

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

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**Form 6-K**

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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, 2018

Commission File Number: 001-35892

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**GW PHARMACEUTICALS PLC**  
(Translation of registrant's name into English)

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

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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):

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):

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**Other Events**

On February 5, 2018, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its first quarter 2018 financial results and operational progress and details of a conference call to be held at 4:30 p.m. EST on February 5, 2017 to discuss the results and operational progress. The press release is attached as Exhibit 99.1 and is incorporated by reference herein. The condensed consolidated income statement, statement of changes in equity, consolidated balance sheets and consolidated cash flow statements for the three months ended December 31, 2017 and 2016 and the related notes thereto contained in Exhibit 99.1 to this Form 6-K are incorporated by reference into the Company’s Form F-3 Registration Statement File No. 333-217329 and Form S-8 Registration Statements File Nos. 333-204389 and 333-217328, and related Prospectuses, as such Registration Statements and Prospectuses may be amended from time to time. The other information contained in Exhibit 99.1 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 5, 2018

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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/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer

Date: February 5, 2018

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## GW Pharmaceuticals plc Reports Fiscal First Quarter 2018 Financial Results and Operational Progress

- Epidiolex<sup>®</sup> (cannabidiol) NDA and MAA applications accepted for review –  
 - NDA PDUFA goal date scheduled for June 27, 2018 -  
 - Conference call today at 4:30 p.m. EST -

**London, UK, Carlsbad, CA, 5 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, announces financial results for the first quarter ended 31 December 2017.

“With the Epidiolex regulatory applications accepted for review in both the US and Europe, and an assigned mid-year FDA decision date, 2018 is expected to be an exciting year for our Company with an anticipated first U.S. approval and launch. The commercial teams are making great progress toward launching Epidiolex with full conviction,” stated Justin Gover, GW’s Chief Executive Officer. “We also continue to see a significant flow of clinical data from the Epidiolex program through both medical meetings such as the American Epilepsy Society and in publication including our recent Lennox-Gastaut syndrome results in *The Lancet*. Beyond Epidiolex, we expect to progress a number of important pipeline programs during 2018 that have the potential to offer additional value.”

### OPERATIONAL HIGHLIGHTS

- Epidiolex (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut syndrome (LGS), Tuberous Sclerosis Complex (TSC) and infantile spasms (IS)
    - o Regulatory:
      - NDA for the adjunctive treatment of seizures associated with LGS and Dravet syndrome accepted for priority review with planned PDUFA goal date of June 27, 2018
      - European submission accepted for review by the EMA. Expected decision in Q1 2019
    - o Clinical data:
      - First Phase 3 LGS trial published in *The Lancet*
      - Second Phase 3 LGS trial publication anticipated in H1 2018
    - o Clinical trials
      - Phase 3 trial in Tuberous Sclerosis Complex ongoing with data expected H2 2018
      - Second Phase 3 trial in Dravet syndrome enrollment complete with data expected H2 2018
      - Part A of two-part Phase 2/3 trial in Infantile Spasms underway
    - o Manufacturing
      - FDA GMP inspections scheduled
    - o Expanded access program and open label extension:
      - Over 2,000 patients now have been exposed to Epidiolex treatment
      - 97 percent of patients who complete Phase 3 trials have entered long term extension
    - o Commercial:
      - Head of U.S. Sales appointed, completing the full U.S. commercial leadership team
      - Active discussions in U.S. with a wide variety of payors and insurance programs
      - EU commercial footprint now in place in five major European markets
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- o Life-cycle management
  - Several new formulations of CBD in development including modified liquid formulations, a solid dose form and an intravenous formulation
- o Intellectual property
  - Several patent applications related to the use of CBD in certain forms of epilepsy being prosecuted with expected Track One decisions in Q2 2018
  - Additional patent applications being filed as new data is generated
- Pipeline progress
  - o CBDV in epilepsy
    - Data from CBDV Phase 2 partial-onset epilepsy study in adults expected in Q1 2018
  - o CBDV in Autism Spectrum Disorders
    - 10-patient investigator-initiated expanded access program for seizures associated with autism underway
    - Investigator-led 100 patient placebo-controlled trial in autism spectrum disorder due to commence in Q2 2018
    - Open label study in Rett syndrome due to commence in Q2 2018 and Phase 2 placebo-controlled trial in Rett syndrome due to commence in Q3 2018
    - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
  - o Sativex® (nabiximols)
    - US development and commercialization rights reacquired – plans underway to commence US pivotal trial in MS spasticity
  - o CBD:THC in Glioblastoma
    - Pivotal clinical development program plans under development
  - o Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
    - Phase 1 trial complete
    - Orphan Drug and Fast Track Designations granted from FDA and EMA
- Board appointments
  - o Three new independent members appointed to Board of Directors.

#### **FINANCIAL HIGHLIGHTS**

- Revenue for the three months ended 31 December 2017 of £5.7 million (\$7.7 million) compared to £2.1 million for the three months ended 31 December 2016.
- Loss for the three months ended 31 December 2017 of £47.0 million (\$63.3 million) compared to £15.6 million for the three months ended 31 December 2016.
- Cash and cash equivalents at 31 December 2017 of £414.8 million (\$559.2 million) compared to £241.2 million as at 30 September 2017.

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 31 December 2017 of \$1.3482 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 2018 financial results today at 4:30 pm 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 or 919-882-2331 (international). For both dial-in numbers please use conference ID # 13675963 and PIN: 24706.

