

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 August, 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 August 7, 2017, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its third quarter financial results and operational progress for the quarter ended June 30, 2017 and details of a conference call to be held at 4:30 p.m. EST on August 7, 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 August, 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/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer

Date: August 7, 2017



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

**- Epidiolex[®] NDA submission process underway –
- Conference call today at 4:30 p.m. EST -**

London, UK, Carlsbad, CA, 7 Aug 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 third quarter ended 30 June 2017.

“I am pleased to report the NDA submission process for Epidiolex is now underway with the final sections of the submission expected to be completed in October. With a clear view now towards our anticipated approval, we are making excellent progress with preparations to ensure a highly successful launch in 2018,” stated Justin Gover, GW’s Chief Executive Officer. “Following the recent publication of our first Phase 3 trial in the *New England Journal of Medicine*, we look forward to additional Epidiolex data publications and presentations in the second half of the year. In addition to Epidiolex, we continue to keep focus on our growing and innovative cannabinoid pipeline where we have advanced 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 progress:
 - NDA rolling submission for both Dravet and LGS indications underway. Pre-clinical module submitted; Clinical module submission in progress; CMC module submission expected in October
 - EMA pre-submission meetings held. Expected EU regulatory submission in Q4 2017
 - o Further clinical progress:
 - Phase 3 Dravet syndrome trial published in *The New England Journal of Medicine*
 - Quality of Life in Childhood Epilepsy published in *Epilepsia*
 - Phase 3 trial in Tuberous Sclerosis Complex ongoing
 - Part A of two-part Phase 3 trial in Infantile Spasms ongoing
 - Numerous abstracts submitted to American Epilepsy Society annual meeting
 - o Manufacturing scale-up on track to deliver significant projected commercial launch inventory:
 - Preparations on track for FDA GMP inspection anticipated in early 2018
 - 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
 - o Commercial progress:
 - U.S. pre-launch commercial leadership team in place
 - Full team of epilepsy specialist Medical and Scientific Liaisons (MSLs) in place with significant medical education initiatives underway and major presence at key target congresses
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- EU commercial team build-out underway and increasing presence at European congresses
 - o Strengthened Epidiolex exclusivity
 - 14 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
 - 6 patents published in the last quarter claiming various methods of treatment using CBD
 - o Life-cycle management
 - Several new formulations of CBD in Phase 1 trials
- Progressed cannabinoid pipeline product candidates:
 - o CBDV Phase 2 partial-onset epilepsy study in adults fully enrolled. Data expected end 2017/early 2018
 - 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 and Phase 2 placebo-controlled trial in planning for H1 2018
 - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
 - o CBD:THC in Glioblastoma
 - Positive survival data from Phase 2 study presented recently at ASCO; further follow-up demonstrates continued increased survival in the CBD:THC arm.
 - o Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
 - Phase 1 trial complete
 - Orphan Drug and Fast Track Designations granted from FDA and EMA
- Management appointments:
 - Dr. Volker Knappertz appointed Chief Medical Officer
 - Douglas Snyder appointed Chief Legal Officer
 - Prof. Ben Whalley appointed as Director of Research

FINANCIAL HIGHLIGHTS

- Cash and cash equivalents at 30 June 2017 of £284.1 million (\$369.5 million) compared to £374.4 million as at 30 September 2016
- Revenue for the nine months ended 30 June 2017 of £6.1 million (\$7.9 million) compared to £8.6 million for the nine months ended 30 June 2016
- Loss for the nine months ended 30 June 2017 of £90.3 million (\$117.5 million) compared to £46.7 million for the nine months ended 30 June 2016

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 30 June 2017 of \$1.30081 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 third quarter 2017 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. For both dial-in numbers please use conference ID # 13667808 and PIN: 19259.



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

Financial and Operational Results for the Third Quarter Ended 30 June 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 has now commenced rolling submission of the New Drug Application, or NDA, to the FDA for Epidiolex in both Dravet syndrome and LGS. This submission is expected to be complete in October 2017. 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 CBD:THC product in the treatment of glioblastoma multiforme. 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[®] (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in 30 countries outside the United States.

Management Appointments

In August 2016, GW announced that Dr. Stephen Wright would be retiring in May 2017 as Chief Medical Officer and in May, GW announced the appointment of his successor, Dr. Volker Knappertz. Dr. Knappertz has over 25 years of clinical trial experience and 17 years of pharmaceutical drug development experience, holding leadership positions with responsibilities for managing international clinical trial and medical affairs programs. Most recently, as the Vice President of clinical development for multiple sclerosis, oncology and biosimilar products at Teva Pharmaceuticals, Dr. Knappertz oversaw multiple regulatory submissions and approvals in the U.S., Canada, Europe and Japan. Prior to joining Teva in 2012, Dr. Knappertz served in clinical and medical roles in CNS, CV, and biologics at Bayer Pharmaceuticals and AstraZeneca. Dr. Knappertz is a U.S. Board certified neurologist who received his residency training at Yale University, where he served as chief resident and was fellowship trained at Wake Forest University. He received his clinical scientist training and M.D. as well as a doctorate degree in research on glioblastoma from the University at Cologne in Germany.

