VOSS CAPITAL

October 2014 | 2365 Rice Blvd Suite #217 | Houston, TX | 77005 |713-328-1126 | t@vosscap.com

Market Capitalization	1,461,927,413
- Cash & Equivalents	287,800,000
+ Preferred Equity	0
+ Minority Interest	0
+ Total Debt	3,264,472
Enterprise Value	1,177,391,885

Investment Memo: Short GWPH

Company Name: GW Pharmaceuticals NV
Based in Salisbury, UK

Benchmark: Nasdaq Biotech Index (Bloomberg: NBI Index, or ETF alternative: IBB US Equity)

Asset Class: Common equity

Expected Timeframe: 1-2 years

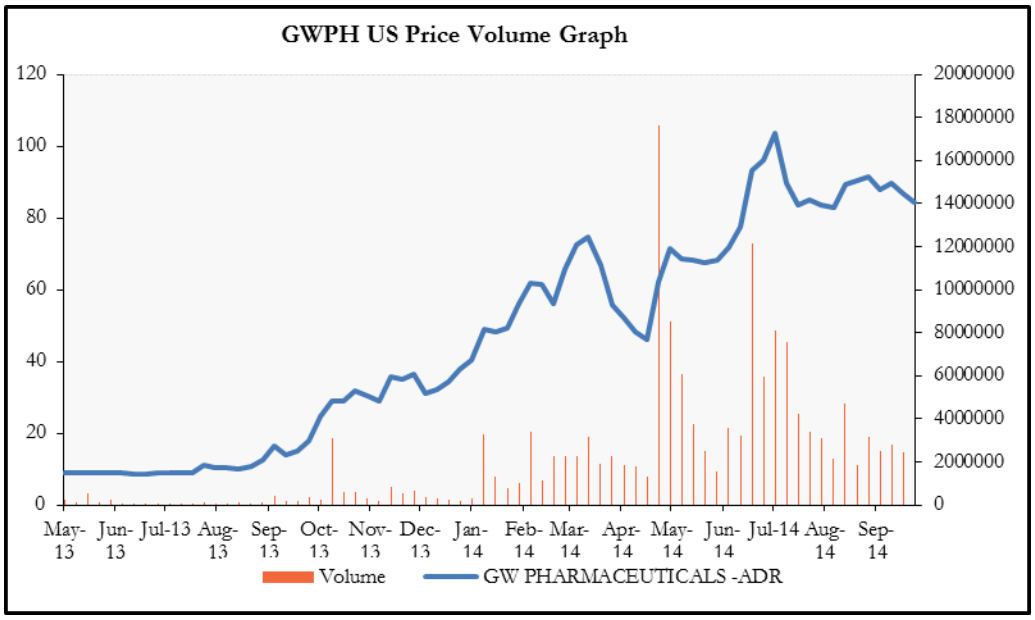
Target Price: < $49

Catalysts: Failure to gain FDA approval, failure to gain insurance coverage, failure to meet sales expectations

Elevator Pitch: GWPH is still years away from an FDA approved therapeutic all the while private medical marijuana dispensaries are becoming entrenched in the marketplace with lower cost substitutes. The very hype and legislative momentum that have elevated the share price will encourage competition and bring about its downfall.

Business Description: GW Pharmaceuticals researches and develops cannabinoid prescription medicines for the treatment of cancer pain, Multiple Sclerosis, and neuropathic pain.

GW has been a listed stock on the AiM all the way back to June 2001. To cash in on the United States biotech frenzy the company floated ADRs in the US in beginning in May 2013. The stock is up 808% since trading here began, for annualized returns of 373.4%.



Telephone:	44-19-8055-7000	**Revenue (M):**	$43
Website:	www.gwpharm.com	**No of Employees:**	188
Address:	Porton Down Science Park Salisbury Wiltshire, SP4 0JQ United Kingdom		
Price:	85.69	**1M Return:**	-6.4%
52 Week High:	111.46	**6M Return:**	53.5%
52 Week Low:	16.39	**52 Wk Return:**	382.8%
52 Week Beta:	1.59	**YTD Return:**	106.3%

If everyone reading this were an accurate representation of America as a whole, you may be surprised but it would mean at least 40% of you have tried smoking pot. As you know in some states now it's been legalized, so it's no longer a *guilty* pleasure. My idea is a high probability, perfectly legal way to make money from betting *on* the Kush Rush….and that idea is to **short GW Pharmaceuticals**. GW is developing pharmaceutical grade cannabinoids derived from cannabis plants for various medical treatments and diseases, namely Epilepsy, multiple sclerosis, Crohn's and general cancer pain. Right now GW has two main drug candidates, one is approved and on market outside the US and both are in the midst of Phase 3 trials in the US. The majority of the company's value is placed on Epidiolex, their liquid formulation of purified CBD for pediatric epilepsy. GW is viewed as the market leader in the medical application of cannabis, which is probably a true statement, but that certainly does not make it a good investment. The prevailing perception is that GW is going to benefit from the increased adoption and more lenient regulations surrounding medical marijuana usage. The reality it is precisely this increased adoption and positive legislative momentum that will lead to their demise as sophisticated medical marijuana growers continue to develop competing low THC products that are already available at a fraction of the future costs of GW's products. These existing alternatives are currently becoming entrenched in the marketplace, while circumventing the unnecessary FDA approval process. At last count, 26 states now allow medical marijuana use. The writing is on the wall. The number of states legalizing it is quickly rising.

The Voss variant view on GWPH and investment thesis can be succinctly summarized as follows: GWPH has had their compounds in various stages of research and development for 15 years (company founded in 1998), has a long history of failed clinical trials, and are still years away from an FDA approved therapeutic all the while private medical marijuana dispensaries are becoming entrenched in the market with lower cost substitutes. GWPH's efficacy profile for both of its lead candidates, Sativex and Epidiolex, are questionable for many of the targeted indications. Medical marijuana dispensaries have much cheaper low THC and high CBD strains available for the treatment of various pediatric epilepsies at **~1/40th** the estimated sales price of GW's future Epidiolex treatment that *may* become commercially available in 2017. There is a groundswell of support building for allowing medical marijuana to be used by children, which will actually be a negative for GWPH in the long run due to increased competition. Additionally, the pharmacokinetics and bioavailability of GW's treatments versus inhaling cannabis are significantly different, with GW's method of ingesting seemingly at a disadvantage. Not surprisingly, the initial TAM being touted for Epidiolex by the company and the sell-side is drastically overstated. Piper Jaffray's initiation report throws out a $3.75 billion opportunity just within the epilepsy market using ridiculous Epidiolex pricing assumption of up to $200k/year. GWPH's shareholder base is likely to get smoked due to demonstrating extreme competitor neglect and must now endure a "sobering effect" as economic reality sets in over time and their high wears off.

There are numerous and obvious blind spots within the analyst community.

The majority of focus and valuation attribution from investors is on the Epidiolex drug as a treatment for epilepsy. Roughly 90% of peak sales are attributed to GW's drug Epidiolex which has a focus on preventing/treating seizures for Dravet

Syndrome and Lennox-Gastraut Syndrome. Epidiolex is still in the proof of concept phase with physician run IND trials currently underway.

