analysis (all patients; n=58)

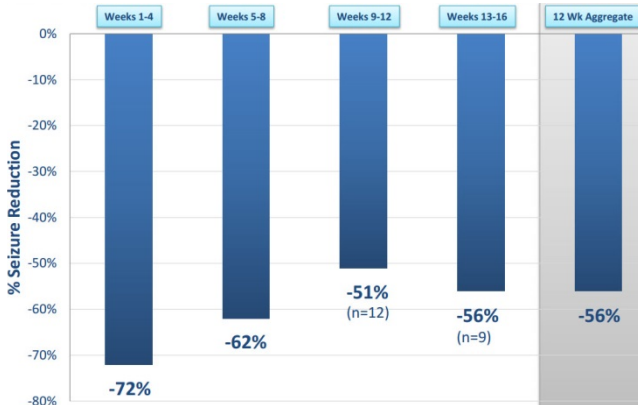


Source: GW R&D Day (October 2014); all-patient analysis

The 'endpoints' used here are relevant in the context of being recognized by the FDA as pivotal study primary efficacy endpoints when approving anti-epileptic drugs. For reference, Lamictal (lamotrigine) is [approved](#) as an adjunctive therapy in pediatric patients with partial seizures on the basis of a 36% median reduction in seizures, compared to 7% on placebo ($p < 0.01$).

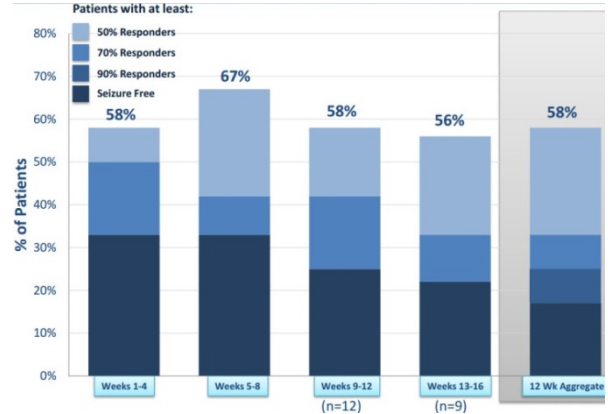
A similar analysis was presented on the 12 patients with DS (average age eight years), which looked only at convulsive seizures. Similarly encouraging results were observed, with a 56% median reduction in seizures over the 12-week period (Exhibit 4), and 58% of patients (7/12) had at least a 50% reduction in seizures (Exhibit 5). Again for reference, Diacomit (stiripentol) was [approved](#) by the EMA for DS on the basis of two relatively small pivotal studies with 67% (8 of 12 patients) and 71% (15/21) of patients with a 50% response rate (vs 5-9% placebo response).

Exhibit 4: Dravet Syndrome (n=12) analysis – median % reduction in convulsive seizures



Source: GW R&D Day (October 2014)

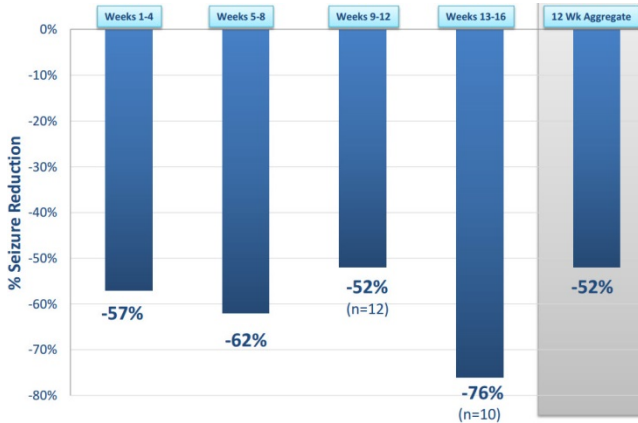
Exhibit 5: Dravet Syndrome (n=12) analysis – responder analysis (convulsive seizures)



Source: GW R&D Day (October 2014); Dravet Syndrome analysis

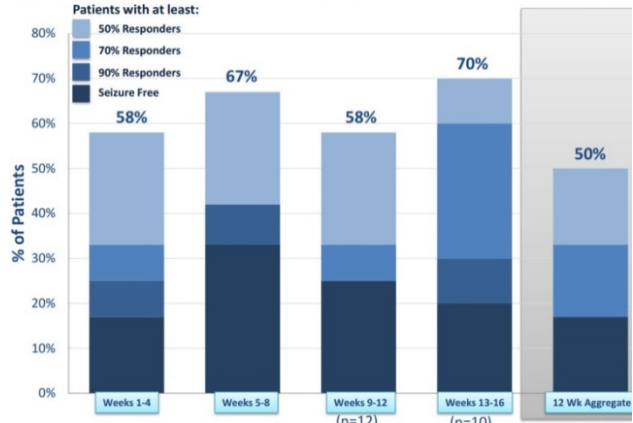
Of particular relevance to LGS, the data also assessed the median reduction in atonic, or ‘drop’, seizures, typically brief lapses in muscle tone that can cause a patient’s head or body to collapse, which can be indicative of LGS. Of the 12 patients with drop seizures at baseline, there was a 52% median reduction in these seizures across the 12-week period (Exhibit 6), and 50% of patients showed a 50% response rate (Exhibit 7).

Exhibit 6: ‘Drop’ seizure (n=12) analysis – median % reduction in seizures



Source: GW R&D Day (October 2014)

Exhibit 7: ‘Drop’ seizure (n=12) analysis – responder analysis



Source: GW R&D Day (October 2014)

Drop seizures are the types of seizures considered by FDA in assessing primary efficacy for LGS studies. For example Lamictal, approved as a treatment for adult and pediatric patients with LGS, significantly reduced drop attacks by 34% compared with 9% on placebo.

The expanded access program also provides an important insight into a product’s safety profile, and GW now has safety data on 151 patients treated with Epidiolex; the 58 patients described above, plus 93 patients yet to report 12-week treatment data. The most common adverse events (AEs occurring in ≥10% of patients and resulting from all causes) were somnolence (19% of patients) and fatigue (11%). Other AEs occurring in ≥5% of patients were diarrhoea, decreased appetite and convulsion. Of these 151 patients, there were two withdrawals from treatment due to adverse events, four withdrawals due to a lack of clinical effect, and 26 (17%) patients reported serious adverse events (SAEs), including two deaths, but none were deemed related to Epidiolex.

