

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Month of December, 2015

Commission File Number: 001-35892

GW PHARMACEUTICALS PLC

(Translation of registrant's name into English)

Sovereign House
Vision Park
Histon
Cambridge CB24 9BZ
United Kingdom
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

Other Events

On December 7, 2015, GW Pharmaceuticals plc issued a press release announcing its financial results for the fourth quarter and twelve months ended September 30, 2015 and provided an update of its operational progress. The press release is attached as Exhibit 99.1 and is incorporated by reference herein. The information contained in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Exhibits

99.1 Press release dated December 7, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GW Pharmaceuticals plc

By: /s/ Adam George
Name: Adam George
Title: Chief Financial Officer

Date: December 7, 2015



GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2015 Financial Results and Operational Progress

- Three Phase 3 Epidiolex clinical trials fully recruited above target sample size – on track for initial data in Q1 2016 -
- Significant clinical activity in multiple cannabinoid pipeline programs -
- Conference Call Today at 4:30 p.m. EST, 9:30 p.m. GMT -

London, UK, 7 Dec 2015: GW Pharmaceuticals plc (NASDAQ: GWPH, AIM: GWP, “GW,” “the Company” or “the Group”), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announces financial results for the fourth quarter and twelve months ended 30 September 2015.

“This last year has seen GW maintain a rapid pace in the progress of our pediatric epilepsy research program, including the start and completion of recruitment of multiple Phase 3 trials for Epidiolex, and the expansion of our expanded access program which has continued to yield promising safety and efficacy data,” stated Justin Gover, GW’s Chief Executive Officer. “We expect to carry this momentum through 2016 with top-line data from four Epidiolex pivotal trials, our first NDA filing, build-out of our U.S. commercial organization, and ongoing data read-outs from a number of clinical pipeline programs.”

2015 HIGHLIGHTS

- Epidiolex[®] (CBD) childhood epilepsy program:
 - o Company sponsored Phase 3 development programs in Dravet syndrome and Lennox-Gastaut syndrome
 - First Phase 3 Dravet syndrome trial fully enrolled above original target sample size (120 randomized) data expected Q1 2016
 - First LGS Phase 3 trial fully enrolled above original target sample size (171 randomized). Data expected Q2 2016
 - Second LGS Phase 3 trial fully enrolled above original target sample size. (>210 expected to randomize). Data expected Q2 2016
 - 2nd Phase 3 Dravet syndrome trial ongoing. Data expected mid 2016
 - NDA submission with FDA expected Q4 2016
 - Phase 3 Tuberous Sclerosis Complex trial expected to commence Q1 2016
 - Additional clinical development for Epidiolex beyond initial three indications expected to commence in H2 2016
 - o Expanded access program:
 - Separate data update announcement issued today at the American Epilepsy Society December 2015 Annual Meeting
 - Approximately 350 children on treatment at 32 U.S. clinical sites
 - Over 850 children authorized for treatment by FDA under Expanded Access Treatment INDs and 6 U.S. State programs
 - o Strategic agreement with Government of New South Wales in Australia to conduct Epidiolex and CBDV clinical trials

- o CBD and CBDV patent portfolio strengthened
- Advanced clinical programs in multiple cannabinoid pipeline product candidates:
 - o Phase 2a CBD schizophrenia study data shows positive proof-of-concept with a reassuring safety profile
 - o Phase 2 CBDV epilepsy study in adults underway with data expected H2 2016
 - o Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) IV CBD Phase 1 clinical program expected to commence in H2 2016
 - Orphan Drug and Fast Track Designations granted from FDA and EMA
 - o Clinical trials within the field of autism spectrum disorders expected to commence in H2 2016
 - o Phase 1b/2a study for the treatment of Recurrent Glioblastoma Multiforme (GBM) fully enrolled with data expected in mid-2016
 - Orphan Drug Designation granted from FDA
 - o Phase 2 study in type-2 diabetes fully enrolled with data expected mid 2016
 - o Phase 2 study of Sativex in spasticity due to cerebral palsy ongoing with data expected mid 2016
- Pre-clinical progress addressing a number of areas of unmet need including autism spectrum disorders, duchenne muscular dystrophy, glioma, ovarian and pancreatic cancers, and chemotherapy-induced cachexia
- U.S. operations established in Carlsbad, California
 - o GW's CEO, Justin Gover, relocates to the U.S.
 - o Seasoned industry executive Julian Gangolli appointed as President, North America
 - o Epilepsy specialist team build-out underway

FINANCIAL HIGHLIGHTS

- Balance sheet further strengthened with successful NASDAQ follow-on offering raising net proceeds after expenses of £127.5 million (\$193.3 million)
- Revenue for the twelve months ended 30 September 2015 of £28.5 million (\$43.2 million) compared to £30.0 million for the twelve months ended 30 September 2014.
- Loss for the twelve months ended 30 September 2015 of £44.6 million (\$67.4 million) compared to £14.7 million for the twelve months ended 30 September 2014.
- Cash and cash equivalents at 30 September 2015 of £234.9 million (\$355.3 million) compared to £164.5 million as at 30 September 2014.

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the 2015 fourth quarter and year-end financial results today at 4:30 p.m. EST / 9:30 p.m. GMT. To participate in the conference call, please dial 877-407-8133 (toll free from the U.S. and Canada), or 0800-756-3429 (toll free from the UK) or 201-689-8040 (international). Investors may also access a live audio webcast of the call via the investor relations section of the Company's website at <http://www.gwpharm.com>. A replay of the call will also be available through the GW website shortly after the call and will remain available for 90 days. Replay Numbers: (toll free):1-877-660-6853, (international):1-201-612-7415. For both dial-in numbers please use conference ID #13626013.

Enquiries:

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GW Pharmaceuticals plc
("GW" or "the Company" or "the Group")

Preliminary Results for the Fourth Quarter and Year Ended 30 September 2015

OPERATIONAL OVERVIEW

GW Overview

GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. In its 17 years of operations, GW has established a world leading position in the development of plant-derived cannabinoid therapeutics through its proven drug discovery and development processes, intellectual property portfolio and regulatory and manufacturing expertise. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex[®], which is approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the United States. GW is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex[®], which is in Phase 3 clinical development for the treatment of Dravet syndrome and Lennox-Gastaut syndrome and which is also expected to enter Phase 3 clinical trials in the treatment of Tuberous Sclerosis Complex in early 2016. GW has a deep pipeline of additional cannabinoid product candidates which includes clinical development across a variety of compounds for both orphan and non-orphan indications.

U.S. Operations Update

In June 2015, GW announced the relocation of the Company's CEO, Justin Gover, to the U.S. and the appointment of Julian Gangolli to the newly created position of President, North America. Previously, Mr Gangolli was President of the North American Pharmaceutical division of Allergan Inc., with responsibility for a 1,400-person integrated commercial operation with sales exceeding \$3.8 billion in 2014. Together, Mr. Gangolli and Mr. Gover are leading GW's growth in the U.S., preparations for the expected NDA submission and build-out of GW's in-house U.S. commercial infrastructure to support the launch of Epidiolex. Mr. Gangolli and Mr. Gover are based at GW's new U.S. office in Carlsbad, California.

U.S. Follow-on Offering

In May 2015, GW successfully completed a U.S. follow-on offering on the NASDAQ Global Market issuing a total of 1,840,000 American Depositary Shares ("ADSs") at a price of \$112.00 per ADS. This total included the full exercise of the underwriter's option and resulted in total net proceeds after expenses of approximately \$193.3 million (£127.5 million). The funds raised in this offering are primarily intended to support further expansion of GW's Epidiolex manufacturing capability and build-up of inventory in preparation for U.S. launch, if Epidiolex is approved; clinical development of other orphan indication opportunities for Epidiolex, with an initial focus on Tuberous Sclerosis Complex; the advancement of other pipeline opportunities, including an intravenous CBD formulation in the treatment of Neonatal Hypoxic-Ischemic Encephalopathy (NHIE); pre-launch commercialization activities for Epidiolex in the United States; and for other general corporate purposes.

Epilepsy in the United States

Epilepsy is one of the most common neurological disorders in children. According to Russ et al in the February 2012 edition of *Pediatrics*, there are 466,000 childhood epilepsy patients in the United States and 765,000 patients in Europe, of which 30%, or about 140,000 patients in the United States and about 230,000 in Europe, are deemed medically intractable or pharmacoresistant. According to Kwan and Brodie in the February 2000 edition of the *New England Journal of Medicine*, 36% of patients with epilepsy were pharmacoresistant. Of the patients in the study, 47% became seizure-free during treatment with their first antiepileptic drug, 13% became seizure-free during treatment with a second anti-epileptic drug as a monotherapy, and 4% became seizure-free with a third anti-epileptic drug or treatment with multiple anti-epileptic drugs. The remaining 36% of patients were classified by the authors as having pharmacoresistant epilepsy. Furthermore it is recognized that some of those that do find relief often suffer side effects severe enough with their current medication that an alternative or adjunct is often sought. The costs of uncontrolled epilepsy are significant, with direct and indirect costs associated with epilepsy totaling more than \$15 billion per year. 50,000 epilepsy related deaths occur each year, more than breast cancer deaths annually.

Epilepsy Drug Development Programs

GW's epilepsy franchise centers around two product candidates, Epidiolex, a liquid formulation of pure plant-derived cannabidiol (CBD), and GWP42006 (CBDV). GW is currently pursuing the development of CBD for a series of individual orphan epilepsy-related indications providing GW with significant new market opportunities. GW retains all rights to commercialize any and all products that evolve from these programs.

Epidiolex®

GW is undertaking a formal development program for Epidiolex in the field of severe, drug-resistant childhood epilepsy with initial focus on conducting formal development programs in the treatment of three indications - Dravet syndrome, Lennox-Gastaut syndrome (LGS) and Tuberous Sclerosis Complex (TSC). The Company has to date received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for Epidiolex for the treatment of both Dravet syndrome and LGS. Additionally, GW has received Fast Track Designation from the FDA and Orphan Designation from the European Medicines Agency (EMA) for Epidiolex for the treatment of Dravet syndrome.

There is a significant effort to identify the mechanisms of action that underpin the clinical effectiveness of Epidiolex (and other cannabinoids) in epilepsy, including investigation of the effect of cannabinoids on epilepsy associated gene expression. Based on recent findings in *The Journal of Pharmacology and Experimental Therapeutics*, CBD is likely to be acting via more than one mechanism of action with the effect of reducing neuronal hyperexcitability. Importantly, the anti-seizure effects of CBD are not dependent on cannabinoid receptors, nor on sodium channels.