In addition to the appointment of Dr. Knappertz as CMO, Professor Ben Whalley was also appointed in May to the newly created position of Head of Research. Previously, Prof. Whalley was Professor of Neuropharmacology at the Reading School of Pharmacy at the University of Reading, U.K. Since 2007, he has been GW's principal academic collaborator in the field of epilepsy pre-clinical research and is the author of key papers related to the pre-clinical studies of CBD and CBDV in the treatment of seizures. In this time, he has become a leading authority on the effects of cannabinoids in the central nervous system.

In July 2017, Douglas Snyder joined GW to the newly created position of Chief Legal Officer. Mr Snyder brings more than 20 years of experience providing counsel in the pharmaceutical industry, at the FDA and in private practice. Prior to joining GW, he led the legal and compliance teams as Senior Vice President, General Counsel, and Secretary for Actelion U.S. Prior to that, Mr Snyder held the position of Senior Vice President, General Counsel, Secretary at Eisai Inc. where he led the Legal, Compliance, Legislative Affairs, Internal Audit and Security Group. From 1999-2005, he was Vice-President, Associate General Counsel for GlaxoSmithKline. During his tenure at GSK, Mr Snyder managed the legal and communications strategies related to some of the Company's most high profile matters concerning the New York Attorney General, the U.S. department of Justice and the FDA. Before joining the pharmaceutical industry, he held the role of Associate General Counsel for the FDA where he counseled the Commissioner, appeared before Congress in key initiatives, and led the initial False Claims/Kickback cases against the pharmaceutical industry.

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: 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. 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. Of those patients on Epidiolex that reported an adverse event, 84 percent reported it to be mild or moderate. This trial is the largest known controlled trial in Dravet syndrome ever conducted. In May 2017, this trial was published in *The New England Journal of Medicine*, accompanied by an editorial.

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 and the pattern of adverse events was consistent with that reported in the Dravet syndrome Phase 3 study. 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 by the end of 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

The Company completed clinical and CMC pre-NDA meetings in the second half of 2016. Recently, the Company requested to FDA that it submit the NDA as a rolling submission, a request which the FDA accepted. This submission has now commenced with the pre-clinical module already having been submitted, the clinical module submission now underway and expected to be completed in the coming weeks, and the CMC module expected to be submitted in October 2017. Subject to satisfactory FDA review, GW anticipates a simultaneous decision of 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 now completed formal pre-submission meetings with the EMA and the designated ‘rapporteur’ regulatory authority. Following these meetings, in which it was agreed that GW could submit a single application for both the Dravet syndrome and LGS indications, the Company is advancing plans to submit a marketing authorization application in Europe in the fourth quarter of 2017.

Epidiolex Follow-On Target 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 on TSC patients 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, 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, 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 a two part Phase 3 trial of Epidiolex in patients with IS. The first part is now underway and the results will determine the Company's 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 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 resulted in no critical or major findings.

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 the NDA submission and the Company believes that it is on track to be ready for FDA GMP pre-approval inspection anticipated in the first quarter of 2018.

Epidiolex Commercialization

GW will commercialize Epidiolex, and any other products in the United States, under the name Greenwich Biosciences, Inc. (Greenwich). The U.S. organization continues to build out an experienced leadership team of medical affairs professionals, marketing and managed markets/payor expertise, many of whom have strong epilepsy knowledge and experience. Over 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 the Child Neurology Society (CNS) Annual Meeting and the American Epilepsy Society (AES) Annual Meeting, which will reinforce awareness of Greenwich Biosciences within the physician community. At the recently held American Academy of Neurology (AAN) Annual Meeting in April of this year clinical data from 3 of its Phase 3 studies had podium presentations.

Specific to the upcoming AES Annual Meeting in December, the Company expects an array of new data to be presented from the placebo-controlled trials, the long-term open-label extension study, and from clinics involved in the Expanded Access Program. Abstracts submitted include pooled 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 is made up of experienced specialists drawn from leading epilepsy companies, currently numbers 13 with plans to expand to 15 by the end of 2017 has enabled the Company to open scientific and consultative communications with key stakeholders, such as the patient and physician 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.

Increased payor initiatives

As the Company moves closer to approval of Epidiolex, a major focus is on payor education and readiness. A number of individual one-on-one and advisory board interactions have already taken place with some of the larger commercial and state/federal payors.

Health Economic Outcomes Research and Compendia data initiatives

The Company has 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

GW continues to focus on support for, and outreach to, the major epilepsy patient advocacy groups. These initiatives include relationship building, advocacy and education.

Implementation of a dedicated sales force

As GW approaches the expected U.S. Epidiolex approval, the Company anticipates hiring approximately 60 sales professionals in the U.S. to target approximately 4,000 – 5,000 physicians. This commercial organization will be defined by a “high touch” patient, payor and physician communication, education and distribution model.

Progress in Europe

Outside the United States, GW continues to advance its organizational 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 and launching products, including within the field of epilepsy. The Company now has in place key staff in medical affairs, market access and marketing disciplines and is rapidly advancing multiple areas of launch planning including activities to put in place a more comprehensive commercial organization in the major European markets as well as continued development of the market access strategy. Alongside this, GW recently attended the 12th Congress of the European Paediatric Neurology Society (EPNS) in Lyon, including the hosting of a Satellite Symposium which was widely attended. GW’s European team are now in final preparations for the 32nd International Epilepsy Congress in Barcelona in September, at which activities will include two scientific symposia, platform and poster presentations of key Phase 3 data and a range of additional medical affairs activities.

