

# GW PHARMACEUTICALS PLC

## **FORM 6-K** (Report of Foreign Issuer)

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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 February, 2017

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

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**Other Events**

On February 7, 2017, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its first quarter 2017 financial results and operational progress and details of a conference call to be held at 8:30 a.m. EST on February 7, 2017 to discuss the results and operational progress. The press release is attached as Exhibit 99.1 and is incorporated by reference herein. On February 7, 2017, the Company also issued a press release announcing achievement of positive results in Phase 2 proof of concept study in Glioma. The press release is attached as Exhibit 99.2 and is incorporated by reference herein. The information contained in Exhibit 99.1 and Exhibit 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth by specific reference in such a filing.

**Exhibits**

99.1 Press release dated February 7, 2017 announcing financial results and operational progress

99.2 Press release dated February 7, 2017 announcing achievement of positive results in Phase 2 proof of concept study in Glioma

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**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: February 7, 2017

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**GW Pharmaceuticals plc Reports First Quarter 2017 Financial Results and Operational Progress**

- Epidiolex<sup>®</sup> NDA submission and launch preparation on track –  
 - New Positive Phase 2 glioma data further demonstrates value of cannabinoid pipeline -  
 -Conference call today at 8:30 a.m. EST-

**London, UK, 7 February 2017** : GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announced financial results for the first quarter ended 31 December 2016.

“As we look forward to 2017, our primary focus is on completing the Epidiolex NDA, which we expect to submit to the FDA in the middle of this year. With three positive Phase 3 trials delivered in 2016, we remain confident in the prospects for Epidiolex’s approval and are accelerating our preparations for a highly successful launch,” stated Justin Gover, GW’s Chief Executive Officer. “Beyond Epidiolex, the value of GW’s cannabinoid platform is further illustrated by promising new clinical data in the field of oncology and we continue to advance a number of additional clinical programs that will yield data this year.”

**OPERATIONAL HIGHLIGHTS**

- Epidiolex<sup>®</sup> (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and infantile spasms (IS)
    - o Regulatory:
      - NDA submission for both Dravet and LGS indications expected mid 2017
      - Preparations advancing for expected EU regulatory submission in H2 2017
    - o Clinical:
      - Positive results in a pivotal Phase 3 Dravet syndrome trial and in two pivotal Phase 3 LGS trials
      - Substantial new data presented at the American Epilepsy Society Annual Meeting in December 2016
    - o Manufacturing scale-up on track to deliver significant commercial launch inventory
      - Pre-NDA CMC meeting held with FDA in November 2016
      - Successful UK regulatory GMP inspection of GW manufacturing facility in December 2016. On track for FDA GMP inspection anticipated in H2 2017
    - o Expanded access program and open label extension:
      - Over 1,200 patients now on Epidiolex treatment
      - 97 percent of patients who complete Phase 3 trials have entered long term extension
    - o Commercial:
      - US commercial team build well underway and pre-launch preparations advancing well
      - EU commercial team now being established
    - o Follow-on indications:
      - Phase 3 trial in TSC ongoing
      - Two part Phase 3 trial in IS commenced in December 2016
    - o Intellectual Property:
      - Patent portfolio being prosecuted with claims directed to the use of CBD in the treatment of epilepsy seizure subtypes and epilepsy syndromes
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- THC:CBD for Glioma
  - Positive Phase 2 placebo-controlled data in Recurrent Glioblastoma Multiforme (GBM) (see separate announcement issued today)
  - Orphan Drug Designation from FDA and EMA
    - Multiple relevant patents granted or in process
- Other cannabinoid pipeline product candidates:
  - CBDV Phase 2 partial-onset epilepsy study in adults ongoing. Part A complete and Part B underway with data expected H2 2017
  - CBDV pre-clinical research ongoing within field of autism spectrum disorders. Phase 2 trials expected to commence in H2 2017
    - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
  - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
    - Phase 1 trial commenced in October 2016
    - Orphan Drug and Fast Track Designations granted from FDA and EMA

## FINANCIAL HIGHLIGHTS

- Revenue for the three months ended 31 December 2016 of £2.1 million (\$2.5 million) compared to £3.7 million for the three months ended 31 December 2015
- Loss for the three months ended 31 December 2016 of £15.6 million (\$19.3 million) compared to £17.7 million for the three months ended 31 December 2015
- Cash and cash equivalents at 31 December 2016 of £360.2 million (\$444.6 million) compared to £374.4 million as at 30 September 2016

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 31 December 2016 of \$1.23429 to £1. 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.

## Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the first quarter 2017 financial results today at 8:30 a.m EST. To participate in the conference call, please dial 877-407-8133 (toll free from the U.S. and Canada) 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):1-877-481-4010, (international):1-919-882-2331. For both dial-in numbers please use conference ID # 13654672.

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**GW Pharmaceuticals plc**  
**(“GW” or “the Company” or “the Group”)**

**Financial and Operational Results for the First Quarter Ended 31 December 2016**

**GW Overview**

GW was founded in 1998 and 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. GW has established the 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. The Company’s lead cannabinoid product candidate is Epidiolex<sup>®</sup>, a liquid formulation of pure plant-derived cannabidiol, or CBD, for which GW retains global commercial rights, and which is in development for a number of rare childhood-onset epilepsy disorders. GW has received Orphan Drug Designation from the U.S. Food and Drug Administration, or FDA, for Epidiolex for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, or LGS, Tuberous Sclerosis Complex, or TSC, and Infantile Spasms, or IS, each of which are severe infantile-onset, drug-resistant epilepsy syndromes. Additionally, GW has received Fast Track Designation from the FDA and Orphan Designation from the European Medicines Agency, or EMA, for Epidiolex for the treatment of Dravet syndrome.

During 2016, GW reported positive results from three pivotal Phase 3 trials of Epidiolex in Dravet syndrome and LGS. The Company expects to submit a New Drug Application, or NDA, to the FDA in mid-2017 for Epidiolex in both Dravet syndrome and LGS. GW is also building experienced commercial teams in the United States and Europe in preparation for the potential future launches of Epidiolex.

GW has a deep pipeline of additional cannabinoid product candidates focusing primarily on orphan pediatric neurologic conditions and oncology. The Company has also reported positive Phase 2 data for its THC:CBD product in the treatment of glioma. The Company’s pipeline includes cannabidivarin, or CBDV, which is in Phase 2 development in the field of epilepsy and is also being researched within the field of autism spectrum disorders, or ASD. In addition, GW has received Orphan Drug Designation and Fast Track Designation from the FDA for intravenous CBD for the treatment of Neonatal Hypoxic Ischemic Encephalopathy, or NHIE, which is expected to enter Phase 1 development in the fourth quarter of 2016.

Previously, GW developed the world’s first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup>, which is approved for the treatment of spasticity due to multiple sclerosis in 31 countries outside the United States.