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

**Financial and Operational Results for the First Quarter Ending 31 December 2017**

**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 pharmaceutical formulation of 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 seizures associated with 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 for Dravet syndrome and conditional grant of rare pediatric disease designation by FDA. GW has also received Orphan Designation from the European Medicines Agency, or EMA, for Epidiolex for Dravet syndrome, LGS, West syndrome (IS) and TSC.

During 2016, GW reported positive results from three pivotal Phase 3 trials of Epidiolex in Dravet syndrome and LGS. In October 2017, the Company completed a rolling submission of the New Drug Application, or NDA, to the FDA for Epidiolex in both LGS and Dravet syndrome. This NDA was accepted by FDA in December 2017 with an assigned PDUFA goal date of 27 June, 2018. The Company also completed its submission to the European Medicines Agency, or EMA in December 2017. This submission has been validated by the EMA and the outcome of this review process is expected in Q1 2019. In preparation for the future launches of Epidiolex, GW is building experienced commercial teams in the United States and Europe.

GW has a deep pipeline of additional cannabinoid product candidates focusing primarily on orphan childhood-onset neurologic conditions and oncology. 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 2017, GW reported positive Phase 2 data for its THC:CBD product in the treatment of glioblastoma multiforme. 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, for which a Phase 1 study has been completed.

Previously, GW developed 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 numerous countries outside the United States. In the U.S., GW has recently reacquired the commercial rights to this product from a former licensing partner and plans to supplement the ex-U.S. data with an additional pivotal trial prior to submitting a future NDA for Sativex.

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## **Appointments to the Board of Directors**

In December 2017, GW announced the appointment of three new independent members to its Board of Directors, Dr. Catherine Mackey, Alicia Secor and Lord William Waldegrave. These additions bring the GW Board to a total of eight members, six of whom are independent. The appointment of these new independent directors has led to changes in the composition of Board subcommittees. These committees are now comprised as follows:

Audit Committee – James Noble (chair), Tom Lynch, Catherine Mackey

Remuneration Committee – Tom Lynch (chair), Cabot Brown, Alicia Secor

Nominations Committee – Cabot Brown (chair), James Noble, William Waldegrave

## **Epidiolex (cannabidiol) 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: LGS, Dravet syndrome, TSC, and IS, each of which are severe childhood-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.

### **LGS**

LGS is a type of epilepsy with multiple types of seizures, particularly tonic (stiffening) and predominantly drop seizures which were defined as atonic, tonic or tonic-clonic seizures involving the entire body, trunk or head that led or could have led to a fall, injury, slumping in a chair or hitting the patient's head on a surface. 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 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, the most common adverse events (occurring in greater than ten percent of Epidiolex-treated patients) were: somnolence, decreased appetite, diarrhea, pyrexia, upper respiratory tract infection, vomiting, and status epilepticus. AEs were of mild or moderate severity in 74.6 percent of patients in the CBD 10 mg/kg arm, 75.0 percent in the CBD 20 mg/kg arm, and 65.8 percent in the placebo arm. In January 2018, the single Epidiolex dose trial was published in *The Lancet*, accompanied by an editorial. Additional data from the second Epidiolex trial was presented at the American Academy of Neurology Annual Meeting in April 2017, and this trial is expected to be published in a medical journal in the first half of 2018.

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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 death occurs before the age of 10 years in 3 out of 4 people (73 percent) with Sudden Unexpected Death in Epilepsy or SUDEP the likely cause in nearly half of those deaths. Patients develop intellectual disability and life-long ongoing seizures. There are currently no FDA-approved treatments specifically indicated for Dravet syndrome.

In 2016, GW reported 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. The most common adverse events (occurring in greater than ten percent of Epidiolex-treated patients) were: somnolence, diarrhea, decreased appetite, fatigue, pyrexia, vomiting, lethargy, upper respiratory tract infection and convulsion. AEs occurred in 93.4 percent of CBD and 74.6 percent of placebo patients; of patients on CBD who reported an AE, 84 percent reported it to be mild or moderate. In May 2017, this trial was published in *The New England Journal of Medicine*, accompanied by an editorial.

Across the Epidiolex development program, the most common reported adverse reactions are somnolence, decreased appetite, diarrhea, pyrexia, fatigue, lethargy, rash, nasopharyngitis, and pneumonia; dose-related reversible elevation of liver transaminases without elevation of bilirubin were also observed.

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. Enrollment is complete in this trial at 186 patients with data expected in the second half of 2018.

### ***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 U.S. and EU Regulatory Submissions***

The Company completed a rolling submission of the Epidiolex NDA in October 2017. In December 2017, the FDA accepted the NDA for review and assigned a PDUFA decision goal date of 27 June, 2018. Subject to satisfactory FDA review, GW anticipates a simultaneous decision for both indications.

In addition, GW has received confirmation from the FDA granting rare pediatric disease designation of cannabidiol in the treatment of LGS and Dravet syndrome. This conditional designation is a pre-cursor to the potential award of a rare pediatric disease priority review voucher which, if awarded, would be granted at the time of NDA approval.

In Europe, GW has submitted a single marketing authorization application in December 2017 for both the Dravet syndrome and LGS indications. This application has been validated by the EMA and the outcome is expected in first quarter of 2019.

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## **U.S. DEA Rescheduling**

Subject to Epidiolex receiving FDA approval, the DEA will receive a recommendation from the FDA to make a scheduling determination and place the product in a schedule other than Schedule I in order for it to be prescribed to patients in the U.S. At the Annual Meeting of the American Epilepsy Society held in December 2017, GW showed data from its human abuse liability study in the Company's scientific exhibit, which demonstrated that CBD has a low potential for abuse when compared to specific Schedule III and Schedule IV drug products. As such, if approved by the FDA, the Company expects Epidiolex to be likely placed in Schedule IV. This rescheduling determination is required by law to be made within 90 days from the later of approval or receiving the FDA's recommendation.