Entering pivotal territory

GW is now planning to initiate four Phase III clinical studies with Epidiolex in Q115, two in DS and two in LGS. This clinical development plan in both indications is ahead of previous expectations

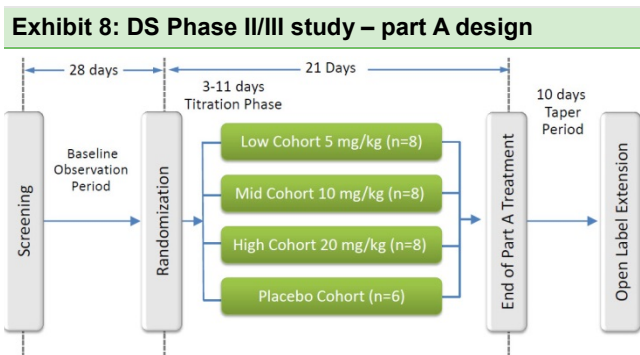
that Phase II studies would be required before launching into pivotal trials. This is undoubtedly a reflection of the need for new treatments in refractory childhood epilepsy and the encouraging data emerging from the expanded access program.

Results from one of these studies (most likely the already underway Phase II/III trial in DS) are expected by the end of 2015. This timeline to completion is also quicker than expected, and reflects the advantages GW has in running these studies at the same epilepsy centers where the physician-led treatment INDs have already been granted. With these physicians and clinical sites already familiar with using Epidiolex, recruitment rates should be improved, and the three sites involved in the early access program have already secured the required DEA license to use Epidiolex (currently classified as a Schedule I drug). With rescheduling of Epidiolex unlikely to happen prior to NDA approval, all clinical sites will require a DEA licence, which can be a protracted process. A number of new centers are undergoing the licensing process.

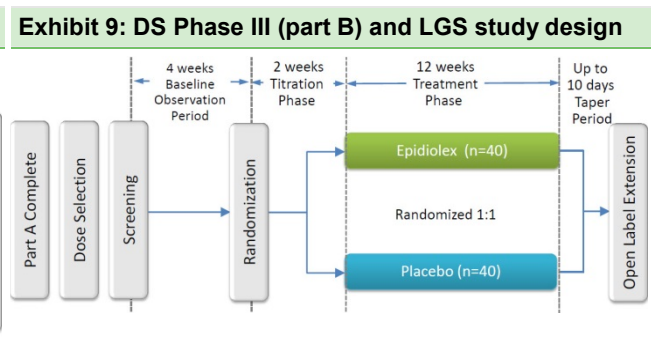
Phase III designs

For DS, a Phase II/III study is underway, with the Phase II ([part A](#)), dose-ranging (5mg/kg; 10mg/kg; 20mg/kg) cohort in 34 patients now complete (Exhibit 8). Each dose cohort was randomized 4:1 for Epidiolex:placebo. For reference, the main doses used to date in the expanded access program range from 2.5mg/kg to 25mg/kg.

Following rapid recruitment of patients, part A of the study has just completed. Of the 34 patients randomized, there were only two withdrawals. An independent data safety monitoring board (DSMB) will now review the data and select the most suitable single dose to be used in the Phase III ([part B](#)) portion, as a double-blind, placebo-controlled design in 80 patients (Exhibit 9). GW currently expects the high dose (20mg/kg) will be acceptable for the Phase III efficacy cohort. The primary efficacy endpoint is the mean percentage change from baseline (four-week observation period) in convulsive seizure frequency, after 14 weeks (2 weeks titration; 12 weeks maintenance) of treatment with Epidiolex. There are multiple secondary efficacy outcomes, including: responder rate (% patients with a ≥50% reduction in seizures), change in seizure subtypes, % patients who are seizure free, use of rescue medication, and improvements in various quality-of-life/daily-living assessments. All patients who complete the study will be eligible to receive Epidiolex under a long-term open label extension study.



Source: GW investor presentation (January 2015)

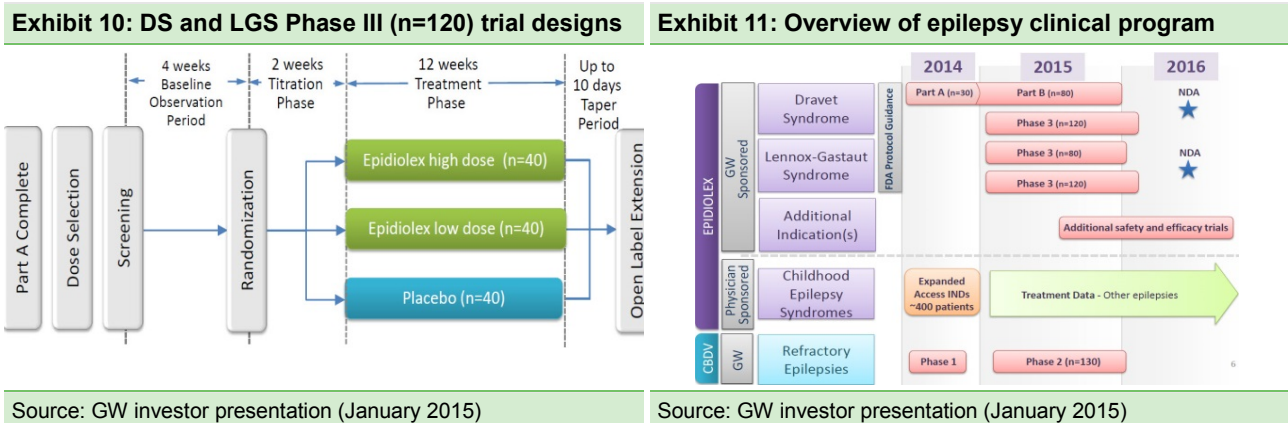


Source: GW investor presentation (January 2015)

For LGS, the [first](#) of the Phase III studies will use the same design as part B of the Phase III study in DS (Exhibit 9). The dose selected will also be determined by the outcome of part A in the DS study; the only significant difference between the studies is the primary efficacy endpoint, which for LGS will be the mean percentage change from baseline in drop seizure frequency (weekly average) during the 12-week maintenance period.

The second Phase III studies in both [DS](#) and [LGS](#) have the same design (Exhibit 10). The studies will be slightly larger (120 patients), although the Epidiolex treatment cohort will be divided into low and high dose groups (40 patients in each). The same primary (seizure reduction; convulsive in DS,

drop in LGS) and secondary endpoints will be used as in the first Phase III study designs. Exhibit 11 summarizes GW's overall clinical program in epilepsy.