Dravet Syndrome

According to Forsgren L. et al. in the 2004 edition of *Epilepsy in Children*, the incidence of epilepsy in the first year of life is 1.5 per 1,000 people, or, by our estimate, 6,450 new epilepsies per year worldwide. According to Dravet et al. in the 2012 edition of *Epileptic Syndromes in Infancy, Childhood and Adolescence*, up to 5% of epilepsies diagnosed in the first year of life are Dravet syndrome, equating to 320 new cases per year in the United States with a mortality rate that studies have shown may be as high as 15% in the first 20 years of life, or, by our estimate, 5,440 patients with Dravet in the United States under the age of 20 years. Applying the same assumptions in Europe, we believe there are an estimated 6,710 Dravet patients in the European Union. It is likely that these figures are a low estimate, however GW believes that this syndrome is likely underdiagnosed.

Epidiolex development in Dravet syndrome

GW commenced a Phase 2/3 clinical trial of Epidiolex for Dravet syndrome in October 2014. This trial is designed as a two-part randomized double-blind, placebo-controlled parallel group dose escalation, safety, tolerability, pharmacokinetic and efficacy trial of single and multiple doses of Epidiolex to treat Dravet syndrome in children who are not responding adequately to other anti-epileptic drugs. The first part of this trial was completed in February 2015, and included a dose-ranging pharmacokinetic and safety evaluation in a total of 34 patients over a 3-week treatment period.

Following a review of the Part A data by an independent panel, Part B of the trial commenced in March 2015 and is a Phase 3 pivotal placebo-controlled safety and efficacy evaluation of Epidiolex (at a dose of 20mg/kg per day) over a 3-month treatment period. Originally expected to recruit 100 patients, this trial reached a total of 120 patients randomized. In April 2015, GW commenced an additional dose-ranging Phase 3 trial in Dravet syndrome which is recruiting 150 patients. This placebo-controlled trial differs from the first Phase 3 trial in that it includes two Epidiolex dose arms, at 20mg/kg and at 10mg/kg. Both of these studies will be the largest known controlled trials in Dravet syndrome.

GW expects to report top-line results from the Phase 2/3 pivotal safety and efficacy study in the first quarter of 2016 and results from the second Phase 3 trial around mid 2016. The primary measure of efficacy in both trials will be the comparison between Epidiolex and placebo in the percentage change from baseline in number of convulsive seizures.

It is important to note that the protocols for both the Epidiolex Dravet syndrome and LGS Phase 3 trials allow for a prospective pooling of data within each indication, which is endorsed by the FDA in its recent guidance (Integrated Summary of Effectiveness “ISE” – October 2015). The recommendations in this guidance reflect the FDA’s current thinking regarding information that industry should include in an ISE to provide an integrated analysis that offers insights beyond those observable in individual clinical trials, where NDA filers are “encouraged to provide an ISE because it represents an opportunity to present a coherent analysis and presentation of the drug’s benefits.”

Lennox-Gastaut Syndrome (LGS)

The Lennox-Gastaut syndrome (LGS) is a type of epilepsy with multiple types of seizures, particularly tonic (stiffening) and atonic (drop) seizures. LGS accounts for about 3% to 4% of childhood epilepsies with the cause of the disorder unknown in 1 out of 4 children. LGS affects between 14,500 – 18,500 children under the age of 18 in the U.S. and over 30,000 children and adults in the U.S. 80% of children with LGS continue to experience seizures, psychiatric, and behavioral deficits in adulthood. Seizures due to LGS are hard to control and they generally require life-long treatment as LGS usually persists into the adult years. Historically, patients with LGS have had few effective treatment options. Intellectual and behavioral problems associated with LGS are common and add to the complexity of this syndrome and the difficulties in managing life with LGS.

Epidiolex development in LGS

In May 2015 we commenced the Phase 3 pivotal trials program for Epidiolex in LGS. The first Phase 3 trial is a placebo-controlled safety and efficacy evaluation of Epidiolex (at a dose of 20mg/kg per day) over a 3-month treatment period. Originally expected to recruit 100 patients, this trial reached a total of 171 patients randomized. The second placebo-controlled Phase 3 trial differs from the first Phase 3 LGS trial in that it includes two Epidiolex dose arms, at 20mg/kg and at 10mg/kg. Originally expected to recruit 150 patients, it has completed enrolment and is estimated to have a total of more than 210 patients randomized. We expect to report top-line results from both trials in the second quarter of 2016. The primary measure of efficacy in both trials will be the comparison between Epidiolex and placebo in the percentage change from baseline in number of drop attacks.

Tuberous Sclerosis Complex (TSC)

TSC is a genetic disorder that causes non-malignant tumors to form in many different organs, with the brain and skin being the most commonly affected tissues. TSC results from a mutation in tumor suppression genes TSC1 or TSC2 and is estimated to affect approximately 50,000 patients in the United States. The most common clinical feature of TSC is epilepsy, which occurs in 75% – 90% of patients, about 70% of whom experience seizure onset in their first year of life. Approximately 60% of these TSC patients (or approximately 25,000 of patients in the U.S.) have treatment-resistant seizures. There are significant comorbidities associated with TSC including cognitive impairment in 50%, autism spectrum disorders in up to 40% and neurobehavioral disorders in over 60% of individuals with TSC.

Epidiolex development in TSC

Based on the findings in the physician-led expanded access program, GW announced earlier this year that its third target indication will be TSC and expects to commence Phase 3 clinical development in early 2016.

Epidiolex U.S. Expanded Access Program

In parallel with the GW's formal clinical trial program, the FDA has granted 20 intermediate expanded access INDs to independent physician investigators in the U.S to treat a total of over 450 children and young adults suffering from intractable epilepsy with Epidiolex. In addition, the FDA has granted further INDs to treat 400 additional patients under expanded access programs supported by 6 U.S. states and for which GW is supplying Epidiolex. The FDA may authorize expanded access programs to facilitate access to investigational drugs for treatment use for patients with a serious or immediately life-threatening disease or condition who lack therapeutic alternatives. The FDA has also granted to physicians 11 individual emergency INDs and 3 individual patient non-emergency INDs. As at mid November, approximately 350 children are on treatment at 32 U.S. clinical sites

Seven abstracts related to GW programs were presented at the 69th Annual Meeting of the American Epilepsy Society including data from the physician-led Epidiolex expanded access program. As reported today in a separate press release from GW, physician reports of clinical effect and safety data were presented on 261 children and young adults with treatment-resistant epilepsy who have been treated with Epidiolex, for a period of at least 12 weeks (Devinsky et al). These data are from 16 clinical sites in the United States and were generated under expanded access INDs authorized by the FDA. In addition, physician reports of safety data were presented on 313 patients (261 patients with 12 weeks treatment effect data plus additional 52 patients still in their first 12 weeks of treatment or who withdrew from treatment). The expanded access program comprises clinical studies performed by individual physicians. Highlights from this data include:

- Included within the information presented is new data issued in a poster presentation on 261 patients enrolled in this expanded access program, representing a two-fold increase in patient numbers over the previous disclosure in April 2015
- Promising signals of efficacy have been reported, with median reduction in total seizures of 45% across all patients after 12 weeks treatment, and maintenance of clinical effect at 36 weeks
- 47% of patients experienced a $\geq 50\%$ reduction in seizures after 12 weeks treatment
- Epidiolex was well tolerated - only 4% of patients withdrew due to side effects
- Additional data in patients with diagnoses of Dravet syndrome, LGS and TSC, the targets of the GW sponsored Phase 3 clinical trial program for Epidiolex, were presented and this data further supports GW's choice of these indications

Additional information on the presentations at the annual meeting can be found online at www.aesnet.org.

CBDV (cannabidivarin) Development Program

GW is developing a second epilepsy product candidate, GWP42006, which features the non-psychoactive cannabinoid CBDV as the primary cannabinoid. CBDV is distinct in chemical structure to CBD and has shown anti-seizure properties across a range of *in vitro* and *in vivo* models. GW has completed a Phase 1 trial of GWP42006 by the oral and intravenous route in 66 healthy subjects. In this trial, GWP42006 was well tolerated even at the highest tested dose. There were no serious or severe adverse events, nor any withdrawals due to adverse events.

In 2015, GW commenced a Phase 2 study of GWP42006 in patients with epilepsy and expects data from that study in the second half of 2016. GWP42006 has the potential for development in the field of pediatric epilepsy as well as the broader epilepsy market.

New South Wales

In October 2015, GW announced that it had signed a Memorandum of Understanding (MOU) with the Government of New South Wales in Australia to progress a research program for Epidiolex and CBDV in children with severe, drug resistant childhood epilepsy. The MOU will facilitate:

- A world first, Phase 2 clinical trial in children for GWP42006 (CBDV)
- A compassionate access program for Epidiolex
- Provision for NSW to host additional Phase 3 clinical trials of Epidiolex
- A Phase 4 clinical trial of Epidiolex (to follow completion of the Phase 3 studies)

CBD/CBDV Intellectual Property Portfolio

GW's patent portfolio related to the use of CBD and/or CBDV includes fourteen patent families containing one or more pending and/or issued patents with claims in the treatment of epilepsy, compositions, extraction techniques, CBD and CBDV extracts and highly purified plant-derived CBD.

These include Notices of Allowance received this year from the U.S. Patent and Trademark Office for patent applications protecting the use of CBD in the treatment of partial seizures and for CBDV in the treatment of patients with epilepsy. The issued patents from these applications will provide an exclusivity period until June 2030 and March 2031 respectively. We have also recently had a patent granted in the UK which claims the use of CBD in combination with certain standard anti-epileptic drugs in the treatment of epilepsy. Equivalent patent applications are being prosecuted in the US and at the European Patent Office.

Epidiolex Manufacturing & Production

GW is actively scaling its growing and manufacturing of Epidiolex to meet anticipated commercial demand, if approved. From its extensive experience in growing CBD botanical raw material, GW is able to utilize a range of growing methods to generate significant quantities of CBD botanical raw material derived from its proprietary CBD plant chemotypes. In 2015, production increased by a factor of approximately 20 times compared with the previous year and is expected to double again in 2016. This will equate to approximately 200 Tonnes in 2016 and when purified and formulated, results in approximately 1.6 million 100mg/ml bottles of Epidiolex. With expectations of significant demand for Epidiolex upon approval, GW plans to continue expansion of its Epidiolex plant growing capacity well beyond this 2016 goal. The finished product, Epidiolex, is a liquid formulation of pure CBD and there are several processing steps beyond growing to ensure that the product is pure, meets the required FDA specification, and can be manufactured at scale to current Good Manufacturing Practice Regulations (cGMP). Each step has already been scaled and a further increase in scale is anticipated during 2016.

