

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 May, 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

Other Events

On May 9, 2017, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its second quarter financial results and operational progress for the quarter ended March 31, 2017 and details of a conference call to be held at 4:30 p.m. EST on May 9, 2017 to discuss the results and operational progress. The press release is attached as Exhibit 99.1 and is incorporated by reference herein. The information contained in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the 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 Earnings Press Release dated May 9, 2017

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: Company Secretary

Date: May 9, 2017



GW Pharmaceuticals plc Reports Fiscal Second Quarter 2017 Financial Results and Operational Progress

- Epidiolex[®] NDA submission expected mid-year–
 - New data in Lennox-Gastaut syndrome presented at the American Academy of Neurology -
 -Conference call today at 4:30 p.m. EST-

London, UK, 9 May 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 second quarter ended 31 March 2017.

“Our primary focus is on the submission of the Epidiolex NDA, which is expected in the middle of this year. Based on the efficacy and safety profile, we are confident in the prospects for an Epidiolex approval and continue to expand the commercial organization in preparation for a highly successful launch,” stated Justin Gover, GW’s Chief Executive Officer. “Beyond Epidiolex, we continue to advance a number of additional exciting clinical programs.”

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 submission for both Dravet and LGS indications expected mid-2017
 - Expected EU regulatory submission in H2 2017
 - Rare pediatric disease designation conditionally granted by FDA – pre-cursor to priority review voucher
 - Orphan Designation granted by European Medicines Agency (EMA) in the treatment of LGS
 - o Clinical:
 - New Phase 3 LGS data presented at the American Academy of Neurology (AAN) Annual Meeting in April 2017
 - 3 podium presentations at AAN
 - Phase 3 Dravet syndrome trial accepted for publication in high status journal with publication expected in Q2
 - Phase 3 trial in Tuberous Sclerosis Complex ongoing
 - Part A of two-part Phase 3 trial in Infantile Spasms underway
 - o Management Update:
 - Scott Giacobello appointed as Chief Financial Officer
 - Adam George appointed as Managing Director – UK
 - 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 Good Manufacturing Practice (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 1,500 patients now exposed to Epidiolex treatment
 - 97 percent of patients who complete Phase 3 trials have entered long term extension
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- o Commercial:
 - U.S. commercial team build well underway and pre-launch preparations advancing well
 - EU commercial team now being established
- o Intellectual Property
 - 13 distinct patent families in prosecution relating to the use of CBD in the treatment of epilepsy; decisions expected for several patents towards end 2017 and H1 2018
- Other cannabinoid pipeline product candidates:
 - o CBDV Phase 2 partial-onset epilepsy study in adults fully enrolled. Data expected Q4 2017
 - o CBDV in field of autism spectrum disorders
 - Expanded access IND granted by FDA for 10 patients with autism
 - Open label study in Rett syndrome to commence Q4 2017 and Phase 2 placebo-controlled trial in planning for Q1 2018.
 - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
 - o Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
 - Phase 1 trial complete. Phase 2 protocol discussions with FDA in H2 2017
 - Orphan Drug and Fast Track Designations granted from FDA and EMA
 - o THC:CBD for Glioma
 - Positive Phase 2 placebo-controlled data in Recurrent Glioblastoma Multiforme (GBM)
 - Abstract accepted at ASCO
 - Orphan Drug Designation from FDA and EMA

FINANCIAL HIGHLIGHTS

- Cash and cash equivalents at 31 March 2017 of £306.3 million (\$383.9 million) compared to £374.4 million as at 30 September 2016
- Revenue for the six months ended 31 March 2017 of £3.7 million (\$4.6 million) compared to £6.3 million for the six months ended 31 March 2016
- Loss for the six months ended 31 March 2017 of £50.0 million (\$62.6 million) compared to £34.5 million for the six months ended 31 March 2016

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 31 March 2017 of \$1.25331 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 second quarter 2017 financial results today at 4:30 pm EST. To participate in the conference call, please dial 800-860-2442 (toll free from the U.S. and Canada) or 412-858-4600 (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 # 13661781.



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

Financial and Operational Results for the Second Quarter Ended 31 March 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[®], 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 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 for the treatment of 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 the treatment of Dravet syndrome and LGS.

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. In February 2017, GW 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, for which a Phase 1 study has been completed.

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

Management Changes

In March 2017, GW announced the appointment of Scott Giacobello as Chief Financial Officer, based at the Company’s U.S. headquarters in Carlsbad, California. Related to this appointment, Adam George, GW’s Chief Financial Officer since 2012, became Managing Director - UK, a newly-created executive role with broad leadership responsibilities for UK operations.

Scott Giacobello brings 25 years of finance and operational experience to GW. He is an accomplished executive who most recently and until its acquisition by Allergan, Inc. in late 2016, served as Chief Financial Officer for Chase Pharmaceuticals Corporation, a clinical stage biopharmaceutical company focused on the development and commercialization of improved treatments for neurodegenerative disorders.