**Epidiolex in Dravet syndrome and LGS**

GW has been conducting pre-clinical research of CBD in epilepsy since 2007 which has shown that CBD has significant anti-epileptiform and anticonvulsant activity using a variety of *in vitro* and *in vivo* models. GW’s strategy for the development of Epidiolex within the field of childhood-onset epilepsy is to initially concentrate formal development efforts on four orphan indications: Dravet syndrome, LGS, TSC, and IS, each of which are severe infantile-onset, drug-resistant epilepsy syndromes. GW expects to further expand the potential market opportunity of Epidiolex by targeting additional orphan seizure disorders for regulatory approval.

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### ***Dravet syndrome***

Dravet syndrome is a severe infantile-onset, genetic, drug-resistant epilepsy syndrome with a distinctive but complex electroclinical presentation. Onset of Dravet syndrome occurs during the first year of life with clonic seizures (jerking) and tonic-clonic (convulsive) seizures in previously healthy and developmentally normal infants. Prognosis is poor and approximately 14 percent of children die during a seizure or from Sudden Unexpected Death in Epilepsy or SUDEP. Patients develop intellectual disability and life-long ongoing seizures. There are currently no FDA-approved treatments specifically indicated for Dravet syndrome.

In March 2016, GW reported positive top-line results from the first Phase 3 pivotal efficacy and safety study in 120 patients, achieving the primary endpoint of a median reduction in monthly convulsive seizures compared with placebo ( $p=0.012$ ). In this study, Epidiolex was generally well tolerated. This trial is the largest known controlled trial in Dravet syndrome ever conducted. Additional data was presented in poster form at the American Epilepsy Society's Annual Meeting in December 2016 showing additional safety and efficacy data associated with this study. These data are available on the GW Pharmaceuticals corporate website. Additionally, GW is working with the investigators in this trial on a manuscript for peer-review publication, which is expected in the first half of 2017.

GW is conducting a second Phase 3 trial of Epidiolex in Dravet syndrome. This placebo-controlled trial differs from the first Phase 3 trial in that it includes two Epidiolex dose arms, at 20 mg/kg per day and at 10 mg/kg per day. GW continues to work to enroll this trial, which is expected to recruit 186 patients.

### ***LGS***

LGS is a type of epilepsy with multiple types of seizures, particularly tonic (stiffening) and atonic (drop) seizures. 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. Drug resistance is one of the main features of LGS.

In 2016, GW reported positive results from two LGS Phase 3 pivotal studies, both achieving the primary endpoint of a median reduction in monthly drop seizures compared with placebo. The first study compared a single Epidiolex 20 mg/kg dose arm to placebo in 171 patients ( $p=0.0135$ ) and the second compared both a 20 mg/kg and 10 mg/kg Epidiolex dose arm to placebo in 225 patients ( $p=0.0047$  and  $p=0.0016$  respectively). In these studies, Epidiolex was generally well tolerated. Additional data from the single dose arm trial was presented in poster form at the American Epilepsy Society's Annual Meeting in December 2016, showing additional safety and efficacy data associated with this study. These data are available on the GW Pharmaceuticals corporate website. Additional data from the second dose ranging study is expected to be presented in the second quarter of 2017.

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### ***Open Label Extension***

All patients in the randomized controlled clinical trials who complete the treatment period are eligible to enroll in a long term open label extension trial. To date, 97 percent of patients who have completed the pivotal treatment period have elected to enroll in the open label extension.

### ***Epidiolex US and EU Regulatory Submissions***

In July 2016, GW met with the FDA in a pre-NDA meeting to discuss a proposed Dravet syndrome NDA. This meeting included discussion of the LGS trial data. As a result of this constructive meeting, GW believes the guidance received was both positive and supportive of the Company's proposed filing strategy to submit a single NDA that includes Phase 3 data from one Dravet trial and two LGS trials which is expected in mid-2017. Subject to satisfactory review, GW anticipates simultaneous approval of both indications and does not expect to wait for results from the second trial in Dravet syndrome prior to this submission. GW's NDA is expected to include data from a number of Phase 1 and Phase 2 studies, as well as safety data in over 1,500 patients from both the expanded access program and pivotal programs, including over 400 patients with one year or more of Epidiolex continuous exposure.

In November 2016, GW held a CMC pre-NDA meeting. At this meeting, understanding was reached on key questions related to the CMC content of our planned NDA submission.

In Europe, GW expects to hold pre-submission meetings with the EMA in the first half of 2017 and is making plans to submit a marketing authorization application in Europe in the second half of 2017.

### ***Epidiolex Follow-On Indications***

#### ***TSC***

TSC is a genetic disorder that causes non-malignant tumors to form in many different organs, primarily in the brain, eyes, heart, kidney, skin and lungs. The most common symptom of TSC is epilepsy, which occurs in 75 to 90 percent of patients, about 70 percent of whom experience seizure onset in their first year of life. There are significant co-morbidities associated with TSC including cognitive impairment, autism spectrum disorders and neurobehavioral disorders.

A number of patients with TSC have been treated with Epidiolex in the expanded access program. Most recent Epidiolex data from the expanded access program was published in *Epilepsia* on 18 patients at Massachusetts General Hospital for Children (Hess *et al* - 2016) on Epidiolex treatment of refractory epilepsy in these patients. The findings from this paper, suggest that cannabidiol may be an effective and well-tolerated treatment option for patients with refractory seizures in TSC.

GW has commenced a Phase 3 trial of Epidiolex in patients with TSC. This dose-ranging trial is a 16-week comparison of Epidiolex versus placebo which is expected to recruit a total of approximately 200 patients, aged one to 65 years, to assess the safety and efficacy of Epidiolex as an adjunctive anti-epileptic treatment. The primary measure of this trial is the percentage change from baseline in seizure frequency during the treatment period. Primary endpoint seizures include focal motor seizures with or without impairment of consciousness or awareness and generalized convulsive seizures.

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### ***Infantile Spasms (IS)***

An infantile spasm is a specific type of seizure seen in an epilepsy syndrome of infancy and childhood known as West syndrome. West syndrome is characterized by infantile spasms, developmental regression, and a specific pattern on electroencephalography, or EEG, testing called hypsarrhythmia (chaotic brain waves). The onset of infantile spasms is usually in the first year of life, typically between 4 to 8 months of age.

In December 2015, at the Annual Meeting of the American Epilepsy Society, safety and efficacy data on nine patients suffering from epileptic spasms from the Epidiolex expanded access program were presented by Massachusetts General Hospital for Children (Abati *et al* ). Epilepsy spasms often remain refractory to standard AEDs. According to this poster, Epidiolex exerted its effects in a short time course, with a response rate of 67 percent after two weeks and 78 percent after one month. Three of nine patients became spasm-free after two weeks of Epidiolex treatment.

GW has commenced the first part of a two-part Phase 3 trial of Epidiolex in patients with IS. This first part is expected to be completed in the first half of 2017.