GWP42006 (CBDV) – a second epilepsy opportunity

GW's second epilepsy product candidate, GWP42006, contains CBDV, which is structurally related to CBD¹ and has shown encouraging anti-epileptic activity in relevant pre-clinical models.² A [66-patient](#) Phase I safety study in healthy adult volunteers has successfully completed. CBDV was well tolerated even at the highest dose (up to 400mg twice daily), no serious or severe adverse events were reported, and there were no withdrawals due to adverse events.

GW is now planning to initiate a Phase IIa study in approximately 130 adult epilepsy patients in Q115. This study is expected to be a dose-ranging, proof-of-concept design, focused on demonstrating safety and efficacy (partial onset seizures) and dose-selection for further clinical investigation.

Refractory childhood epilepsy

Epilepsy is the most common neurological condition reported in children, and is particularly debilitating when seizures are poorly controlled. DS and LGS are two forms of childhood epilepsy that are difficult to manage and often refractory to anti-epileptic drugs (AEDs).

DS is a rare form, characterized by severe, intractable seizures that begin in infancy. Affected children go on to develop cognitive, behavioral and motor impairment. The majority of children (70-80%) have a mutation in the SCN1A gene, which is part of a gene cluster that encodes voltage-gated sodium channels. Pre-clinical data suggest that SCN1A mutations result in abnormal functioning of sodium channels in the brain, which leads to decreased activity of inhibitory (GABAergic) neurons and contributes to seizure generation.³ Seizures in DS are usually refractory to AEDS. Valproic acid is typically used as a first-line agent, with add-on therapies including stiripentol (Diacomit), topiramate, clobazam and levetiracetam. Stiripentol was approved as an orphan drug in Europe (2007) as adjunctive therapy to valproate and/or clobazam. In the US, stiripentol has orphan status but is not in active clinical development.

LGS is a very severe variety of childhood epilepsy, characterized by tonic (stiffening) and atonic (drop) seizures that begin in infancy and can lead to progressive mental retardation. The seizures are hard to control and the syndrome can persist into adult years, requiring life-long treatment. Treatment is difficult, because the seizures often do not respond to seizure medications or AEDs. Partial relief of seizures, and falls and injuries from seizures, may be obtained by valproic acid, lamotrigine (Lamictal), topiramate, felbamate, clonazepam, rufinamide and clobazam.

1 CBD has a propyl side chain while CBDV has a pentyl side chain.
 2 Hill et al, Br J Pharmacol 2012;167(8):1629-42.
 3 Escayg et al, Epilepsia 2010 September;51(9):1650-1658

The market opportunity – c 42,000 addressable DS and LGS patients

The incidence of DS ranges from 1:20,000 to 1:40,000 births, which suggests an overall disease prevalence of c 5,500 patients in the US and 6,700 European patients. We assume that the majority (c 90%) are diagnosed and receive front-line AEDs given the symptoms (seizures, developmental delay) and availability of genetic testing. Moreover, we assume that the majority (90%) of diagnosed patients require adjunctive therapy given the refractory nature of seizures. This implies an addressable population of c 4,500 patients in the US and c 5,500 patients in Europe.

Incidence estimates for LGS vary but accounts for approximately 2-5% of all childhood epilepsies. This suggests 16,000 patients with LGS in the US and 24,000 in Europe. Assuming similar treatment rates as with DS, this implies an addressable LGS population of c 13,000 patients in the US and c 19,000 patients in Europe.

Our forecast assumptions for Epidiolex in DS and LGS are summarized in Exhibit 12. Across both indications in the US and Europe, we estimate peak sales of approximately \$800m. We assume that GW commercializes the product in these regions, using a specialty sales and marketing force.

Exhibit 12: Epidiolex forecast assumptions in DS and LGS

	Dravet Syndrome			Lennox-Gastaut Syndrome			Notes
	US	Europe	Total	US	Europe	Total	
Addressable patients	4,500	5,500	10,000	13,000	19,000	32,000	
Launch year	2017	2017		2017	2017		Assumes positive Phase III data in late-2015/early 2016, NDA filing by end-2016 and regulatory approvals in 2017.
Peak year (FY)	2021	2021		2021	2021		Peak sales five years post launch.
Peak market share	50%	25%		50%	25%		High unmet need for more effective AEDs – available drugs only partially control seizures.
Annual price (US\$)	50,000	25,000		50,000	25,000		CBD has orphan drug designation and could achieve premium pricing if effective as adjunct therapy.
Peak sales (\$m)	\$150m	\$50m	\$200m	\$435m	\$185m	\$620m	
Peak operating profit	\$100m	\$30m	\$130m	\$320m	\$130m	\$440m	Assumes GW commercializes directly using specialty sales marketing force in US (30 headcount) and EU (30 headcount) for both DS and LGS, annual cost of \$300k per rep, COGS of 25%.

Source: Edison Investment Research

In terms of the potential competitive landscape of new treatment options for the treatment of DS and LGS, we highlight (Exhibit 13) two companies – Insys Therapeutics and Zogenix – that are planning to initiate Phase III clinical studies with their respective candidates in 2015. Importantly from GW's perspective, with its Phase III studies with Epidiolex about to start in Q115, Epidiolex is slightly ahead of the competition and could therefore benefit from first-mover advantage should it gain regulatory approval. Insys's candidate, an oral cannabidiol solution, would appear to be the most direct potential competitor to Epidiolex.

Exhibit 13: Competitive pipeline of novel treatments for DS and LGS

Product	Company	Description	Status	Notes
Oral cannabidiol solution	Insys Therapeutics	Oral CBD	Phase I (PK) study; Phase III planned (H215)	Q115: 24-pt Phase I (PK) study planned; 2x Phase III studies in DS (n=86) and LGS (n=86) planned to start in H215, with results in H116.
Brabafen (ZX008)	Zogenix	Low-dose fenfluramine	Phase III-ready (Q315)	Phase III study in DS to start in Q315. Orphan drug designation in EU and US. Oct 2014: Zogenix acquired Brabant Pharma for \$35m upfront + \$95m milestones. Long-term study (n=15) showed 93% of patients were either seizure-free or reduced seizure frequency over 12-year treatment period.

Source: Edison Investment Research; clinicaltrials.gov

Sativex – MS spasticity and cancer pain

Sativex is an oromucosal spray consisting of a formulated extract of the cannabis sativa plant that contains the principal cannabinoids delta-9-tetrahydrocannabinol (THC) and CBD. Multiple sclerosis (MS) affects approximately 1.3 million people worldwide, of which up to 80% suffer from spasticity, a symptom of MS characterized by muscle stiffness and uncontrollable spasms. There is no cure

for spasticity and Sativex provides an alternative for patients who fail to respond to conventional oral therapies (Baclofen/Zanaflex).