As Managing Director - UK, Adam George will be instrumental in ensuring that GW's UK operations achieve our strategic and operating goals, which include pipeline development, manufacturing scale-up, and European commercialization. Mr. George will continue as Company Secretary and is providing Mr. Giacobello with full support through the CFO transition.

These important leadership appointments reflect GW's continuing evolution into a transatlantic commercial-stage biopharmaceutical company. In anticipation of Epidiolex approval and launch, and with GW now solely listed on Nasdaq, the Company expects to transition from being a Foreign Private Issuer reporting under IFRS to become a domestic registrant reporting under U.S. GAAP and in U.S. dollars in future years.

As previously disclosed in 2016, Dr. Stephen Wright has retired from his position as Chief Medical Officer (CMO) effective May 1. Dr. Wright will continue to support GW in a new, part-time role as Senior Medical Advisor with dedicated focus on completing the Epidiolex NDA to the FDA and the European Marketing Authorization Application to the EMA. The Company's expectation is that Dr. Wright will continue to support these regulatory activities until at least Epidiolex receives approval from the FDA. As part of the same announcement last year, GW also announced that the Company had commenced a search to find a new CMO, which it has now identified. GW expects its new CMO to formally start within the next few weeks and the Company will provide a formal announcement with more details at that time.

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.

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 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 in the Investor section. Additionally, this trial has recently been accepted for publication in a high-status journal, which is expected in the second quarter 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 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, and additional data from the two dose arms was presented at the American Academy of Neurology Annual Meeting in April 2017, both showing additional safety and efficacy data associated with these studies. These data are available on the GW Pharmaceuticals corporate website in the Investor section. Additionally, GW is working with the investigators in these studies on manuscripts for peer-review publication, the first of which is expected in 2017.

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

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. There are two principal final elements on which we are focusing. The first is the integrated safety analysis, a significant body of data on 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. The second is manufacturing data from our expanded scale production. Both of these final areas of focus are progressing well and will determine the exact timing of the submission. 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.

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 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 and is preparing for an FDA GMP inspection anticipated in the second half of 2017.

In Europe, GW has held initial country-level regulatory consultations and expects to hold a formal pre-submission meeting with the EMA in the near future 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. Data is expected from this trial in 2018.

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, 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 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 and support organization. GW will commercialize Epidiolex, and any other products in the United States, under the name Greenwich Biosciences, Inc. (Greenwich). Julian Gangolli, President, North America, is leading the commercial organization in the United States, which is based in Carlsbad, California. In 2016, the U.S. organization grew to include an experienced leadership team of medical affairs professionals, clinical trial management specialists and commercial staff, many of whom have strong epilepsy knowledge and experience. In 2017, Greenwich is continuing to expand its commercial organization in preparation of an expected 2018 Epidiolex approval and launch. The key near-term objectives for the U.S. commercial team include:

Increased visibility at major U.S. medical congresses

Working with clinicians, the Company expects to continue dissemination of important scientific data from the Epidiolex clinical program and anticipates data presentations at important upcoming medical congresses such as AES, AAN, and CNS, which will reinforce awareness of Greenwich Biosciences within the physician community.

Continued Medical Affairs and Medical Science Liaison team build-out

The U.S. Medical Affairs team has enabled the Company to open scientific and consultative communications with key stakeholders, such as the patient and physician communities in the U.S. In 2017, this team will continue to develop Dravet/LGS disease state information, roll-out programs in cannabinoid education, and intensify interaction with key epilepsy opinion leaders to collect their insights related to the science emerging from the Epidiolex program. The Company currently has 7 Medical and Scientific Liaisons in place, and is expecting this number to increase to 15 by the end of 2017.

Increased payor initiatives

As the Company moves closer to approval of Epidiolex, a major focus is on payor education and readiness. These initiatives are assisted by new FDA guidance on appropriate interactions with payors prior to NDA submission/approval which allows for detailed discussion around the data and potential pricing and contracting strategies ahead of product launch.

Health Economic Outcomes Research and Compendia data initiatives

The Company now has an experienced team of professionals focused on the development of various pharmaco-economic data to assist payor and formulary rationale, including burden of illness/cost offset data and use of the Expanded Access Program clinical data as compendia support to demonstrate the “real-life” usage.

Patient advocacy initiatives

Greenwich will continue to focus on support for, and outreach to, the major epilepsy patient advocacy groups. These initiatives include relationship building, education, and identification of patient and caregiver advocates for a potential FDA Advisory Committee meeting.

Implementation of a dedicated sales force

As Greenwich approaches the expected Epidiolex approval, the Company anticipates hiring approximately 50 to 60 sales professionals to target 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.