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

### ***TSC***

TSC is a genetic disorder that causes developmental changes in the nervous system and skin, as well as the formation of non-malignant tumors in multiple organ systems, 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 recently, the Epidiolex treatment experience in 18 TSC patients with refractory epilepsy from the Massachusetts General Hospital for Children enrolled in the expanded access program has been published in *Epilepsia* (Hess *et al* - 2016). The findings from this study 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 seizure types include focal motor seizures with or without impairment of consciousness or awareness and generalized convulsive seizures. Data from this trial is expected in the second half of 2018.

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

Infantile spasms are specific types of seizures seen in an epilepsy syndrome of infancy and childhood also known as West syndrome. West syndrome is characterized by infantile spasms, developmental regression, and a specific pattern on electroencephalography, 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, open-label 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 publication, Epidiolex exerted its effects within a short period of time, with a response rate of 67 percent after two weeks and 78 percent after one month. Three of nine patients became spasm-free two weeks after Epidiolex treatment.

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GW has commenced a two part Phase 2/3 trial of Epidiolex in patients with IS. The first part is now underway and the results, which are expected in the second quarter of 2018, will determine next steps.

### **Epidiolex Manufacturing**

GW manufactures Epidiolex through utilization of in-house and external third party facilities for various steps in the production process. The Company has expanded various parts of the production process both in-house and with external third parties in readiness for commercial launch. These expanded facilities are included in the NDA. GW is continuing to scale-up its Epidiolex manufacturing process in anticipation of post-U.S. launch and EU demand.

FDA inspection of these facilities is scheduled. In December 2016, GW hosted a GMP inspection from the UK's regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA). This inspection resulted in no critical or major findings.

### **Epidiolex Commercialization**

#### **U.S. Operation Status**

In the U.S., GW operates via its subsidiary, Greenwich Biosciences. The U.S. organization's leadership team is now in place with the recent appointment of a Head of Sales. In preparation of an expected 2018 Epidiolex approval and launch, the Company continues to build out an experienced leadership team of medical affairs professionals, marketing and market access/payor expertise, many of whom have strong epilepsy knowledge and experience.

The key near-term objectives for the U.S. commercial team include:

#### **Continued visibility at major U.S. medical congresses**

We expect to continue dissemination of important scientific data from the Epidiolex clinical program and anticipate data presentations at important upcoming medical congresses, all of which will reinforce awareness of Greenwich Biosciences within the physician community. Specific to the AES Annual Meeting held in December 2017, an array of new data was presented from the placebo-controlled trials, the long-term open-label extension study, and from physicians involved in the Expanded Access Program. Data presented by the Company included pooled RCT analyses, health economic data in Dravet syndrome and LGS, mechanism of action, and additional PK drug interaction data.

#### **Continued Medical Affairs and Medical Science Liaison team build-out**

The U.S. Medical Affairs team, which in addition to a very experienced in-house team has expanded its field-based operation to include 15 experienced Medical Science Liaison specialists with extensive epilepsy or other neurology experience, has enabled the Company to open scientific and consultative communications with key stakeholders, such as the physician and patient communities in the U.S. This team is developing Dravet/LGS disease state information, rolling out programs in cannabinoid education, and intensifying interaction with key epilepsy opinion leaders to collect their insights related to the science emerging from the Epidiolex program.

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**Increased payor initiatives**

As the Company moves closer to approval of Epidiolex, a major focus is on payor education and readiness, and the Company has had a number of individual one on one and advisory board interactions with a wide variety of payors and insurance programs, including most of the larger commercial and state/federal payors to gather insights in anticipation of commercial launch.

**Health Economic Outcomes Research and Compendia data initiatives**

Greenwich has employed an experienced team of professionals focused on the development of a comprehensive pharmaco-economic dossier, including burden of illness and economic cost offset data in addition to clinical data for compendia support to assist and inform payor and formulary access and reimbursement decision making.

**Patient advocacy initiatives**

The Company continues to focus on support for, and outreach to, the major epilepsy patient advocacy groups. These initiatives include awareness building, advocacy and education. These interactions continue to give the Company important insights into how to help families along their journey, and most importantly, provides a potent reminder of just how much unmet need there is in these communities.

**Implementation of a dedicated sales force**

As Greenwich approaches the expected U.S. Epidiolex approval decision, the Company anticipates hiring approximately 60 to 70 sales professionals in the U.S. to target approximately 4,000 to 5,000 physicians who may treat patients with LGS or Dravet syndrome.

**Progress in Europe**

Outside the United States, GW continues to make good organizational progress for the commercialization of Epidiolex in Europe and the rate of this progress is accelerating following the December submission of the MAA. This European commercial effort is being led by Chief Operating Officer Chris Tovey, who has significant experience commercializing and launching pharmaceutical products, including within the field of epilepsy. GW continues to hire high quality and relevant staff in the areas of medical affairs, market access and marketing, all with strong epilepsy or specialist disease experience. Significant progress has been made in hiring country leadership and local medical staff in the five major European markets and these staff have all now been trained and are engaged in local activities supporting market access, medical affairs and commercial plans.

Significant progress is also being made in consolidating the profile of GW in the epilepsy field as the key Epidiolex data is communicated through international and national medical congresses as well as through prestigious international medical journals such as *The New England Journal Of Medicine* and *The Lancet*. Significant focus is now being placed on the specific activities associated with securing acceptable and prompt pricing and reimbursement post MAA approval.