Sativex is approved as a treatment for MS spasticity in 27 countries (outside the US) and is currently available in 15 countries. The product is licensed to a number of partners across global territories, including: Almirall (EU ex. UK/Mexico), Otsuka (US), Bayer (UK/Canada), Novartis (Aus/NZ/Asia/Middle East/Africa) and Ipsen (Latin America ex. Mexico). GW receives upfront fees, milestones and royalties from these collaborations. In-market 10ml vial sales volumes grew 50% in FY14, to approximately 165,000 vials. GW recorded \$6.66m in Sativex commercial-related revenues in FY14, double the \$3.28m received in FY13.

Sativex is not yet approved in the US for MS spasticity, and GW/Otsuka are seeking to secure a special protocol assessment (SPA) from the FDA, effectively agreeing to the design of a single Phase III study in the US that would be required for approval. This SPA could be received in Q115.

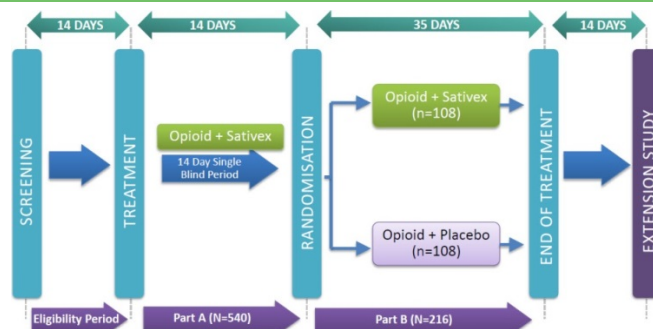
Cancer pain – still an opportunity

The potential expansion of Sativex into new indications beyond MS spasticity has been a key focus for GW and its partners. The use of Sativex to treat cancer-related pain is the biggest and most advanced opportunity so far. US partner Otsuka is conducting and fully-funding an extensive Phase III program involving three studies for cancer pain in the US.

The results from the first of these studies ([SPRAY III](#)) in 399 patients were recently reported. The use of Sativex, as an adjunctive treatment to chronic opioid therapy, did not meet the primary efficacy endpoint of showing a statistically significant improvement in pain scores compared to placebo. Pain was assessed by the patient using a 0-10 numeric rating scale (NRS), comparing the percentage change in pain score between baseline to the end of the five-week treatment period (3-to-10 sprays per day). Secondary efficacy endpoints (changes in sub-scores of NRS) were also not met. However, there was a trend towards efficacy (but not statistically significant) for patients recruited from US clinical sites (~30% of the overall study population), an effect that was also observed in the Phase IIb trial. The reasons for this are unclear at this stage, but could be due to differences in the standard opioid regimens used (types and dosing) and baseline characteristics of the patients enrolled (older and/or sicker patients in Europe/Mexico/Puerto Rico).

The results of the [second](#) Phase III study, identical in design to the first trial, are expected in H215. While the outcome of the first study would normally imply a similarly negative read-out in the second trial, the history of pain drug development where multiple approved agents have produced contradictory and/or 'failed' studies, suggests a positive result is still possible. And should the second study be positive, there is a third clinical study ongoing which could then be used to support an NDA filing. This [third](#) trial has an 'enriched', two-part study design (Exhibit 14), whereby patients are only selected for enrolment into the main efficacy (part B) portion of the study if they 'respond' (>15% improvement in pain score) to Sativex in the initial 14-day (part A) treatment period. Final results are expected in Q415, but only become relevant if the second Phase III is successful.

Exhibit 14: Sativex third Phase III cancer pain trial: 'enriched' design



Source: GW investor presentation (January 2015)

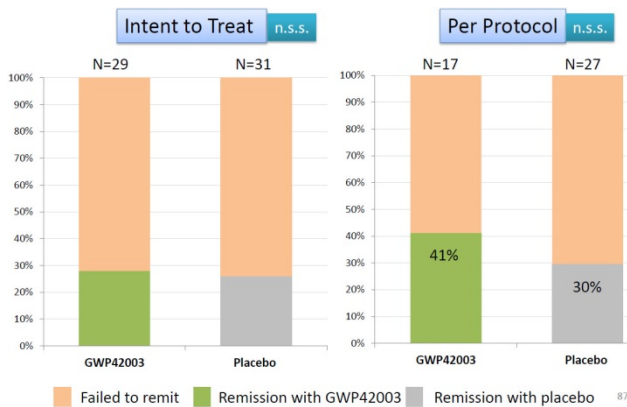
Other pipeline developments

GWP42003 for ulcerative colitis: modified dose required

In October 2014, GW reported top-line results from its Phase IIa study with a GWP42003 extract (primarily CBD, but also 4% THC and non-cannabinoid components) in the treatment of ulcerative colitis (UC). This study ([GWID10160](#)) enrolled 60 adult patients with UC unable to gain remission after first-line treatment with salicylates (5-ASA), and in some cases immunosuppressive therapy (anti-TNF α antibodies). GWP42003 was given as a twice-daily oral capsule, in a dose titration regimen with an upper target dose of 250mg twice-daily, for a total treatment period of 10 weeks.

The primary efficacy endpoint of percentage disease remission (≤ 2 Mayo score) was not met on either an intent-to-treat (active: n=29 vs. placebo: n=31) or a per-protocol (active: n=17 vs. placebo: n=27) basis (Exhibit 15). Of the 29 patients randomized to treatment with GWP42003, 12 withdrew early due to THC-like adverse effects (four withdrew early from the placebo arm). The baseline Mayo score across all patients was 7.2 (Mayo score ranges from 0 (no UC) to 12 (severe UC)).

Exhibit 15: UC Phase IIa primary endpoint: disease remission (≤ 2 Mayo Score)



Source: GW R&D Day (October 2014)

Exhibit 16: UC Phase IIa secondary endpoint: patient global impression of change



Source: GW R&D Day (October 2014)

However, with a high rate of early withdrawals due to adverse events in the treatment arm (likely due to over-aggressive dose titration and THC-related toxicity), perhaps the most relevant analysis of the data is from the patients that completed the study (per-protocol, or protocol-compliant). Although this patient group did not meet the primary disease remission endpoint, statistically significant improvements were observed with the secondary endpoints, including: physician assessment of disease severity (82% of treated patients had normal/mild disease vs 52% with placebo) and patient global impression of change (93% of treated patients regarded their condition as 'improved' vs 60% with placebo; Exhibit 16).