GW believes it is on track to be ready for FDA pre-approval inspection from H2 2016 onwards.

U.S. Legislative Update

Following NDA approval of a drug containing a Schedule I controlled substance, that substance must be rescheduled as a Schedule II, III, IV or V substance before it can be marketed. On November 17, 2015, H.R. 639, Improving Regulatory Transparency for New Medical Therapies Act, passed through both houses of Congress and on November 25, the Bill was signed into law. The new law removes uncertainty associated with timing of the DEA rescheduling process after NDA approval. Specifically, it requires DEA to issue an “interim final rule,” pursuant to which a manufacturer may market its product within 90 days of FDA approval. The new law also preserves the period of orphan marketing exclusivity for the full seven years such that this period only begins after DEA scheduling. This contrasts with the previous situation whereby the orphan “clock” began to tick upon FDA approval, even though the product could not be marketed until DEA scheduling was complete.

Other Orphan/Neurology Pipeline Programs

Schizophrenia

GW’s product candidate, an oral formulation of GWP42003 (CBD), has shown notable anti-psychotic effects in accepted pre-clinical models of schizophrenia and has also demonstrated the ability to reduce the characteristic movement disorders induced by currently available anti-psychotic agents.

In September 2015, GW announced positive top line results from an exploratory Phase 2a placebo-controlled clinical trial of CBD in 88 patients with schizophrenia who had previously failed to respond adequately to first line anti-psychotic medications. Over a series of exploratory endpoints, CBD was consistently superior to placebo, with the most notable differences being in the PANSS positive sub-scale ($p=0.018$), the Clinical Global Impression of Severity ($p=0.04$) and Clinical Global Impression of Improvement ($p=0.02$). The proportion of responders (improvement in PANSS Total score greater than 20%) on CBD was higher than that of participants on placebo and the Scale for Assessment of Negative Symptoms showed a trend in favour of CBD which reached statistical significance for patients taking CBD together with one of the leading first line anti-psychotic medications. The safety profile of CBD was particularly reassuring, with no serious adverse events and an overall frequency of adverse events very similar to placebo

GW believes that the signals of efficacy demonstrated in this trial, together with a notably reassuring safety profile, provide the Company with the prospect of new and distinct cannabinoid neuropsychiatric product pipeline opportunity as the mechanism of CBD does not appear to rely on the dopamine D2 receptor augmentation of standard antipsychotics. GW is now analysing the data to fully understand the appropriate next steps regarding product development in schizophrenia with future research likely focused on pediatric orphan neuropsychiatric indications.

Neonatal Hypoxic-Ischemic Encephalopathy (NHIE)

NHIE is acute or sub-acute brain injury resulting from deprivation of oxygen during birth (hypoxia). GW estimates 6,500 to 12,000 cases of NHIE occur in the U.S. each year. Of these, 35% are expected to die in early life and 30% are expected to develop persistent neurologic disability. There are currently no FDA-approved medicines specifically indicated for NHIE. The current standard of care for NHIE patients is to induce whole-body hypothermia. Even if a patient is put into induced hypothermia there is still a significant rate of morbidity and mortality, with a meta-analysis of the available data revealing a 27% death rate. Among the patients who survive NHIE, 28% suffer from major neurodevelopment issues and 26% develop Cerebral Palsy.

GW intends to commence a clinical development program with the FDA and expects to start a Phase 1 clinical study in healthy volunteers for an intravenous CBD formulation in the treatment of NHIE in H1 2016. GW has received Orphan Drug and Fast Track Designations from the FDA for CBD for the treatment of NHIE and has recently received Orphan Designation from the European Medicines Agency for the treatment of Perinatal Asphyxia, an alternate term that describes the same condition.

Autism Spectrum Disorders

Many of the pediatric intractable epilepsy conditions within the Epidiolex Expanded Access Program share considerable overlap with Autism Spectrum Disorders (ASD). Early clinical observations from treating physicians suggest a potential role for cannabinoids in addressing problems associated with ASD; they may be able to treat deficits in cognition, behavior and communication. Consequently, there are several ongoing initiatives within GW to evaluate a range of cannabinoids in pre-clinical models of ASD, with a focus on, but not limited to, those caused by single genetic aberrations. These conditions often fall within the orphan disease space and GW is working with investigators to gain clinical experience in the use of different cannabinoids with the aim to commence clinical trials in 2016.

Glioma

GW is testing its product candidate GWP42002:GWP42003 (THC/CBD) in the treatment of recurrent glioblastoma multiforme, or GBM, a particularly aggressive brain tumor which is considered a rare disease by the FDA and the EMA. The Company has received Orphan Drug Designation from the FDA for GWP42002:GWP42003 for the treatment of Glioma. In pre-clinical models, GW has shown these cannabinoids used together to be orally active in the treatment of glioma xenografts and have shown tumor response to be positively associated with tissue levels of cannabinoids.

GW has completed recruitment of a 20 patient placebo-controlled Phase 1b/2a trial in recurrent GBM. Data from this trial is expected around mid-2016.

Other Pipeline Programs

Sativex in 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, or THC, and CBD. Otsuka Pharmaceutical Co. Ltd, hold exclusive rights to commercialize Sativex in the U.S. and have funded a Phase 3 program to treat persistent pain in people with advanced cancer who experience inadequate pain relief from optimized chronic opioid therapy, the current standard of care.

This Phase 3 program consisted of three pivotal Phase 3 trials. Whilst Sativex did not meet the primary endpoint in these trials, a pre-specified subgroup analysis of US patients across the Phase 3 trials showed a statistically significant improvement for Sativex compared to placebo (n=248, p=0.02), with several significantly positive secondary efficacy endpoints. GW and Otsuka plan to meet with the FDA with a view to identifying the extent of additional clinical data required for a possible future NDA submission.

Sativex in Spasticity

Sativex is currently approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the U.S.

Sativex is also undergoing a Phase 2 80 patient placebo controlled trial in children with spasticity due to cerebral palsy. Results from this trial are expected in mid 2016.

Type-2 Diabetes

GW is testing its product candidate GWP42004 in the treatment of type-2 diabetes. GWP42004 is an orally administered product which features plant-derived tetrahydrocannabivarin (THCV) as its active ingredient. THCV is distinct from THC and does not share its intoxicating psychoactive effects. Pre-clinical models have shown evidence of pancreatic islet cell protection, and an earlier small scale proof of concept study have shown GWP42004 to have promising effects on glucose and insulin status in patients with Type 2 diabetes. The ongoing study will compare the efficacy, safety and tolerability of three doses of GWP42004 with placebo in a total of 200 patients and is expected to report data in mid-2016. GW believes that if the Phase 2 study confirms the earlier Phase 2 findings, GWP42004 would have the potential to offer a novel orally-administered treatment option in this large potential market.

Pre-clinical developments

In addition to GW's extensive in-house research organization, the Company has established a global network of leading scientists in the cannabinoid field including 36 academic institutions in nine countries. GW's proprietary cannabinoid product platform allows the Company to discover, develop and commercialize additional novel first-in-class cannabinoid products across a broad range of therapeutic areas. Some of the more advanced programs include:

- Assessment of the effect of cannabinoids on cognitive and behavioural function in animal models of conditions characterised as being on the 'autism spectrum'. These animal models include both genetically determined abnormalities of neurobehaviour, and chemically-induced models, and include Rett syndrome and Fragile X among others.
 - The use of CBD and other cannabinoid candidates in Duchenne muscular dystrophy (DMD), the most common inherited lethal childhood orphan disease in the world, where new discoveries lead researchers to conclude that muscle cells respond positively to CBD by increasing metabolic output and improving mitochondrial function,
 - In Glioma, cannabinoids induce glioma stem-like cell differentiation and inhibit gliomagenesis and research suggests that a combination of cannabinoids with other anticancer agents can eliminate GICs (Glioma Initiating Cells) which can cause recurrence of tumors after surgery. These findings are significant as GICs are resistant to most anticancer therapies and therefore reduce the apparent effectiveness of conventional brain cancer therapies,
 - In various other cancers including ovarian and pancreatic cancer, pre-clinical research has shown that cannabinoids can act in concert with current cancer treatments such as chemotherapy and radio therapy to enhance therapeutic response in animal models,
 - The use of the cannabinoid CBG in the treatment of chemotherapy-induced cachexia where pre-clinical data supports a multi-modal action that includes a protective effect on overall loss of muscle mass, stimulation of feeding, and a normalized metabolic profile,
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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the condensed consolidated financial information contained herein. GW presents its consolidated financial information in pounds sterling and using the recognition and measurement principles of International Financial Reporting Standards, or IFRS, as endorsed by the European Union and as issued by the International Accounting Standards Board, or IASB.

Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 30 September 2015, the Condensed Consolidated Income Statement, Condensed Consolidated Statement of Comprehensive Income, Condensed Consolidated Statement of Changes in Equity and the Condensed Consolidated Cash Flow Statement for the three months and for the year ended 30 September 2015 have been translated into U.S. dollars at the rate on 30 September 2015 of \$1.5127 to £1.00. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

Overview

GW generates revenue from Sativex product sales, license fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. The accounting policies that GW applies in recognizing these revenues are set out in detail in Note 2.

The principal factors affecting GW's profitability and operating cash flow are the amount and timing of GW-funded research and development expenditure, the rate of growth of Sativex product revenues, the amount of development and approval milestone receipts from the Company's commercial partners.

Expenditure on research and development activities is recognised as an expense in the period in which the expense is incurred. GW incurs research and development expenditures that are funded from GW's own cash resources. This typically relates to core research and development spend on the Company's staff and research facilities plus spend on the Epidiolex development program and certain pipeline product Phase 2 trials, currently in the areas of adult epilepsy, glioma, schizophrenia, and type-2 diabetes. GW refers to this as "GW-funded research and development expenditure."