**2017 American Epilepsy Society Annual Meeting Data**

In December 2017, over 25 abstracts related to the Epidiolex clinical program were presented at the 71<sup>st</sup> Annual Meeting of the American Epilepsy Society, or AES. These poster presentations included new data from the Epidiolex pivotal program, data on long-term Epidiolex data from the expanded access program, drug-drug interactions and burden of illness data. The GW-authored posters are available in a 6-K filing dated 4 December, 2017.

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

In parallel with GW's formal clinical trial program, the FDA has authorized access to Epidiolex to approximately 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 six 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 4 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. Multiple IND sponsors have published open-label data from their programs, including the posters presented at the AES Annual Meeting described above.

## **Epidiolex Intellectual Property**

In addition to orphan exclusivity, GW seeks 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 fourteen distinct patent families which are either granted or filed. Most of the patent families in this portfolio claim the use of CBD in the treatment of particular childhood epilepsy syndromes, seizure sub-types and interactions with other concomitantly dosed anti-seizure drugs. To date, this has resulted in 3 patents granted by the United States Patent and Trademark Office (USPTO) and numerous patent applications being prosecuted at the USPTO under the Track One Prioritized Patent Examination Program with expected decisions beginning in the second quarter of 2018. Should the NDA for Epidiolex be approved, GW expects a number of its granted patents to be listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book).

## **Epidiolex Formulation Development**

In addition to the initial launch formulation, GW continues to develop additional formulations of CBD as part of its life cycle management plan. As well as developing improved liquid formulations, the Company is developing a solid dose form to provide more convenient administration, particularly for adults and older children across our target indications, while sufficient range of dose sizes will maintain the current flexibility for titrating and amending the total daily dose. An intravenous formulation is also under development which is intended to provide short-term replacement or emergency therapy for patients unable to take the oral solution while hospitalized.

## **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. In pre-clinical studies, 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 differing physico-chemical characteristics.

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GW has completed enrolment of 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 enrolled 32 patients and the dose-ranging pharmacokinetic and safety data was reviewed by an independent panel. GW has closed recruitment for the placebo-controlled safety and efficacy phase of the study with 162 patients randomized. Data from this part of the trial is expected in the first quarter of 2018.

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 functioning 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 childhood-onset 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 on various clinical initiatives for CBDV within the field of ASD and has received Orphan Drug Designation from the FDA in the treatment of Rett syndrome.

A physician-led expanded access IND to treat seizures associated with autism has been granted by FDA in 10 patients and a number of patients have commenced treatment. In addition, an investigator led 100 patient placebo controlled trial in ASD is due to commence in the second quarter of 2018.

In Rett Syndrome, an open label study is due to commence in the second quarter of 2018 and a Phase 2 placebo-controlled trial is expected to commence in the third quarter of 2018. GW has incorporated scientific input from both the FDA and EMA on the study design.

In October 2017, a number of abstracts were presented at a symposium on the endocannabinoid system and the autism spectrum disorders, hosted by the Italian Society of Pharmacology. These abstracts included science that was developed in concert with numerous academic partners and highlighted a range of *in vitro* and *in vivo* ASD models including Rett syndrome-like phenotype rodent models and models related to cognitive and social impairment.

#### **Sativex<sup>®</sup> (nabiximols) for MS Spasticity**

Sativex is an oromucosal spray of a formulated extract that contains the principal cannabinoids CBD and THC in a 1:1 ratio (as well as specific minor cannabinoids and other non-cannabinoids). At this time, GW has received regulatory approval for, and is marketing Sativex through partners in a number of countries outside the United States.

In December 2017, GW reacquired full ownership from a former licensing partner of the U.S. development and commercialization rights to Sativex, which enables GW to develop, seek approval for, and commercialize Sativex in the United States. GW is now evaluating the optimal route to submit an NDA in the MS spasticity indication, which the Company believes may require the conduct of an additional single pivotal trial. During 2018, GW plans on consulting with the FDA regarding this development plan.

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### **2017 ECTRIMS data**

In 2017, new Sativex data was presented at the ECTRIMS Congress in Paris, France. These data, from a trial of Sativex as add-on therapy vs. further optimized first-line ANTispastics (SAVANT) was a prospective, parallel group, randomized, double-blind, placebo-controlled two-phase trial conducted in Europe. The characteristics of the patient population were comparable to those in previous clinical trials and observational studies of Sativex in resistant MS spasticity.

In this trial, initial responders to Sativex were identified by a Minimal Clinically Important Difference (MCID) change in their spasticity score, defined as  $\geq 20$  percent improvement from baseline in the MS spasticity 0-10 numerical rating scale (NRS) score. Non-early responders were removed from the study. After 12 weeks of randomized treatment in early responders, the Clinically Important Difference (CID) responder rate was significantly higher in favor of Sativex over placebo (77.4 vs 32.1 percent;  $p < 0.0001$ ), demonstrating a broad therapeutic gain despite allowing for dosage adjustments of concomitant antispasticity medication. Overall, Sativex CID responders represented 43 percent of patients exposed to Sativex at the start of the trial period. This is similar to the 36 percent figure reported in a large placebo-controlled trial which did not have a wash-out period and did not allow adjustment of other antispasticity medication dosages.