### ***Epidiolex Manufacturing***

GW manufactures Epidiolex through utilization of in-house and external third party facilities for various steps in the production process. The Company is scaling-up various parts of the production process both in-house and with external third parties in readiness for commercial launch.

In December 2016, GW hosted a GMP inspection from the UK's regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA). This inspection was successful with no critical or major findings.

The Company believes that it is on track to be ready for FDA pre-approval inspection anticipated in the second half of 2017.

### ***Epidiolex Commercialization***

GW is planning to commercialize Epidiolex in the United States and elsewhere using its own sales and marketing organization. GW will commercialize Epidiolex, and any other products in the United States, under the name Greenwich Biosciences, Inc.

In June 2015, the Company appointed Julian Gangolli to the newly created position of President, North America and he is leading GW's commercial organization in the United States, which is based in Carlsbad, California. GW is now actively building its U.S commercial organization, which includes an experienced team of medical affairs professionals, clinical trial management specialists and commercial staff, many of whom have strong epilepsy knowledge and experience. The Company expects to expand this organization in 2017. The medical affairs team, a key facet of GW's commercial strategy, has allowed the Company to open scientific and consultative communications with key stakeholders, such as the patient and physician communities in the United States.

The Company expects to implement a "high efficiency" commercial deployment model expected to include a dedicated sales force of approximately 50 to 60 sales professionals targeting approximately 4,000 – 5,000 U.S. physicians. This commercial organization will be defined by a "high touch" patient, payor and physician communication, education and distribution model, and one in which the medical affairs organization will play a significant role in establishing strong relationships with physicians and patient organizations.

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Outside the United States, GW is taking the initial steps toward preparations for Epidiolex commercialization in Europe. This European commercial effort is being led by our Chief Operating Officer, Chris Tovey, who has a wealth of experience commercializing products approved for the treatment of epilepsy. The Company has begun to hire key staff in medical affairs and marketing disciplines to begin laying the groundwork for a more comprehensive commercialization organization.

### ***U.S. Expanded Access Program (EAP)***

In parallel with GW's formal clinical trial program, the FDA has authorized access to Epidiolex to over 1,100 patients through a combination of Investigational New Drug Applications (INDs) to independent physician investigators in the U.S and expanded access programs supported by seven U.S. states, for which GW is supplying Epidiolex free of charge. These include individual emergency and non-emergency INDs. The longest duration of patient use in the EAP is over 3 years. The FDA may authorize expanded access INDs 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. As at 1 January 2017, approximately 650 patients were receiving treatment under expanded access INDs at 31 U.S. clinical sites.

### **Epidiolex Intellectual Property**

In addition to orphan exclusivity, GW has been seeking to protect Epidiolex through the expansion of its patent portfolio. GW's patent portfolio relating to the use of CBD in the treatment of epilepsy includes twelve distinct patent families which are either granted or filed. The latest expiry date of these families is July 2036. This portfolio includes patent families with claims directed to the use of CBD in the treatment of epilepsy seizure subtypes, particular childhood epilepsy syndromes, and formulations. To date, this has resulted in 2 patents granted by the United States Patent and Trademark Office (USPTO) and numerous patent applications being prosecuted at the USPTO. GW anticipates filing additional patent applications in 2017, claiming the use of Epidiolex as new data is generated, and expects more of the Company's pending patent applications to be decided by USPTO during 2017. Should the NDA for Epidiolex be approved, GW expects a number of these granted patents to be listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). In addition, other patent families provide protection for epilepsy related inventions such as extraction techniques, CBD extracts and highly purified CBD.

### ***Epidiolex Formulation Development***

In addition to the initial launch formulation, GW continues to develop additional liquid, solid dose and intravenous formulations of CBD as part of its life cycle management plan.

### ***Mechanism of action***

There is a significant effort utilizing *in vitro*, *in vivo* and other models of epilepsy 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. As recently reported in *Neurotherapeutics* (Ibeas *et al* 2015), 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.

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## **CBDV (cannabidivarin) Development Program**

In addition to Epidiolex, GW's product candidates also include the cannabinoid CBDV. CBDV has shown anti-epileptic properties across a range of *in vitro* and *in vivo* models of epilepsy. CBDV was also found to provide additional efficacy when combined with drugs currently used to control epilepsy. Positive results using genetic biomarkers for response have been identified. CBDV looks to be differentiated from CBD in four key ways: efficacy profile in seizure models, metabolic profile, pharmacological profile and has different physico-chemical characteristics.

GW has commenced a double-blind, randomized, placebo-controlled two-part trial to investigate the pharmacokinetics, followed by efficacy and safety of CBDV as add-on therapy in adult patients with inadequately controlled focal seizures. The first part of this trial is completed with enrollment of 32 patients and the dose-ranging pharmacokinetic and safety data has been reviewed by an independent panel. GW has commenced the efficacy part of the trial and expects to recruit an additional 130 patients with data from this part of the trial is expected H2 2017.

GW has signed a Memorandum of Understanding (MOU) with the NSW Government in Australia to advance a research program for Epidiolex and CBDV in children with severe, drug resistant childhood epilepsy. The MOU facilitates a world first, Phase 2 clinical trial in children using CBDV.

GW has also evaluated CBDV in both general and syndromic pre-clinical models of Autism Spectrum Disorders (ASD) yielding promising signals on cognitive and social endpoints as well as repetitive behaviors. These animal models include both genetically determined and chemically-induced models of neurobehavioral abnormalities, and include Rett syndrome and Fragile X syndrome among others .

Many of the pediatric intractable epilepsy conditions within the Epidiolex expanded access program share considerable overlap with ASD and these conditions often fall within the orphan disease space. Initial clinical observations from treating physicians suggest a potential role for cannabinoids in addressing problems associated with ASD such as deficits in cognition, behavior and communication. GW is working with investigators and early open-label clinical experience is expected to commence in H1 2017 with Phase 2 placebo-controlled trials within ASD expected to commence in the second half of 2017.

## **Oncology**

Beginning in 2007, GW has conducted substantial pre-clinical oncologic research on several cannabinoids in various forms of cancer including brain, lung, breast, pancreatic, melanoma, ovarian, gastric, renal, prostate and bladder. Cannabinoids have been shown to promote autophagy (the process of regulated self-degradation by cells) via several distinct mechanisms, including acting on the AKT/mTOR pathway, an important intracellular signalling pathway that is overactive in many cancers.

In glioma, the combination of THC and CBD showed good efficacy in various animal models of glioma, particularly when used in combination with temozolomide. These pre-clinical studies justified the initiation of a Phase 2 clinical study.