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 (plus the District of Columbia which will be starting in August), 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 3.5 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.

In the July 2017 e-publication of *Epilepsia* (Rosenberg *et al*), the authors assessed caregiver-reported Quality of Life in Childhood Epilepsy (QOLCE) in a subset of patients enrolled in the EAP (n=48). Following 12 weeks of CBD, median percent change in seizure frequency was -39.4%, with a $\geq 50\%$ responder rate of 41.7%. Patients experienced a mean of 8.1 points improvement in QOLCE ($p < 0.001$). Of the 16 subdomains, those with significant improvement included energy/fatigue, memory, control/helplessness, other cognitive functions, social interactions, behavior, and global QOL. QOLCE improvements were not correlated to changes in seizure frequency or adverse events, suggesting that CBD may have beneficial effects on patient QOL that are distinct from its seizure-reducing effects. As previously reported by Devinsky *et al* in 2015, the EAP found CBD was generally well-tolerated; common adverse events included somnolence, decreased appetite, diarrhea, fatigue, and convulsions.

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 fourteen 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.

Over the last quarter, six patents have been published on the USPTO site claiming various methods of treatment using cannabidiol. All of these applications have been filed as "Track One" applications in March 2017, which means the USPTO should make its final determination as to whether to grant these applications by the end of March 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 its 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 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.

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. 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 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 162 patients randomized. Data from this part of the trial is expected at the end of 2017 or early 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 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 CBDV within the field of ASD. A physician-led expanded access IND to treat seizures associated with autism has been granted by FDA in 10 patients. 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 and a Phase 2 placebo-controlled trial in this condition are expected to commence in the first half of 2018. GW has received scientific advice from both the FDA and EMA on the study design.

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 CBD and THC 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 a combination of CBD and THC in recurrent glioblastoma multiforme, or GBM, a particularly aggressive brain tumor which is considered a rare disease by the FDA and the EMA. The results from this Phase 2 study were presented in a poster at American Society of Clinical Oncology (ASCO) Annual Meeting in June. This study, which evaluated a number of safety and exploratory efficacy endpoints, 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. CBD:THC 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 Company has received Orphan Drug Designation from both agencies for its product for the treatment of glioma.

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 the Company expects to consult with external experts and regulatory agencies on a pivotal clinical development program for CBD:THC 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 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), for which GW has commenced a rolling NDA submission with the FDA for the treatment of Dravet syndrome and Lennox-Gastaut syndrome. The Company continues to evaluate Epidiolex in additional epilepsy conditions and currently has ongoing Phase 3 clinical trials in 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 30 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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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 30 June 2017, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and nine months ended 30 June 2017 have been translated into U.S. dollars at the rate on 30 June 2017 of \$1.30081 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 statement. The current period tax charge relates to U.S. taxation on the taxable profit for the Group's U.S. subsidiary, Greenwich Biosciences, Inc.

Results of Operations:

Comparison of the three months ended 30 June 2017 and 30 June 2016

Revenue

Total revenue for the three months ended 30 June 2017 was £2.4 million, compared to £2.3 million for the three months ended 30 June 2016. This increase of £0.1 million primarily comprises:

- £0.3 million increase in Sativex product sales revenues to £1.8 million for the three months ended 30 June 2017 compared to £1.5 million for the three months ended 30 June 2016. In-market sales volumes sold by GW's commercial partners for the three months ended 30 June 2017 were 23% higher than the three months ended 30 June 2016. Sales volumes to partners increased by 51% over the same period, primarily due to increased shipments to Germany, offset in part by a decrease in sales price
- £0.2 million decrease in research and development fees to £0.2 million for the three months ended 30 June 2017 from £0.4 million for the three months ended 30 June 2016. This reflects the impact of the conclusion of the Group's partner-funded Sativex Phase 3 cancer pain clinical trials during the prior financial period

Cost of sales

Cost of sales for the three months ended 30 June 2017 of £1.1 million represents a £0.4 million increase over the £0.7 million recorded in the three months ended 30 June 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 30 June 2017 of £28.0 million increased by £2.4 million compared to the £25.6 million incurred in the three months ended 30 June 2016.