Compared with placebo, Sativex also demonstrated significance in key secondary endpoints: mean spasticity NRS (-3.5 vs -1.6;  $p < 0.0001$ ); mean pain NRS (-3.2 vs -1.8;  $p = 0.0013$ ); and mean modified Ashworth's scale (-0.30 vs -0.06;  $p = 0.0007$ ). In all, 22.6 percent and 13.2 percent of patients treated with Sativex or placebo, respectively, reported TEAEs, which were mainly mild to moderate. There were no new safety concerns. Sativex as add-on therapy was shown to improve resistant MS spasticity providing clinically relevant changes. It was demonstrated to be a better alternative than readjusting first-line antispasticity medications and it was not associated with any relevant safety concerns.

### **Oncology**

Beginning in 2007, GW has conducted substantial pre-clinical oncologic research on several cannabinoids in models of various forms of cancer including brain, lung, breast, pancreatic, melanoma, ovarian, gastric, renal, prostate and bladder.

In February 2017, GW completed a placebo-controlled Phase 2 study of a combination of CBD and THC in recurrent glioblastoma multiforme, or GBM, the most common and most aggressive brain cancer. This study evaluated a number of safety and exploratory efficacy endpoints and showed that patients with documented recurrent glioblastoma treated with CBD:THC 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 CBD:THC group was greater than 550 days compared with 369 days in the placebo group. Further follow-up demonstrates continued increased survival in the CBD:THC arm. In this study, CBD:THC was generally well tolerated. The results from this Phase 2 study were presented in a poster at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The Company has received Orphan Drug Designation from both FDA and EMA for its product for the treatment of glioblastoma.

GW believes that the signals of efficacy demonstrated in this study further reinforce the potential role of cannabinoids in the field of oncology.

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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 percent are expected to die in early life and 30 percent 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 completed a Phase 1 trial of GWP42003 in healthy volunteers for an intravenous CBD formulation in the treatment of NHIE. GW plans to consult with FDA on the most appropriate design for an efficacy and safety study in neonates.

### **Schizophrenia**

GW's cannabinoids have shown notable anti-psychotic effects in 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 and Greenwich Biosciences**

*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, along with its U.S. subsidiary Greenwich Biosciences, is advancing an orphan drug program in the field of childhood-onset epilepsy with a focus on Epidiolex (cannabidiol), for which GW has submitted an NDA to the FDA and an MAA with the EMA for the adjunctive treatment of seizures associated with LGS and Dravet syndrome. The Company continues to evaluate Epidiolex in additional epilepsy conditions and currently has ongoing clinical trials in 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 numerous 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 glioblastoma, schizophrenia and epilepsy. For further information, please visit [www.gwpharm.com](http://www.gwpharm.com).*

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**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 and Epidiolex 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 the Company's regulatory processes, and the level of 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 4 December 2017. 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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## 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 2017, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the 3 months ended 31 December 2017 have been translated into U.S. dollars at the rate on 31 December 2017 of \$1.3482 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 the SEC on Form 20-F on 4 December 2017.

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.

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. 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 an above-the-line credit. 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 2017 and 31 December 2016:*

#### *Revenue*

Total revenue for the three months to 31 December 2017 was £5.7 million, compared to £2.1 million for the three months ended 31 December 2016.

License, collaboration and technical access fees increased by £2.4 million to £2.8 million for the three months ended 31 December 2017 compared to £0.4 million for the three months ended 31 December 2016. This increase is related to the mutually-agreed termination of the Group's Sativex research and collaboration agreement with Otsuka Pharmaceuticals during the current quarter. As a result of this agreement being terminated the rights to market Sativex in the United States have returned to the Group, and certain deferred revenue fees have been accelerated as all required obligations have now been completed.

Sativex sales totalled £1.7 million, an increase of £0.2 million compared to £1.5 million for the quarter ended 31 December 2016. In-market sales volumes sold by GW's commercial partners for the three months ended 31 December 2017 were 36% higher than the three months ended 31 December 2016. Sales volumes to partners increased by 23% over the same period due to increased shipments to a number of territories, with Italy being the greatest increase.

Revenue from research and development fees amounted to £1.3 million during the three months ended 31 December 2017. This represents an increase of £1.1 million compared to the £0.2 million recognised in the three months ended 31 December 2016. As with the licence collaboration and technical access fees above, this increase is due to the accelerated recognition of the remaining Otsuka Pharmaceuticals deferred revenue on termination of the agreement.

#### *Cost of sales*

Cost of sales for the three months ended 31 December 2017 of £0.9 million represents an increase of £0.2 million from the £0.7 million recorded in the three months ended 31 December 2016. This increase is in line with the increase in Sativex sales.

#### *Research and development expenditure*

Total research and development expenditure for the three months ended 31 December 2017 of £30.3 million increased by £5.4 million compared to the £24.9 million incurred in the three months ended 31 December 2016. The increase is due to:

- £2.3 million increase in research and development staff and employment-related expenses linked to increased global headcount associated with the Group's Epidiolex NDA and EMA filings, and ongoing pipeline and Epidiolex development programs
  - £1.9 million increase in costs of growing an increased volume of plant material for the Epidiolex program
  - £1.0 million increase in other property-related overheads and depreciation of R&D assets related to the epilepsy development program
  - £0.2 million increase in direct epilepsy and other GW-funded clinical program costs reflecting progress in ongoing trials including our Phase III clinical trial for the use of Epidiolex with Dravet Syndrome
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### *Sales, general and administrative expenses*

Sales, general and administrative expenses for the three months ended 31 December 2017 of £17.4 million increased by £10.7 million compared to the £6.7 million incurred in the three months ended 31 December 2016. This increase is related to:

- £5.0 million increase in staff costs driven by increased headcount as we continue to expand our commercialization capabilities in the U.S. and Europe
- £4.4 million increase in marketing, contractor and consultancy costs associated with commercial preparation, regulatory submission and marketing efforts
- £0.9 million increase in pre-launch commercialization costs in the U.S
- £0.4 million increase in respect of property and travel costs, primarily for the continued build out of U.S. based operations

### *Net foreign exchange gains and losses*

Net foreign exchange movements for the three months ended 31 December 2017 resulted in a loss of £2.6 million, a decrease of £14.4 million compared to the £11.8 million gain recorded for the three months ended 31 December 2016. In both periods the gain/loss 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 1.33577 at 30 September 2017 to 1.3428 at 31 December 2017. Dollar denominated cash deposits totalled \$528.4 million at 31 December 2017 and \$242.0 million at 30 September 2017.