As such, GW still believes that the results from this Phase IIa trial warrant further investigation into the potential of GWP42003 to treat UC patients, although modifications to the compound formulation (ie reduced THC content), and a less aggressive dose titration regimen, will be required.

UC is a form of inflammatory bowel disease (IBD), classified as an autoimmune disease, characterized by T-cells infiltrating the colon. Average prevalence rates are approximately 200 cases per 100,000 individuals. This suggests a total US and Europe patient population in the region of 1.6 million. Crohn's disease (CD) is similar to UC but slightly more severe and less prevalent.

Treatment of UC ranges from anti-inflammatory agents such as aminosaliclates, particularly mesalamine (5-aminosalicylic acid, or 5-ASA), and corticosteroids, to immunosuppressive drugs (eg azathioprine) and anti-TNF antibodies such as Remicade, Humira and Simponi. Actavis's mesalamine product, Asacol, achieved ~\$800m of sales in 2012, while sales of Humira for UC are

expected to reach \$500m by 2018 (EvaluatePharma). Newer agents such as Entyvio (vedolizumab; Takeda) and Xeljanz (tofacitinib; Pfizer) are expected to grow the market, which Decision Resources estimates will increase from \$2.1bn in 2012 to \$3.6bn by 2022.

GWP42003 for schizophrenia: Phase IIa data in H215

In March 2014, GW initiated a Phase IIa trial of GWP42003 for the treatment for schizophrenia. This [study](#) has completed enrolment of approximately 80 patients who will receive GWP42003 (500mg CBD) as oral solution (or placebo), twice daily for six weeks. GWP42003 (or placebo) is being added to the patient's existing anti-psychotic therapy, effectively as an adjunctive therapy in the first line treatment of schizophrenia or a related psychotic disorder.

The primary efficacy endpoint is the change from baseline in a patient's positive and negative syndrome scale (PANSS) total score, and headline results are expected in H215.

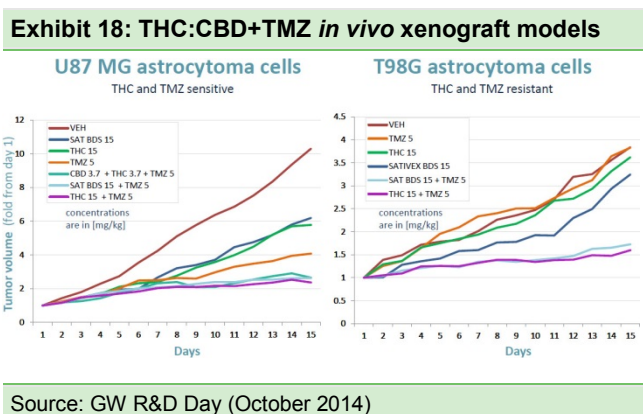
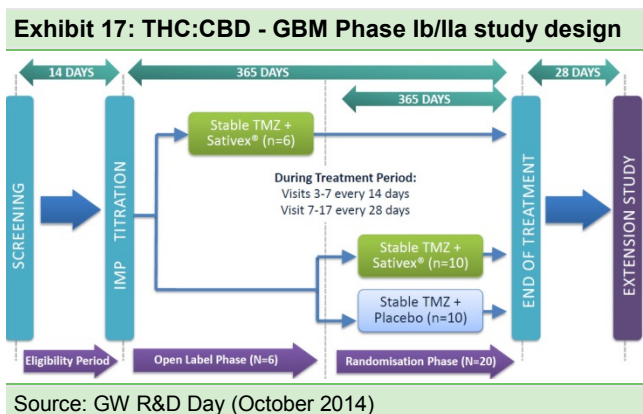
Schizophrenia is a chronic disease that manifests through disturbances of perception, thought, cognition, emotion, motivation and motor activity. Schizophrenia is often described in terms of positive and negative (or deficit) symptoms. Positive symptoms include delusions, disordered thoughts/speech, hallucinations, and generally respond to treatment with anti-psychotic drugs. Negative symptoms are 'deficits' in normal emotional responses/thought processes, and typically respond less well to medication. Over a lifetime, about 1% of a population may develop some level of schizophrenia.

GWP42003 has shown anti-psychotic effects in pre-clinical models of schizophrenia, while reducing movement disorders sometimes induced by approved anti-psychotic agents. A 42-patient clinical study⁴ (not GW-sponsored) showed that cannabidiol was as effective as amisulpride (anti-psychotic agent) in reducing positive symptoms, yet more effective in reducing negative symptoms, after four weeks of treatment.

GWP42002/GWP42003 (THC:CBD) for glioma: Phase Ib/IIa results in 2016

GW initiated a Phase Ib/IIa study in 2013 of its cannabinoid combination (THC:CBD), as used in Sativex, in patients with recurrent glioblastoma multiforme (GBM) or glioma, the most common and aggressive type of primary brain cancer. The Phase Ib safety part in six patients has completed, and the Phase IIa efficacy [part](#) in 20 patients is now underway.

Patients will receive THC:CBD (Sativex), or placebo, in combination with temozolomide, the standard front-line chemotherapy for glioma (Exhibit 17). The primary endpoint is safety, comparing the incidence of adverse events between the groups, with secondary efficacy endpoints measuring progression free survival (PFS) at six months and one-year overall survival (OS). Recruitment is expected to complete in 2015, with headline results in 2016.



4 Leweke, F et al (2012). Cannabidiol enhances anandamide signaling and alleviates psychotic symptoms of schizophrenia. *Transl Psychiatry*. Mar 2012; [2\(3\): e94](#).

The rationale for advancing THC:CBD into the clinic is based on encouraging anti-cancer activity for this combination in animal models of GBM. In these pre-clinical studies, THC:CBD reduced the growth of GBM tumors and enhanced the efficacy of standard care chemotherapy (Exhibit 18).

Gliomas are malignant primary brain tumors that originate in the glial (supportive) cells in the brain. GBM is the most common and most aggressive type with a reported incidence of two to three per 100,000. Patients have a grim prognosis; median survival following diagnosis and current 'gold standard' treatment is approximately 15 months and five-year survival rates are <5%. Standard of care for GBM is surgery (tumour resection), followed by radiotherapy, front-line chemotherapy (temozolomide, TMZ) and potentially second-line bevacizumab (Roche's Avastin). In 2009, the FDA granted accelerated approval to Avastin for recurrent GBM, based on positive radiographic findings in two single-arm Phase II trials. However, subsequent results of two large Phase III studies have shown that Avastin modestly improves PFS but not OS in newly diagnosed patients. The lack of survival benefit with Avastin highlights the challenging nature of GBM and the high unmet need.