Major blind spot: Enter stage left, Charlotte's Web. The Charlotte's Web strain of cannabis is effective as an Epidiolex alternative due to its similarly high CBD content combined with low THC and thus no psychoactive effects, making it appropriate for children's medical use so as to not affect the user's daily routine/functionality. Charlotte's Web was developed by the Stanley Brothers by crossbreeding a certain strain of marijuana with industrial hemp. Their process created a new variety of plant with lower THC and higher CBD content. A key point is that **we cannot find a single mention of Charlotte's Web in *any* Wall Street report including all initiation reports on GWPH.** Similar in form to Epidiolex, the Stanley Brothers extract a CBD enhanced oil that they call Realm Oil for the medical treatment of epilepsy for children. They are planning to move their Charlotte's Web operations to Uruguay with the plan of completing clinical trials and then importing the product into any US state. They are doing this in order to try and help patients all over the country by providing a low-cost treatment for child epilepsy. There is a wait-list of thousands of families to receive Charlotte's Web for their children. For the many children who are resistant to current anti-epileptic treatments, it is not hard to see why a family would want to go ahead and try Charlotte's Web before any conclusive clinical trials have been completed. Charlotte Figi, for whom Charlotte's Web is named (it was previously called "Hippie's Disappointment" due to lack of psychoactive effects), is said to have gone from having a seizure every 20-25 minutes down to 0-1 per week with the Stanley Brother's prepared tincture. Up until recently the data and evidence has been purely anecdotal. The Stanley Brother's non-profit, the Realm of Caring Foundation, reports that 85% of children on their strain of Charlotte's Web have witnessed a 50% or greater reduction in the number of total seizures once starting treatment. While more studies take place and the anecdotal evidence in favor of Charlotte's Web's efficacy piling up, it will become further entrenched within the market place at a fraction of the future cost of Epidiolex. The Stanley Brothers have devoted 80% of their crops to low THC strains and in late September just announced that they have started shipping Charlotte's Web oil to all 50 states, as they've gotten the production process to consistently come under the 0.3% THC content threshold to be considered hemp, not marijuana—so it thereby is classified as a hemp derived food product. The oil the Realm of Caring will be shipping to all states will have a lower CBD-to-THC ratio of 30:1 versus regular Charlotte's Web oil's ratio of 48:1. The street is under estimating the growing sophistication and funding of private competitors offering alternative treatments, such as the Stanley Brothers. To wit, from a Morgan Stanley report from August 6th, 2014: "It seems highly unlikely to us that any plant based competitor would emerge with the scale and sophistication that GW has in terms of plant yields, batch to batch consistency, and growing process."

Private players are working on their quality control for consistency of drug and uniform dosing: "This will be the future of Charlotte's Web," said Jared Stanley. "Same plant, same quality control, same medicine. Our national wait list climbs by 100, 200 every day," he said. "It's currently around 7,000 to 8,000." In an epilepsyu.com poll, 61% of parents said they would move if it would allow them to obtain cannabis derived medicine for their child.

The premise that American medicine is grounded firmly in precise synthetic pharmaceuticals versus variable organic compounds benefits GW's perception, as the precision may offer a greater sense of safety among doctors and parents administering the drugs. However, there are 483 compounds in cannabis, so aside from just cannabinoids, there may be benefits from other compounds acting synergistically and synthetics won't capture the full array of compounds. The synergistic effect is known as the "Entourage Effect" and beneficial functions may be lost if only one substance is extracted from the plant and ingested.

Aside from no mention of some of the other available treatments, there are no listed price comparisons in Wall Street reports. Widely available Medical Marijuana treatments cost patients anywhere from $25-250/month.

Insurance coverage:

At 8,000 people waiting to get on Charlotte's Web, this is already well over half of the stated US TAM from Dravet Syndrome patients. Each treatment will obviously not be effective for all users, but one of the only ways to get families to switch off of

Charlotte's Web in the future is either with superior efficacy (which is yet TBD) or to get full insurance coverage with out of pocket co-pay near or below that of Chartlotte's Web ($50/month).

Under the Controlled Substance Act, all compounds derived from marijuana are classified by the DEA as Schedule 1 drugs:

> Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

- The most recent rescheduling petition for marijuana reclassification was filed in 2002 and was denied by the DEA in July 2011. Marijuana advocacy group Americans for Safe Access then subsequently filed an appeal in January 2012 with the DC Circuit, which was heard in October 2012 and denied in January 2013.
- California was the first state to legalize medical marijuana. In 2003, the California legislature clarified that laws legalizing marijuana do not require insurance providers "to be liable for any claim for reimbursement for the medical use of marijuana." (Cal. Health & Safety Code § 11362.785(d))
- Colorado has the most liberal laws in the nation related to marijuana use. Its constitution likewise specifies that no insurer shall be required to pay for medical marijuana. (Col. Const., Art. XVIII § 14 (10)(a).)"
- "Nothing in this act shall be construed to require a government medical assistance program or private health insurer to reimburse a person for costs associated with the medical use of marijuana, or an employer to accommodate the medical use of marijuana in any workplace." N.J.S.A. 26:61-14

In addition to these substantial legal hurdles for future insurance coverage insurance companies may push back on how much GW can charge for Epidiolex and Sativex when there are existing products available in the same form and efficacy at a fraction of the estimated cost of Epidiolex.

On October 8th, 2014, England's National Institute for Health and Care Excellence (NICE) recommended that Sativex not be used for treatment for multiple sclerosis patients because it is deemed to not be cost-effective. NICE said the medicines "…**provide only a modest benefit at a significant cost to the NHS, with Sativex costing £50,000 per quality-adjusted life year. Well above NICE's threshold of £30,000 per QALY.**" Sativex is intended for use in addition to other treatments so with only slight incremental benefit it is therefore even harder to justify reimbursement from a cost-benefit perspective.

Pricing:

"As an Orphan Drug for refractory epilepsy, we believe GWPH could legitimately charge $150-200K/year for therapy." – Piper Jaffray report.

According to the Epilepsy Foundation of Colorado, Charlotte's Web treatment cost between $100-600/month, or $1,200-$7,200/year. Another way to corroborate this pricing is to compare Charlotte's Web stated price per mg of CBD of their hemp oil of $0.05 to the recommended 2-6mg per pound of the patient per day. If the average 5 year old child weighs 40 pounds and uses 4 mg/lb, then the annual cost would be $2,920, right in the middle of the stated range. This annual cost pales in comparison to the $50,000 average estimate of the sell-side for future cost of Epidiolex, which would be anywhere from 6.9x - 41.7x more expensive than the currently available Charlotte's Web treatment. For some patients who can demonstrate the need for financial assistance, the Stanley Brother's Realm of Caring Foundation will charge as low as $50/month for the treatment. If Epidiolex is approved and if it obtains insurance coverage, insurers will certainly require proof from patients and doctors that cheaper existing alternatives were tried and either failed to help or were not well tolerated due to adverse side affects.

Although perhaps less of a serious threat and emphasis for our research, in addition to cheap alternatives available for purchase there is an infinite amount of literature and resources available that teach people how to create their own CBD oils at

home. Either way, the market is not standing still waiting with baited breath until 2017 when GW's treatment might eventually become available.

Legislative Momentum for Medical Marijuana Usage

While medical marijuana users have already been self-medicating for years, there has been a bit of a chicken versus egg dilemma for legislation. Medicinal marijuana has been restricted in large part due to lack of scientific research and published studies, yet the research is hard to undertake due to the tough restrictions, but now the national view of medicinal cannabis is changing. There has not been enough focus in the analyst community on the rapidly changing perceptions of the populace and legislators, and the inevitable outcomes that will result that are actually negative for GWPH. Just in 2014 there has been 11 states that have passed some form of legislation loosening the restrictions around cannabis strains with low THC content for medicinal purposes. This will increase the national adoption and usage of high CBD/low THC strains such as Charlotte's Web, rendering GW's potentially FDA approved Epidiolex as an expensive alternative in an increasingly crowded competitive landscape.
It is hard to believe, but California had passed an initiative to legalize medical cannabis as far back as 1996. As of this writing, there are now 23 states (New York being the 23rd. A poll showed that a high 88% of New Yorkers were in favor of the legalization of medical marijuana) that have legalized cannabis for medical usage and three more have pending legislation. The more marijuana becomes widely available, the less likely families are to spend upwards of $50k a year out of pocket to pay for Epidiolex if it is approved.