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, market access and marketing disciplines to begin laying the groundwork for a more comprehensive commercial 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 May 2017, approximately 600 patients were receiving treatment under expanded access INDs at 36 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 thirteen distinct patent families which are either granted or filed. The latest expiry date of these families is February 2037. Most of the patent families in this portfolio claim the use of CBD in the treatment of particular childhood epilepsy syndromes or seizure sub-types. These medical use and method of treatment type patent families are supported by additional patent families claiming CBD formulations. 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. Our current expectation is that a number of these pending patent applications may be granted by USPTO towards the end of 2017 and the first half of 2018. GW also anticipates filing additional patent applications in 2017, claiming the use of Epidiolex, as new data is generated. 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.

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 closed recruitment for the placebo-controlled safety and efficacy phase of the study with approximately 150 patients expected to be randomized. Data from this part of the trial is expected in the fourth quarter of 2017.

GW has also evaluated CBDV in both general and syndromic pre-clinical models of 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 on various clinical initiatives for CBD within the field of ASD. A physician-led expanded access IND has been granted by FDA to treat 10 patients with autism. For patients with Rett Syndrome, a condition in which treatment-resistant seizures are a common problem, CBDV has received Orphan drug Designation from the FDA. An open label study in Rett Syndrome is expected to commence in the second half of 2017 and a Phase 2 placebo-controlled trial in this condition is expected to commence in early 2018. GW has received scientific advice from the EMA on the study design, and advice is expected shortly from the FDA as well.

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 signaling 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.

Earlier this year, GW completed a placebo-controlled Phase 2 study 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, dizziness, nausea, headache, and constipation. The results of some biomarker analyses are still awaited. The abstract from the Phase 2 study has been accepted at American Society of Clinical Oncology (ASCO) Annual Meeting.

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 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 in the second half of 2017 on the most appropriate design for an efficacy and safety study in neonates.

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 (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[®], 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.

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 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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GW Pharmaceuticals plc

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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 March 2017, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and six months ended 31 March 2017 have been translated into U.S. dollars at the rate on 31 March 2017 of \$1.25331 to £1.00. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

Overview

GW generates revenue from Sativex product sales, license fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. The accounting policies that GW applies in recognizing these revenues are set out in detail in 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 statements. The current period tax charge relates to U.S. taxation on the taxable profit for the Group's U.S. subsidiary.

Results of Operations:

Comparison of the three months ended 31 March 2017 and 31 March 2016:

Revenue

Total revenue for the three months to 31 March 2017 was £1.6 million, compared to £2.6 million for the three months ended 31 March 2016.

The majority of revenue this quarter comprises sales of Sativex totaling £1.2 million; this represents an increase of £0.1 million compared to the quarter ended 31 March 2016. In-market sales volumes sold by GW's commercial partners for the three months ended 31 March 2017 were 20% higher than the three months ended 31 March 2016. Sales volumes to partners increased by 14% over the same period, due to increased shipments to Germany, offset in part by a decrease in sales price.

Revenue from research and development fees amounted to £0.1 million during the three months ended 31 March 2017. This represents a decrease of £1.2 million compared to the three months ended 31 March 2016, and 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 March 2017 compared to £0.3 million for the three months ended 31 March 2016, as a result of the mutual termination agreement with Novartis over rights for Sativex. 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 March 2017 of £0.7 million is £0.2 million higher than the £0.5 million recorded in the three months ended 31 March 2016 due to an increase in shipments of Sativex to commercial partners.

Research and development expenditure

Total research and development expenditure for the three months ended 31 March 2017 of £27.2 million increased by £1.5 million compared to the £25.7 million incurred in the three months ended 31 March 2016. This increase is primarily due to:

- £3.9 million increase in staff and employment-related expenses linked to increased global headcount combined with transition of the Group's clinical headcount from partner funded studies to the GW funded Epidiolex development program
- £2.2 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program; offset by
- £4.6 million decrease in epilepsy and other GW funded clinical program costs – reflecting the completion of two Lennox-Gastaut syndrome Epidiolex studies and one Dravet syndrome study

Sales, general and administrative expenses

Sales, general and administrative expenses for the three months ended 31 March 2017 of £9.3 million increased by £6.1 million compared to the £3.2 million incurred in the three months ended 31 March 2016. This increase is related to:

- £3.2 million increase in payroll costs driven by increased headcount within the Group's expanding commercial operations
 - £1.8 million increase in respect of pre-launch commercialization costs in the U.S.
-

- £0.7 million increase in the charge in respect of the provision for payroll taxes on unrealized staff share option gains
- £0.3 million increase in respect of property and travel costs, primarily to the U.S. by staff involved in the expansion of U.S. based operations
- £0.1 million increase in respect of increased accountancy and audit costs arising from the Group's expansion

Net foreign exchange gains / (losses)

Net foreign exchange loss for the three months ended 31 March 2017 was a loss of £4.0 million, a decrease of £8.5 million compared to the £4.5 million gain recorded for the three months ended 31 March 2016. In both periods the gain or loss recognized relates to the remeasurement of the Group's U.S. dollar denominated cash deposits to pounds sterling at the closing U.S. dollar to Sterling exchange rate at 31 March 2017. The Sterling to U.S. dollar exchange rate has moved from 1.23429 at 31 December 2016 to 1.25331 at 31 March 2017. Dollar denominated cash deposits totaled \$331.5 million at 31 March 2017 and \$343.8 million at 31 December 2016.