A proportion of GW's research and development expenditure is funded by the Company's collaboration partners. GW refers to this as "partner-funded research and development expenditure". Most of this expenditure during the period relates to the Sativex cancer pain development for the U.S. market which is wholly funded by Otsuka.

Sales, general and administrative expenses consist primarily of salaries, employer payroll taxes and benefits related to GW's executive, finance, business development and support functions. Other sales, general and administrative expenses include costs associated with managing commercial activities and the costs of compliance with the day-to-day requirements of being a listed public company on NASDAQ in the U.S. and on the AIM Market in the United Kingdom, including insurance, general administration overhead, investor relations, legal and professional fees, audit fees and fees for taxation services.

Net foreign exchange gains/losses primarily result from unrealized gains/losses on translating the Group's U.S. dollar denominated cash deposits to pounds sterling at the closing U.S. dollar to pounds sterling exchange rate.

As a UK resident Group with operations in the U.S., GW is subject to both UK and U.S. corporate taxation. GW's tax recognized represents the sum of the tax currently payable or recoverable, and deferred tax. Deferred tax assets are recognized only to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilized. As a company that carries out extensive research and development activities, GW benefits from the UK research and development tax credit regime, whereby the Company's principal research subsidiary company, GW Research Limited, is able to surrender the trading losses that arise from its research and development activities for a cash rebate. This has resulted in a tax credit for each of the periods reported herein, as disclosed in the tax benefit line of the condensed consolidated income statements. The current period tax charge relates to U.S. taxation on the taxable profit for the Group's U.S. subsidiary.

Results of Operations:

Comparison of the three months ended 30 September 2015 and 30 September 2014:

Revenue

Total revenue for the three months to 30 September 2015 was £5.6 million, compared to £7.4 million for the three months ended 30 September 2014. The decrease of £1.8 million comprises:

- £2.0 million decrease in research and development fees to £4.1 million for the three months ended 30 September 2015 from £6.1 million for the three months ended 30 September 2014. The decreased research and development fees reflect decreased research and development expenditure which has been recharged to Otsuka. Further details of this are given in the expenditure section below.
- £0.2 million increase in Sativex product sales revenues to £1.1 million for the three months ended 30 September 2015 compared to £0.9 million for the three months ended 30 September 2014.

Sativex in-market sales volumes sold by GW's commercial partners for the three months ended 30 September 2015 were 18% higher than the three months ended 30 September 2014.

GW's sales volume to partners increased by 47% in the three months ended 30 September 2015 compared to the three months ended 30 September 2014 due to increased shipments to Germany. GW's revenues from Sativex have grown with volume, but the extent of growth has been limited by the impact of a price reduction in Italy.

Cost of sales

Cost of sales for the three months ended 30 September 2015 of £0.7 million represents an increase of £0.3 million from the £0.4 million recorded in the three months ended 30 September 2014 linked to the increase in the volume of vial shipments to commercial partners.

Research and development expenditure

Total research and development expenditure for the three months ended 30 September 2015 of £25.5 million increased by £13.2 million compared to the £12.3 million incurred in the three months ended 30 September 2014.

Partner funded research and development expenditure decreased by £2.0 million to £4.1 million for the three months ended 30 September 2015 from £6.1 million for the three months ended 30 September 2014. This reflects decreased expenditure following the completion of the two remaining Sativex Phase 3 cancer pain trials and reduced expenditure as the activities associated with the Sativex cancer pain program have been completed.

GW-funded research and development expenditure increased by £15.2 million to £21.4 million for the three months ended 30 September 2015 from £6.2 million for the three months ended 30 September 2014. The increase is due to:

- £8.7 million increase in epilepsy and other GW-funded clinical program costs reflecting the costs associated with GW's ongoing Phase 3 Dravet and Lennox-Gastaut syndrome Epidiolex studies, costs of our other pipeline studies and the costs of providing regulatory support and Epidiolex under FDA-authorized expanded access INDs.
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- £2.9 million increase in staff and employment-related expenses resulting from increased headcount as the Group expands its team in the UK and the U.S. to enable execution of the epilepsy development program.
- £2.0 million increase in other property-related overheads and depreciation of R&D assets.
- £1.6 million increase in costs of growing an increased volume of plant material for the Epidiolex development program.

Sales, general and administrative expenses

Sales, general and administrative expenses for the three months ended 30 September 2015 of £5.0 million increased by £3.2 million compared to the £1.8 million incurred in the three months ended 30 September 2014. This net increase is due to:

- £1.6 million increase in pre-launch commercialization costs in the U.S.
- £1.0 million increase in payroll costs driven by increased headcount as we start to recruit our US based commercial team.
- £0.4 million increase in respect of property and travel costs, primarily to the U.S. by staff involved in the establishment of U.S. based operations.
- £0.2 million increase in respect of increased accountancy, audit and investor relations costs arising from GW's U.S. listing and Sarbanes-Oxley compliance.

Net foreign exchange gains

Net foreign exchange gains for the three months ended 30 September 2015 was a gain of £6.9 million, an increase of £1.5 million compared to the £5.4 million gain recorded for the three months ended 30 September 2014. In both periods the gain recognized relates to the retranslation of the Group's U.S. dollar denominated cash deposits to pounds sterling at 30 September 2015. The Sterling to U.S. dollar exchange rate has moved from 1.5703 at 30 June 2015 to 1.5127 at 30 September 2015. Dollar denominated cash deposits totalled \$275 million (£181.8 million equivalent) at 30 September 2015 and averaged \$290 million in the period (£191.7 million equivalent).

Taxation

The tax benefit was £6.4 million for the three months ended 30 September 2015. This represents an increase of £4.5 million compared to a £1.9 million benefit recorded in the three months ended 30 September 2014.

In the three months ended 30 September 2015, GW recorded a tax benefit of £6.4 million made up of the recognition of an accrued £6.5 million research and development tax credit expected to be claimable by GW Research Limited in respect of the research and development expenditure incurred in the three months ended 30 September 2015. This was offset by a £0.1 million reduction in the deferred tax asset held by the Group's commercial subsidiary GW Pharma Limited, as the company utilizes brought forward losses to offset against its current period profits.

In the three months ended 30 September 2014, the tax benefit was £1.9 million. This reflected the recognition of a £2.2 million increase in the research and development tax credit claim that the Group subsequently in respect of research and development expenditure incurred in 2014, offset by the recording of £0.3 million of deferred tax expense associated with profits earned in the period by GW Pharma Limited, the Group's principal commercial subsidiary, due to the utilization of tax losses in the period.

Results of Operations:

Comparison of year ended 30 September 2015 and 30 September 2014:

Revenue

Total revenue for the year ended 30 September 2015 was £28.5 million, compared to £30.0 million for the year ended 30 September 2014. The decrease of £1.5 million comprises:

- £1.5 million decrease in research and development fees to £22.8 million for the year ended 30 September 2015 compared to £24.3 million for the year ended 30 September 2014. This increase reflects decreased research and development costs recharged to Otsuka as activities associated with the Sativex cancer pain programme have come to an end.
- £0.2 million decrease in Sativex product sales revenues to £4.2 million for the year ended 30 September 2015 compared to £4.4 million for the year ended 30 September 2014.
- £0.2 million increase in development and approval milestones to £0.2 million for the year ended 30 September 2015 compared to £nil for the year ended 30 September 2014. The milestones received and recognised in 2015 have been linked to regulatory filings by our Sativex commercial partner in Latin America.

Sativex in-market sales volumes sold by GW's commercial partners for the year ended 30 September 2015 were 22% higher than the year ended 30 September 2014. GW's sales volume to partners similarly increased by 22% in the year ended 30 September 2015 compared to the year ended 30 September 2014 due to increased shipments to Germany and Italy.

Sativex product sales revenue continues to be negatively impacted by the decision in January 2015 of the Italian Medicines Agency to impose a maximum budget for Sativex sales in Italy for 2013 and 2014. This budget has been exceeded, and therefore reimbursement may be required for the excess. An additional £0.2 million rebate provision was recognized in the year ended 30 September 2015 reflecting management's best estimate of the probable settlement. The Group continues to recognize revenue on Italian shipments on a restricted basis as a result of this.

Cost of sales

Cost of sales for the year ended 30 September 2015 of £2.6 million represents an increase of £0.5 million compared to the £2.1 million recorded in the year ended 30 September 2014. This increase reflects the growth in the volume of Sativex inventory shipped to commercial partners in the year ended 30 September 2015.

Research and development expenditure

Total research and development expenditure for the year ended 30 September 2015 of £76.8 million increased by £33.3 million compared to the £43.5 million incurred in the year ended 30 September 2014.

Partner funded research and development expenditure decreased by £1.5 million to £22.8 million for the year ended 30 September 2015 from £24.3 million for the year ended 30 September 2014. This reflects decreased expenditure following the completion of the three Sativex Phase 3 cancer pain trials during the year.

GW-funded research and development expenditure increased by £34.8 million to £54.0 million for the year ended 30 September 2015 from £19.2 million for the year ended 30 September 2014. The increase is due to:

- £17.5 million increase in epilepsy and other GW-funded clinical program costs reflecting the costs associated with GW's ongoing Phase 3 Dravet and Lennox-Gastaut syndrome Epidiolex studies, costs of our other pipeline studies and costs of providing regulatory support and Epidiolex under FDA-authorized expanded access INDs.
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- £9.2 million increase in staff and employment-related expenses as a result of increased headcount as the Group expands its team in the UK and the U.S. to enable execution of the epilepsy development program.
- £4.1 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program.
- £4.0 million increase in other property-related overheads and depreciation of R&D assets.

Sales, general and administrative expenses

Sales, general and administrative expenses for the year ended 30 September 2015 of £12.6 million increased by £5.3 million compared to the £7.3 million incurred in the year ended 30 September 2014. This net increase is due to:

- £4.4 million increase in pre-launch commercialization costs in the U.S.
- £0.8 million increase in property and travel costs, primarily to the U.S. by staff involved in the establishment of U.S. based operations.
- £0.7 million increase in accountancy, audit and investor relation costs arising from GW's U.S. listing and Sarbanes-Oxley compliance.
- £0.6 million decrease in employee-related expenses, comprising:
 - o a £2.0 million decrease in the charge in respect of the provision for payroll taxes on unrealized staff share option gains; offset by
 - o a £1.4 million increase in payroll costs driven by increased headcount.