- £2.6 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program
- £0.5 million increase in overheads associated with running 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; offset by
- £0.3 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 in the prior financial year
- £0.2 million decrease in research and development staff and employment-related expenses linked to completion of three Phase 3 clinical trials during the comparative period
- £0.2 million decrease in partner-funded research and development expenditure to £0.2 million for the three months ended 30 June 2017 from £0.4 million for the three months ended 30 June 2016. This decrease reflects the conclusion and close out of the Sativex Phase 3 cancer pain clinical trials compared to the prior financial period

Sales, general and administrative expenses

Sales, general and administrative expenses for the three months ended 30 June 2017 of £11.8 million increased by £6.2 million compared to the £5.6 million incurred in the three months ended 30 June 2016. This net increase is due to:

- £3.3 million increase in pre-launch commercialization costs
-

- £2.0 million increase in payroll costs driven by increased headcount within the Group's expanding commercial operations
- £0.7 million increase in respect of property and travel costs, primarily due to the expansion of U.S. based operations
- £0.2 million increase in accountancy, audit and investor relation costs arising from the Group's expansion

Net foreign exchange gains / (losses)

Net foreign exchange loss for the three months ended 30 June 2017 was a loss of £8.4 million, compared to the £11.2 million gain recorded for the three months ended 30 June 2016. In both periods the exchange movement 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 30 June. The Sterling to U.S. dollar exchange rate has moved from 1.25331 at 31 March 2017 to 1.30081 at 30 June 2017. Dollar denominated cash deposits totalled \$331.5 million at 31 March 2017 and \$257.0 million at 30 June 2017.

Taxation

The tax benefit was £6.2 million for the three months ended 30 June 2017. This represents an increase of £0.1 million compared to a £6.1 million benefit recorded in the three months ended 30 June 2016.

In the three months ended 30 June 2017, GW recorded a tax benefit of £6.2 million made up of: (i) the recognition of an accrued £5.6 million research and development tax credit expected to be claimable by GW Research Limited in respect of research and development expenditure incurred in the three months ended 30 June 2017; and (ii) the recognition of an additional £0.6 million of research and development tax credits in respect of the year ended 30 September 2016 as part of the process for finalising tax returns for that period.

In the three months ended 30 June 2016, GW recorded a tax benefit of £6.1 million made up of: (i) the recognition of an accrued £4.8 million research and development tax credit expected to be claimable by GW Research Limited in respect of research and development expenditure incurred in the three months ended 30 June 2016; (ii) the recognition of £0.3 million of research and development federal tax credits in respect of the year ended 30 September 2015 for the Group's U.S. subsidiary, Greenwich Biosciences, Inc.; and (iii) recording of £1.0 million of current tax credit in respect of activities of the Group's U.S. subsidiary, Greenwich Biosciences, Inc. during the year ended 30 September 2016.

Loss

The Group reported a loss after tax for the three months ended 30 June 2017 of £40.4 million compared with a loss after tax for the three months ended 30 June 2016 of £12.2 million.

Results of Operations:

Comparison of the nine months ended 30 June 2017 and 30 June 2016:

Revenue

Total revenue for the nine months ended 30 June 2017 was £6.1 million, compared to £8.6 million for the nine months ended 30 June 2016. This decrease of £2.5 million primarily comprises:

- £3.4 million decrease in research and development fees to £0.5 million for the nine months ended 30 June 2017 compared to £3.9 million for the nine months ended 30 June 2016. This reflects the impact of the conclusion of the Group's partner-funded Sativex Phase 3 cancer pain clinical trials; offset by
- £0.7 million increase in Sativex product sales revenues to £4.4 million for the nine months ended 30 June 2017 compared to £3.7 million for the nine months ended 30 June 2016. In-market sales volumes sold by GW's commercial partners for the nine months ended 30 June 2017 were 19% higher than the nine months ended 30 June 2016. Sales volumes to partners increased by 26% over the same period, due primarily to increased shipments to Germany
- £0.2 million increase in license collaboration and technical access fees to £1.1 million for the nine months ended 30 June 2017 compared to £0.9 million for the nine months ended 30 June 2016, as a result of the mutual termination agreement with Novartis over rights for Sativex.

Cost of sales

Cost of sales for the nine months ended 30 June 2017 of £2.5 million is an increase of £0.6 million compared to the £1.9 million recorded in the nine months ended 30 June 2016. This reflects an increase in shipments of Sativex to commercial partners.

Research and development expenditure

Total research and development expenditure for the nine months ended 30 June 2017 of £80.0 million increased by £4.5 million compared to the £75.5 million incurred in the nine months ended 30 June 2016. This increase is due to:

- £5.5 million increase in research and development staff and employment-related expenses linked to increased global headcount combined with the transition of the Group's clinical headcount from partner-funded Sativex trials to the GW-funded Epidiolex development program
 - £5.2 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program
 - £2.3 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; offset by
 - £5.1 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 in the prior financial year
 - £3.4 million decrease in partner-funded research and development expenditure to £0.5 million for the nine months ended 30 June 2017 from £3.9 million for the nine months ended 30 June 2016. This decrease reflects the conclusion and close out of the Sativex cancer pain clinical trials compared to the previous period
-

Sales, general and administrative expenses

Sales, general and administrative expenses for the nine months ended 30 June 2017 of £27.7 million increased by £15.2 million compared to the £12.5 million incurred in the nine months ended 30 June 2016. This net increase is due to:

- £7.4 million increase in payroll costs driven by increased headcount within the Group's expanding commercial operations
- £5.7 million increase in pre-launch commercialization costs
- £1.8 million increase in property and travel costs, primarily due to the expansion of U.S. based operations.
- £0.3 million increase in accountancy, audit and investor relation costs arising from the Group's expansion.