Taxation

Our tax credit was £5.0 million for the three months ended 31 March 2017, which represents a decrease of £0.4 million compared to a £5.4 million credit recorded in the three months ended 31 March 2016.

In the three months ended 31 March 2017, GW recorded a tax benefit of £5.0 million made up of: (i) the recognition of an accrued £4.8 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 March 2017; and (ii) the recording of £0.2 million of current tax benefit in respect of the Group's U.S subsidiary, Greenwich Biosciences, Inc.

In the three months ended 31 March 2016, GW recorded a tax credit of £5.4 million made up of (i) the recognition of an accrued £4.9 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 March 2016; (ii) the recognition of an additional £0.6 million research and development tax credit claimed by GW Research Limited in respect of research and development expenditure incurred in the year ended 30 September 2015; and (iii) the recording of £0.1 million of current tax expense in respect of taxable profits of the Group's U.S. subsidiary, Greenwich Biosciences, Inc.

Loss

The Group reported a loss after tax for the three months ended 31 March 2017 of £34.4 million compared with a loss after tax for the three months ended 31 March 2016 of £16.8 million.

Results of Operations:

Comparison of the six months ended 31 March 2017 and 31 March 2016:

Revenue

Total revenue for the six months ended 31 March 2017 was £3.7 million, compared to £6.3 million for the six months ended 31 March 2016.

The majority of revenue comprises sales of Sativex totaling £2.6 million; this represents an increase of £0.4 million compared to the six months ended 31 March 2016. In-market sales volumes sold by GW's commercial partners for the six months ended 31 March 2017 were 17% higher than the three months ended 31 March 2016. Sales volumes to partners increased by 11% over the same period, due primarily to increased shipments to Germany.

Revenue from research and development fees amounted to £0.2 million during the six months ended 31 March 2017. This represents a decrease of £3.3 million compared to the six months ended 31 March 2016, and 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 £0.2 million to £0.8 million for the six months ended 31 March 2017 compared to £0.6 million for the six months ended 31 March 2016, as a result of the mutual termination agreement with Novartis over rights for Sativex.

Cost of sales

Cost of sales for the six months ended 31 March 2017 of £1.4 million is £0.2 million higher than the £1.2 million recorded in the six months ended 31 March 2016 due to an increase in shipments of Sativex to commercial partners.

Research and development expenditure

Total research and development expenditure for the six months ended 31 March 2017 of £52.1 million increased by £2.2 million compared to the £49.9 million incurred in the six months ended 31 March 2016. This increase is due to:

- £8.8 million increase in staff and employment-related expenses linked to increased global headcount combined with the transition of the Group's clinical headcount from partner funded studies to the GW funded Epidiolex development program
- £2.6 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program
- £1.9 million increase in other overheads associated with conducting clinical trials such as depreciation of R&D assets, consumables and other property-related overheads. This increase has been impacted by the Group's refocus of assets on GW funded activities from partner funded Sativex trials
- £7.8 million decrease in epilepsy and other GW funded clinical program costs – reflecting the completion of two Lennox-Gastaut syndrome Epidiolex studies and one Dravet syndrome study
- £3.3 million decrease in partner-funded research and development expenditure to £0.2 million for the six months ended 31 March 2017 from £3.5 million for the six months ended 31 March 2016. This decrease reflects the conclusion and close out of the Sativex Phase 3 cancer pain clinical trials compared to the previous period

Sales, general and administrative expenses

Sales, general and administrative expenses for the six months ended 31 March 2017 of £16.0 million increased by £9.1 million compared to the £6.9 million incurred in the six months ended 31 March 2016. This increase reflects:

- A £5.1 million increase in payroll costs driven by increased headcount within the Group's expanding commercial operations
 - A £2.4 million increase in respect of pre-launch commercialization costs in the U.S.
 - A £1.1 million increase in respect of property and travel costs, primarily to the U.S. by staff involved in the expansion of U.S. based operations
 - A £0.4 million increase in the charge in respect of the provision for payroll taxes on unrealized staff share option gains
 - A £0.1 million increase in respect of increased accountancy and audit costs arising from the Group's expansion
-

Net foreign exchange gains

Net foreign exchange gains for the six months ended 31 March 2017 was a gain of £7.8 million, a decrease of £0.3 million compared to the £8.1 million gain recorded for the six months ended 31 March 2016. In both periods the gain recognized relates to the remeasurement of the Group's U.S. dollar denominated cash deposits to pounds sterling at the closing U.S. dollar to Sterling exchange rate at 31 March. The Sterling to U.S. dollar exchange rate has moved from 1.29128 at 30 September 2016 to 1.25331 at 31 March 2017. Dollar denominated cash deposits totaled \$331.5 million at 31 March 2017 and \$345.5 million at 30 September 2016.