Net foreign exchange gains

Net foreign exchange gains for the year ended 30 September 2015 was a gain of £6.2 million, an increase of £3.0 million compared to the £3.2 million gain recorded for the year ended 30 September 2014. In both periods the gain recognized relates to the retranslation of the Group's U.S. dollar denominated cash deposits to pounds sterling as at 30 September 2015. Dollar denominated cash deposits totalled \$275 million (£181.8 million equivalent) at 30 September 2015 and averaged \$222 million in the period (£146.8 million equivalent).

Taxation

The tax benefit was £12.5 million for the year ended 30 September 2015, which represents an increase of £7.6 million compared to a £4.9 million benefit recorded in the year ended 30 September 2014.

In the year ended 30 September 2015, GW recorded a tax benefit of £12.5 million made up of: (i) the recognition of an accrued £12.6 million research and development tax credit expected to be claimable by GW Research Limited in respect of the research and development expenditure incurred in the year ended 30 September 2015; (ii) the recognition of an additional £0.2 million of research and development tax credits in respect of the year ended 30 September 2014 in its principal research subsidiary, GW Research Limited, following a successful claim for that period and; (iii) recording of £0.3 million of current tax expense in respect of taxable profits of the Group's U.S. subsidiary, GW Pharmaceuticals Inc.

In the year ended 30 September 2014, GW recorded a tax credit of £4.9 million made up of: (i) the recognition of an accrued £5.3 million research and development tax credit to be claimable by GW Research Limited in respect of the research and development expenditure incurred in the year ended 30 September 2014; (ii) the recognition of an additional £0.3 million of research and development tax credits in respect of the year ended 30 September 2013 in its principal research subsidiary, GW Research Limited, following the submission of tax returns for that period; (iii) the recognition of an additional £0.8 million deferred tax asset in respect of cumulative trading losses which GW intends to utilize to offset future trading profits by GW Pharma Limited, the Group's principal commercial trading subsidiary and (iv) recording of £1.5 million of deferred tax expense due to the fact that previously recognized losses have been utilized to offset profits earned in the year by GW Pharma Limited.

Profit/Loss

The Group reported a loss after tax for the year ended 30 September 2015 of £44.6 million compared with a loss after tax for the year ended 30 September 2014 of £14.7 million.

Liquidity and Capital Resources

Cash Flow

Net cash outflow from operating activities for the year ended 30 September 2015 of £46.5 million was £33.9 million higher than the £12.6 million outflow from operating activities for the year ended 30 September 2014, principally reflecting the increase in investment in Epidiolex and other pipeline research and development activities offset by additional tax benefit.

Capital expenditure for the year ended 30 September 2015 of £17.9 million, consisting primarily of ongoing upgrades to our cannabinoid extraction and Epidiolex manufacturing and growing facilities, was £10.6 million higher than the £7.3 million for the year ended 30 September 2014.

Net cash flow from financing activities decreased by £15.9 million to a £128.4 million inflow in the year ended 30 September 2015 compared to a £144.3 million inflow for the year ended 30 September 2014 due to a £7.8 million reduction in fit out funding receipts, a £5.3 million reduction in warrant exercise proceeds, a £3.8 million reduction in proceeds from the exercise of employee share options, a £0.2 million increase in lease payments, offset by a £1.2 million increase in net new equity funding.

As at 30 September 2015, GW had a closing cash position of £234.9 million compared to £164.5 million as at 30 September 2014.

Property, plant and equipment

Property, plant and equipment at 30 September 2015 increased by £17.1 million to £28.7 million from £11.6 million at 30 September 2014. This increase reflects the upgrade and expansion of new cannabinoid extraction facilities and growing facilities for Epidiolex production.

Inventories

Inventories at 30 September 2015 remained consistent at £4.8 million compared with the £4.8 million at 30 September 2014. Inventories consist of finished goods, consumable items and work in progress and are stated net of a £0.1 million realizable value provision (30 September 2014: £0.4 million). During the year ended 30 September 2015, the provision for inventories reduced by £0.3 million as a result of having utilized some of the Group's previously provided for inventory in research and development.

Trade receivables and other assets

Trade receivables and other assets at 30 September 2015 increased by £1.0 million to £2.9 million from £1.9 million at 30 September 2014. This is due to an increase in prepaid rent, insurance and R&D material costs.

Trade and other payables

Current trade and other payables at 30 September 2015 increased by £11.6 million to £24.0 million from £12.4 million at 30 September 2014. This increase reflects a £12.1 million increase in trade payables and accruals as a result of the continued expansion of GW funded clinical trials and manufacturing capability, offset by a £0.5 million decrease in the provision held for revenue rebates to our commercial partners.

Non-current trade and other payables at 30 September 2015 increased by £0.5 million to £8.4 million from £7.9 million at 30 September 2014. This increase results from accrued interest on the finance facility provided by the Group's landlord for the cannabinoid extraction facility currently under construction.

Headcount

Average headcount for the year ended 30 September 2015 was 322 (30 September 2014: 223).

Guidance

Looking forwards, as our partner-funded Sativex cancer pain program ends, we expect both our R&D fee revenues and the associated partner-funded R&D expenditure to continue to reduce and to cease completely by 31 March 2016.

Although our R&D fee revenues will decrease significantly in 2016, the majority of the costs associated with these clinical activities are pass-through costs, so the impact on our income statement loss for the year will be limited to the \$9-10 million of GW staff resource that was being partner funded. These staff now become available to focus on our core Epidiolex program.

Consistent with the use of proceeds commitments made in mid-2015, we expect the core cash outflow to increase in 2016. We expect to further increase the scale of growing and manufacturing facilities as we build inventory in preparation for the launch of Epidiolex. Capital expenditure associated with this expansion will be in the range of £13-15 million (\$20-23 million) for 2016.

We also expect to continue to increase clinical research and development spend as our programme of Epidiolex Dravet and LGS trials progress towards completion and as we prepare for NDA submission. Core operating cash outflow for the six months to 31 March 2016 is expected to be in the range of £32-37 million (\$48-56 million). Thereafter the rate of expenditure will be highly dependent on the timing of key decisions to be taken re the scaling up of our commercial team.

GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 30 September 2015

	Three months ended 30 September 2015 \$000's	Three months ended 30 September 2015 £000's	Three months ended 30 September 2014 £000's
Revenue	8,463	5,595	7,419
Cost of sales	(1,033)	(683)	(419)
Research and development expenditure	(38,510)	(25,457)	(12,269)
Sales, general and administrative expenses	(7,545)	(4,988)	(1,844)
Net foreign exchange gain	10,399	6,874	5,411
Operating loss	(28,226)	(18,659)	(1,702)
Interest income	125	83	50
Interest expense	(22)	(15)	(2)
Loss before tax	(28,123)	(18,591)	(1,654)
Tax benefit	9,618	6,358	1,936
(Loss)/profit for the period	<u>(18,505)</u>	<u>(12,233)</u>	<u>282</u>
(Loss)/profit per share – basic and diluted	(7.1)c	(4.7)p	0.1p

All activities relate to continuing operations.

GW Pharmaceuticals plc
Condensed consolidated income statement
Year ended 30 September 2015

	Notes	Year ended 30 September 2015 \$000's	Year ended 30 September 2015 £000's	Year ended 30 September 2014 £000's
Revenue	3	43,172	28,540	30,045
Cost of sales		(3,960)	(2,618)	(2,060)
Research and development expenditure	4	(116,153)	(76,785)	(43,475)
Sales, general and administrative expenses		(19,013)	(12,569)	(7,337)
Net foreign exchange gain		9,382	6,202	3,188
Operating loss		(86,572)	(57,230)	(19,639)
Interest income		369	244	130
Interest expense		(113)	(75)	(61)
Loss before tax		(86,316)	(57,061)	(19,570)
Tax benefit	5	18,906	12,498	4,911
Loss for the year		<u>(67,410)</u>	<u>(44,563)</u>	<u>(14,659)</u>
Loss per share – basic and diluted	6	(27.4)c	(18.1)p	(7.0)p

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the year ended 30 September 2015

	Year ended 30 September 2015 £000's	Year ended 30 September 2014 £000's
Loss for the year	(44,563)	(14,659)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	(71)	(2)
Other comprehensive loss for the year	(71)	(2)
Total comprehensive loss for the year	<u>(44,634)</u>	<u>(14,661)</u>

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Year ended 30 September 2015

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total Equity £000's
Balance at 1 October 2013	178	84,005	20,184	(68,965)	35,402
Issue of share capital	51	127,315	-	-	127,366
Expense of new equity issue	-	(1,067)	-	-	(1,067)
Exercise of share options	4	5,014	-	-	5,018
Exercise of warrants	4	5,284	(922)	922	5,288
Share-based payment transactions	-	-	-	1,238	1,238
Loss for the period	-	-	-	(14,659)	(14,659)
Other comprehensive expense	-	-	(2)	-	(2)
Balance at 30 September 2014	<u>237</u>	<u>220,551</u>	<u>19,260</u>	<u>(81,464)</u>	<u>158,584</u>
Balance at 1 October 2014	237	220,551	19,260	(81,464)	158,584
Issue of share capital (note 12)	22	127,812	-	-	127,834
Expense of new equity issue	-	(271)	-	-	(271)
Exercise of share options	2	1,183	-	-	1,185
Share-based payment transactions	-	-	-	2,488	2,488
Loss for the year	-	-	-	(44,563)	(44,563)
Deferred tax attributable to unrealized share option gains	-	-	-	84	84
Other comprehensive expense	-	-	(71)	-	(71)
Balance at 30 September 2015	<u>261</u>	<u>349,275</u>	<u>19,189</u>	<u>(123,455)</u>	<u>245,270</u>

GW Pharmaceuticals plc
Condensed consolidated balance sheet
As at 30 September 2015