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GW has recently completed a placebo-controlled Phase 2 trial of THC:CBD in 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 both Agencies for its product for the treatment of glioma. This study, which evaluated a number of safety and exploratory efficacy endpoints, showed that patients with documented recurrent glioblastoma treated with THC:CBD as add-on therapy to dose-intense temozolomide, had an 83 percent one year survival compared with 53 percent for patients on placebo (plus dose-intense temozolomide) ( $p=0.042$ ). Median survival time for the THC:CBD group was greater than 550 days compared with 369 days in the placebo group. THC:CBD was generally well tolerated with treatment emergent adverse events leading to discontinuation in two patients in each group. The most common adverse events (three patients or more and greater than placebo) were vomiting (75%), dizziness (67%) and nausea (58%), headache (33%), constipation (33%). The results of some biomarker analyses are still awaited.

GW believes that the signals of efficacy demonstrated in this study further reinforce the potential role of cannabinoids in the field of oncology and provide the Company with the prospect of a new and distinct cannabinoid product candidate in the treatment of additional oncology indications. These data are also a catalyst for the acceleration of GW's oncology research interests and over the coming months, the Company expects to consult with external experts and regulatory agencies on a pivotal clinical development program for THC:CBD in GBM and to expand its research interests in other cancers.

GW's portfolio of intellectual property related to the use of cannabinoids in oncology includes a number of issued patents and pending applications in both the U.S. and Europe. This portfolio is designed to protect the use of various cannabinoids individually or in combination, in the treatment of a variety of oncology-specific disorders and product formulations.

### **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.

GW has received Orphan Drug Designation and Fast Track Designation from the FDA for CBD for the treatment of NHIE. GW has also received Orphan Drug Designation from the EMA for CBD for the treatment of perinatal asphyxia, an alternate term that describes the same condition. Under an IND, GW has commenced a Phase 1 trial of GWP42003 in healthy volunteers for an intravenous CBD formulation in the treatment of NHIE with data expected in 2017.

### **Other Pipeline Programs**

#### ***Sativex for Cerebral Palsy in Children***

GW has completed a Phase 2 clinical trial of Sativex in 72 children aged 8 to 18 years with spasticity due to cerebral palsy or traumatic central nervous system injury who have not responded adequately to existing anti-spasticity medications. This trial was conducted as a post approval pediatric investigational requirement from the EMA following the approval of Sativex in spasticity due to Multiple Sclerosis. The study did not show a statistically significant difference between Sativex and placebo.

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## **Schizophrenia**

GW's product candidate, an oral formulation of CBD, has shown notable anti-psychotic effects in accepted pre-clinical models of schizophrenia and 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. GW is evaluating appropriate next steps regarding product development in schizophrenia with future research likely focused on pediatric orphan neuropsychiatric indications.

### **About GW Pharmaceuticals plc**

*Founded in 1998, 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. GW is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex<sup>®</sup> (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup>, which is approved for the treatment of spasticity due to multiple sclerosis in 31 countries outside the United States. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, schizophrenia and epilepsy. For further information, please visit [www.gwpharm.com](http://www.gwpharm.com).*

### **Forward-looking statements**

*This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding financial performance, the timing of clinical trials, the timing and outcomes of regulatory or intellectual property decisions, the relevance of GW products commercially available and in development, the clinical benefits of Sativex<sup>®</sup> and Epidiolex<sup>®</sup> and the safety profile and commercial potential of Sativex and Epidiolex. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex, Epidiolex and other products by consumer and medical professionals. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission including the most recent Form 20-F filed on 5 December 2016. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.*

### **Enquiries:**

#### **GW Pharmaceuticals plc**

Stephen Schultz, VP Investor Relations

401 500 6570

#### **Sam Brown (U.S. Media Enquiries)**

Mike Beyer

312 961 2502

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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, which has been prepared in accordance with International Accounting Standard 34, Interim Financial Reporting. GW presents its condensed consolidated financial information in pounds sterling.

*Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 31 December 2016, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the 3 months ended 31 December 2016 have been translated into U.S. dollars at the rate on 31 December 2016 of \$1.23429 to £1.0000. 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 the Group's Annual Report as filed with SEC on Form 20-F on 5 December 2016.

Expenditure on research and development activities is recognized 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, and neonatal hypoxia. GW refers to this as "GW-funded research and development expenditure."

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, up to 5 December 2016, 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 statement. The current period tax charge relates to U.S. taxation on the taxable profit for the Group's U.S. subsidiary.

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## Results of Operations:

### *Comparison of the three months ended 31 December 2016 and 31 December 2015:*

#### *Revenue*

Total revenue for the three months to 31 December 2016 was £2.1 million, compared to £3.7 million for the three months ended 31 December 2015.

The majority of revenue this quarter comprises sales of Sativex totalling £1.5 million; this represents an increase of £0.4 million compared to the quarter ended 31 December 2015. In-market sales volumes sold by GW's commercial partners for the three months ended 31 December 2016 were 14% higher than the three months ended 31 December 2015. Sales volumes to partners increased by 8% over the same period due to increased shipments to Germany and Spain.

Revenue from research and development fees amounted to £0.2 million during the three months ended 31 December 2016. In line with previously provided guidance, this represents a decrease of £2.1 million compared to the three months ended 31 December 2015. This expected decrease reflects the impact of the conclusion of the Group's partner-funded Sativex Phase 3 cancer pain clinical trials during the prior financial year.

License collaboration and technical access fees increased by £0.1 million to £0.4 million for the three months ended 31 December 2016, as a result of the mutual termination agreement with Novartis over rights for Sativex, compared to £0.3 million for the three months ended 31 December 2015. This resulted in the acceleration of remaining income in line with the agreed transition period.

#### *Cost of sales*

Cost of sales for the three months ended 31 December 2016 of £0.7 million is unchanged from the £0.7 million recorded in the three months ended 31 December 2015. Although Sativex sales volumes increased during the period, this was offset by a reduction in the unit costs of goods sold compared to the comparative period.

#### *Research and development expenditure*

Total research and development expenditure for the three months ended 31 December 2016 of £24.9 million increased by £0.8 million compared to the £24.1 million incurred in the three months ended 31 December 2015 .

GW-funded research and development expenditure increased by £2.8 million to £24.7 million for the three months ended 31 December 2016 from £21.9 million for the three months ended 31 December 2015 . The increase is due to:

- £4.9 million increase in research and development staff and employment-related expenses linked to increased global headcount combined with the transition of the Group's clinical headcount from partner funded Sativex trials to the GW funded pipeline activities and Epidiolex development program.
  - £0.5 million increase in other property-related overheads and depreciation of R&D assets related to the epilepsy development program.
  - £0.5 million increase in costs of growing an increased volume of plant material for the Epidiolex program.
  - £3.1 million decrease in direct epilepsy and other GW-funded clinical program costs reflecting the reduction in costs associated with GW's finalisation of the Phase 3 Dravet and Lennox-Gastaut syndrome Epidiolex studies.
-

Development-partner funded research and development expenditure decreased by £2.1 million to £0.2 million for the three months ended 31 December 2016 from £2.3 million for the three months ended 31 December 2015 . This reflects decreased expenditure following the completion of the Sativex Phase 3 cancer pain trials programme during the prior financial year.