Taxation

The tax benefit was £7.6 million for the six months ended 31 March 2017, which represents a decrease of £1.3 million compared to a £8.9 million benefit recorded in the six months ended 31 March 2016.

In the six months ended 31 March 2017, GW recorded a tax benefit of £7.6 million made up of: (i) the recognition of an accrued £7.2 million research and development tax credit to be claimable by GW Research Limited in respect of the research and development expenditure incurred in the six months ended 31 March 2017; (ii) the recording of £0.2 million of tax benefit in respect of an additional deferred tax asset recognized on timing differences for Greenwich Biosciences, Inc. (formerly GW Pharmaceuticals Inc.); and (iii) the recording of an additional £0.2 million of tax benefit in respect of the year ended 30 September 2016.

In the six months ended 31 March 2016, GW recorded a tax benefit of £8.9 million made up of: (i) the recognition of an accrued £8.6 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 six months ended 31 March 2016; (ii) the recognition of an additional £0.6 million of research and development tax credits in respect of the year ended 30 September 2015 in its principal research subsidiary, GW Research Limited, as part of the process for finalizing tax returns for that period and; (iii) recording of £0.3 million of current tax expense in respect of taxable profits of the Group's U.S. subsidiary, Greenwich Biosciences, Inc.

Loss

The Group reported a loss after tax for the six months ended 31 March 2017 of £50.0 million compared with a loss after tax for the six months ended 31 March 2016 of £34.5 million.

Liquidity and Capital Resources

Cash Flow

Net cash outflow from operating activities for the six months ended 31 March 2017 of £66.0 million was £19.6 million higher than the £46.4 million outflow from operating activities for the six months ended 31 March 2016, principally reflecting the increase in investment in the Epidiolex scale up and development activities.

Capital expenditure for the six months ended 31 March 2017 of £9.4 million, consisting primarily of planned upgrades to our cannabinoid growing facilities, was £4.6 million higher than the £4.8 million for the six months ended 31 March 2016, reflecting completion of a number of significant capital projects for commercialization.

Net cash outflow from financing activities increased by £1.7 million to a £1.2 million net outflow in the six months ended 31 March 2017 compared to a £0.5 million inflow for the six months ended 31 March 2016 due to the commencement of repayments on finance leases and the fit-out funding, and a decrease in proceeds on the exercise of employee share options.

As at 31 March 2017, GW had a closing cash position of £306.3 million compared to £374.4 million as at 30 September 2016.

Property, plant and equipment

Property, plant and equipment at 31 March 2017 increased by £1.7 million to £40.6 million from £38.9 million at 30 September 2016.

During the three months to 31 March 2017, the Group's flagship cannabinoid extraction facility was validated as meeting the required quality standards for commercial manufacture of Epidiolex. As a result of this, assets with a total cost of £21 million were reclassified out of Assets Under Construction and depreciation commenced over a range of useful economic lives up to a maximum of 20 years.

Inventories

Inventories at 31 March 2017 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 six months ended 31 March 2017, the provision for inventories remained constant.

Trade receivables and other assets

Trade receivables and other assets at 31 March 2017 increased by £2.6 million to £7.2 million from £4.6 million at 30 September 2016, primarily due to prepayments for property, plant and equipment not yet delivered totaling £1.9 million. In addition, there was a £0.4 million increase in recoverable indirect taxes on Group expenditure.

Trade and other payables

Current trade and other payables at 31 March 2017 decreased by £8.2 million to £23.0 million from £31.2 million at 30 September 2016. This reflects a decrease of £3.5 million in accruals for clinical trials, and a decrease in other creditors and accruals of £4.9 million, primarily arising from the settlement of the Group's outstanding fees associated with capital expenditure.

Headcount

Average headcount for the six months ended 31 March 2017 was 508 (six months ended 31 March 2016: 412).

Guidance

We expect total cash outflow for 2017 to be at the upper end of our previous guidance range of \$130 to \$150 million U.S. dollars. This guidance includes \$30 million dollars of capital expenditure and operating spend of \$100 to \$120 million U.S. dollars.

GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 31 March 2017

	Notes	Three months ended 31 March 2017 \$000's	Three months ended 31 March 2017 £000's	Three months ended 31 March 2016 £000's
Revenue	2	2,039	1,627	2,649
Cost of sales		(861)	(687)	(542)
Research and development expenditure		(34,036)	(27,157)	(25,749)
Sales, general and administrative expenses		(11,643)	(9,290)	(3,242)
Net foreign exchange (loss) / gain		(4,998)	(3,988)	4,488
Operating loss		(49,499)	(39,495)	(22,396)
Interest income		392	313	131
Interest expense		(192)	(153)	(16)
Loss before tax		(49,299)	(39,335)	(22,281)
Tax benefit	3	6,226	4,968	5,449
Loss for the period		<u>(43,073)</u>	<u>(34,367)</u>	<u>(16,832)</u>
Loss per share – basic and diluted		(14.2c)	(11.3p)	(6.4p)
Loss per ADS – basic and diluted ⁽¹⁾		(170.4c)	(135.6p)	(76.8p)
Weighted average ordinary shares outstanding (in millions) – basic and diluted			303.7	262.6

All activities relate to continuing operations.

⁽¹⁾ Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the three months ended 31 March 2017

	Three months ended 31 March 2017 £000's	Three months ended 31 March 2016 £000's
Loss for the period	<u>(34,367)</u>	<u>(16,832)</u>
Items that may be reclassified subsequently to profit or loss		
Exchange loss on retranslation of foreign operations	(177)	(46)
Other comprehensive loss for the period	(177)	(46)
Total comprehensive loss for the period	<u>(34,544)</u>	<u>(16,878)</u>

GW Pharmaceuticals plc
Condensed consolidated income statement
Six months ended 31 March 2017

	Notes	Six months ended 31 March 2017 \$000's	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Revenue	2	4,616	3,683	6,316
Cost of sales		(1,757)	(1,402)	(1,229)
Research and development expenditure		(65,261)	(52,071)	(49,888)
Sales, general and administrative expenses		(20,020)	(15,974)	(6,867)
Net foreign exchange gain		9,810	7,827	8,089
Operating loss		(72,612)	(57,937)	(43,579)
Interest income		734	586	194
Interest expense		(305)	(243)	(35)
Loss before tax		(72,183)	(57,594)	(43,420)
Tax benefit	3	9,564	7,631	8,886
Loss for the period		<u>(62,619)</u>	<u>(49,963)</u>	<u>(34,534)</u>
Loss per share – basic and diluted		(20.7c)	(16.5p)	(13.2p)
Loss per ADS – basic and diluted ⁽¹⁾		(248.4c)	(198.0p)	(158.4p)
Weighted average ordinary shares outstanding (in millions) – basic and diluted			303.2	262.0

All activities relate to continuing operations.

⁽¹⁾ Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the six months ended 31 March 2017

	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Loss for the period	<u>(49,963)</u>	<u>(34,534)</u>
Items that may be reclassified subsequently to profit or loss		
Exchange gain/(loss) on retranslation of foreign operations	241	(99)
Other comprehensive gain/(loss) for the period	241	(99)
Total comprehensive loss for the period	<u>(49,722)</u>	<u>(34,633)</u>

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Six months ended 31 March 2017

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total £000's
Balance at 1 October 2015	261	349,275	19,189	(123,455)	245,270
Exercise of share options	2	623	-	-	625
Share-based payment transactions	-	-	-	3,164	3,164
Loss for the period	-	-	-	(34,534)	(34,534)
Deferred tax attributable to unrealized share option gains	-	-	-	4	4
Other comprehensive loss	-	-	(99)	-	(99)
Balance at 31 March 2016	<u>263</u>	<u>349,898</u>	<u>19,090</u>	<u>(154,821)</u>	<u>214,430</u>
2016					
Balance at 1 October 2016	302	556,477	19,538	(177,827)	398,490
Exercise of share options	2	88	-	-	90
Share-based payment transactions	-	-	-	4,768	4,768
Loss for the period	-	-	-	(49,963)	(49,963)
Deferred tax attributable to unrealized share option gains	-	-	-	595	595
Other comprehensive income	-	-	241	-	241
Balance at 31 March 2017	<u>304</u>	<u>556,565</u>	<u>19,779</u>	<u>(222,427)</u>	<u>354,221</u>