	Notes	As at 30 September 2015 \$000's	As at 30 September 2015 £000's	As at 30 September 2014 £000's
Non-current assets				
Intangible assets - goodwill		7,881	5,210	5,210
Other intangible assets		371	245	-
Property, plant and equipment		43,464	28,733	11,639
Deferred tax asset		632	418	277
		52,348	34,606	17,126
Current assets				
Inventories	7	7,194	4,756	4,777
Taxation recoverable		19,122	12,641	5,251
Trade receivables and other assets	8	4,346	2,873	1,857
Cash and cash equivalents		355,292	234,872	164,491
		385,954	255,142	176,376
Total assets		438,302	289,748	193,502
Current liabilities				
Trade and other payables	9	(36,338)	(24,022)	(12,376)
Current tax liabilities		(554)	(366)	-
Obligations under finance leases	11	(167)	(111)	(126)
Deferred revenue	10	(4,945)	(3,269)	(4,827)
		(42,004)	(27,768)	(17,329)
Non-current liabilities				
Trade and other payables	9	(12,775)	(8,445)	(7,927)
Obligations under finance leases	11	(2,330)	(1,540)	(1,781)
Deferred revenue	10	(10,173)	(6,725)	(7,881)
Total liabilities		(67,282)	(44,478)	(34,918)
Net assets		371,020	245,270	158,584
Equity				
Share capital		395	261	237
Share premium account		528,348	349,275	220,551
Other reserves		29,027	19,189	19,260
Accumulated deficit		(186,750)	(123,455)	(81,464)
Total equity		371,020	245,270	158,584

GW Pharmaceuticals plc
Condensed consolidated cash flow statement
For the year ended 30 September 2015

	Year ended 30 September 2015 \$000's	Year ended 30 September 2015 £000's	Year ended 30 September 2014 £000's
Loss for the year	(67,410)	(44,563)	(14,659)
Adjustments for:			
Interest income	(369)	(244)	(130)
Interest expense	113	75	61
Tax benefit	(18,906)	(12,498)	(4,911)
Depreciation of property, plant and equipment	3,404	2,250	1,398
Impairment of property, plant and equipment	917	606	-
Amortization of intangible assets	79	52	-
Net foreign exchange gains	(9,503)	(6,282)	(1,876)
Increase/(decrease) in provision for inventories	50	33	(408)
Loss on disposal of property, plant and equipment	2	1	2
Share-based payment charge	3,748	2,478	1,238
	(87,875)	(58,092)	(19,285)
(Increase)/decrease in inventories	(18)	(12)	292
Increase in trade receivables and other assets	(1,528)	(1,010)	(142)
Increase in trade and other payables and deferred revenue	10,934	7,228	3,328
Cash used in operations	(78,487)	(51,886)	(15,807)
Research and development tax credits received	8,191	5,415	3,181
Net cash outflow from operating activities	(70,296)	(46,471)	(12,626)
Investing activities			
Interest received	357	236	145
Purchases of property, plant and equipment	(27,101)	(17,915)	(7,254)
Purchase of intangible assets	(171)	(114)	-
Proceeds from sales of property, plant and equipment	3	2	14
Net cash outflow from investing activities	(26,912)	(17,791)	(7,095)
Financing activities			
Proceeds on exercise of share options	1,793	1,185	5,018
Proceeds of new equity issue	193,374	127,834	127,367
Expenses of new equity issue	(410)	(271)	(1,067)
Proceeds of warrant exercise	-	-	5,288
Interest paid	(112)	(74)	(61)
Proceeds from fit out funding	-	-	7,822
Repayments of obligations under finance leases	(386)	(255)	(100)
Net cash inflow from financing activities	194,259	128,419	144,267
Effect of foreign exchange rate changes on cash and cash equivalents	9,415	6,224	1,876
Net increase in cash and cash equivalents	106,466	70,381	126,422
Cash and cash equivalents at beginning of the period	248,826	164,491	38,069
Cash and cash equivalents at end of the period	355,292	234,872	164,491

1. General information

The financial information set out in this preliminary announcement does not constitute statutory financial statements for the years ended 30 September 2015 or 2014, for the purpose of the Companies Act 2006, but is derived from those financial statements. Statutory financial statements for 2015, on which the Group's auditors have given an unqualified report which does not contain statements under s. 498(2) or (3) of the Companies Act 2006, will be filed with the Registrar of Companies by 31 March 2016. Statutory financial statements for 2014 have been filed with the Registrar of Companies. The Group's auditors have reported on those accounts; their reports were unqualified and did not contain statements under s. 498(2) or (3) of the Companies Act 2006.

Whilst the financial information included in this press release has been prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted for use in the European Union and as issued by the International Accounting Standards Board, this announcement does not itself contain sufficient information to comply with IFRS. The accounting policies applied in preparing this financial information are consistent with the Group's financial statements for the year ended 30 September 2015.

The Group's principal risks and uncertainties are included in the Annual Report on Form 20-F for the year ended 30 September 2015 which will be filed with the SEC on 3 December 2015.

The financial information for the three-month periods ended 30 September 2015 and 2014 is unaudited.

Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Consolidated Balance Sheet as at 30 September 2015 and in the Consolidated Income Statement, Consolidated Statement of Changes in Equity, Consolidated Statement of Comprehensive Income and Consolidated Cash Flow Statement for the year and the three months ended 30 September 2015 have been translated into U.S. dollars at the rate on 30 September 2015 of \$1.5127 to £1.00. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

The Board of Directors of the Company approved this statement on 7 December 2015.

2. Selected accounting policies

Selected Group accounting policies are summarised below.

Going Concern

The Directors have considered the financial position of the Group, its cash position and forecast cash flows for the 12-month period from the date of signing these financial statements when considering going concern. They have also considered the Group's key risks and uncertainties affecting the likely development of the business. In the light of this review, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for at least a 12-month period from the balance sheet date. Accordingly, they continue to adopt the going concern basis in preparing these financial statements.

Basis of Consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company (its subsidiaries) made up to 30 September each year. Subsidiaries are all entities over which the Group has the power to govern the financial and operating policies of the entity concerned, generally accompanying a shareholding of more than one half of the voting rights.

Intangible Assets – Goodwill

Goodwill arising in a business combination is recognised as an asset at the date that control is acquired. Goodwill is measured as the excess of the sum of consideration transferred, the amount of any non-controlling interest in the acquiree and the fair value of the acquirer's previously held equity interest (if any) in the entity over the net of the acquisition date amounts of the identifiable assets and liabilities assumed.

Goodwill is not amortised but is tested for impairment at least annually.

Intangible Assets – Other

Other intangible assets are stated at cost less provisions for amortisation and impairments. Licences, patents, know-how, software and marketing rights separately acquired or acquired as part of a business combination are amortised over their estimated useful lives using the straight-line basis from the time they are available for use. The estimated useful lives for determining the amortisation take into account patent lives and related product application, but do not exceed their lifetime. Asset lives are reviewed annually and adjusted where necessary. Contingent milestone payments are recognised at the point that the contingent event becomes certain. Any subsequent development costs incurred by the Group and associated with acquired licences, patents, know-how or marketing rights are written off to the income statement when incurred, unless the criteria for recognition of an internally generated intangible asset are met, usually when a regulatory filing has been made in a major market and approval is considered highly probable.

Revenue

Revenue is measured at the fair value of the consideration received or receivable and represents amounts receivable for goods and services provided in the normal course of business net of value added tax and other sales-related taxes. The Group recognises revenue when the amount can be reliably measured; when it is probable that future economic benefits will flow to the Group; and when specific criteria have been met for each of the Group's activities, as described below.

The Group's revenue arises from product sales, licensing fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. Agreements with commercial partners generally include non-refundable up-front license and collaboration fees, milestone payments, the receipt of which is dependent upon the achievement of certain clinical, regulatory or commercial milestones, as well as royalties on product sales of licensed products, if and when such product sales occur, and revenue from the supply of products. For these agreements, total arrangement consideration is attributed to separately identifiable components on a reliable basis that reasonably reflects the selling prices that might be expected to be achieved in stand-alone transactions. The then allocated consideration is recognised as revenue in accordance with the principles described below.

The percentage of completion method is used for a number of revenue streams of the Group. For each of the years ended 30 September 2015 and 30 September 2014, there were no discrete events or adjustments which caused the Group to revise its previous estimates of completion associated with those revenue arrangements accounted for under the percentage of completion method.

Product Sales

Revenue from the sale of products is recognised when the Group has transferred to the buyer the significant risks and rewards of ownership of the goods, the Group no longer has effective control over the goods sold, the amount of revenue and costs associated with the transaction can be measured reliably, and it is probable that the Group will receive future economic benefits associated with the transaction. Product sales have no rights of return other than where products are damaged or defective.

The Group maintains a rebate provision for expected reimbursements to our commercial partners in circumstances in which actual net revenue per vial differs from expected net revenue per vial as a consequence of, as an example, ongoing pricing negotiations with local health authorities. The amount of our rebate provision is based on, amongst other things, monthly unit sales and in-market sales data received from commercial partners and represents management's best estimate of the rebate expected to be required to settle the present obligation at the end of the reporting period. Provisions for rebates are established in the same period that the related sales are recorded.

Licensing Fees

Licensing fees received in connection with product out-licensing agreements, even where such fees are non-refundable, are deferred and recognised over the period of the license term.

Collaboration Fees

Collaboration fees are deferred and recognised as services are rendered based on the percentage of completion method.

Technical Access Fees

Technical access fees represent amounts charged to licensing partners to provide access to, and to commercially exploit data that the Group possesses or which can be expected to result from Group research programmes that are in progress. Non-refundable technical access fees that involve the delivery of data that the Group possesses and that permit the licensing partner to use the data freely and where the Group has no remaining obligations to perform are recognised as revenue upon delivery of the data. Non-refundable technical access fees relating to data where the research programme is ongoing are recognised based on the percentage of completion method.

Development and Approval Milestone Fees

Development and approval milestone fees are recognised as revenue based on the percentage of completion method on the assumption that all stages will be completed successfully, but with cumulative revenue recognised limited to non-refundable amounts already received or reasonably certain to be received.

Research and Development Fees

Revenue from partner-funded contract research and development agreements is recognised as research and development services are rendered. Where services are in-progress at period end, the Group recognises revenues proportionately, in line with the percentage of completion of the service. Where such in-progress services include the conduct of clinical trials, the Group recognises revenue in line with the stage of completion of each trial so that revenues are recognised in line with the expenditures.

Royalties

Royalty revenue is recognised on an accrual basis in accordance with the substance of the relevant agreement, provided that it is probable that the economic benefits will flow to the Group and the amount of revenue can be measured reliably.

Research and Development

Expenditure on research and development activities is recognised as an expense in the period in which it is incurred prior to achieving regulatory approval.

An internally generated intangible asset arising from the Group's development activities is recognised only if the following conditions are met:

- an asset is created that can be identified;
- it is probable that the asset created will generate future economic benefits; and
- the development cost of the asset can be measured reliably.

