

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, 2016

Commission File Number: 001-35892

**GW PHARMACEUTICALS PLC**

(Translation of registrant's name into English)

Sovereign House  
Vision Park  
Histon  
Cambridge CB24 9BZ  
United Kingdom

(Address of principal executive offices)

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

Form 20-F  Form 40-F

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

Yes  No

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

Yes  No

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**Other Events**

On May 5, 2016, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its second quarter financial results and details of a conference call to be held at 8:00 a.m. EDT on May 5, 2016 to discuss the results. 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**

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99.1 Press release dated May 5, 2016

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**SIGNATURES**

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

**GW Pharmaceuticals plc**

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

Date: May 5, 2016

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**GW Pharmaceuticals plc Reports Second Quarter and Half-Year 2016 Financial Results  
and Operational Progress**

**- Positive Phase 3 Epidiolex pivotal trial in Dravet syndrome –  
- Initial LGS Phase 3 pivotal data expected in June -  
-Conference call today at 9:00 a.m. EDT, 2:00 p.m. BST-**

**London, UK, 5 May 2016:** GW Pharmaceuticals plc (NASDAQ: GWPH, AIM: GWP, GW, the Company or the Group), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announced financial results for the second quarter and half-year ended 31 March 2016.

“Following positive results in our first Phase 3 trial of Epidiolex in Dravet syndrome, GW is now entering an exciting new chapter as we start to prepare the company’s first NDA submission to the FDA and step up plans for Epidiolex commercialization,” stated Justin Gover, GW’s Chief Executive Officer. “The robust data from this first Phase 3 trial in Dravet syndrome provides additional confidence for future clinical trials of Epidiolex and we look forward to results from our Phase 3 trials in Lennox-Gastaut syndrome in the near future. In addition, we continue to expand our research through exploring further indications for Epidiolex as well as ongoing Phase 2 clinical programs for a number of our pipeline candidates.”

**RECENT OPERATIONAL HIGHLIGHTS**

- Epidiolex<sup>®</sup> (CBD) orphan epilepsy program:
    - o Company sponsored Phase 3 development programs in Dravet syndrome, Lennox-Gastaut syndrome (LGS) and Tuberous Sclerosis Complex (TSC)
      - Positive results in first Phase 3 Dravet syndrome trial
        - Full publication of trial results expected in Q4 2016
        - Second Phase 3 Dravet syndrome trial ongoing
      - Pre-NDA meeting with FDA requested
      - Two LGS Phase 3 trials fully enrolled; Data from first trial expected in June
      - 98% transition rate of eligible patients from pivotal Phase 3 trials to long term open label extension
      - Phase 3 TSC trial commenced, Orphan Drug Designation received from FDA
      - Additional clinical development for Epidiolex expected to commence in H2 2016
    - o Expanded access program:
      - Recent updates at the American Academy of Neurology (AAN) Annual Meeting showing consistent treatment effect and safety profile in state-sponsored clinical programs from Alabama and Georgia
      - Over 900 children and young adults authorized for treatment by FDA under Expanded Access Treatment INDs and 6 U.S. State programs
  - Advanced clinical programs in multiple cannabinoid pipeline product candidates:
    - o CBDV Phase 2 partial-onset epilepsy study in adults ongoing. Part A complete and Part B underway with data expected Q1 2017
    - o CBDV pre-clinical research ongoing within field of autism spectrum disorders. Initial clinical evaluation is expected to commence in H2 2016, with Phase 2 trials expected to commence in Q1 2017
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- o Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD Phase 1 clinical program expected to commence in Q4 2016
  - Orphan Drug and Fast Track Designations granted from FDA and EMA
- o THCv Phase 2 study in type-2 diabetes completed - data expected in Q2/3 2016
- o THC:CBD Phase 1b/2a study for the treatment of Recurrent Glioblastoma Multiforme (GBM) fully enrolled with data expected in Q4 2016
  - Orphan Drug Designation granted from FDA and EMA
- o Sativex® Phase 2 study in spasticity due to cerebral palsy ongoing with data expected Q4 2016
- Pre-clinical progress addressing a number of areas of unmet need including autism spectrum disorders, Duchenne muscular dystrophy, glioma, ovarian and pancreatic cancers