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 31 March 2017

	Notes	As at 31 March 2017 \$000's	As at 31 March 2017 £000's	As at 30 September 2016 £000's
Non-current assets				
Intangible assets - goodwill		6,530	5,210	5,210
Other intangible assets		1,271	1,014	629
Property, plant and equipment		50,873	40,591	38,947
Deferred tax asset		6,340	5,059	3,873
		<u>65,014</u>	<u>51,874</u>	<u>48,659</u>
Current assets				
Inventories		5,819	4,643	4,248
Taxation recoverable		35,773	28,543	21,322
Trade receivables and other assets		9,069	7,236	4,556
Cash and cash equivalents		383,870	306,285	374,392
		<u>434,531</u>	<u>346,707</u>	<u>404,518</u>
Assets held for sale		1,139	909	-
Total assets		<u>500,684</u>	<u>399,490</u>	<u>453,177</u>
Current liabilities				
Trade and other payables	4	(28,841)	(23,013)	(31,170)
Current tax liabilities		(192)	(153)	(883)
Obligations under finance leases		(287)	(229)	(211)
Deferred revenue		(3,056)	(2,438)	(2,686)
		<u>(32,376)</u>	<u>(25,833)</u>	<u>(34,950)</u>
Non-current liabilities				
Trade and other payables	4	(12,245)	(9,770)	(9,423)
Obligations under finance leases		(6,089)	(4,858)	(4,959)
Deferred revenue		(6,026)	(4,808)	(5,355)
Total liabilities		<u>(56,736)</u>	<u>(45,269)</u>	<u>(54,687)</u>
Net assets		<u>443,948</u>	<u>354,221</u>	<u>398,490</u>
Equity				
Share capital		381	304	302
Share premium account		697,548	556,565	556,477
Other reserves		24,789	19,779	19,538
Accumulated deficit		(278,770)	(222,427)	(177,827)
Total equity		<u>443,948</u>	<u>354,221</u>	<u>398,490</u>

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the six months ended 31 March 2017

	Six months ended 31 March 2017 \$000's	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Loss for the period	(62,619)	(49,963)	(34,534)
Adjustments for:			
Interest income	(734)	(586)	(194)
Interest expense	305	243	35
Tax benefit	(9,564)	(7,631)	(8,886)
Depreciation of property, plant and equipment	2,895	2,310	1,540
Impairment of property, plant and equipment	119	95	-
Reversal of impairment of property, plant and equipment	(271)	(216)	-
Amortization of intangible assets	109	87	27
Net foreign exchange gains	(9,810)	(7,827)	(8,377)
Increase/(decrease) in provision for inventories	59	47	(45)
Decrease in deferred signature fees	(1,031)	(823)	(592)
Share-based payment charge	5,976	4,768	3,164
Loss on disposal of property, plant and equipment	707	564	-
	<u>(73,859)</u>	<u>(58,932)</u>	<u>(47,862)</u>
(Increase)/decrease in inventories	(554)	(442)	138
Increase in trade receivables and other assets	(2,089)	(1,667)	(498)
(Decrease)/increase in trade and other payables and deferred revenue	(5,148)	(4,108)	2,740
Income taxes paid	(1,038)	(828)	(894)
Net cash outflow from operating activities	<u>(82,688)</u>	<u>(65,977)</u>	<u>(46,376)</u>
Investing activities			
Interest received	548	437	186
Purchases of property, plant and equipment	(11,274)	(8,995)	(4,655)
Purchases of intangible assets	(536)	(428)	(149)
Net cash outflow from investing activities	<u>(11,262)</u>	<u>(8,986)</u>	<u>(4,618)</u>
Financing activities			
Proceeds on exercise of share options	113	90	625
Expenses of new equity issue	(168)	(134)	-
Interest paid	(579)	(462)	(35)
Repayments of fit out funding	(822)	(656)	-
Repayment of obligations under finance leases	(103)	(82)	(55)
Net cash (outflow)/inflow from financing activities	<u>(1,559)</u>	<u>(1,244)</u>	<u>535</u>
Effect of foreign exchange rate changes on cash and cash equivalents	10,150	8,100	8,271
Net decrease in cash and cash equivalents	<u>(85,359)</u>	<u>(68,107)</u>	<u>(42,188)</u>
Cash and cash equivalents at beginning of the period	469,229	374,392	234,872
Cash and cash equivalents at end of the period	<u>383,870</u>	<u>306,285</u>	<u>192,684</u>

1. Significant accounting policies

Basis of preparation

These unaudited condensed consolidated interim financial statements for the three and six month periods ended 31 March 2017 and 31 March 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 9 May 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 adopted early 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 March 2017, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and six months ended 31 March 2017 have been translated into U.S. dollars at the rate on 31 March 2017 of \$1.25331 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 March 2017 the Group had cash and cash equivalents of £306.3 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.

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.

2. Segmental Information (continued)

Segmental revenues and results

For the Three Months Ended 31 March 2017

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	1,165	-	-	1,165	-	1,165
Research and development fees	-	(57)	126	69	-	69
License, collaboration & technical access fees	393	-	-	393	-	393
Total revenue	1,558	(57)	126	1,627	-	1,627
Cost of sales	(687)	-	-	(687)	-	(687)
Research and development expenditure	-	48	(26,344)	(26,296)	(861)	(27,157)
Segmental result	871	(9)	(26,218)	(25,356)	(861)	(26,217)
Sales, general and administrative expenses						(9,290)
Net foreign exchange loss						(3,988)
Operating loss						(39,495)
Interest income						313
Interest expense						(153)
Loss before tax						(39,335)
Tax benefit						4,968
Loss for the period						(34,367)

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.