Net foreign exchange gains / (losses)

Net foreign exchange loss for the nine months ended 30 June 2017 was a loss of £0.6 million, compared to a £19.3 million gain recorded for the nine months ended 30 June 2016. In both periods the exchange movement recognized relates to the remeasurement of the Group's US dollar denominated cash deposits to pounds sterling at the closing US dollar to Sterling exchange rate at 30 June. The Sterling to U.S. dollar exchange rate has moved from 1.29128 at 30 September 2016 to 1.30081 at 30 June 2017. Dollar denominated cash deposits totalled \$345.5 million at 30 September 2016 and \$257.0 million at 30 June 2017.

Taxation

The tax benefit was £13.9 million for the nine months ended 30 June 2017, which represents a decrease of £1.1 million compared to a £15.0 million benefit recorded in the nine months ended 30 June 2016.

In the nine months ended 30 June 2017, GW recorded a tax benefit of £13.9 million comprising: (i) the recognition of an accrued £12.8 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 nine months ended 30 June 2017; (ii) the recognition of an additional £0.7 million of research and development tax credits in respect of the year ended 30 September 2016 as part of the process for finalising UK and US tax returns for that period; and (iii) the recording of £0.4 million of tax benefit in respect of an additional deferred tax asset recognised on timing differences for Greenwich Biosciences, Inc.

In the nine months ended 30 June 2016, GW recorded a tax benefit of £15.0 million comprising: (i) the recognition of an accrued £13.4 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 nine months ended 30 June 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 finalising tax returns for that period; (iii) the recognition of £0.3 million of research and development federal tax credits in respect of the year ended 30 September 2015 in its U.S. subsidiary, Greenwich Biosciences, Inc., following the submission of an orphan drug tax credit claim and; (iv) recording of £0.7 million of current tax credit in respect of activities of Greenwich Biosciences, Inc. for the year ended 30 September 2016.

Loss

The Group reported a loss after tax for the nine months ended 30 June 2017 of £90.3 million compared with a loss after tax for the nine months ended 30 June 2016 of £46.7 million.

Liquidity and Capital Resources

Cash Flow

Net cash outflow from operating activities for the nine months ended 30 June 2017 of £75.3 million was £18.1 million higher than the £57.2 million outflow from operating activities for the nine months ended 30 June 2016, principally reflecting the increase in investment in Epidiolex and other pipeline research and development activities, combined with the scale up in US operations in anticipation of commercial activities.

Capital expenditure for the nine months ended 30 June 2017 of £13.0 million, consisting primarily of upgrades to our cannabinoid growing facilities, was £6.7 million higher than the £6.3 million for the nine months ended 30 June 2016 reflecting completion of a number of significant capital projects for commercialization.

Net cash flow from financing activities decreased by £1.9 million to a £1.7 million outflow in the nine months ended 30 June 2017 compared to a £0.2 million inflow for the nine months ended 30 June 2016 principally reflecting the commencement of repayments towards finance leases and funding received for the Group's cannabinoid extraction facilities which were completed during the current period.

As at 30 June 2017, GW had a closing cash position of £284.1 million compared to £374.4 million as at 30 September 2016.

Property, plant and equipment

Property, plant and equipment at 30 June 2017 increased by £1.9 million to £40.8 million from £38.9 million at 30 September 2016. This increase primarily reflects the expansion of the Group's commercial growing facilities and final completion of the Group's flagship cannabinoid extraction facility during the period.

Inventories

Inventories at 30 June 2017 decreased by £0.1 million to £4.1 million compared with the £4.2 million at 30 September 2016. Inventories consist of finished goods, consumable items and work in progress and are stated net of a £nil million realizable value provision (30 September 2016: £0.1 million). During the nine months ended 30 June 2017, the provision for inventories reduced by £0.1 million as a result of having utilized some of the Group's previously provided for inventory in research and development.

Trade receivables and other assets

Trade receivables and other assets at 30 June 2017 increased by £5.3 million to £9.9 million from £4.6 million at 30 September 2016. This is primarily due to an increase in prepaid costs in relation to goods, services and deposits paid for capital expenditure not yet received by the Group.

Trade and other payables

Current trade and other payables at 30 June 2017 decreased by £4.6 million to £26.6 million from £31.2 million at 30 September 2016. This decrease primarily reflects a reduction in accruals relating to GW-funded clinical trials, following the conclusion of a number of the Epidiolex Phase 3 trials

Non-current trade and other payables at 30 June 2017 decreased by £0.3 million to £9.1 million compared with £9.4 million at 30 September 2016.

Headcount

Average headcount for the nine months ended 30 June 2017 was 519 (30 June 2016: 429).

Guidance

We expect total cash outflow for 2017 to be in the range of £126 to £134 million pounds (\$165 to \$175 million dollars at current rates). This is a slight increase to our previous guidance which was approximately \$150 million dollars. The increase in our US dollar guidance is driven in large part by the weakening of the dollar against the pound sterling.

GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 30 June 2017

	Notes	30 June 2017 \$000's	30 June 2017 £000's	30 June 2016 £000's
Revenue	2	3,138	2,412	2,329
Cost of sales		(1,444)	(1,110)	(711)
Research and development expenditure		(36,339)	(27,936)	(25,609)
Sales, general and administrative expenses		(15,286)	(11,751)	(5,603)
Net foreign exchange (loss) / gain		(10,940)	(8,410)	11,190
Operating loss		(60,871)	(46,795)	(18,404)
Interest income		593	456	98
Interest expense		(346)	(266)	(18)
Loss before tax		(60,624)	(46,605)	(18,324)
Tax benefit	3	8,126	6,247	6,109
Loss for the period		(52,498)	(40,358)	(12,215)
Loss per share – basic and diluted		(17.3c)	(13.3p)	(4.6p)
Loss per ADS – basic and diluted ⁽¹⁾		(207.6c)	(159.6p)	(55.2p)
Weighted average ordinary shares outstanding (in millions) – basic and diluted			303.9	262.9

All activities relate to continuing operations.

⁽¹⁾ Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the three months ended 30 June 2017

	30 June 2017 £000's	30 June 2016 £000's
Loss for the period	(40,358)	(12,215)
Items that may be reclassified subsequently to profit or loss		
Exchange (loss)/gain on retranslation of foreign operations	(508)	266
Other comprehensive (loss)/gain for the period	(508)	266
Total comprehensive loss for the period	(40,866)	(11,949)

GW Pharmaceuticals plc
Condensed consolidated income statement
Nine months ended 30 June 2017

	Notes	30 June 2017 \$000's	30 June 2017 £000's	30 June 2016 £000's
Revenue	2	7,928	6,095	8,645
Cost of sales		(3,268)	(2,512)	(1,940)
Research and development expenditure		(104,074)	(80,007)	(75,497)
Sales, general and administrative expenses		(36,065)	(27,725)	(12,470)
Net foreign exchange (loss) / gain		(757)	(583)	19,279
Operating loss		(136,236)	(104,732)	(61,983)
Interest income		1,355	1,042	292
Interest expense		(662)	(509)	(53)
Loss before tax		(135,543)	(104,199)	(61,744)
Tax benefit	3	18,053	13,878	14,995
Loss for the period		(117,490)	(90,321)	(46,749)
Loss per share – basic and diluted		(38.7c)	(29.8p)	(17.8p)
Loss per ADS – basic and diluted ⁽¹⁾		(464.4c)	(357.6p)	(213.6p)
Weighted average ordinary shares outstanding (in millions) – basic and diluted			303.4	262.3

All activities relate to continuing operations.

⁽¹⁾ Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the nine months ended 30 June 2017

	30 June 2017 £000's	30 June 2016 £000's
Loss for the period	(90,321)	(46,749)
Items that may be reclassified subsequently to profit or loss		
Exchange (loss)/gain on retranslation of foreign operations	(267)	166
Other comprehensive (loss)/gain for the period	(267)	166
Total comprehensive loss for the period	(90,588)	(46,583)

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Nine months ended 30 June 2017

	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	633	-	-	635
Share-based payment transactions	-	-	-	5,900	5,900
Loss for the period	-	-	-	(46,749)	(46,749)
Deferred tax attributable to unrealized share option gains	-	-	-	366	366
Other comprehensive gain	-	-	166	-	166
Balance at 30 June 2016	<u>263</u>	<u>349,908</u>	<u>19,355</u>	<u>(163,938)</u>	<u>205,588</u>
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	-	-	-	8,141	8,141
Loss for the period	-	-	-	(90,321)	(90,321)
Deferred tax attributable to unrealized share option gains	-	-	-	(251)	(251)
Other comprehensive loss	-	-	(267)	-	(267)
Balance at 30 June 2017	<u>304</u>	<u>556,565</u>	<u>19,271</u>	<u>(260,258)</u>	<u>315,882</u>

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 30 June 2017

	Notes	As at 30 June 2017 \$000's	As at 30 June 2017 £000's	As at 30 September 2016 £000's
Non-current assets				
Goodwill		6,777	5,210	5,210
Other intangible assets		1,232	947	629
Property, plant and equipment		53,122	40,838	38,947
Deferred tax asset		6,944	5,338	3,873
		<u>68,075</u>	<u>52,333</u>	<u>48,659</u>
Current assets				
Inventories		5,354	4,116	4,248
Taxation recoverable		16,860	12,961	21,322
Trade receivables and other assets		12,926	9,937	4,556
Cash and cash equivalents		369,539	284,084	374,392
		<u>404,679</u>	<u>311,098</u>	<u>404,518</u>
Assets held for sale		1,182	909	-
Total assets		<u>473,936</u>	<u>364,340</u>	<u>453,177</u>
Current liabilities				
Trade and other payables	4	(34,652)	(26,639)	(31,170)
Current tax liabilities		(1,131)	(870)	(883)
Obligations under finance leases		(263)	(202)	(211)
Deferred revenue		(3,007)	(2,312)	(2,686)
		<u>(39,053)</u>	<u>(30,023)</u>	<u>(34,950)</u>
Non-current liabilities				
Trade and other payables	4	(11,830)	(9,094)	(9,423)
Obligations under finance leases		(6,253)	(4,807)	(4,959)
Deferred revenue		(5,898)	(4,534)	(5,355)
Total liabilities		<u>(63,034)</u>	<u>(48,458)</u>	<u>(54,687)</u>
Net assets		<u>410,902</u>	<u>315,882</u>	<u>398,490</u>
Equity				
Share capital		395	304	302
Share premium account		723,985	556,565	556,477
Other reserves		25,068	19,271	19,538
Accumulated deficit		(338,546)	(260,258)	(177,827)
Total equity		<u>410,902</u>	<u>315,882</u>	<u>398,490</u>