Over 100 families have uprooted and moved to Colorado to get Charlotte's Web for their affected children and they're now known as "Marijuana Refugees." The reason they have to move is that anything grown in Colorado has to stay in Colorado. There are thousands of families on a waiting list to receive the Stanley's Brother's Charlotte's Web. There is another common roadblock and that is getting doctors to prescribe it. Doctors are still skeptical due to lack of robust scientific studies. As more and more scientific data becomes made public on the efficacy of the cheaper low THC/high CBD bred strains coming out of the private dispensaries, they will continue to gain in popularity and acceptance within the medical community.

There are several legislative conflicts ongoing between the states and federal government. H.R. 5226 was just been introduced in the House of Representatives on July 28th, 2014—the bill is called Charlotte's Web Medical Hemp Act of 2014. It was introduced and sponsored by Representative Scott Perry, a Republican Congressman from Pennsylvania. The bill has a growing list of 26 co-sponsors from a wide variety of states. The purpose of the bill is to "To amend the Controlled Substances Act to exclude therapeutic hemp and cannabidiol from the definition of marihuana, and for other purposes."

"The term `therapeutic hemp' means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

In a June of this year North Carolina state legislators approved a bill to allow CBD oil to pediatric seizures. One state Senator tried to get a 10-year sunset provision added to the bill so that families would have to switch to the potentially FDA approved Epidiolex. This sunset provision was shot down and deemed unnecessary, leaving the market wide open and competition for GW completely open-ended.

Sativex

GW has one drug that has been approved in 27 countries (not the US) and is currently being marketed in 14 more countries. The drug is called Sativex and is used for the treatment of multiple sclerosis pain (MS Spasticity) and cancer pain for patients who have responded poorly to available opioid therapies.

- Sativex is a spray that is used under the tongue for efficient absorption. However, it can take up to 3-4 hours for peak levels of THC to be attained in the patients (versus minutes for inhaling via smoking cannabis)
- Sativex is a standardized extract from cloned cannabis plants grown under controlled conditions indoors. One strain of plants yield principally THC (>90% of the total cannabinoids), while a different strain produces mostly cannabidiol (>85%). Extracts from these two strains of plants are then blended together to produce Sativex.
- "Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy."
- Sativex is intended to be used in addition to the patient's current anti-spasticity medication.

GWPH's Sativex has been on the market for seven years. Sativex was first approved in Canada in August 2007 for the treatment of cancer pain and then later in the EU for MS spasticity. The drug has only achieved $29.7mm in TTM sales despite years of being on the market and in place marketing partnerships with many pharma heavyweights. Sativex is also now on Phase 3 trials in the US for cancer pain. The Phase 3 read out for cancer pain data due out by end of 2014.

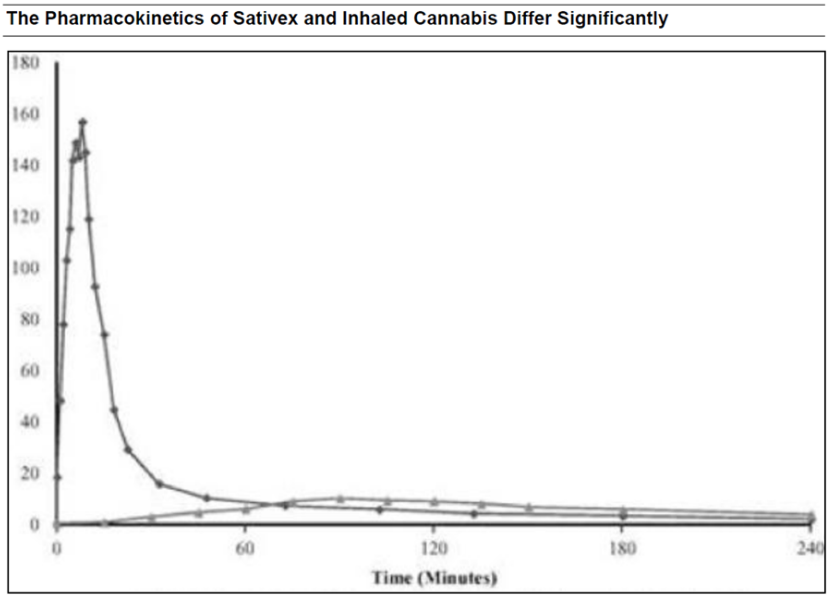
Kyle Bass is fond of saying that brevity of financial memory is about two years. Judging from the price action of many stocks lately I think he is being a bit too generous, but in any case, **the market and analyst community have certainly forgotten about the weak Phase 2b results on Sativex in the US that were originally reported in March 2010**. GW's Phase 2b study on Sativex failed to meet its primary endpoint so like any good biotech they pulled a switcheroo and changed the Phase 3 primary endpoint to the Phase 2b's previous secondary endpoint.

Sativex previous Phase 2b data from US trial:

- Reported in peer reviewed journal, The Journal of Pain, published on April 9th, 2012
- Randomized, double-blind, placebo-controlled, graded dose study
    - Dose ranging study with three arms:
        - Low dose (1-4 sprays/day), medium dose (6-10 sprays/day), high dose (11-16 sprays/day)
- 360 patients with advanced cancer and chronic pain despite a stable opioid regiment, 263 completed the study
- Five weeks of treatment—pain and sleep disruption measured daily
- **Primary endpoint for 30% responder rate for pain response status was not met:**
    - "The 30% responder rate primary analysis was not significant for nabiximols [the US adopted name for Sativex] versus placebo."
    - "It was estimated that the response rate in the placebo group would be approximately 20%, leading to a response rate of approximately 40% in the active drug group."

- There were no significant differences in pain response among different dose groups that were randomized to placebo

- Secondary endpoint was met:
  - A secondary continuous responder analysis of average daily pain from baseline to end of study demonstrated that the proportion of patients reporting analgesia was greater for nabiximols than placebo overall
- **No dosing response**: "Other questionnaires showed no significant group differences."
  - **No statistical significance for medium dose group in pain reduction or sleep disruption**
  - Examination of the individual nabiximols dose groups showed that the effect was significant only in the two lower dose groups
  - Why might there be no dose response on Sativex? As time goes on you need less of a dose to achieve the same effects due to cannabinoids being fat soluble compounds. This is why pot smokers can fail drug test even weeks after smoking. Another potential reason for no dosing response is that research shows CBD to have biphasic properties. To demonstrate what this means, consider alcohol consumption. Alcohol has a stimulating effect (you become happy, uninhibited, etc.) when consuming up to a blood alcohol level of ~0.5%. If you binge drink past .05% alcohol will then have the effect of a depressant, not stimulant. This is known as biphasic when a substance produces different effects or even opposite effects at different doses.
- **"**Adverse events were dose-related and only the high-dose group compared unfavorably with placebo."
  - **Discontinuation due to adverse events was 28% for the high-dose group**
- These old Phase 2b data have faded from memory and the results do not portend well for the ongoing Phase 3 trials.
  - Timeline to potential negative catalyst: Data is due out before the end of the year. The analyst community is universally optimistic on the outcome and Sativex makes up a large portion of their NAV estimates, leaving much room for disappoint and negative surprise later this year if results are poor.
- In Piper Jaffray's initiation report, they called for >$500 million in global Sativex sales.
  - There is major risk to the Phase 3 results due out and hence a large portion of Wall Street's embedded sales estimates.
  - Even if it reaches commercialization phase, the sales estimates for Sativex are overly optimistic
- There is no standard test that provides a perfectly objective measure of pain, so it is difficult to precisely measure the benefit of Sativex on patients. Clinical trials have relied on the patient's own subjective reports using numerical point scales (e.g. "no-pain" to "worst possible pain") to generate daily pain scores for each patient. The medical opinion and data are arguably still mixed for Sativex and CBD treatment for pain. In one of the earlier long term trials, 89 patients opted to receive Sativex in an open-label study. The average treatment was for 288 days, with some remaining on Sativex for over two years and all told **~2/3 eventually withdrew due to adverse effects or perceived lack of efficacy.**
- Why else might Sativex sales be over-stated? Sativex must compete with the rapidly increasing availability of low THC medical marijuana due to it being legal now in 23 states (and rising). Shown below from the Journal of Analytical Toxicology, inhaling cannabis has an immediate peak effect on a patient for pain relief, compared to Sativex's method of ingestion which has a delayed peak-onset at around ~90 minutes. If an individual is okay with smoking cannabis (e.g. doesn't mind the smell, doesn't mind potential social taboo, can find a place to do this at work or other "non-private" places) they will likely choose this method of medication over the Sativex spray. This likely explains part of the Sativex weakness and sales disappointment thus far.
- One of the main benefits of Sativex over smoking would be control over consistency of dosing.