### *Taxation*

The tax charge was £2.5 million for the three months ended 31 December 2017. This represents a decrease of £5.2 million compared to a £2.7 million benefit recorded in the three months ended 31 December 2016.

In the three months ended 31 December 2017 GW recorded a tax charge of £2.5 million in respect of taxable profits of the Group's U.S. subsidiary, Greenwich Biosciences, Inc. due primarily to the revaluation of certain deferred tax balances following the signing into law of the Tax Cuts and Jobs Act in December 2017 in the U.S.

GW is no longer entitled to a tax benefit claimable by GW Research Limited in respect of research and development expenditure incurred, following the Group exceeding the small and medium enterprise thresholds. £0.7 million of benefit associated with the large company research and development tax credit in the UK is recorded within Interest and Other Income for the three months 31 December 2017.

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.; 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.

## **Liquidity and Capital Resources**

### *Cash Flow*

Net cash outflow from operating activities for the three months ended 31 December 2017 of £39.5 million was £15.5 million higher than the £24.0 million outflow from operating activities for the three months ended 31 December 2016, principally reflecting the increase in scale up and development activities relating to Epidiolex.

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Capital expenditure for the three months ended 31 December 2017 of £6.9 million, consisting primarily of planned upgrades to our cannabinoid production facilities, was £5.3 million higher than the £1.6 million for the three months ended 31 December 2016, reflecting the commencement of a number of significant capital investment projects including the expansion of the Group's cannabinoid extraction facility.

Net cash inflow from financing activities increased by £223.4 million to a £222.4 million net inflow in the three months ended 31 December 2017 compared to a £1.0 million net outflow for the three months ended 31 December 2016 due to the completion of a successful equity funding round during the quarter.

As at 31 December 2017, GW had a closing cash position of £414.8 million compared to £241.2 million as at 30 September 2017.

#### *Property, plant and equipment*

Property, plant and equipment at 31 December 2017 increased by £2.4 million to £46.1 million from £43.7 million at 30 September 2017. During the current quarter, construction efforts commenced on the expansion of the Group's cannabinoid extraction facility. This long-term investment will expand the Group's material processing capabilities in order to support anticipated demand.

#### *Inventories*

Inventories at 31 December 2017 decreased by £0.2 million to £4.0 million from £4.2 million at 30 September 2017. Inventories consist of Sativex finished goods, consumable items and work in progress. During the three months ended 31 December 2017, the provision for inventories remained constant at £0.1 million.

#### *Trade receivables and other current assets*

Trade receivables and other current assets at 31 December 2017 increased by £2.3 million to £13.5 million from £11.2 million at 30 September 2017, due to an increase in prepayments for property, plant and equipment not yet delivered of £1.7 million and an increase in recoverable indirect taxes on Group expenditure of £0.6 million.

#### *Trade and other payables*

Current trade and other payables at 31 December 2017 increased by £0.9 million to £34.0 million from £33.1 million at 30 September 2017. This increase reflects an increase in trade payables and accruals as a result of the continued expansion of GW's commercial and manufacturing capability.

#### *Current tax liabilities*

Current tax liabilities at 31 December 2017 increased by £3.7 million to £4.5 million from £0.8 million at 30 September 2017. This increase includes a one-off increase following the signing into law of the Tax Cuts and Jobs Act in December 2017 in the U.S., and the revaluation of certain deferred tax balances.

#### *Deferred revenue*

Current deferred revenue at 31 December 2017 decreased by £1.4 million to £0.9 million from £2.3 million at 30 September 2017. This decrease reflects the acceleration of deferred income associated with the termination of the license agreement with Otsuka Pharmaceutical Co., Ltd.

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Non-current deferred revenue at 31 December 2017 decreased by £2.5 million to £1.8 million from £4.3 million at 30 September 2017. This decrease reflects the acceleration of £2.3 million of deferred income associated with the termination of the license agreement with Otsuka Pharmaceutical Co., Ltd., and the recognition of £0.2 million of deferred income associated with ongoing Sativex license agreements.

*Headcount*

Average headcount for the three months ended 31 December 2017 was 593 (31 December 2016: 500).

*Guidance*

There are no proposed changes to the 2018 guidance, as provided at the time of GW's 2017 year end results announcement on 4 December 2017.