2. Segmental Information (continued)

Segmental revenues and results

For the Three Months Ended 31 March 2016

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	1,077	-	-	1,077	-	1,077
Research and development fees	-	1,181	88	1,269	-	1,269
License, collaboration & technical access fees	303	-	-	303	-	303
Total revenue	1,380	1,181	88	2,649	-	2,649
Cost of sales	(542)	-	-	(542)	-	(542)
Research and development expenditure	-	(1,499)	(23,663)	(25,162)	(587)	(25,749)
Segmental result	838	(318)	(23,575)	(23,055)	(587)	(23,642)
Sales, general and administrative expenses						(3,242)
Net foreign exchange gain						4,488
Operating loss						(22,396)
Interest income						131
Interest expense						(16)
Loss before tax						(22,281)
Tax benefit						5,449
Loss for the period						(16,832)

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.

2. Segmental Information (continued)

Segmental revenues and results

For the Six Months Ended 31 March 2017

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	2,637	-	-	2,637	-	2,637
Research and development fees	-	(35)	258	223	-	223
License, collaboration & technical access fees	823	-	-	823	-	823
Total revenue	3,460	(35)	258	3,683	-	3,683
Cost of sales	(1,402)	-	-	(1,402)	-	(1,402)
Research and development expenditure	-	2	(50,254)	(50,252)	(1,819)	(52,071)
Segmental result	2,058	(33)	(49,996)	(47,971)	(1,819)	(49,790)
Sales, general and administrative expenses						(15,974)
Net foreign exchange gain						7,827
Operating loss						(57,937)
Interest income						586
Interest expense						(243)
Loss before tax						(57,594)
Tax benefit						7,631
Loss for the period						(49,963)

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.

2. Segmental Information (continued)

Segmental revenues and results

For the Six Months Ended 31 March 2016

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	2,197	-	-	2,197	-	2,197
Research and development fees	-	3,341	185	3,526	-	3,526
License, collaboration & technical access fees	593	-	-	593	-	593
Total revenue	2,790	3,341	185	6,316	-	6,316
Cost of sales	(1,229)	-	-	(1,229)	-	(1,229)
Research and development expenditure	-	(4,061)	(44,831)	(48,892)	(996)	(49,888)
Segmental result	1,561	(720)	(44,646)	(43,805)	(996)	(44,801)
Sales, general and administrative expenses						(6,867)
Net foreign exchange gain						8,089
Operating loss						(43,579)
Interest income						194
Interest expense						(35)
Loss before tax						(43,420)
Tax benefit						8,886
Loss for the period						(34,534)

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.

2. Segmental Information (continued)

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

Three months ended 31 March 2017

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Customer A	863	-	-	863
Customer B	380	-	-	380

Three months ended 31 March 2016

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Customer A	843	-	-	843
Customer B	340	-	-	340
Customer C	70	1,181	88	1,339

Six months ended 31 March 2017

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Customer A	2,021	-	-	2,021
Customer B	776	-	-	776

Six months ended 31 March 2016

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Customer A	1,786	-	-	1,786
Customer B	654	-	-	654
Customer C	140	3,341	185	3,666

2. Segmental Information (continued)

Geographical analysis of revenue by destination of customer

	Three months ended 31 March 2017 £000's	Three months ended 31 March 2016 £000's	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
UK	506	240	822	466
Europe (excluding UK)	983	908	2,319	1,880
United States	12	1,250	104	3,481
Canada	-	163	180	304
Asia	126	88	258	185
	<u>1,627</u>	<u>2,649</u>	<u>3,683</u>	<u>6,316</u>

3. Tax benefit

	Three months ended 31 March 2017 £000's	Three months ended 31 March 2016 £000's	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Current period research and development tax credit	(4,827)	(4,946)	(7,221)	(8,586)
Adjustments in respect of prior year tax	(191)	(640)	(191)	(591)
Deferred tax credit	280	-	-	-
Reclassification of amounts previously reversed from equity	255	-	-	-
Current period tax (benefit)/charge	(485)	137	(219)	291
Total credit for the period	<u>(4,968)</u>	<u>(5,449)</u>	<u>(7,631)</u>	<u>(8,886)</u>

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

In the three and six months ended 31 March 2017 and 2016, the Group recognized the estimated benefit for qualifying research and development expenditures incurred during each period, 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 March	30 September
	2017	2016
	£000's	£000's
Amounts falling due within one year		
Other creditors and accruals	11,058	15,899
Clinical trial accruals	5,948	9,503
Trade payables	4,327	3,433
Other taxation and social security	1,210	1,490
Fit out funding	376	845
Onerous lease provision	94	-
	23,013	31,170
Amounts falling due after one year		
Other creditors and accruals	1,595	1,081
Fit out funding	8,155	8,342
Onerous lease provision	20	-
	9,770	9,423

Fit out funding represents £8.5 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 £1.9 million (30 September 2016: £1.6 million), net of payments to date of £1.2 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.