The Group has determined that regulatory approval is the earliest point at which the probable threshold can be achieved. All research and development expenditure incurred prior to achieving regulatory approval is therefore expensed as incurred.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is calculated using the weighted average cost method. Cost includes materials, direct labour, depreciation of manufacturing assets and an attributable proportion of manufacturing overheads based on normal levels of activity. Net realisable value is the estimated selling price, less all estimated costs of completion and costs to be incurred in marketing, selling and distribution.

If net realisable value is lower than the carrying amount, a write down provision is recognised for the amount by which the carrying amount exceeds its net realisable value.

Inventories manufactured prior to regulatory approval are capitalised as an asset but provided for until there is a high probability of regulatory approval of the product. At the point when a high probability of regulatory approval is obtained, the provision is adjusted appropriately to increase the carrying value to expected net realisable value, which may not exceed original cost.

Adjustments to the provision for inventories manufactured prior to regulatory approval are recorded as a component of research and development expenditure. Adjustments to the provision against commercial product related inventories manufactured following achievement of regulatory approval are recorded as a component of cost of goods.

Taxation

The tax expense represents the sum of the tax currently payable or recoverable and deferred tax.

The tax payable or recoverable is based on taxable profit for the year. Taxable profit differs from profit before tax as reported in the consolidated income statement because it excludes items of income or expense that are taxable or deductible in other years and it further excludes items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates and laws that have been enacted or substantively enacted by the balance sheet date.

Deferred tax is the tax expected to be payable or recoverable on differences between carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit, and is accounted for using the balance sheet liability method. Deferred tax liabilities are generally recognised for all taxable temporary differences and deferred tax assets are recognised only to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilised. Such assets and liabilities are not recognised if the temporary difference arises from the initial recognition of goodwill or from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

Deferred tax liabilities are recognised for taxable temporary differences arising on investments in subsidiaries and associates, and interests in joint ventures, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary difference will not reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient future taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax is calculated at the tax rates that are expected to apply in the period when the liability is settled or the asset is realised based on tax laws and rates that have been enacted at the balance sheet date. Deferred tax is charged or credited in the consolidated income statement, except when it relates to items charged or credited in other comprehensive income, in which case the deferred tax is also dealt with in other comprehensive income.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis.

(Loss)/Earnings per Share

Basic earnings or loss per share represents the profit or loss for the year, divided by the weighted average number of ordinary shares in issue during the year, excluding the weighted average number of ordinary shares held in the GW Pharmaceuticals All Employee Share Scheme (the "ESOP") during the year to satisfy employee share awards.

Diluted earnings or loss per share represents the profit or loss for the year, divided by the weighted average number of ordinary shares in issue during the year, excluding the weighted average number of shares held in the ESOP during the year to satisfy employee share awards, plus the weighted average number of dilutive shares resulting from share options or warrants where the inclusion of these would not be antidilutive.

Foreign Currency

The individual financial statements of each Group company are presented in the currency of the primary economic environment in which it operates (its functional currency). For the purpose of the consolidated financial statements, the results and financial position of each Group company are expressed in Pounds Sterling.

In preparing the financial statements of the individual companies, transactions in currencies other than the entity's functional currency (foreign currencies) are recorded at the rate of exchange at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are retranslated at the rates of exchange prevailing at that date. Non-monetary items carried at fair value that are denominated in foreign currencies are translated at the rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

For the purpose of presenting consolidated financial statements, the assets and liabilities of the Group's foreign operations are translated at exchange rates prevailing on the balance sheet date. Income and expense items are translated at the average exchange rate for the period, unless exchange rates fluctuate significantly during the period, in which case the exchange rates at the date of transactions are used. Exchange differences arising, if any, are recognised in other comprehensive income and accumulated in equity.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation and any recognised impairment loss. Depreciation is provided so as to write off the cost of assets, less their estimated residual values, over their useful lives using the straight-line method, as follows:

Plant, machinery and lab equipment	3–10 years
Office and IT equipment	3–4 years
Leasehold improvements	4–15 years or term of the lease if shorter

Assets under finance leases are depreciated over their expected useful lives on the same basis as owned assets or, where shorter, over the term of the relevant lease.

No depreciation is provided on assets under the course of construction. Cost includes professional fees and, for qualifying assets, borrowing costs capitalised in accordance with the Group's accounting policy. Depreciation on these assets commences when the assets are available for use.

The gain or loss arising on disposal or scrapping of an asset is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognised in operating profit.

Share-based Payments

The Group operates a number of equity-settled share-based compensation plans under which the Company receives services from employees as consideration for equity instruments (options) of the Company. The fair value of the employee services received in exchange for the grant of the awards is recognised as an expense. The total amount to be expensed is determined by reference to the fair value of the options granted (excluding the effect of any non-market-based performance and service vesting conditions) at the date of grant.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest. At each balance sheet date, the Group revises its estimate of the number of equity instruments expected to vest as a result of the effect of non-market-based performance and service vesting conditions. The impact of the revision of the original estimates, if any, is recognised in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to equity reserves.

Equity-settled share-based payment transactions with parties other than employees are measured at the fair value of the goods or services received, except where that fair value cannot be estimated reliably, in which case they are measured at the fair value of the equity instruments granted, measured at the date of grant.

Financial Liabilities

Financial liabilities are classified as either financial liabilities "at fair value through profit and loss" or "other financial liabilities". For each reporting period covered herein, the Group's financial liabilities were restricted to "other financial liabilities".

Other Financial Liabilities

Trade payables are initially recognised at fair value and then held at amortised cost which equates to nominal value. Long-term payables are discounted where the effect is material.

All borrowings are initially recorded at the amount of proceeds received, net of transaction costs. Borrowings are subsequently carried at amortised cost, using the effective interest method. The difference between the proceeds, net of transaction costs, and the amount due on redemption being recognised as a charge to the income statement over the period of the relevant borrowing.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

3. Segmental Information

Operating Segments

Information reported to the Company's Board of Directors, the chief operating decision maker for the Group, for the purposes of resource allocation and assessment of segment performance is focused on the stage of product development. The Group's reportable segments are as follows:

- **Commercial:** The Commercial segment distributes and sells the Group's commercial products. Currently Sativex is promoted through strategic collaborations with major pharmaceutical companies for the currently approved indication of spasticity due to MS. The commercial segment will include revenues from the direct marketing of other future approved commercial products. The Group has licensing agreements for the commercialisation of Sativex with Almirall S.A. in Europe (excluding the United Kingdom) and Mexico, Otsuka Pharmaceutical Co. Ltd. ("Otsuka") in the U.S., Novartis Pharma AG in Australia, New Zealand, Asia (excluding Japan, China and Hong Kong), the Middle East and Africa, Bayer HealthCare AG in the United Kingdom and Canada, Neopharm Group in Israel and Ipsen Biopharm Ltd. in Latin America (excluding Mexico and the Islands of the Caribbean). Commercial segment revenues include product sales, royalties, license, collaboration, and technical access fees, and development and approval milestone fees.
- **Sativex Research and Development:** The Sativex Research and Development ("Sativex R&D") segment seeks to maximise the potential of Sativex through the development of new indications. The focus during the period for this segment was the Phase 3 clinical development programme of Sativex for use in the treatment of cancer pain. The Group also believe that MS spasticity represents an attractive indication for the U.S. and consequently, the Group intends to pursue an additional clinical development programme for this significant market opportunity. In addition, Sativex has shown promising efficacy in Phase 2 trials in other indications such as neuropathic pain, but these areas are not currently the subject of full development programmes. Sativex Research and Development segment revenues consist of research and development fees charged to Sativex licensees.
- **Pipeline Research and Development:** The Pipeline Research and Development ("Pipeline R&D") segment seeks to develop cannabinoid medications other than Sativex across a range of therapeutic areas using the Group's proprietary cannabinoid technology platform. The Group's product pipeline includes Epidiolex®, a treatment for Dravet syndrome and Lennox-Gastaut syndrome, a second epilepsy product candidate as well as other product candidates in Phase 1 and 2 clinical development for glioma, adult epilepsy, type-2 diabetes and schizophrenia. Pipeline Research and Development segment revenues consist of research and development fees charged to Otsuka under the terms of our pipeline research collaboration agreement.

The accounting policies of the reportable segments are consistent with the Group's accounting policies. Segment result represents the result of each segment without allocation of share-based payment expenses, and before sales, general and administrative expenses, interest expense, interest income and tax.

No measures of segment assets and segment liabilities are reported to the Group's Board of Directors in order to assess performance and allocate resources. There is no intersegment activity and all revenue is generated from external customers.

3. Segmental Information (continued)

Segmental revenues and results

For the Year Ended 30 September 2015

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	4,255	-	-	4,255	-	4,255
Research and development fees	-	22,275	535	22,810	-	22,810
License, collaboration and technical access fees	1,287	-	-	1,287	-	1,287
Development and approval milestones	188	-	-	188	-	188
Total revenue	5,730	22,275	535	28,540	-	28,540
Cost of sales	(2,618)	-	-	(2,618)	-	(2,618)
Research and development expenditure	-	(26,398)	(48,862)	(75,260)	(1,525)	(76,785)
Segmental result	3,112	(4,123)	(48,327)	(49,338)	(1,525)	(50,863)
Sales, general and administrative expenses						(12,569)
Net foreign exchange gain						6,202
Operating loss						(57,230)
Interest income						244
Interest expense						(75)
Loss before tax						(57,061)
Tax benefit						12,498
Loss for the year						(44,563)

The following is an analysis of depreciation and the movement in the provision for inventories by segment for the year ended 30 September 2015:

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total Reportable Segments £'000	Unallocated Costs £'000	Consolidated £'000
Depreciation	(107)	(530)	(1,500)	(2,137)	(113)	(2,250)
Amortization	-	-	(4)	(4)	(48)	(52)
Impairment of property, plant and equipment	-	(606)	-	(606)	-	(606)
Increase in provision for inventories	(33)	-	-	(33)	-	(33)

1 Unallocated costs represent the portion of share-based payment expenditures which is included in research and development expenditure, but which is not allocated to segments. The remaining share-based payment expenditure is included within sales, general and administrative expenses, which is similarly excluded from segmental result.