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	Notes	Three months ended 31 December 2017 \$000's	Three months ended 31 December 2017 £000's	Three months ended 31 December 2016 £000's
<b>Revenue</b>	3	7,728	5,732	2,056
Cost of sales		(1,190)	(883)	(715)
Research and development expenditure		(40,818)	(30,276)	(24,914)
Sales, general and administrative expenses		(23,445)	(17,390)	(6,684)
Net foreign exchange (loss)/gain		(3,442)	(2,553)	11,815
<b>Operating loss</b>		(61,167)	(45,370)	(18,442)
Interest expense		(320)	(237)	(90)
Interest and other income		1,621	1,202	273
<b>Loss before tax</b>		(59,866)	(44,405)	(18,259)
Tax (expense)/benefit	4	(3,433)	(2,546)	2,663
<b>Loss for the period</b>		(63,299)	(46,951)	(15,596)
<b>Loss per share – basic and diluted</b>		(20.3c)	(15.0p)	(5.2p)
<b>Loss per ADS – basic and diluted<sup>(1)</sup></b>		(243.6c)	(180.0p)	(62.4p)
<b>Weighted average ordinary shares outstanding (in millions) – basic and diluted</b>			312.1	302.7

All activities relate to continuing operations.

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

Condensed consolidated statement of comprehensive loss  
Three months ended 31 December 2017 and 2016

	Three months ended 31 December 2017 £000's	Three months ended 31 December 2016 £000's
<b>Loss for the period</b>	(46,951)	(15,596)
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange (loss)/gain on retranslation of foreign operations	(187)	418
<b>Other comprehensive (loss)/gain for the period</b>	(187)	418
<b>Total comprehensive loss for the period</b>	(47,138)	(15,178)

	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 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>

<b>Balance at 1 October 2017</b>	304	556,570	18,822	(297,521)	278,175
Issue of share capital	33	223,037	-	-	223,070
Expenses of new equity issue	-	(903)	-	-	(903)
Share-based payment transactions	-	-	-	4,127	4,127
Loss for the period	-	-	-	(46,951)	(46,951)
Deferred tax attributable to unrealized share option gains	-	-	-	469	469
Other comprehensive expense	-	-	(187)	-	(187)
<b>Balance at 31 December 2017</b>	<b>337</b>	<b>778,704</b>	<b>18,635</b>	<b>(339,876)</b>	<b>457,800</b>

	Notes	As at 31 December 2017 \$000's	As at 31 December 2017 £000's	As at 30 September 2017 £000's
<b>Non-current assets</b>				
Intangible assets - goodwill		7,024	5,210	5,210
Other intangible assets		2,258	1,675	1,049
Property, plant and equipment		62,117	46,074	43,666
Deferred tax asset		10,508	7,794	6,282
		<u>81,907</u>	<u>60,753</u>	<u>56,207</u>
<b>Current assets</b>				
Inventories		5,344	3,964	4,244
Taxation recoverable		27,838	20,648	20,072
Trade receivables and other current assets		18,222	13,516	11,217
Cash and cash equivalents		559,227	414,795	241,175
		<u>610,631</u>	<u>452,923</u>	<u>276,708</u>
<b>Total assets</b>		<u>692,538</u>	<u>513,676</u>	<u>332,915</u>
<b>Current liabilities</b>				
Trade and other payables	5	(45,895)	(34,042)	(33,119)
Current tax liabilities		(6,017)	(4,463)	(838)
Obligations under finance leases		(280)	(208)	(205)
Deferred revenue		(1,195)	(886)	(2,307)
		<u>(53,387)</u>	<u>(39,599)</u>	<u>(36,469)</u>
<b>Non-current liabilities</b>				
Trade and other payables	5	(13,199)	(9,790)	(9,256)
Obligations under finance leases		(6,341)	(4,703)	(4,755)
Deferred revenue		(2,405)	(1,784)	(4,260)
<b>Total liabilities</b>		<u>(75,332)</u>	<u>(55,876)</u>	<u>(54,740)</u>
<b>Net assets</b>		<u>617,206</u>	<u>457,800</u>	<u>278,175</u>
<b>Equity</b>				
Share capital		454	337	304
Share premium		1,049,849	778,704	556,570
Other reserves		25,124	18,635	18,822
Accumulated deficit		(458,221)	(339,876)	(297,521)
<b>Total equity</b>		<u>617,206</u>	<u>457,800</u>	<u>278,175</u>



	Three months ended 31 December 2017 \$000's	Three months ended 31 December 2017 £000's	Three months ended 31 December 2016 £000's
<b>Loss for the period</b>	(63,299)	(46,951)	(15,596)
Adjustments for:			
Interest expense	320	237	90
Interest and other income	(1,621)	(1,202)	(273)
Tax expense/(benefit)	3,433	2,546	(2,663)
Depreciation of property, plant and equipment	2,069	1,535	1,059
Impairment of property, plant and equipment	-	-	95
Amortization of intangible assets	127	94	18
Net foreign exchange losses/(gains)	3,442	2,553	(11,815)
Increase in provision for inventories	36	27	28
Decrease in deferred signature fees	(3,716)	(2,756)	(429)
Share-based payment charge	5,564	4,127	2,166
Loss on disposal of property, plant and equipment	5	4	557
	(53,640)	(39,786)	(26,763)
Decrease/(increase) in inventories	341	253	(416)
Increase in trade receivables and other current assets	(465)	(345)	(1,974)
Increase in trade and other payables and deferred revenue	219	162	5,613
Income taxes paid	-	-	(450)
Research and development tax credits received	232	172	-
<b>Net cash outflow from operating activities</b>	(53,313)	(39,544)	(23,990)
<b>Investing activities</b>			
Interest received	684	507	138
Purchases of property, plant and equipment	(8,785)	(6,516)	(1,376)
Purchases of intangible assets	(562)	(417)	(220)
<b>Net cash outflow from investing activities</b>	(8,663)	(6,426)	(1,458)
<b>Financing activities</b>			
Proceeds on exercise of share options	-	-	90
Proceeds of new equity issue	300,743	223,070	-
Expenses of new equity issue	(425)	(315)	(134)
Interest paid	(320)	(237)	(247)
Repayments of fit out funding	(127)	(94)	(564)
Repayments of obligations under finance leases	(67)	(50)	(95)
<b>Net cash inflow/(outflow) from financing activities</b>	299,804	222,374	(950)
Effect of foreign exchange rate changes on cash and cash equivalents	(3,753)	(2,784)	12,253
<b>Net increase/(decrease) in cash and cash equivalents</b>	234,075	173,620	(14,145)
Cash and cash equivalents at beginning of the period	325,152	241,175	374,392
<b>Cash and cash equivalents at end of the period</b>	559,227	414,795	360,247