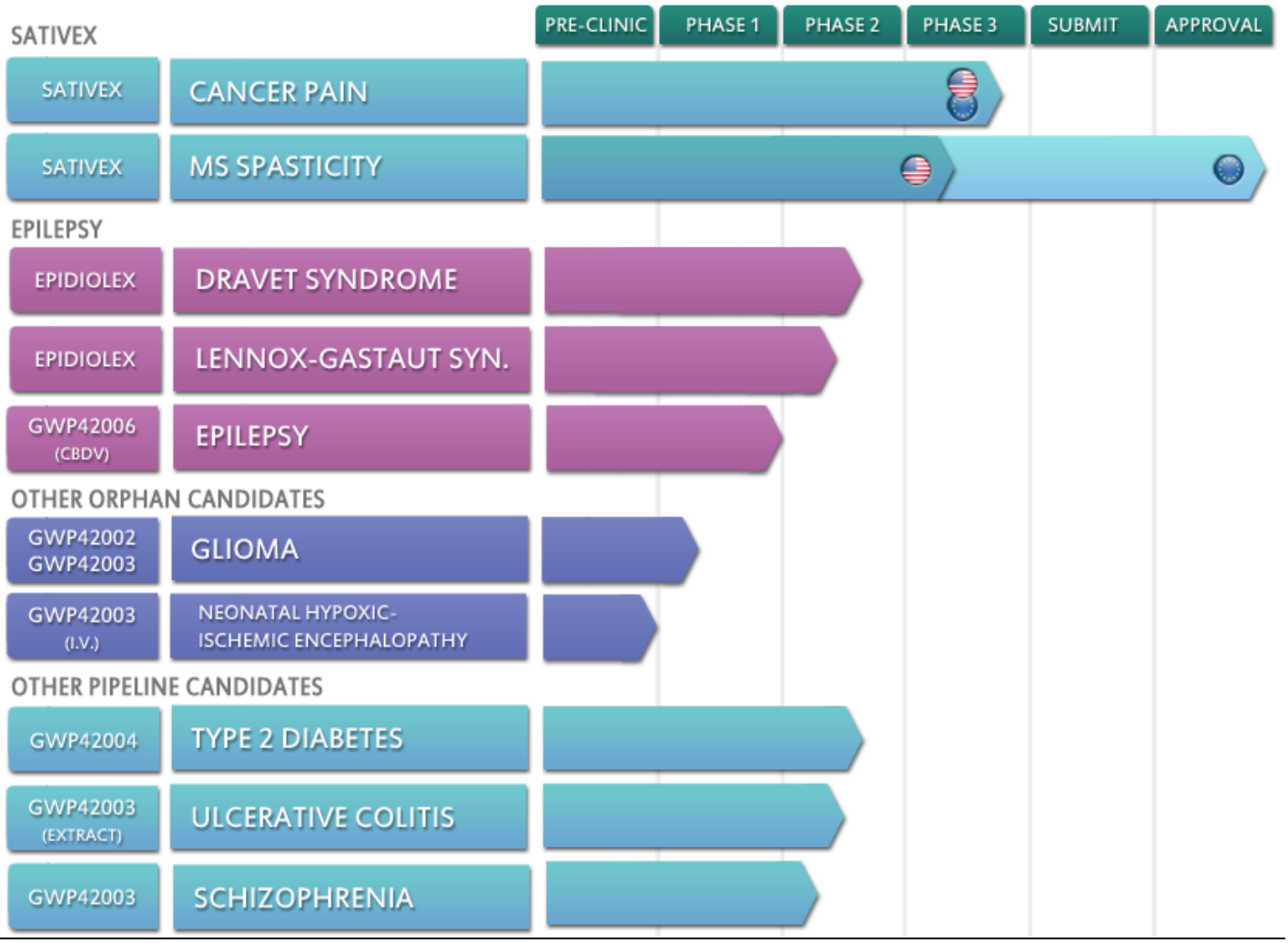


Graphic Source: Journal of Analytical Toxicology; Line with sharp peak represents PK of inhaled THC. Shallower sloping line with peak at ~90 minutes is Sativex. Y-Axis: Plasma Concentration (ng/ml).
The chart above shows an important point of why even if Sativex is approved for cancer pain in the US it may not be preferred to inhalation options.

Sativex Marketing Partners:

1. Otsuka Pharaceutical Co. Ltd.: subsidiary of Otsuka Group. Revenue was ~$13b in FY 2012
    a. Collaborating on the US development of Sativex
        i. Phase III clinical trials currently underway for Sativex in the US
    b. GWPH has granted Otsuka an exclusive license to develop and market Sativex in the US. GWPH is responsible for the manufacture and supply of Sativex to Otsuka
    c. They jointly oversee US clinical development and regulatory activities
    d. GWPH has 20% net royalty on Sativex US sales
2. Novartis Pharma AG
    a. GWPH has entered into an exclusive license agreement for Novartis to commercialize Sativex in Australia, New Zealand, Asia (excluding China, Japan, Hong Kong), the Middle East (excluding Israel and Palestine), and Africa.
3. Almirall S.A.
    a. Spain's largest pharma company
    b. GWPH has licensed Sativex's European (excluding the UK) marketing rights to Almirall
    c. GWPH has 17-20% net royalty on Sativex sales
4. Bayer Healthcare AH
    a. GWPH has licensed Sativex's UK and Canadian marketing rights to Bayer
5. Ipsen Pharma S.A.S.
    a. Exclusive marketing and distribution agreement for Sativex in Latin America (excludes Mexico and Islands of the Caribbean)
6. Neopharm Group
    a. Exclusive Sativex marketing rights in Israel/Palestin

Development Pipeline:



1. Epidiolex, synthetic of CBD for treatment of epilepsy.
    a. The bulk of investor attention and valuation can be attributed to Epidiolex
    b. Liquid formulation of purified CBD extract
    c. Epidiolex has received Orphan Status for the treatment of Dravet Sydrome
        i. In most recent study results, sub-group showing best results were the 9 Dravet patients who showed a median seizure reduction of 63% over a 12-week testing period.
        ii. Also have Orphan Status for Lennox-Gastaut Syndrome
        iii. Orphan status allows the company the benefit of no generic competition for 7 years in the US and 10 years in the EU
    d. Phase 3 for Dravet syndrome commencing 1H 2015
    e. Update: additional data released from physician led open label IND studies on October 14th:
        i. Initial data is promising, with the best results within the Dravet patient sub-group
        ii. Company has data on 58 patients
            1. 31 new patients
                a. Decline in response rate witnessed in second batch of patients
            2. 12 suffer from Dravet Syndrome

a. Median reduction in seizures of 51-72%
3. 12 suffer from atonic-seizures, common with LGS

iii. 40% of total group had a 50% or better reduction in seizure frequency
1. Data was weaker than previous read-out from June report of at least 48% obtaining a 50% reduction in seizure frequency

iv. 33% obtained a 70% reduction
v. 25% obtained a 90% reduction
vi. 17% were seizure free
vii. Too few LGS patients so far to get a meaningful read on efficacy within that sub-group
viii. Still only done as an open label study with no placebo control group

f. Epidiolex is currently not partnered and GW has retained full global commercial rights making this their most financially important drug and DS/LGS their most important indications

2. GWP42006: CBDV cannabinoid showing anti-epileptic properties. In Phase 2b.
a. Otsuka Pharaceutical Co. Ltd had the right to opt-in to CBDV program for epilepsy but did not exercise it.

3. GWP42003: Phase 2a, ulcerative colitis, data recently released
a. Prior to disappointing results, many sell-side reports were once again proven overly aggressive by attributing up to $15 per share in added value from GWP42003
i. To wit, from Leerink Swan report dated September 3rd, 2014:

> "We believe that investors largely treat GWPH's pipeline beyond Epidiolex and Sativex as all upside, and overlook the UC trial specifically since data has been delayed and the study is being conducted at ex-US sites. Increasing our probability of success in UC from 0% to 35% adds ~$15/share to our DCF (~14% upside to our valuation, ~16% to the current stock price), but we believe that positive results could produce a stock move of greater magnitude given its positive readthrough on GWPH's cannabinoid platform which is being examined in various blockbuster indications including schizophrenia, diabetes in glioma."

b. Phase 2a did not achieve statistical significance for its primary endpoint
i. Of the 29 patients in the GWP42003 arm, 30% dropped out due to adverse side effects
ii. The trial did meet secondary end points, so management will push forward with continued investigation

c. Possible read-through from the Phase 2a trial portends poorly for Sativex and Epidiolex's probability for success

4. GWP42002: Phase 2b, for type two diabetes treatment, treatment of glioma
5. Additional potential indications for Epidiolex mentioned at GW's R&D Day include autism and ADHD.
a. There are plenty of others mentioned. Piper Jaffray mentions migraines, Rett Syndrome, Schizophrenia, cerebral palsy, any type of pain, etc. While there may be validity to all of these arguments, they still neglect to mention the increased option for self-medication using marijuana and rapidly increasing number of medical marijuana dispensaries around the country with currently available tinctures, edibles, etc. (if patients do not want to smoke, can't smoke at work, or don't want to smell like weed) that will capture much of the same beneficial effects of GW's treatments for a fraction of the cost.

6. There will be a very prolonged and lengthy news cycle surrounding pipeline development.

Epidiolex is being used as an additional treatment within a broader regimen for treatment-resistant children and young adults (average age = 10.5 years in Expanded Access IND trial). These children are using an average of 2.7 other Anti-epileptic drugs in addition to Epidiolex. There are over 50 existing seizure and epilepsy drugs, for a list see epilepsy.com.

History Rhymes

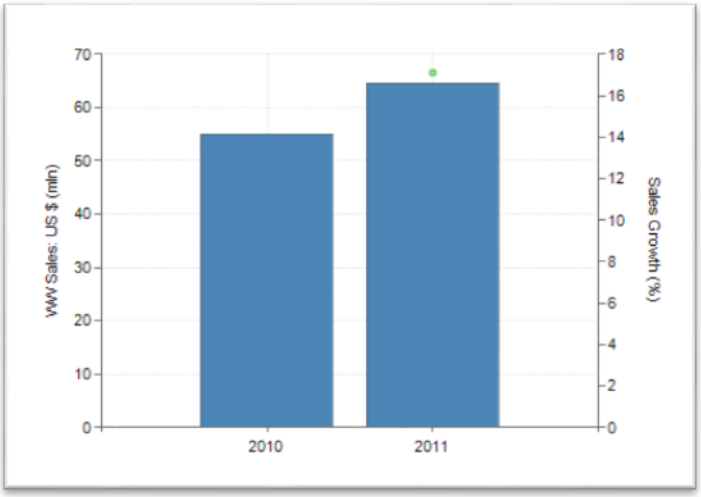
Biotech remains a great industry for alpha generating short ideas. In Q2 of this year, the Healthcare sector set an all-time stock market record for number of IPOs from any single sector in a single quarter. Said another way, biotech equity supply continues to flood the market in a speculative frenzy.

A great current theme for shorting in a tough market is waiting for hyped up biotech companies' new products to hit the market, as many of the recent high profile drug launches are disappointing relative to Wall Street's unrealistic sales expectations. We can look to a few historical case studies of past FDA approved synthetic cannabinoid drug launches to see how the current situation with GW and Sativex/ Epidiolex could play out in the commercialization phase.

Case Study #1:

Research on synthetics analogs of THC to try and separate out the medical benefits from the psychotropic actions can be traced back to the 1970s. Very few of them persisted long enough to produce commercially marketed products. Eli Lilly was one of the few with its drug, Cesamet (nabilone).

Cesamet is an FDA approved medicine for nausea and vomiting caused by cancer chemotherapy. It is used when other drugs have not been able to control these symptoms. Cesamet is prepared in solid form in capsules and the dosing is usually 1 or 2 mg twice daily. Cesamet showed promising results for the treatment of anxiety, but Eli Lilly decided to focus on the target market of treating nausea in patients undergoing chemotherapy. Cesamet achieved FDA approval in 1985 and was eventually pulled from the market in 89 due to low sales. The rights to Cesamet were eventually bought by Valeant Pharma in 2004 and they began marketing the drug in Canada, achieving a very respectable 85% market share of cannabinoid drug share in the country. Valeant followed this up with FDA marketing approval for a re-release in the US in 2006. The latest available data we could find is shown below, with Cesamet doing $65 million in sales in 2011. Compare this $65 million to a total Anti-emetics drug therapy market of over $1.6 billion, for a decent ~4% market share.



Case Study #2:

Marinol- Marinol was an AbbVie owned drug that is a synthetic form of THC in a gel cap used to treat nausea and vomiting from chemotherapy treatment and later used for poor appetite in AIDS patients. It was originally approved in 1985.

It is difficult to find exact sales for the drug by year but we can see annual sales were $78 million in 2004, sales were $105 million in 2007, and $190 million in 2008 once made available by multiple manufacturers in the form of a generic. The DEA classified Marinol into the less restrictive Schedule III category of drugs (pure THC is Schedule I).

Case Study #3:

Pharmos Corp (PARS): Pharmos was developing Dexanabinol for the treatment of traumatic brain injury. Dexanabinol was touted by the company as a billion dollar opportunity a mere three days before their lead candidate was declared a failure. "There is currently no FDA-approved drug to treat this condition, which is a roughly $1 billion worldwide market opportunity," says Ray McKee, vice president of investor relations and corporate development at Pharmos. "Patients with TBI are primarily young, and the societal burden of this condition costs the US healthcare system over $50 billion annually." Note several months earlier the CEO was touting the market opportunity as only "about $500 million" (see Law of Hype #3 for rules on ratcheting up TAM).