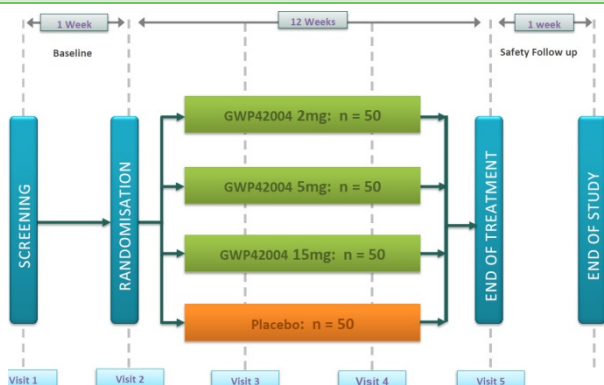
In the US, an estimated 23,130 malignant brain and CNS tumors will be diagnosed in 2013, which includes around 10,500 cases of GBM (source: National Cancer Institute). In Europe, there are c 42,500 new cases of brain/CNS cancer annually, which includes c 13,000 patients with GBM. We estimate that the majority of US and European patients (90%) receive front-line TMZ, with a smaller proportion of these patients (75%) eligible for second-line therapy due to rapid disease progression or death. As such, we estimate the addressable market for THC:CBD in recurrent GBM at c 7,000 patients in the US and c 9,000 in Europe.

GWP42004 for type II diabetes: Phase IIb in 200 patients ongoing

GWP42004 is an oral cannabinoid therapy containing tetrahydrocannabivarin (THCV) as its primary component. THCV is distinct from THC and does not share its intoxicating psychoactive effects. The drug has shown encouraging anti-diabetic effects in a Phase IIa study in Type II diabetes and in March 2014, GW initiated a Phase IIb [dose-ranging study](#) in 200 patients (Exhibit 19). Patients will receive GWP42004, or placebo, as an add-on therapy to metformin over a 12-week treatment period. The primary endpoint is the change from baseline in mean glycosylated haemoglobin A1c (HbA1c) level. At baseline and at the end of treatment, a fasting blood sample is taken to measure HbA1c levels, calculated at a percentage of total haemoglobin. A decrease from baseline percentage point, or a negative value, indicates an improvement. Trial results are expected in 2016.

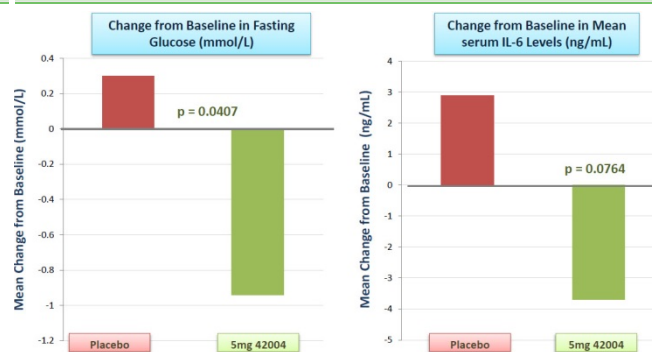
This study follows encouraging Phase IIa results in 62 patients, showing evidence of improvements in glycaemic control, beta-cell function and inflammatory markers (Exhibit 20).

Exhibit 19: GWP42004 Phase IIb diabetes study design



Source: GW R&D Day (October 2014)

Exhibit 20: GWP42004 Phase IIa diabetes data



Source: GW R&D Day (October 2014)

Type II diabetes is characterized by elevated blood glucose and an array of metabolic dysfunctions. It is caused by the interaction of environmental (eg obesity) and genetic factors, which leads to the combination of resistance to insulin action, inadequate insulin secretion and excessive glucagon

secretion. The International Diabetes Federation expects the global prevalence of diabetes to rise from 366 million in 2011 to 552 million by 2030. This includes 24 million diabetic individuals in the US and 53 million in Europe. Pharmacotherapy aims to control blood glucose levels (target haemoglobin A1C [HbA1c] levels <7%), eliminate symptoms and prevent complications. Patients usually start on oral therapies (ie metformin, DPP-4 inhibitors) with injectable agents (GLP-1 agonists) and/or insulin added as the disease progresses.

Valuation

Our DCF-based valuation of GW now stands at \$1.75bn or \$88.51 per ADR (previously \$1.3bn or \$73/ADR or 366p to 485p underlying). This change results from a number of updates we have made to our model, most importantly increasing our probability of success for Epidiolex in DS and LGS to 50% from 20%, as a result of the compelling expanded access program data presented at GW's R&D day, and acceleration of Epidiolex's clinical program. With Phase III studies in both indications to largely complete by end-2015/early 2016, the potential launch of Epidiolex in the US and Europe has been brought forward to 2017, vs 2018 (DS) and 2019 (LGS) previously. The bulk of our valuation is now attributable to Epidiolex and is mirrored by increased investor expectations that have seen GW's stock rise +130% since the program was formally announced in Nov 2013.

We have also added new pipeline product opportunities to our model (GWP42003 for ulcerative colitis and schizophrenia; GWP42006 for adult epilepsy), include \$238m in cash (at 31 Dec 2014) and have adjusted the £/\$ FX rate to £/\$1.52 (previously £/\$1.67). Our key model inputs are summarized in Exhibit 21.

Exhibit 21: GW's DCF model input assumptions

Product	Indication	Status	Probability of success (%)	Launch year (CY)	Peak sales (\$m)	Peak market share (%)	Effective royalty
Sativex	MS Spasticity	US: Phase III Ex-US: market	US: 65% Ex-US: 100%	US: 2018 ex-US: 2011	US: 165 Ex-US: 100	US: 6% Ex-US: 5-10%	US: 25% Ex-US: 20-35%
Sativex	Cancer pain	Phase III	40%	2017	565	US: 5% Ex-US: 5%	US: 25% Ex-US: 20-35%
Epidiolex	Dravet Syndrome	Phase II/III	50%	2017	200	50%	66%
Epidiolex	Lennox-Gastaut	Phase III-ready	50%	2017	600	50%	74%
GWP42003	Ulcerative colitis	Phase IIa	15%	2021	500	25%	20%
GWP42004	Type 2 diabetes	Phase IIb	30%	2020	1,000	10%	20%
GWP42002:GWP42003	Recurrent GBM	Phase Ib/IIa	30%	2020	250	30%	35%
GWP42003	Schizophrenia	Phase IIa	20%	2022	1,000	10%	20%
GWP42006 (CBDV)	Adult epilepsy	Phase IIa-ready	25%	2023	675	10%	20%

Source: Edison Investment Research

Our valuation model includes risk-adjusted, discounted cash flows (12.5% WACC) for all the product opportunities in Exhibit 21, over an initial 10-year period (2015-2024), and a 1% terminal value based on free cash flow in 2024.