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the nine months ended 30 June 2017

	Nine months ended 30 June 2017 \$000's	Nine months ended 30 June 2017 £000's	Nine months ended 30 June 2016 £000's
Loss for the period	(117,490)	(90,321)	(46,749)
Adjustments for:			
Interest income	(1,355)	(1,042)	(292)
Interest expense	662	509	53
Tax benefit	(18,053)	(13,878)	(14,995)
Depreciation of property, plant and equipment	4,918	3,781	2,526
Impairment of property, plant and equipment	124	95	-
Reversal of impairment of property, plant and equipment	(281)	(216)	-
Amortization of intangible assets	219	168	42
Net foreign exchange losses/(gains)	758	583	(19,382)
Increase/(decrease) in provision for inventories	104	80	(45)
Decrease in deferred signature fees	(1,427)	(1,097)	(881)
Share-based payment charge	10,590	8,141	5,900
Loss on disposal of property, plant and equipment	787	605	-
	(120,444)	(92,592)	(73,823)
Decrease in inventories	68	52	323
(Increase)/decrease in trade receivables and other assets	(2,490)	(1,914)	57
(Decrease)/increase in trade and other payables and deferred revenue	(1,664)	(1,279)	4,155
Cash used in operations	(124,530)	(95,733)	(69,288)
Income taxes paid	(1,661)	(1,277)	(1,150)
Research and development tax credits received	28,200	21,679	13,281
Net cash outflow from operating activities	(97,991)	(75,331)	(57,157)
Investing activities			
Interest received	1,262	970	290
Purchases of property, plant and equipment	(16,896)	(12,989)	(6,255)
Purchase of intangible assets	(609)	(468)	(363)
Net cash outflow from investing activities	(16,243)	(12,487)	(6,328)
Financing activities			
Proceeds on exercise of share options	118	91	635
Expenses of new equity issue	(174)	(134)	-
Interest paid	(948)	(729)	(53)
Repayment of fit out funding	(973)	(748)	(240)
Repayment of obligations under finance leases	(208)	(160)	(98)
Net cash (outflow)/inflow from financing activities	(2,185)	(1,680)	244
Effect of foreign exchange rate changes on cash and cash equivalents	(1,053)	(810)	19,546
Net decrease in cash and cash equivalents	(117,472)	(90,308)	(43,695)
Cash and cash equivalents at beginning of the period	487,011	374,392	234,872
Cash and cash equivalents at end of the period	369,539	284,084	191,177

1. Significant accounting policies

Basis of preparation

These unaudited condensed consolidated interim financial statements for the three and nine month periods ended 30 June 2017 and 30 June 2016 of GW Pharmaceuticals plc and subsidiaries (collectively, the “Group”) have been prepared in accordance with International Accounting Standard 34 – “Interim Financial Reporting” (“IAS 34”), as issued by the International Accounting Standards Board (“IASB”) and as endorsed by the European Union. These statements were approved by the Board on 7 August 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, as issued by the IASB and as adopted by the European Union. 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 30 June 2017, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and nine months ended 30 June 2017 have been translated into U.S. dollars at the rate on 30 June 2017 of \$1.30081 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 30 June 2017 the Group had cash and cash equivalents of £284.1 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 Company's Board of Directors, the chief operating decision maker for the Group, for the purposes of resource allocation and assessment of segment performance is focused on the stage of product development. The Group's reportable segments are as follows:

- **Commercial:** The Commercial segment distributes and sells the Group's commercial products. Currently Sativex® is promoted through strategic collaborations with major pharmaceutical companies for the currently approved indication of spasticity due to 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 30 June 2017

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	1,790	-	-	1,790	-	1,790
Research and development fees	-	125	111	236	-	236
License, collaboration and technical access fees	276	-	-	276	-	276
Development and approval milestones	110	-	-	110	-	110
Total revenue	2,176	125	111	2,412	-	2,412
Cost of sales	(1,110)	-	-	(1,110)	-	(1,110)
Research and development expenditure	-	(99)	(26,765)	(26,864)	(1,072)	(27,936)
Segmental result	1,066	26	(26,654)	(25,562)	(1,072)	(26,634)
Sales, general and administrative expenses						(11,751)
Net foreign exchange loss						(8,410)
Operating loss						(46,795)
Interest income						456
Interest expense						(266)
Loss before tax						(46,605)
Tax benefit						6,247
Loss for the period						(40,358)

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 30 June 2016

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	1,522	-	-	1,522	-	1,522
Research and development fees	-	357	62	419	-	419
License, collaboration and technical access fees	290	-	-	290	-	290
Development and approval milestones	98	-	-	98	-	98
Total revenue	1,910	357	62	2,329	-	2,329
Cost of sales	(711)	-	-	(711)	-	(711)
Research and development expenditure	-	(426)	(24,408)	(24,834)	(775)	(25,609)
Segmental result	1,199	(69)	(24,346)	(23,216)	(775)	(23,991)
Sales, general and administrative expenses						(5,603)
Net foreign exchange gain						11,190
Operating loss						(18,404)
Interest income						98
Interest expense						(18)
Loss before tax						(18,324)
Tax benefit						6,109
Loss for the period						(12,215)