PARS' enterprise value peaked at $355.8 million in early 2004.

> "Jerusalem Post: Pharmos soars on FDA approval
>
> Oct. 01 (The Jerusalem Post) -- Shares of Pharmos Corporation rose more than 40 percent to $2.83 in morning trading Tuesday after it announced two big wins, Fast Track approval by the US Food and Drug Administration for its traumatic brain injury (TBI) treatment Dexanabinol, and $21 million of convertible debt financing from six institutional investors. With its Fast Track designation, the FDA "acknowledges TBI as a serious, often life-threatening condition for which no approved therapies exist," Pharmos said in a statement. Dexanabinol is designed to block the toxins that lead to deadly inflammation in the brain following a head trauma. Pharmos said it is the only treatment available for this usage, and estimates the annual market potential for the drug to be $500 million in the US, and more than $1 billion worldwide. Dexanabinol was discovered at the Hebrew University and uses a synthetic derivative of the active ingredient in marijuana, tetrahydrocannabinol (THC). Pharmos also said its new funding could be used to fund future acquisitions. Some $16m. of its new financing will be available to fund acquisitions, while the other $5m. will be used for working capital purposes, the company said. The company already had cash stores of about $23m. as of June." (Copyright 2003 The Jerusalem Post)

- Like Sativex currently for the treatment of chronic cancer pain, PARS' Dexanabinol had received FDA Fast Track designation.
- PARS was around $9 (using reverse-split adjusted prices) prior to the Fast Track approval by the FDA in October 2003 and proceeded to a high of $22.82 in March of 2004. By the end of the year the stock was at $5 and change and it still would have provided as a good short entry as one year forward it was at $2. It is still traded and it's last quoted price was $0.0421.
- Amazingly, insiders were able to cash out $19,425,974 (!) worth of their stock holdings in the year prior to PARS' big disappointment, selling large blocks just weeks prior to its 66% one-day decline when they announced a failure for their lead product.
- In reviewing the old sell-side reports, the stock had almost unanimous buy ratings heading into its precipitous collapse. Much like in GWPH's case, well before a Phase III read-out was available on their lead product, the company began investigations in adjacent market opportunities (namely going from Traumatic Brain Injury to Open Heart Surgery patients) that the sell-side sank their teeth into to come up with wildly optimistic scenarios (Law of Hype #3: slowly increase your perceived TAM over time).
- Prior to collapse, the sell-side revenue estimates exceeded $530 million for PARS (source: FERRIS, BAKER WATTS report, dated November 22nd, 2004). RBC's price target was consistently 150-200% above the market price prior to collapse, derived from assuming 40% market penetration and slapping a 30x multiple their 2008 EPS estimates (in 2004). I point all of this out to demonstrate the history of excitement surrounding cannabinoid drugs prior to their launch. Additionally, like GWPH's Epidiolex, Pharmos' Dexanabinol had received Orphan Drug status from the FDA, feeding the hype engulfing the company.
- Each of the aforementioned case studies went through a sobering up effect as hyped-up commercialization potential was not realized. Depending on the frame of reference, both Marinol and Cesamet were commercial successes in their own right, yet both eventually succumbed to generic competition as their patents expired. GW's pipeline could face a similar fate in the long-run preventing Wall Street's peak sales estimates in the out year from being reached.

Theoretical TAM Exercise:

The company estimates TAM is loosely as follows:

- 466,000 children with epilepsy in the US
    - 20% show pharmaco-resistance to currently available drugs
        - 466,000 *20% = 93,200 total potential patients
            - This is even farther down the road—initial indication is for DS patients only
- REALITY:
    - With Epidiolex they are specifically targeting Dravet Syndrome patients
        - 5,440 US Dravet Syndrome patients, 6,700 in the EU
        - (5,440 + 6,700)= 12,140 * $50,000 price = $607,000,000 in sales potential **if capturing 100% of Dravet Syndrome opportunity whereas Piper Jaffray, who has the highest PT, has mentioned up to $3.75 billion for the epilepsy opportunity alone due to large potential off-label use**
    - However, pricing is assumed to achieve ultra-orphan status due to limited patient pool. Unlike ultra-orphan drugs, Epidiolex has alternatives with similar efficacy widely available.
    - 8,000 patients already taking or on waiting list for Charlotte's Web, which is a large portion o

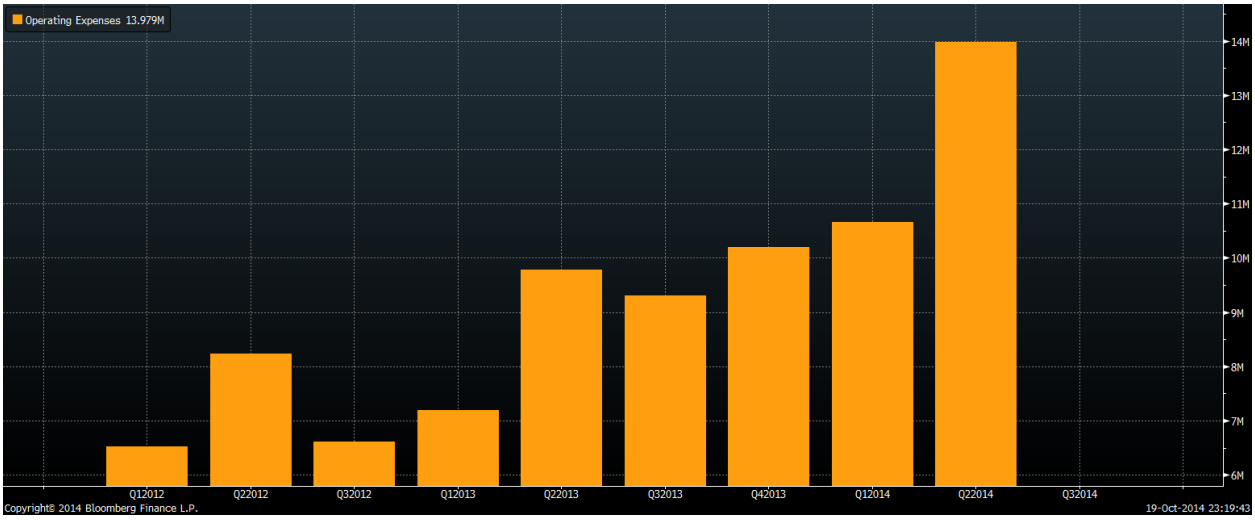
Financials Overview

Revenue Q2: $7.6mm, $30.4mm annualized, $7.3mm in Q2 2013, showing no growth in Sativex sales.