We note that our \$1.75bn (\$88.51/ADR) valuation represents fair value for the stock today, ahead of further potential catalysts in 2015, most notably Phase III results with Epidiolex. For illustration, increasing the probability of success to 65% on positive outcomes from the first study would raise our overall valuation to approximately \$2.17bn or \$110/ADR. Epidiolex also holds wider potential in other refractory forms of childhood epilepsy that we do not currently capture in our model, and we note that GW has plans to expand the Epidiolex development program in 2015.

We have also made the following adjustments:

- **Sativex (cancer pain):** we have lowered the probability of success to 40% (vs 65% previously), and pushed back potential launch by one year to 2017, following the failure of the first Phase III study to meet the primary efficacy endpoint. However, the program has two further opportunities to progress in this indication, with results from the second Phase III in H215, and the third 'enriched' study in Q415. We note that many approved neurology/pain

medications have recorded failed and/or contradictory trial results in development, such is the variability/subjectivity in seeking to improve pain scores.

- **GWP42003 (ulcerative colitis):** following release of Phase IIa data, we now include this program in our valuation, albeit on a low probability of success (15%). The pilot study data did not show statistical significance on the primary endpoint of disease remission, but this was in part connected to the high rate of early withdrawals due to THC-like adverse events. Patients who remained on the drug showed good evidence of efficacy. With dose titration adjustments and a reduced THC content, further development for UC may be warranted.
- **GWP42003 (schizophrenia):** with headline Phase IIa results expected in H215, we now include this program, but again with a low probability of success (20%), reflecting the early stage of development and traditionally high attrition rates in R&D for this indication. Positive Phase IIa data would therefore represent upside potential to our current valuation.
- **GWP42006/CBDV (adult epilepsy):** with this program about to enter a 130-patient Phase IIa study in Q115, we also include this program, particularly as it fits the strategy to build a cannabinoid-based franchise for epilepsy.
- **GWP42004 (Type II diabetes) and GWP42002:GWP42003 (GBM):** we have pushed back the potential launch dates for both these programs by one year to 2020, to reflect more realistic clinical development timelines in these indications.

Our financial model assumes GW commercializes Epidiolex directly in the US and EU markets with a small specialty sales and marketing team. We assume that GW develops THC:CBD (Sativex) through to regulatory approval for GBM, with GW receiving a 35% effective royalty (transfer price less COGS). We assume the rest of the programs (ulcerative colitis, type II diabetes, schizophrenia and adult epilepsy) are partnered for late-stage development and commercialization.

Sensitivities

GW Pharmaceuticals is subject to sensitivities common to most biopharmaceutical companies, such as potential clinical or regulatory failure or delay, commercialization risks (launch, uptake, pricing, reimbursement and competition) and reliance on partners. With Sativex launched for MS spasticity in a number of European and international markets, GW is a commercial-stage business and hence a lower-risk investment proposition. However, with the significant funds raised during 2014, GW has renewed its focus on pipeline development, in particular the advancement of Epidiolex as well as investment into various exploratory studies in other indications.

Key stock-specific sensitivities include: (1) Epidiolex clinical progress as GW is particularly exposed to the outcome of the clinical program in refractory childhood epilepsy as well as the potential regulatory timeline and commercial factors; (2) Sativex sales growth for MS spasticity in ex-US markets; and (3) the success or failure of clinical trials for other pipeline products (ie ulcerative colitis, refractory glioma, schizophrenia, Type 2 diabetes and adult epilepsy).

Financials

GW ended Q115 (31 December 2014) with \$238m in cash, boosted by net proceeds of approximately \$210m from equity financings in 2014. This mainly comprised two separate offerings of ADSs on the NASDAQ exchange, for gross proceeds of \$169.8m (1.96m ADRs sold at \$86.83/ADR) in June 2014, and \$101m (2.8m ADRs sold at \$36.00/ADR) in January 2014. This should provide GW with the resources to fully execute its clinical and commercial plans for Epidiolex, the primary reason why cash burn is expected to significantly increase in FY15e. Coupled with the 4x Phase III clinical studies for Epidiolex in 2015, GW plans to increase the scale

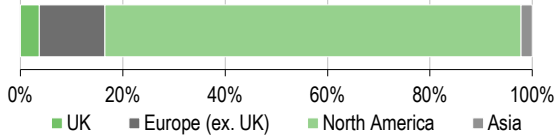
of growing and manufacturing activities in preparation for the launch of Epidiolex, as well as greater spend on US commercial operations to support Epidiolex commercialization.

As a result, GW has guided that net cash outflow from operating activities is expected to increase to approximately \$76m in FY15e, while capex will rise to approximately \$33m, to complete construction of the Sativex manufacturing facility and expand Epidiolex growing and manufacturing facilities. This suggests a total cash outflow in FY15e of \$109m, although this should decrease in 2016, particularly with lower Epidiolex clinical expenditure, should the Phase III studies recruit according to plan. Our financial model is summarized in Exhibit 22.