#### *Sales, general and administrative expenses*

Sales, general and administrative expenses for the three months ended 31 December 2016 of £6.7 million increased by £3.1 million compared to the £3.6 million incurred in the three months ended 31 December 2015 . This increase is related to:

- £1.5 million increase in payroll costs driven by increased headcount as we continue to expand our U.S.-based commercialization capabilities.
- £0.8 million increase in respect of property and travel costs, primarily for the continued build out of U.S. based operations.
- £0.8 million increase in pre-launch commercialization costs in the U.S.

#### *Net foreign exchange gains*

Net foreign exchange gains for the three months ended 31 December 2016 was a gain of £11.8 million, an increase of £8.2 million compared to the £3.6 million gain recorded for the three months ended 31 December 2015 . In both periods the gain recognized primarily relates to the retranslation of the Group's U.S. dollar denominated cash deposits to pounds sterling at 31 December . The Sterling to U.S. dollar exchange rate has moved from 1.29128 at 30 September 2016 to 1.23429 at 31 December 2016 . Dollar denominated cash deposits totalled \$343.8 million at 31 December 2016 and \$345.5 million at 30 September 2016.

#### *Taxation*

The tax benefit was £2.7 million for the three months ended 31 December 2016 . This represents a decrease of £0.7 million compared to a £3.4 million benefit recorded in the three months ended 31 December 2015.

In the three months ended 31 December 2016, GW recorded a tax benefit of £2.7 million made up of: (i) the recognition of an accrued £2.4 million research and development tax credit to be claimable by GW Research Limited in respect of the research and development expenditure incurred in the three months ended 31 December 2016; (ii) the recording of £0.3 million of current tax charge in respect of taxable profits of the Group's U.S. subsidiary, Greenwich Biosciences, Inc (formerly GW Pharmaceuticals Inc.); and (iii) the recording of £0.6 million of tax benefit in respect of an additional deferred tax asset recognised on timing differences for Greenwich Biosciences, Inc.

In the three months ended 31 December 2015, GW recorded a tax benefit of £3.4 million made up of: (i) the recognition of an accrued £3.6 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 three months ended 31 December 2015 and; (ii) the recording of £0.2 million of current tax expense in respect of taxable profits of the Group's U.S. subsidiary, Greenwich Biosciences, Inc.

### **Liquidity and Capital Resources**

#### *Cash Flow*

Net cash outflow from operating activities for the three months ended 31 December 2016 of £24.0 million was £6.0 million higher than the £18.0 million outflow from operating activities for the three months ended 31 December 2015, principally reflecting the increase in investment in the Epidiolex scale up and development activities.

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Capital expenditure for the three months ended 31 December 2016 of £1.6 million, consisting primarily of planned upgrades to our cannabinoid growing facilities, was £0.3 million lower than the £1.9 million for the three months ended 31 December 2015, reflecting completion of a number of significant capital projects.

Net cash outflow from financing activities increased by £1.5 million to a £1.0 million net outflow in the three months ended 31 December 2016 compared to a £0.5 million inflow for the three months ended 31 December 2015 due to the commencement of repayments on finance leases and the fit-out funding.

As at 31 December 2016, GW had a closing cash position of £360.2 million compared to £374.4 million as at 30 September 2016.

#### *Property, plant and equipment*

Property, plant and equipment at 31 December 2016 decreased by £1.1 million to £37.8 million from £38.9 million at 30 September 2016. During the current quarter, the Group realigned its Epidiolex growing and production capabilities to support scalable commercial production processes in anticipation of the expected future US launch. As part of this process, property, plant and equipment with a carrying value of £0.9 million was reclassified to assets held for sale. An impairment of £0.1 million was recognised on associated property, plant and equipment and a further £0.6 million of assets were disposed of.

#### *Inventories*

Inventories at 31 December 2016 increased by £0.4 million to £4.6 million from £4.2 million at 30 September 2016. Inventories consist of Sativex finished goods, consumable items and work in progress and are stated net of a £0.1 million realizable value provision (30 September 2016: £0.1 million). During the three months ended 31 December 2016, the provision for inventories remained constant.

#### *Trade receivables and other assets*

Trade receivables and other assets at 31 December 2016 increased by £2.3 million to £6.9 million from £4.6 million at 30 September 2016, primarily due to prepayments for property, plant and equipment not yet delivered totalling £1.2 million. In addition to this amount, there was a £1.1 million increase in recoverable indirect taxes on Group expenditure.

#### *Trade and other payables*

Current trade and other payables at 31 December 2016 increased by £5.3 million to £36.5 million from £31.2 million at 30 September 2016. This increase reflects an increase in trade payables and accruals as a result of the continued expansion of GW-funded clinical trials and manufacturing capability.

#### *Headcount*

Average headcount for the three months ended 31 December 2016 was 500 (31 December 2015: 389).

#### *Guidance*

There are no proposed changes to the 2017 guidance, as provided at the time of GW's 2016 year end results announcement on 5 December 2016.

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GW Pharmaceuticals plc  
Condensed consolidated income statement  
Three months ended 31 December 2016 and 2015

	Notes	Three months ended 31 December 2016 \$000's	Three months ended 31 December 2016 £000's	Three months ended 31 December 2015 £000's
<b>Revenue</b>	2	2,538	<b>2,056</b>	3,667
Cost of sales		(883)	<b>(715)</b>	(687)
Research and development expenditure		(30,751)	<b>(24,914)</b>	(24,139)
Sales, general and administrative expenses		(8,250)	<b>(6,684)</b>	(3,625)
Net foreign exchange gain		14,583	<b>11,815</b>	3,601
<b>Operating loss</b>		(22,763)	<b>(18,442)</b>	(21,183)
Interest income		337	<b>273</b>	63
Interest expense		(111)	<b>(90)</b>	(19)
<b>Loss before tax</b>		(22,537)	<b>(18,259)</b>	(21,139)
Tax benefit	3	3,287	<b>2,663</b>	3,437
<b>Loss for the period</b>		(19,250)	<b>(15,596)</b>	(17,702)
<b>Loss per share – basic and diluted</b>		(6.4c)	<b>(5.2p)</b>	(6.8p)
<b>Loss per ADS – basic and diluted <sup>(1)</sup></b>		(76.8c)	<b>(62.4p)</b>	(81.6p)
<b>Weighted average ordinary shares outstanding (in millions) – basic and diluted</b>			<b>302.7</b>	261.4

All activities relate to continuing operations.

<sup>(1)</sup> Each ADS represents 12 ordinary shares.