## **1. Significant accounting policies**

### **Basis of preparation**

These unaudited condensed consolidated interim financial statements as at 31 December 2017 and for the three month periods ended 31 December 2017 and 31 December 2016 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 5 February 2018.

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 2017 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 2017 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 Income Statement, the Condensed Consolidated Balance Sheet as at 31 December 2017, and the Condensed Consolidated Cash Flow Statement for the three months ended 31 December 2017 have been translated into U.S. dollars at the rate on 31 December 2017 of \$1.3482 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 2017 the Group had cash and cash equivalents of £414.8 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

In accordance with IFRS 8 – “Operating Segments”, the chief operating decision maker (CODM), who is responsible for allocating resources and assessing performance of the Group, has been identified as a sub-group of the Executive Leadership Team (ELT), consisting of those members charged with executive management of the Group’s business activities.

During the current quarter, the Group’s research and collaboration agreement with Otsuka Pharmaceuticals was terminated by mutual agreement. As part of this process, the rights to develop and commercialise Sativex in the United States were returned to the Group. As a result of this, the recognition of certain advance payments and deferred signature fee income balances in the profit and loss account was accelerated on the basis that no further obligations remain to be fulfilled by the Group. The Group’s CODM considered that, following this termination, the nature of the Group’s operations have changed such that a review of operating segments was performed. The results of this identified that reporting a single operating segment has become appropriate, and reflects the Group’s strategy of discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. Accordingly, the information required under IFRS 8 “Operating Segments”, including the respective comparative information, has been presented for the single operating segment in Note 3 below.

The Group has licensing agreements for the commercialisation of Sativex® with Almirall S.A. in Europe (excluding the United Kingdom) and Mexico, Bayer HealthCare AG in the United Kingdom and Canada, Neopharm Group in Israel, Emerge Health Pty. Ltd. in Australasia and Malaysia and Ipsen Biopharm Ltd. in Latin America (excluding Mexico and the Islands of the Caribbean). Revenues include product sales, royalties, licence, collaboration and technical access fees, and development and approval milestone fees.

## 3. Revenue

Revenues arising from the Group’s activities during the period were as follows:

	<b>Three months ended 31 December 2017 £000’s</b>	Three months ended 31 December 2016 £000’s
Product sales	<b>1,675</b>	1,472
Research and development fees	<b>1,301</b>	154
License, collaboration and technical access fees	<b>2,756</b>	430
	<b><u>5,732</u></b>	<u>2,056</u>

Revenues from the Group’s major customers are included within revenue as follows:

	<b>Three months ended 31 December 2017 £000’s</b>	Three months ended 31 December 2016 £000’s
Customer A	<b>3,853</b>	224
Customer B	1,262	1,159
Customer C	461	397

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Geographical analysis of turnover by destination of customer:

	<b>Three months ended 31 December 2017 £000's</b>	Three months ended 31 December 2016 £000's
UK	413	317
Europe (excluding UK)	1,262	1,335
United States	3,693	92
Canada	189	180
Asia/Other	175	132
	<u>5,732</u>	<u>2,056</u>

#### 4. Tax expense/(benefit)

	<b>Three months ended 31 December 2017 £000's</b>	Three months ended 31 December 2016 £000's
Current period research and development tax credit	-	(2,394)
Deferred tax credit	(1,523)	(280)
Reclassification of amounts previously charged to equity	469	(255)
Current period tax charge	3,600	266
Total charge/(credit) for the period	<u>2,546</u>	<u>(2,663)</u>

In the three months ended 31 December 2017, the Group recognized the impact of The Tax Cuts and Jobs Act (the Act), which was signed into law on 22 December 2017, and thus substantively enacted at this date.

With effect from 1 October 2017, the Group is also no longer able to qualify tax credits in respect of the Small and medium sized enterprises (SME) R&D relief under the Finance Act 2000. The Group now qualifies for the Research and Development Expenditure Credit, available to large enterprises in the UK. An above-the-line credit of £0.7 million has been recorded within Interest and Other Income for the three months ended 31 December 2017.

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.

## 5. Trade and other payables

	31 December 2017 £000's	30 September 2017 £000's
<b>Amounts falling due within one year</b>		
Other creditors and accruals	23,427	19,335
Trade payables	4,707	5,807
Clinical trial accruals	4,557	5,520
Other taxation and social security	921	2,032
Fit out funding	396	389
Onerous lease provision	34	36
	<u>34,042</u>	<u>33,119</u>
<b>Amounts falling due after one year</b>		
Fit out funding	7,857	7,957
Other creditors and accruals	1,930	1,288
Onerous lease provision	3	11
	<u>9,790</u>	<u>9,256</u>

Fit out funding represents £8.3 million (30 September 2017: £8.3 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 £2.4 million (30 September 2017: £2.2 million), net of payments to date of £1.9 million (30 September 2017: £1.7 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.

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