Exhibit 22: Financial summary

	\$000s	2012	2013	2014	2015e	2016e	2017e
Year end 30 September		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue		50,342	41,488	45,668	37,470	36,610	114,201
Cost of sales		(1,275)	(1,940)	(3,131)	(4,188)	(6,039)	(9,768)
Gross profit		49,067	39,549	42,537	33,281	30,571	104,433
EBITDA		4,251	(13,475)	(25,845)	(64,118)	(62,494)	14,916
Operating profit (before goodwill and except.)		3,105	(14,978)	(27,970)	(66,243)	(64,619)	12,791
Intangible amortization		0	0	0	0	0	0
Share-based payment		(1,520)	(936)	(1,882)	(1,919)	(1,958)	(1,997)
Operating profit		1,585	(15,914)	(29,851)	(68,162)	(66,577)	10,794
Net Interest		302	173	105	625	351	175
Profit before tax (norm)		3,408	(14,805)	(27,865)	(65,618)	(64,268)	12,966
Profit before tax (as reported)		1,888	(15,741)	(29,746)	(67,537)	(66,225)	10,969
Tax		1,897	8,827	7,465	10,944	9,850	(1,316)
Profit after tax (as reported)		3,785	(6,914)	(22,282)	(56,593)	(56,376)	9,652
Average number of shares outstanding (m)		133.0	151.5	210.4	236.7	236.7	236.7
Average number of ADS outstanding (m)		11.1	12.6	17.5	19.7	19.7	19.7
EPS - normalized (\$)		0.04	(0.04)	(0.10)	(0.23)	(0.23)	0.05
EPS - basic (\$)		0.03	(0.05)	(0.11)	(0.24)	(0.24)	0.04
EPS - diluted (\$)		0.03	(0.04)	(0.10)	(0.23)	(0.23)	0.04
Earnings per ADS - normalized (\$)		0.48	(0.47)	(1.16)	(2.77)	(2.76)	0.59
Earnings per ADS - basic (\$)		0.34	(0.55)	(1.27)	(2.87)	(2.86)	0.49
Earnings per ADS - diluted (\$)		0.33	(0.53)	(1.22)	(2.76)	(2.75)	0.47
Dividend per ADS (\$)		0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed assets		11,616	17,603	26,032	57,313	66,588	72,063
Intangible assets		7,919	7,919	7,919	7,919	7,919	7,919
Tangible assets		3,696	8,324	17,691	49,006	58,281	63,756
Deferred tax asset		0	1,360	421	388	388	388
Current assets		53,626	71,992	268,092	161,718	84,484	89,724
Stocks		5,376	7,085	7,261	8,197	10,007	13,997
Debtors		2,414	2,634	2,823	3,952	4,544	5,226
Cash		44,590	57,865	250,027	140,449	69,933	70,501
Other		1,246	4,408	7,982	9,120	0	0
Current liabilities		(17,576)	(19,336)	(26,340)	(24,702)	(24,513)	(24,456)
Creditors		(13,853)	(14,501)	(19,003)	(15,202)	(15,963)	(16,761)
Short-term borrowings		0	0	0	0	0	0
Deferred revenue & advance payments		(3,722)	(4,835)	(7,337)	(9,500)	(8,550)	(7,695)
Long-term liabilities		(15,393)	(16,448)	(26,735)	(26,156)	(22,803)	(19,895)
Long-term borrowings		0	0	0	0	0	0
Deferred revenue		(15,393)	(13,552)	(11,979)	(11,400)	(10,260)	(9,234)
Other long-term liabilities		0	(2,896)	(14,756)	(14,756)	(12,543)	(10,661)
Net assets		32,273	53,811	241,048	168,172	103,757	117,436
CASH FLOW							
Operating cash flow		2,087	(15,656)	(24,027)	(76,276)	(65,870)	9,310
Net interest		392	254	220	625	351	175
Tax		651	4,305	4,835	7,114	6,402	(1,316)
Capex		(2,003)	(3,409)	(11,026)	(33,440)	(11,400)	(7,600)
Expenditure on intangibles		0	0	0	0	0	0
Acquisitions/disposals		0	0	21	0	0	0
Financing		418	27,783	222,137	(7,600)	0	0
Dividends		0	0	0	0	0	0
Net cash flow		1,544	13,276	192,161	(109,577)	(70,516)	568
Opening net debt/(cash)		(43,045)	(44,590)	(57,865)	(250,027)	(140,449)	(69,933)
HP finance leases initiated		0	0	0	0	0	0
Closing net debt/(cash)		(44,590)	(57,865)	(250,027)	(140,449)	(69,933)	(70,501)

Source: GW Pharmaceuticals accounts, Edison Investment Research. Note: Solely for the convenience of the reader the financial summary table has been converted at a rate of US\$1.52 to £1. GW Pharmaceuticals reports statutory accounts in £ sterling. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

Contact details	Revenue by geography (2014)
1 Cavendish Place London W1G 0QF United Kingdom +44 (0)20 7291 0555 www.gwpharma.com	

CAGR metrics	Profitability metrics	Balance sheet metrics	Sensitivities evaluation
EPS 2013-17e	N/A ROCE 16e	N/A Gearing 16e	N/A Litigation/regulatory ●
EPS 2015-17e	N/A Avg ROCE 2013-17e	N/A Interest cover 16e	N/A Pensions ○
EBITDA 2013-17e	N/A ROE 16e	N/A CA/CL 16e	N/A Currency ●
EBITDA 2015-17e	N/A Gross margin 16e	83.5% Stock days 16e	N/A Stock overhang ○
Sales 2013-17e	28.8% Operating margin 16e	N/A Debtor days 16e	N/A Interest rates ○
Sales 2015-17e	74.6% Gr mgn / Op mgn 16e	N/A Creditor days 16e	N/A Oil/commodity prices ○

Management team

Chairman : Dr Geoffrey Guy
 Founder of GW and has served as chairman since 1998. He has over 30 years' experience in medical research and drug development. He founded Ethical Holdings (now Amarin) in 1985 and Phytopharm in 1989. He holds a BSc in pharmacology (University of London), a medical degree (MBBS) from St Bartholomew's Hospital and a diploma in pharmaceutical medicine (Royal College of Physicians).

CEO : Justin Gover
 CEO since 1999. He has over 17 years' experience in the pharmaceutical industry. As CEO, he is responsible for directing operations and leads equity financings and business development activities. Prior to GW, he was head of corporate affairs at Ethical Holdings (1995-97), where he was responsible for strategic corporate activities. He holds an MBA from INSEAD and a BSc (hons) from Bristol University.

R&D director : Dr Stephen Wright
 R&D director since 2004. He has over 20 years' experience in drug development. Prior to GW, he was SVP of clinical research and development at Ipsen. He has direct US drug development experience, first as medical director of Immunosciences, then venture head of neuroscience at Abbott. He is a fellow of the Royal College of Physicians and Faculty of Pharmaceutical Medicine and visiting professor at University of Reading. He holds an MD and MA (University of Cambridge) and a medical degree (MBBS) from Royal London Hospital.

CFO: Adam George
 CFO since 2012, he also serves as company secretary. Prior to his current role, he served as financial controller from 2007 and was finance director (2004-07) and group financial controller (2001-04) of Believe It Group (now 4Com). He holds a BSc in biology (Bristol University) and is a qualified chartered accountant.

Principal shareholders	(%)
Prudential plc group of companies	13.2
Capital Research and Management Company	10.39
Dr Geoffrey Guy (Chairman)	6.10

Companies named in this report

Almirall, Bayer, Insys Therapeutics (INSY), Novartis, Otsuka, Zogenix (ZGNX)

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