Condensed consolidated statement of comprehensive loss  
For the three months ended 31 December 2016 and 2015

	Three month ended 31 December 2016 £000's	Three months ended 31 December 2015 £000's
<b>Loss for the period</b>	<b>(15,596)</b>	(17,702)
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange gain/(loss) on retranslation of foreign operations	418	(53)
<b>Other comprehensive gain/(loss) for the period</b>	<b>418</b>	(53)
<b>Total comprehensive loss for the period</b>	<b>(15,178)</b>	(17,755)

GW Pharmaceuticals plc  
Condensed consolidated statement of changes in equity  
Three months ended 31 December 2016 and 2015

	Share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total £000's
<b>Balance at 1 October 2015</b>	261	349,275	19,189	(123,455)	245,270
Exercise of share options	2	562	-	-	564
Share-based payment transactions	-	-	-	1,306	1,306
Loss for the period	-	-	-	(17,702)	(17,702)
Deferred tax attributable to unrealized share option gains	-	-	-	(74)	(74)
Other comprehensive loss	-	-	(53)	-	(53)
<b>Balance at 31 December 2015</b>	<b>263</b>	<b>349,837</b>	<b>19,136</b>	<b>(139,925)</b>	<b>229,311</b>
<b>Balance at 1 October 2016</b>	302	556,477	19,538	(177,827)	398,490
Exercise of share options	2	88	-	-	90
Share-based payment transactions	-	-	-	2,166	2,166
Loss for the period	-	-	-	(15,596)	(15,596)
Deferred tax attributable to unrealized share option gains	-	-	-	(255)	(255)
Other comprehensive income	-	-	418	-	418
<b>Balance at 31 December 2016</b>	<b>304</b>	<b>556,565</b>	<b>19,956</b>	<b>(191,512)</b>	<b>385,313</b>

GW Pharmaceuticals plc  
Condensed consolidated income statement  
Three months ended 31 December 2016 and 2015

	Notes	As at 31 December 2016 \$000's	As at 31 December 2016 £000's	As at 30 September 2016 £000's
<b>Non-current assets</b>				
Intangible assets - goodwill		6,431	5,210	5,210
Other intangible assets		1,206	977	629
Property, plant and equipment		46,647	37,792	38,947
Deferred tax asset		5,351	4,335	3,873
		<u>59,635</u>	<u>48,314</u>	<u>48,659</u>
<b>Current assets</b>				
Inventories		5,722	4,636	4,248
Taxation recoverable		29,272	23,716	21,322
Trade receivables and other assets		8,488	6,877	4,556
Cash and cash equivalents		444,649	360,247	374,392
		<u>488,131</u>	<u>395,476</u>	<u>404,518</u>
Assets held for sale		1,122	909	-
		<u>1,122</u>	<u>909</u>	<u>-</u>
<b>Total assets</b>		<u>548,888</u>	<u>444,699</u>	<u>453,177</u>
<b>Current liabilities</b>				
Trade and other payables	4	(45,093)	(36,534)	(31,170)
Current tax liabilities		(909)	(736)	(883)
Obligations under finance leases		(204)	(165)	(211)
Deferred revenue		(3,096)	(2,508)	(2,686)
		<u>(49,302)</u>	<u>(39,943)</u>	<u>(34,950)</u>
<b>Non-current liabilities</b>				
Trade and other payables	4	(11,667)	(9,452)	(9,423)
Obligations under finance leases		(6,060)	(4,910)	(4,959)
Deferred revenue		(6,271)	(5,081)	(5,355)
		<u>(6,271)</u>	<u>(5,081)</u>	<u>(5,355)</u>
<b>Total liabilities</b>		<u>(73,300)</u>	<u>(59,386)</u>	<u>(54,687)</u>
<b>Net assets</b>		<u>475,588</u>	<u>385,313</u>	<u>398,490</u>
<b>Equity</b>				
Share capital		375	304	302
Share premium account		686,963	556,565	556,477
Other reserves		24,631	19,956	19,538
Accumulated deficit		(236,381)	(191,512)	(177,827)
		<u>(236,381)</u>	<u>(191,512)</u>	<u>(177,827)</u>
<b>Total equity</b>		<u>475,588</u>	<u>385,313</u>	<u>398,490</u>

GW Pharmaceuticals plc  
Condensed consolidated cash flow statements  
For the three months ended 31 December 2016 and 2015

	Three months ended 31 December 2016 \$000's	<b>Three months ended 31 December 2016 £000's</b>	Three months ended 31 December 2015 £000's
<b>Loss for the period</b>	(19,250)	<b>(15,596)</b>	(17,702)
Adjustments for:			
Interest income	(337)	<b>(273)</b>	(63)
Interest expense	111	<b>90</b>	19
Tax benefit	(3,287)	<b>(2,663)</b>	(3,437)
Depreciation of property, plant and equipment	1,307	<b>1,059</b>	736
Impairment of property, plant and equipment	117	<b>95</b>	-
Amortization of intangible assets	22	<b>18</b>	14
Net foreign exchange gains	(14,583)	<b>(11,815)</b>	(3,762)
Increase in provision for inventories	35	<b>28</b>	7
Decrease in deferred signature fees	(530)	<b>(429)</b>	(289)
Share-based payment charge	2,673	<b>2,166</b>	1,306
Loss on disposal of property, plant and equipment	687	<b>557</b>	-
	<u>(33,035)</u>	<u><b>(26,763)</b></u>	<u>(23,171)</u>
(Increase)/decrease in inventories	(513)	<b>(416)</b>	56
Increase in trade receivables and other assets	(2,436)	<b>(1,974)</b>	(2,401)
Increase in trade and other payables and deferred revenue	6,929	<b>5,613</b>	7,931
Income taxes paid	(555)	<b>(450)</b>	(366)
<b>Net cash outflow from operating activities</b>	<u>(29,610)</u>	<u><b>(23,990)</b></u>	<u>(17,951)</u>
<b>Investing activities</b>			
Interest received	170	<b>138</b>	70
Purchases of property, plant and equipment	(1,698)	<b>(1,376)</b>	(1,782)
Purchases of intangible assets	(272)	<b>(220)</b>	(119)
<b>Net cash outflow from investing activities</b>	<u>(1,800)</u>	<u><b>(1,458)</b></u>	<u>(1,831)</u>
<b>Financing activities</b>			
Proceeds on exercise of share options	111	<b>90</b>	564
Expenses of new equity issue	(165)	<b>(134)</b>	-
Interest paid	(305)	<b>(247)</b>	(20)
Repayments of fit out funding	(696)	<b>(564)</b>	-
Repayments of obligations under finance leases	(117)	<b>(95)</b>	(26)
<b>Net cash (outflow)/inflow from financing activities</b>	<u>(1,172)</u>	<u><b>(950)</b></u>	<u>518</u>
Effect of foreign exchange rate changes on cash and cash equivalents	<u>15,123</u>	<u><b>12,253</b></u>	<u>3,705</u>
<b>Net decrease in cash and cash equivalents</b>	<u>(17,459)</u>	<u><b>(14,145)</b></u>	<u>(15,559)</u>
Cash and cash equivalents at beginning of the period	<u>462,108</u>	<u><b>374,392</b></u>	<u>234,872</u>
<b>Cash and cash equivalents at end of the period</b>	<u><u>444,649</u></u>	<u><u><b>360,247</b></u></u>	<u><u>219,313</u></u>