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 Nine Months Ended 30 June 2017

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	4,427	-	-	4,427	-	4,427
Research and development fees	-	90	369	459	-	459
License, collaboration and technical access fees	1,099	-	-	1,099	-	1,099
Development and approval milestones	110	-	-	110	-	110
Total revenue	5,636	90	369	6,095	-	6,095
Cost of sales	(2,512)	-	-	(2,512)	-	(2,512)
Research and development expenditure	-	(97)	(77,019)	(77,116)	(2,891)	(80,007)
Segmental result	3,124	(7)	(76,650)	(73,533)	(2,891)	(76,424)
Sales, general and administrative expenses						(27,725)
Net foreign exchange loss						(583)
Operating loss						(104,732)
Interest income						1,042
Interest expense						(509)
Loss before tax						(104,199)
Tax benefit						13,878
Loss for the period						(90,321)

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 Nine Months Ended 30 June 2016

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs ¹ £'000	Consolidated £'000
Revenue:						
Product sales	3,719	-	-	3,719	-	3,719
Research and development fees	-	3,698	247	3,945	-	3,945
License, collaboration and technical access fees	883	-	-	883	-	883
Development and approval milestones	98	-	-	98	-	98
Total revenue	4,700	3,698	247	8,645	-	8,645
Cost of sales	(1,940)	-	-	(1,940)	-	(1,940)
Research and development expenditure	-	(4,487)	(69,239)	(73,726)	(1,771)	(75,497)
Segmental result	2,760	(789)	(68,992)	(67,021)	(1,771)	(68,792)
Sales, general and administrative expenses						(12,470)
Net foreign exchange gain						19,279
Operating loss						(61,983)
Interest income						292
Interest expense						(53)
Loss before tax						(61,744)
Tax benefit						14,995
Loss for the period						(46,749)

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:

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
<i>Three months ended 30 June 2017</i>				
Customer A	1,535	-	-	1,535
Customer B	398	-	-	398
Customer C	70	126	110	306
<i>Three months ended 30 June 2016</i>				
Customer A	1,280	-	-	1,280
Customer B	381	-	-	381
Customer C	70	356	62	488
<i>Nine months ended 30 June 2017</i>				
Customer A	3,556	-	-	3,556
Customer B	1,174	-	-	1,174
Customer C	210	90	369	669
<i>Nine months ended 30 June 2016</i>				
Customer A	3,066	-	-	3,066
Customer B	1,035	-	-	1,035
Customer C	210	3,698	247	4,155

Geographical analysis of revenue by destination of customer

	Three months ended 30 June 2017 £000's	Three months ended 30 June 2016 £000's	Nine months ended 30 June 2017 £000's	Nine months ended 30 June 2016 £000's
UK	374	361	1,196	827
Europe (excluding UK)	1,528	1,295	3,846	3,176
United States	196	426	300	3,908
Canada	204	184	384	488
Asia	110	63	369	246
	<u>2,412</u>	<u>2,329</u>	<u>6,095</u>	<u>8,645</u>

3. Tax benefit

	Three months ended 30 June 2017 £000's	Three months ended 30 June 2016 £000's	Nine months ended 30 June 2017 £000's	Nine months ended 30 June 2016 £000's
Current period research and development tax credit	(5,568)	(4,774)	(12,789)	(13,361)
Adjustments in respect of prior year tax credit	(541)	(349)	(732)	(940)
Deferred tax credit	(355)	-	(355)	-
Reclassification of amounts previously charged to equity	(251)	-	(251)	-
Current period tax charge/(credit)	468	(986)	249	(694)
Total credit for the period	<u>(6,247)</u>	<u>(6,109)</u>	<u>(13,878)</u>	<u>(14,995)</u>

The research and development tax credit relates to research and development expenditure claimed under the Finance Act 2000 in the UK, or claimed under the orphan credit scheme in the United States. In June 2017, the Group received £21.7 million in respect of research and development expenditure incurred in the UK for the year ended 30 September 2016.

In the three and nine months ended 30 June 2017 and 2016, the Group recognized the full estimated benefit for qualifying research and development expenditures incurred during each period. 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 amended to the extent that sufficient future taxable profits will be available to allow all or part of the asset to be recovered.

4. Trade and other payables

	30 June 2017 £000's	30 September 2016 £000's
Amounts falling due within one year		
Other creditors and accruals	15,597	15,899
Clinical trial accruals	5,738	9,503
Trade payables	3,940	3,433
Other taxation and social security	943	1,490
Fit out funding	383	845
Onerous lease provision	38	-
	<u>26,639</u>	<u>31,170</u>
Amounts falling due after one year		
Fit out funding	8,057	8,342
Other creditors and accruals	1,017	1,081
Onerous lease provision	20	-
	<u>9,094</u>	<u>9,423</u>

Fit out funding represents £8.4 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 £2.0 million (30 September 2016: £1.6 million), net of payments to date of £1.4 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.