3. Segmental Information (continued)

Segmental revenues and results

For the Year Ended 30 September 2014

	Commercial ¹ £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ² £'000	Consolidated £'000
Revenue:						
Product sales	4,382	-	-	4,382	-	4,382
Research and development fees	-	23,618	667	24,285	-	24,285
License, collaboration and technical access fees	1,378	-	-	1,378	-	1,378
Total revenue	5,760	23,618	667	30,045	-	30,045
Cost of sales	(2,060)	-	-	(2,060)	-	(2,060)
Research and development credit/(expenditure)	847	(26,444)	(17,103)	(42,700)	(775)	(43,475)
Segmental result	4,547	(2,826)	(16,436)	(14,715)	(775)	(15,490)
Sales, general and administrative expenses						(7,337)
Net foreign exchange gain						3,188
Operating loss						(19,639)
Interest income						130
Interest expense						(61)
Loss before tax						(19,570)
Tax benefit						4,911
Loss for the year						(14,659)

The following is an analysis of depreciation and the movement in the provision for inventories by segment for the year ended 30 September 2014:

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total Reportable Segments £'000	Unallocated Costs £'000	Consolidated £'000
Depreciation	(111)	(662)	(566)	(1,339)	(59)	(1,398)
Decrease/(increase) in provision for inventories	847	(261)	(178)	408	-	408

- 1 The research and development credit in the commercial segment is the element of the inventory provision movement that relates to commercial inventory.
- 2 Unallocated costs represent the portion of share-based payment expenditures which is included in research and development expenditure, but which is not allocated to segments. The remaining share-based payment expenditure is included within sales, general and administrative expenses, which is similarly excluded from segmental result.

3. Segmental Information (continued)

Revenues from the Group's largest customer are included within the above segments as follows:

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Year ended 30 September 2015	280	22,275	535	23,090
Year ended 30 September 2014	280	23,618	667	24,565

Revenues from the Group's second largest customer, the only other customer where revenues amount for more than 10% of the Group's revenues, are included within the above segments as follows:

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Year ended 30 September 2015	3,385	–	–	3,385
Year ended 30 September 2014	3,494	–	–	3,494

Geographical analysis of turnover by destination of customer

	Year ended 30 September 2015 £000's	Year ended 30 September 2014 £000's
UK	1,158	1,099
Europe (excluding UK)	3,592	3,864
United States	22,555	23,904
Canada	700	518
Asia/Other	535	660
	28,540	30,045

4. Research and development expenditure

	Year ended 30 September 2015 £000's	Year ended 30 September 2014 £000's
GW-funded research and development	53,975	19,190
Development partner-funded research and development	22,810	24,285
Total	76,785	43,475

5. Tax benefit

	Year ended 30 September 2015 £000's	Year ended 30 September 2014 £000's
Current period research and development tax credit	(12,641)	(5,251)
Current period tax charge	366	-
Adjustments in respect of prior year tax credit	(165)	(278)
Recognition of previously unrecognized deferred tax asset	(335)	(829)
Current period utilization of deferred tax assets	277	1,447
Total credit for the year	<u>(12,498)</u>	<u>(4,911)</u>

The research and development tax credit relates to research and development expenditure claimed under the Finance Act 2000. The current period tax charge relates to the estimated overseas taxable profit for the Group's U.S. subsidiary.

At 30 September 2015 the Group had tax losses available for carry forward of approximately £74.0 million (2014: £34.3 million). Of such carried forward losses, the Group has recognized a deferred tax asset of £1.9 million (2014: £0.6 million) up to the level of deferred tax liabilities arising in the same jurisdiction and additionally an asset supportable by taxable income projections of £nil million (2014: £1.4 million). The Group has also recognized a deferred tax asset of £0.4 million (2014: £nil) in respect of taxable temporary timing differences relating to future potential share option deductions in another jurisdiction supportable by taxable income projections. In addition, the Group has not recognized deferred tax assets relating to other temporary differences of £20.7 million (2014: £11.6 million). These deferred tax assets have not been recognized as the Group's management considers that there is insufficient future taxable income, taxable temporary differences and feasible tax-planning strategies to utilize all of the cumulative losses and therefore it is probable that the deferred tax assets will not be realized in full. If future income differs from current projections, this could significantly impact the tax charge or benefit in future periods.

6. Loss per share

The calculations of loss per share are based on the following results and numbers of shares.

	Year ended 30 September 2015	Year ended 30 September 2014
	£000's	£000's
Loss for the year – basic and diluted	<u>(44,563)</u>	<u>(14,659)</u>
	Year ended 30 September 2015	Year ended 30 September 2014
	Million	Million
Weighted average number of ordinary shares	246.4	210.4
Less: ESOP trust ordinary shares ⁽¹⁾	-	-
Weighted average number of ordinary shares for purposes of basic earnings per share	246.4	210.4
Effect of potentially dilutive shares arising from share options and warrants ⁽²⁾	-	-
Weighted average number of ordinary shares for purposes of diluted earnings per share	<u>246.4</u>	<u>210.4</u>
Loss per share—basic	(18.1)p	(7.0)p
Loss per share—diluted	(18.1)p	(7.0)p

- (1) As at 30 September 2015, 33,054 ordinary shares were held in the ESOP trust (30 September 2014: 34,706). The effect is less than 0.1 million ordinary shares for each of the years ended 30 September 2015 and 2014, and consequently these have not been presented above.
- (2) The Group incurred a loss in each of the financial years above. As a result, the inclusion of potentially dilutive share options in the diluted loss per share calculation would have an antidilutive effect on the loss per share for the period. The impact of 7.8 million share options have therefore been excluded from the diluted loss per share calculation for the year ended 30 September 2015 (30 September 2014: 9.5 million).

7. Inventories

	30 September 2015	30 September 2014
	£000's	£000's
Raw materials	317	210
Work in progress	3,686	3,885
Finished goods	753	682
Total inventories, net of provision	<u>4,756</u>	<u>4,777</u>

Inventory is stated net of a provision for inventories, calculated in accordance with the Group's accounting policy. The movement in the provision for inventories is as follows:

	£000's
Opening balance – as at 1 October 2013	1,601
Write-down of inventories	625
Write off of inventories included in the provision	(842)
Reversal of write-down of inventories	(1,033)
Closing balance as at 30 September 2014	<u>351</u>
Opening balance – as at 1 October 2014	351
Write-down of inventories	98
Write off of inventories included in the provision	(318)
Reversal of write-down of inventories	(65)
Closing balance as at 30 September 2015	<u>66</u>

Inventories with a carrying value of £2.7 million are considered to be recoverable after more than one year from the balance sheet date, but within the Group's normal operating cycle (30 September 2014: £3.2 million).

8. Trade receivables and other receivables

	30 September 2015 £000's	30 September 2014 £000's
Amounts falling due within one year		
Trade receivables	373	612
Other receivables	956	809
Prepayments and accrued income	1,544	436
	<u>2,873</u>	<u>1,857</u>

9. Trade and other payables

	30 September 2015 £000's	30 September 2014 £000's
Amounts falling due within one year		
Other creditors and accruals	10,714	5,976
Clinical trial accruals	8,374	3,138
Trade payables	3,795	2,342
Fit out funding	348	218
Other taxation and social security	791	702
	<u>24,022</u>	<u>12,376</u>
Amounts falling due after one year		
Fit out funding	8,445	7,927
	<u>32,467</u>	<u>20,303</u>

Fit out funding represents £8.8 million owed to the Group's landlord reflecting the liability to repay the £7.8 million of fit out funding received to fund the expansion and upgrades to manufacturing facilities and associated accrued interest of £1.0 million. This is expected to be repaid upon the completion of construction, currently expected to be during the second quarter of the year ending 30 September 2016, over a 15-year term. The Group has estimated that £0.4 million will be due within one year and the remaining £8.4 million is due after one year.

10. Deferred revenue

	30 September 2015 £000's	30 September 2014 £000's
Amounts falling due within one year		
Deferred license, collaboration and technical access fee income (1)	1,260	1,366
Advance research and development fees (2)	2,009	3,461
	<u>3,269</u>	<u>4,827</u>
Amounts falling due after one year		
Deferred license, collaboration and technical access fee income (1)	6,725	7,881
	<u>9,994</u>	<u>12,708</u>

- (1) Deferred revenues result mainly from the unamortized portion of up-front license fees received in 2005 of £12.0 million from Almirall S.A. and collaboration and technical access fees from other Sativex licensees.
 - (2) Advance research and development fees represent amounts received from Otsuka for activities to be carried out on behalf of Otsuka. These amounts will be recognized as revenue in future periods as the services are rendered.
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11. Amounts payable under finance leases

	Minimum lease payments	
	30 September 2015 £000's	30 September 2014 £000's
Amounts payable under finance leases:		
Within one year	176	200
In the second to fifth years inclusive	703	838
After five years	<u>1,206</u>	<u>1,382</u>
	2,085	2,420
Less: future finance charges	<u>(434)</u>	<u>(513)</u>
Present value of lease obligations	<u>1,651</u>	<u>1,907</u>

	Present value of minimum lease payments	
	30 September 2015 £000's	30 September 2014 £000's
Amounts payable under finance leases:		
Amounts due for settlement within 12 months	111	126
Amounts due for settlement after 12 months	<u>1,540</u>	<u>1,781</u>
	<u>1,651</u>	<u>1,907</u>

At as 30 September 2015, the weighted average lease term remaining is 12.1 years (30 September 2014: 12.3 years). All lease obligations are denominated in sterling.

12. Share Capital

As at 30 September 2015 the share capital of the Company allotted, called-up and fully paid amounts was as follows:

	2015 £000's	2014 £000's
Allotted, called-up and fully paid		
261,180,173 (2014: 236,636,895) ordinary shares of 0.1p each	<u>261</u>	<u>237</u>

12. Share Capital (continued)

Changes to the number of ordinary shares in issue have been as follows:

	Number of Shares	Total Nominal Value £000's	Total Share Premium £000's	Total Consideration £000's
As at 1 October 2014	236,646,895	237	220,551	220,788
Issue of new shares	22,093,601	22	127,541	127,563
Exercise of share options	2,439,677	2	1,183	1,185
As at 30 September 2015	261,180,173	261	349,275	349,536

13. Contingent liability

As at 30 September 2015 certain fees associated with ongoing capital expenditure have been estimated. The final fees payable are expected to be agreed and paid when construction is completed, scheduled for the second quarter of the year ending 30 September 2016. The Group estimates that there is a possible contingent liability for incremental fees of up to £0.4 million of capital expenditure.

14. Availability of Information

A copy of this statement is available from the company website at www.gwpharm.com or from the Company Secretary at Sovereign House, Vision Park, Histon, Cambridge, CB24 9BZ.