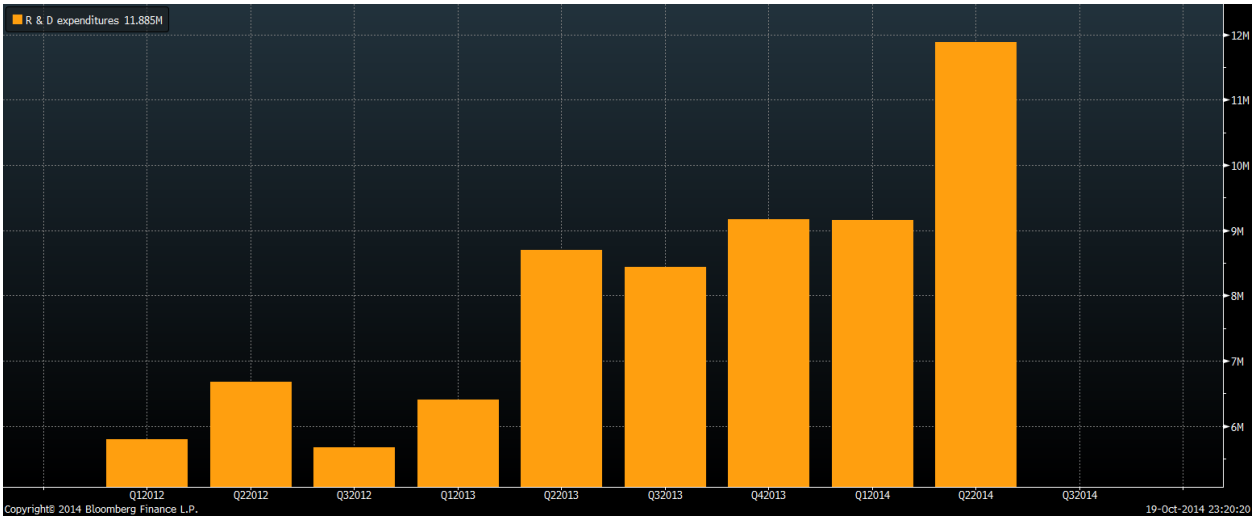
Loss for three months ended June 30th, 2014 was $11.9 million, or $47.6 million annualized.

Balance Sheet: Unfortunately, GWPH does have quite the cash hoard built up from three equity offerings that happened in quick succession. At the end of the latest quarter they had $287.8 million, or several years' worth of cash burn.

Growth of Quarterly Op-Ex:



R&D Expenditures quarterly since Q1 2012:



R&D run-rate is $47.54 million. Annualized operating losses are $28.368 million.

Valuation exercise: At a 4x sales multiple of 25% Dravet Syndrome opportunity penetration by 2021 and $40k/year pricing, discounted back at 12%, a generous assumption of 4x $100 million in Sativex sales by 2021 also discounted back at 12%, combined with full credit for their current cash balance of $287 million, yields a current EV of $687.6 million and market cap of $974.6 million, or price target of $49.41, 27% below the current market price.

Trading Comp:

Insys Therapeutics is valued at an enterprise value of $1.292 billion, only slightly exceeding GWPH's $1.18 billion even after its recent ~30% relative decline. INSY's TTM sales are $166.7 million with 2015 estimates sitting at $265.5, for 24.4%

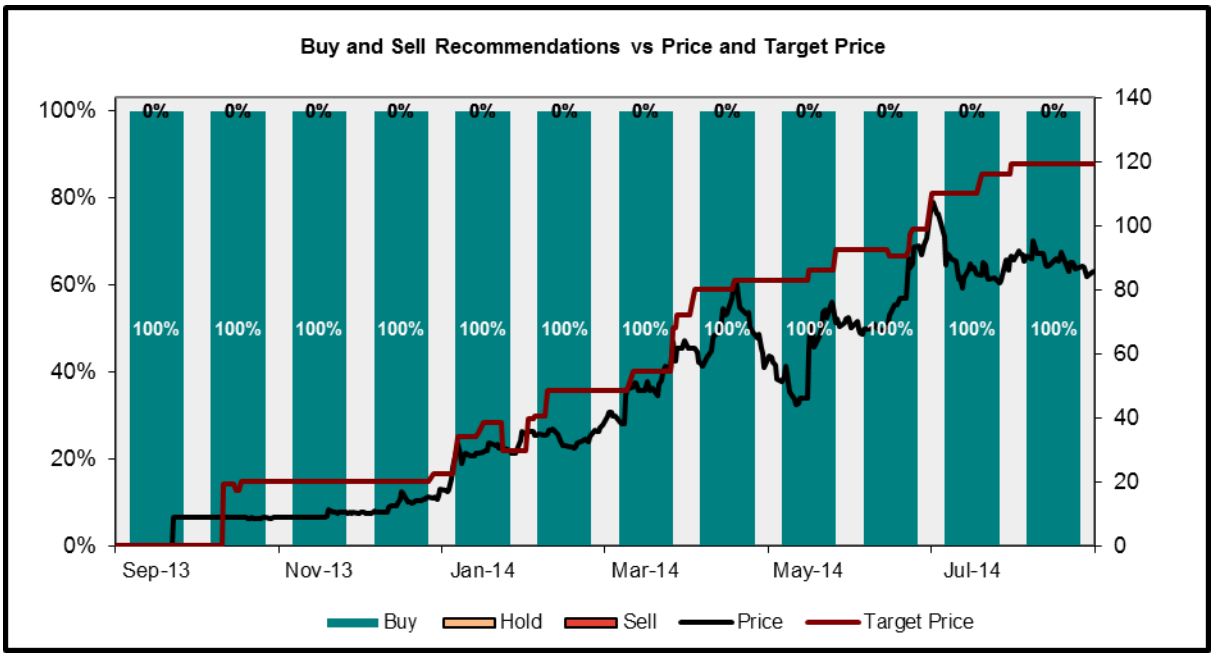
estimated growth over 2014. In reviewing various sell-side valuation reports for INSY, it is clear in their sum of the parts analysis that their CBD based pipeline receives little to no valuation consideration.

From a recent RBC initiation when the stock price was $38:

- Subsys: $33
- Dronabinol: $10
- Spray Technology: $7
- Cash: $2
- Price target of $51
- Zero consideration given for INSY's pharmaceutical CBD treatment for LGS or Dravet Syndrome, which have both also received orphan drug status from the FDA.
- Zero consideration given for INSY's treatment for glioblastoma multiforme, which has received orphan drug status. Neither of these have started clinical trials so they are in earlier stages of development, but it is interesting to note the diverging focus and valuations between INSY and GWPH despite similar aspirations. INSY is unlikely to beat GWPH to the punch, but will be nipping on their heels. With over $222 million in annualized sales and similar potential embedded within their early stage CBD product pipeline, INSY warrants a look for a pair trade/high-beta hedge against a GWPH short.
- Also, interestingly the short interest on INSY is 54.4% of its float, versus ~9.1% for GWPH

Sentiment:

Bloomberg shows that GWPH has never had anything other than a buy rating since its US IPO. A sampling of price targets demonstrates the extreme valuations Wall Street is calling for: Cowen PT $110, Leering PT $110, Piper Jaffray PT $147—the lowest of these would translate into a $2.2 billion equity valuation. The average price target is 88% higher than current price, even with stock up 133% in the last twelve months. Of course the sell side loves it, as it has had upward price momentum since inception…until recently…and bequeaths profitable gifts of frequent and increasingly large new equity issuances. As it continues to weaken, they will most certainly start to sour on it. Discount rates seem too low as 11% seems to be the discount rate of choice. The sell-side has adopted the usual "bullish no matter what happens" mentality. For example from a Piper Jaffray report on October 3rd this year: "…if [topline data] erodes somewhat, which we doubt it will, it's still fine."



History of Equity Offerings:

- 3/19/13 announcement date for $50mm, 3.5mm ADRs. Pricing date of 5/1/13 at offer price of $8.90 for proceeds of $31.15mm. Underwriters: Lazard, Cowen, Canaccord, Roth Capital. Poorly subscribed offering, receiving far less than originally planned $50mm in proceeds.
- 12/20/13 announcement date for $79.4mm of 2mm ADRs at $39.70. Pricing date of 1/9/14, upsized to 2.4411mm ADRs for $87.88mm of proceeds, but priced below range at $36.00. Green Shoe exercised for total Post Shoe Amount of $101.062 million. Underwriters: Morgan Stanley, Cowen, Piper Jaffray, Canaccord Genuity.
- 6/17/14 announcement date for shelf registration, $147.611mm of 1.7mm ADRs. The size of the follow-ons getting aggressively larger. 500,000 were offered by selling shareholders for which the company received no proceeds. Pricing date 6/18/14 at $86.83. The company received net proceeds of $118 million. Underwriters: Morgan Stanley, Bank of America Merrill Lynch, Cowen, Piper Jaffray. Diluted share count has risen to 209.6 million, up from 133.0 million at the time of the IPO.