## 1. Significant accounting policies

### Basis of preparation

These unaudited condensed consolidated interim financial statements as at 31 December 2016 and for the three month periods ended 31 December 2016 and 31 December 2015 of GW Pharmaceuticals plc and subsidiaries (collectively, the “Group”) have been prepared in accordance with International Accounting Standard 34 – “Interim Financial Reporting”, as issued by the International Accounting Standards Board (“IASB”) and as endorsed by the European Union. These statements were approved by the Board on 7 February 2017.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the IASB and as adopted by the European Union have been condensed or omitted as permitted by IAS 34. The balance sheet as at 30 September 2016 was derived from the audited financial statements.

The significant accounting policies and methods of computation adopted in the preparation of these condensed consolidated interim financial statements are consistent with those used in the preparation of the Group’s annual audited financial statements for the year ended 30 September 2016 in accordance with IFRS. These condensed consolidated interim financial statements include all adjustments necessary to fairly state the results of the interim period and the Group believes that the disclosures are adequate to make the information presented not misleading. Interim results are not necessarily indicative of results to be expected for the full year.

The Group has not early adopted any standard, interpretation or amendment that was issued but is not yet effective.

Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 31 December 2016, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three months ended 31 December 2016 have been translated into U.S. dollars at the rate on 31 December 2016 of \$1.23429 to £1.0000. 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 Directors do not consider the business to be seasonal or cyclical.

### Going concern

At 31 December 2016 the Group had cash and cash equivalents of £360.2 million. 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 this report 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 date of this report. Accordingly, they continue to adopt the going concern basis in preparing these financial statements.

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## 2. Segmental Information

### *Operating Segments*

Information reported to the Group'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 multiple sclerosis ("MS"). The Commercial segment will include revenues from the direct marketing of other future approved commercial products. The Group has licensing agreements for the commercialization of Sativex with Almirall S.A. in Europe (excluding the UK) and Mexico, Otsuka Pharmaceutical Co. Ltd. ("Otsuka") in the US, Bayer HealthCare AG in the UK 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, licence, 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 maximize the potential of Sativex through the development of new indications. 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 R&D segment revenues consist of R&D 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 our proprietary cannabinoid technology platform. The Group's product pipeline includes Epidiolex, in development as a treatment for Dravet syndrome, Lennox-Gastaut syndrome, Tuberous Sclerosis Complex and Infantile Spasms, as well as other product candidates in Phase 1 and 2 clinical developments for glioma, adult epilepsy, neonatal hypoxia, autism spectrum disorders and schizophrenia. Pipeline R&D segment revenues consist of R&D 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.

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**Segmental revenues and results**

For the Three Months Ended 31 December 2016

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs <sup>1</sup> £'000	Consolidated £'000
<b>Revenue:</b>						
Product sales	1,472	-	-	1,472	-	1,472
Research and development fees	-	22	132	154	-	154
License, collaboration and technical access fees	430	-	-	430	-	430
<b>Total revenue</b>	<b>1,902</b>	<b>22</b>	<b>132</b>	<b>2,056</b>	<b>-</b>	<b>2,056</b>
Cost of sales	(715)	-	-	(715)	-	(715)
Research and development expenditure	-	(46)	(23,910)	(23,956)	(958)	(24,914)
<b>Segmental result</b>	<b>1,187</b>	<b>(24)</b>	<b>(23,778)</b>	<b>(22,615)</b>	<b>(958)</b>	<b>(23,573)</b>
Sales, general and administrative expenses						(6,684)
Net foreign exchange gain						11,815
<b>Operating loss</b>						<b>(18,442)</b>
Interest income						273
Interest expense						(90)
Loss before tax						(18,259)
Tax benefit						2,663
<b>Loss for the period</b>						<b>(15,596)</b>

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.

**Segmental revenues and results**

For the Three Months Ended 31 December 2015

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs <sup>1</sup> £'000	Consolidated £'000
<b>Revenue:</b>						
Product sales	1,120	-	-	1,120	-	1,120
Research and development fees	-	2,160	97	2,257	-	2,257
License, collaboration and technical access fees	290	-	-	290	-	290
<b>Total revenue</b>	<b>1,410</b>	<b>2,160</b>	<b>97</b>	<b>3,667</b>	<b>-</b>	<b>3,667</b>
Cost of sales	(687)	-	-	(687)	-	(687)
Research and development expenditure	-	(2,562)	(21,168)	(23,730)	(409)	(24,139)
<b>Segmental result</b>	<b>723</b>	<b>(402)</b>	<b>(21,071)</b>	<b>(20,750)</b>	<b>(409)</b>	<b>(21,159)</b>
Sales, general and administrative expenses						(3,625)
Net foreign exchange gain						3,601
<b>Operating loss</b>						<b>(21,183)</b>
Interest income						63
Interest expense						(19)
Loss before tax						(21,139)
Tax benefit						3,437
<b>Loss for the period</b>						<b>(17,702)</b>

- 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.

GW Pharmaceuticals plc

Notes to the condensed consolidated financial statements

Three months ended 31 December 2016 and 2015

Revenues from the Group's major customers are included within the above segments as follows:

*Three months ended 31 December 2016*

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Customer A	1,159	-	-	1,159
Customer B	397	-	-	397
Customer C	70	22	132	224
Customer D	209	-	-	209

*Three months ended 31 December 2015*

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Customer A	943	-	-	943
Customer B	314	-	-	314
Customer C	70	2,160	97	2,327
Customer D	29	-	-	29

**Geographical analysis of turnover by destination of customer**

	Three months ended 31 December 2016 £000's	Three months ended 31 December 2015 £000's
UK	317	226
Europe (excluding UK)	1,335	973
United States	92	2,230
Canada	180	141
Asia/Other	132	97
	<b>2,056</b>	<b>3,667</b>

### 3. Tax benefit

	Three months ended 31 December 2016	Three months ended 31 December 2015
	£000's	£000's
Current period research and development tax credit	(2,394)	(3,640)
Adjustments in respect of prior year tax charge	-	49
Deferred tax credit	(280)	-
Reclassification of amounts previously charged to equity	(255)	-
Current period tax charge	266	154
<b>Total credit for the period</b>	<b>(2,663)</b>	<b>(3,437)</b>

Tax credits relate to UK research and development tax credits claimed under the Finance Act 2000.

In the three months ended 31 December 2016, the Group recognized the full estimated benefit for qualifying current year research and development expenditures incurred during the year, based on the Group's sustained history of agreeing such claims with HMRC. Any difference in the credit ultimately received is recorded as an adjustment in respect of prior year.