Ownership:

Ownership is mostly concentrated in the mega-Mutual fund type of companies:

Holder Name	Position	Position Change	Market Value	% of Ownership	Report Date	Source	Country
CAPITAL RESEARCH GLO	2,048,820	185,720	175,563,386	10.40%	7/31/2014	13G	UNITED STATES
PRUDENTIAL PLC	870,905	0	74,627,849	4.42%	6/26/2014	RNS-MAJ	BRITAIN
FMR LLC	770,927	-36,900	66,060,735	3.91%	7/31/2014	ULT-AGG	UNITED STATES
FRANKLIN ADVISERS IN	446,870	-24,630	38,292,290	2.27%	6/30/2014	13F	UNITED STATES
FEDERATED INVESTORS	401,514	73,700	34,405,735	2.04%	6/30/2014	13F	UNITED STATES
ALLIANCEBERNSTEIN LP	373,440	91,600	32,000,074	1.90%	6/30/2014	13F	UNITED STATES
CHESAPEAKE PARTNERS	354,278	198,923	30,358,082	1.80%	6/30/2014	13F	UNITED STATES
FARALLON CAPITAL MAN	352,500	-311,500	30,205,725	1.79%	6/30/2014	13F	UNITED STATES
JANUS CAPITAL MANAGE	344,932	79,187	29,557,223	1.75%	6/30/2014	13F	UNITED STATES
WELLS FARGO & COMPAN	342,512	11,872	29,349,853	1.74%	7/31/2014	ULT-AGG	UNITED STATES
VHCP MANAGEMENT LLC	311,853	-332,523	26,722,684	1.58%	6/30/2014	13F	UNITED STATES
MORGAN STANLEY	252,062	36,622	21,599,193	1.28%	6/30/2014	ULT-AGG	UNITED STATES
JENNISON ASSOCIATES	199,316	8,743	17,079,388	1.01%	6/30/2014	13F	UNITED STATES
T ROWE PRICE ASSOCIA	145,724	-153,115	12,487,090	0.74%	6/30/2014	13F	UNITED STATES

Capital Research Global Advisors is one of the largest investment advisors in the world. They own hundreds of stocks and frankly despite how crazy it sounds $175mm appears to be on the normal side in terms their position sizing.

Conclusion

If one were to invert ("Invert, always invert") the famous phrase "If you don't know history you're doomed to repeat it" it could be alternately stated, "Those who know history have the opportunity to repeat it." Shorting these previously hyped-up cannabis drug companies provided great opportunities for savvy investors. It is no surprise that history appears to be rhyming once again, providing investors with another great alpha generating trading opportunity in the biotech space as GWPH's high wears off. There is extreme risk in shorting "open ended growth stories" – so it is best to utilize options trades and hedges along the way. We want to have bearish options trades set up around clinical trial announcements. Regardless of clinical trial outcomes, our two year price target is ~30% lower than the current price, but where GWPH would still have a > $600 million EV. This is based on a 4x peak probable sales number in 2021 discounted back at 12%. While clinical development remains on track, if they do happen to fail to get approval for cancer pain treatment for Sativex in the US or Epidiolex for variations of pediatric epilepsy, our price target will move substantially lower. If they do get to the market in the US, any positive news cycle and reinvigorated hyping may present additional opportunities to add short exposure as the sales projections in the long run are unlikely to pan out.

Links of Interest and Additional Sources:

Bios Research: www.biosres.com

http://www.epilepsycolorado.org/index.php?s=10907

http://time.com/3264691/medical-marijauna-epilepsy-research-charlottes-web-study/

http://clinicaltrials.gov/ct2/show/NCT02229032?term=Dravet&rank=1

https://www.youtube.com/watch?v=i2qFDb8LExo

Dr. Sanjay Gupta did a full documentary called Weed 2 – Cannabis Madness that first aired on March 14th, 2014 that highlighted GWPH's efforts.

http://www.fda.gov/ohrms/dockets/dockets/05n0479/05N-0479-emc0004-04.pdf

http://www.cesamet.com/patient-home.asp

http://www.cbsnews.com/news/a-look-at-fda-okd-marijuana-drug/

http://www.evaluategroup.com/View/12455--1002-modData/product/cesamet

http://en.wikipedia.org/wiki/Medical_cannabis_in_the_United_States

https://www.youtube.com/watch?v=ciQ4ErmhO7g

http://www.cnn.com/2014/07/28/health/federal-marijuana-bill/index.html

http://www.huffingtonpost.com/2014/05/21/insurance-medical-marijuana_n_5361521.html

http://www.lifehealthpro.com/2014/03/18/insurance-coverage-for-medical-marijuana-not-anyti?t=individual-health&page=2

http://www.drugwatch.com/2014/06/16/health-insurance-medical-marijuana/

Sativex US Phase 2b trial info: http://www.jpain.org/article/S1526-5900(12)00019-3/pdf

Comprehensive list of clinical studies and case reports with cannabis:

http://www.cannabis-med.org/studies/ww_en_db_study_search.php

"THCA Tincture works just as well as CBD for Pediatric Seizures, Here's How to Make it":

http://www.tokesignals.com/parents-thca-tincture-works-just-as-well-as-cbd-for-pediatric-seizures-heres-how-to-make-it/

Glossary of Important Terms that were referred to:

Seizure: abnormal electrical disturbances in the brain

Epilepsy = wide spectrum of disorders, different types of seizures, many causes, generally defined as two or more seizures occurring greater than 24 hours apart

CBD= phytocannabinoids cannabidiol. Cannabinoids are a class of chemical compounds that repress certain brain receptors. Cannabidol is one of 85 identified different cannabinoids that have been isolated from the cannabis plant.

THC = tetrahydrocannibinol, gives weed its psycadelic/high effect

Tincture = alcoholic extract of a plant, or in this case referring to weed oil

Somnolence = strong desire for sleep or sleeping for unusually long periods (this is the top side affect in GW's clinical trials, hopefully not one from reading this report).

Dravet Syndrome = also known as Severe Myoclonic Epilepsy of Infancy (SMEI), is a rare and catastrophic form of intractable epilepsy that begins in infancy.

Lennox-Gastaut Syndrome (LGS) = a severe form of epilepsy in young children

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GWPH follows many of Voss' top Laws of Hype (@LawsofHype |www.lawsofhype.com), including Law #3: Stand for an Ideal. Pick a moral fight. Save the world. We are not against companies picking a side of a moral fight or standing for an ideal, simply objectively pointing out that many of the best hyped-up stocks predictably fall into this category and use it to tug at emotional heart strings that lure in compassionate investors who bypass the desire for empirical evidence or reasonable valuations. Looking all the way back to PARS, it too was utilizing this Law of Hype, per their Q3 2004 conference call a questioner (Gabriel Fernandez) highlights this affect, "Can the neurosurgical societies help in obtaining these all patients receive the drug? **To me this is a moral issue.**" Do you notice that bubble areas repeat themselves over and over again? Car companies of the future (see $TSLA and the Tucker Car Corporation or the 1940s), green energy stocks, biotech, now weed stocks? These are generally poster children for Laws of Hype #1, #2 and #3, and offer tremendous long-term shorting opportunities.

All smoking puns intended

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