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.

### 4. Trade and other payables

	31 December 2016	30 September 2016
	£000's	£000's
<b>Amounts falling due within one year</b>		
Other creditors and accruals	21,217	15,899
Clinical trial accruals	8,637	9,503
Trade payables	4,350	3,433
Fit out funding	370	845
Other taxation and social security	1,841	1,490
Onerous lease provision	119	-
	<b>36,534</b>	<b>31,170</b>
<b>Amounts falling due after one year</b>		
Other creditors and accruals	1,161	1,081
Fit out funding	8,254	8,342
Onerous lease provision	37	-
	<b>9,452</b>	<b>9,423</b>

Fit out funding represents £8.6 million (30 September 2016: £9.2 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 interest of £1.8 million (30 September 2016: £1.6 million), net of payments to date of £1.0 million (30 September 2016: £0.2 million). The repayments of this liability commenced on 27 May 2016 after the Group occupied the facility. Repayments will continue over the remainder of the 15-year term.



## GW Pharmaceuticals Achieves Positive Results in Phase 2 Proof of Concept Study in Glioma

### - GW intends to advance oncology research and development efforts -

**London, UK, 7 Feb 2017** : GW Pharmaceuticals plc (Nasdaq: GWPH, “GW,” “the Company” or “the Group”), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, today announced positive top-line results from an exploratory Phase 2 placebo-controlled clinical study of a proprietary combination of tetrahydrocannabinol (THC) and cannabidiol (CBD) in 21 patients with recurrent glioblastoma multiforme, or GBM. GBM is a particularly aggressive brain tumor, with a poor prognosis. GW has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for THC:CBD in the treatment of glioma.

The study showed that patients with documented recurrent GBM treated with THC:CBD had an 83 percent one year survival rate compared with 53 percent for patients in the placebo cohort ( $p=0.042$ ). Median survival for the THC:CBD group was greater than 550 days compared with 369 days in the placebo group. THC:CBD was generally well tolerated with treatment emergent adverse events leading to discontinuation in two patients in each group. The most common adverse events (three patients or more and greater than placebo) were vomiting (75%), dizziness (67%) nausea (58%), headache (33%), and constipation (33%). The results of some biomarker analyses are still awaited.

“The findings from this well-designed controlled study suggest that the addition of a combination of THC and CBD to patients on dose-intensive temozolomide produced relevant improvements in survival compared with placebo and this is a good signal of potential efficacy,” said Professor Susan Short, PhD, Professor of Clinical Oncology and Neuro-Oncology at Leeds Institute of Cancer and Pathology at St James’s University Hospital and principal investigator of the study. “Moreover, the cannabinoid medicine was generally well tolerated. These promising results are of particular interest as the pharmacology of the THC:CBD product appears to be distinct from existing oncology medications and may offer a unique and possibly synergistic option for future glioma treatment.”

“We believe that the signals of efficacy demonstrated in this study further reinforce the potential role of cannabinoids in the field of oncology and provide GW with the prospect of a new and distinct cannabinoid product candidate in the treatment of glioma,” stated Justin Gover, GW’s Chief Executive Officer. “These data are a catalyst for the acceleration of GW’s oncology research interests and over the coming months, we expect to consult with external experts and regulatory agencies on a pivotal clinical development program for THC:CBD in GBM and to expand our research interests in other forms of cancer.”

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The study, designed to evaluate a number of safety and efficacy endpoints, comprised an initial phase where the safety of THC:CBD in combination with dose-intense temozolomide (an oral alkylating agent that is a standard first-line treatment for GBM) was assessed in 2 cohorts of 3 patients each. Following a satisfactory independent safety evaluation, the study then entered a randomized placebo-controlled phase where 12 patients were randomized to THC:CBD as add-on therapy compared with 9 patients randomized to placebo (plus standard of care).

Beginning in 2007 and prior to initiating this study, GW conducted substantial pre-clinical oncologic research on several cannabinoids in various forms of cancer including brain, lung, breast, pancreatic, melanoma, ovarian, gastric, renal, prostate and bladder. These studies have resulted in approximately 15 publications and show the multi-modal effects of cannabinoids on a number of the key pathways associated with tumor growth and progression. Cannabinoids have been shown to promote autophagy (the process of regulated self-degradation by cells) via several distinct mechanisms, including acting on the AKT/mTOR pathway, an important intracellular signalling pathway that is overactive in many cancers.

In glioma, THC and CBD appear to act via distinct signalling pathways. The combination of THC and CBD showed good efficacy in various animal models of glioma, particularly when used in combination with temozolomide. Initial *in vitro* studies showed that the combined administration of THC and CBD led to a synergistic reduction in the viability of U87MG glioma cells when compared to the administration of each cannabinoid individually. The co-administration of temozolomide with THC and CBD had further synergistic effects, causing a significant reduction in cell viability. These pre-clinical studies justified the initiation of the Phase 2 clinical study.

GW's portfolio of intellectual property related to the use of cannabinoids in oncology includes a number of issued patents and pending applications in both the U.S. and Europe. This portfolio is designed to protect the use of various cannabinoids individually or in combination, in the treatment of a variety of oncology-specific disorders and product formulations.

### **About GBM**

Gliomas are tumors that arise from glial cells mainly in the brain but can also be found within the spinal cord. Within the category of Glioma there are multiple different tumor types. GBM is the most common Glioma and is one of the most common primary brain tumors, accounting for 15.6% of all primary brain tumors (Ostrom et al. 2013). They are also the most aggressive with only 28.4% of patients surviving one year and only 3.4% surviving to year five (Brodbeck et al. 2015). Studies of patients with high-grade gliomas showed that headache was the most common initial presenting symptom. These headaches can be persistent lasting more than six months and are often associated with other symptoms, including seizures, visual disturbances, cognitive impairment and nausea and vomiting depending on the location and growth rate of the tumor.

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## **About GW Pharmaceuticals plc**

*Founded in 1998, 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. GW is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex<sup>®</sup> (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup> (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in 31 countries outside the United States. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, schizophrenia and epilepsy. For further information, please visit [www.gwpharm.com](http://www.gwpharm.com).*

## **Forward-looking statements**

*This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding financial performance, the timing of clinical trials, the timing and outcomes of regulatory or intellectual property decisions, the relevance of GW products commercially available and in development, the clinical benefits of Sativex<sup>®</sup> and Epidiolex<sup>®</sup> and the safety profile and commercial potential of Sativex and Epidiolex. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including (inter alia), the success of GW's research strategies, the applicability of the discoveries made therein, the successful and timely completion of uncertainties related to the regulatory process, and the acceptance of Sativex, Epidiolex and other products by consumer and medical professionals. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including the most recent Form 20-F filed on 5 December 2016. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.*

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