## FINANCIAL HIGHLIGHTS

- Cash and cash equivalents at 31 March 2016 of £192.7 million (\$276.8 million) compared to £234.9 million as at 30 September 2015.
- Revenue for the six months ended 31 March 2016 of £6.3 million (\$9.1 million) compared to £14.3 million for the six months ended 31 March 2015. This decrease primarily reflects the expected reduction in R&D fees associated with the conclusion of partner funded Sativex Phase 3 cancer pain trials.
- Loss for the six months ended 31 March 2016 of £34.5 million (\$49.6 million) compared to £10.9 million for the six months ended 31 March 2015.

## Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the second quarter and half-year 2016 financial results today at 9:00 a.m. EDT / 2:00 p.m. BST. 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):1-877-660-6853, (international):1-201-612-7415. For both dial-in numbers please use conference ID # 13636232.

## Enquiries:

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

**Financial Results for the Second Quarter and Half-Year Ended 31 March 2016**

**GW Overview**

GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. In its nearly 20 years of operations, GW has established a world leading position in the development of plant-derived cannabinoid therapeutics through its proven drug discovery and development processes, intellectual property portfolio and regulatory and manufacturing expertise. GW is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex<sup>®</sup>, which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome (LGS) and Tuberous Sclerosis Complex (TSC). Previously, GW commercialized the world’s first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup>, which is approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the United States. GW has a deep pipeline of additional cannabinoid product candidates which includes clinical development across a variety of compounds for both orphan and non-orphan indications.

**Epidiolex**

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

*Dravet syndrome*

GW’s development program in Dravet syndrome is comprised of two Phase 3 pivotal, double-blind, placebo-controlled trials designed to evaluate the safety and efficacy of Epidiolex to treat Dravet syndrome in children who are not responding adequately to other anti-epileptic drugs. The primary measure of efficacy in both trials is the comparison between Epidiolex and placebo in the percentage change in number of monthly convulsive seizures (reported tonic-clonic, tonic, clonic and atonic seizures) during the 14 week treatment period (which includes 2 weeks dose titration) compared with the 4 week baseline observation period.

In March 2016, GW reported positive top-line results from the first Phase 3 pivotal efficacy and safety study in 120 patients. For the primary endpoint, patients taking Epidiolex achieved a median reduction in monthly convulsive seizures of 39% compared with a reduction on placebo of 13%, which was statistically significant (p=0.01). A series of sensitivity analyses of the primary endpoint confirmed the robustness of this result. Results from secondary efficacy endpoints reinforced the overall effectiveness observed with Epidiolex. In this study, Epidiolex was generally well tolerated, with 84% of adverse events reported to be mild or moderate.

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Data from this trial is currently being written up for peer-review publication. This publication is expected to occur in the fourth quarter of 2016.

GW is also recruiting an additional dose-ranging Phase 3 trial in Dravet syndrome which is recruiting 150 patients. This placebo-controlled trial differs from the first Phase 3 trial in that it includes two Epidiolex dose arms, at 20mg/kg and at 10mg/kg. This second Phase 3 pivotal trial in Dravet syndrome is expected to continue to recruit patients until after the pre-NDA meeting scheduled for mid-year 2016.

Both of these studies will be the largest known controlled trials in Dravet syndrome.

#### *LGS*

GW's development program in LGS comprises two pivotal Phase 3, double-blind, placebo-controlled trials designed to evaluate the safety and efficacy of Epidiolex to treat LGS in patients (children and adults) who are not responding adequately to other anti-epileptic drugs. The primary measure of efficacy in both trials will be the comparison between Epidiolex and placebo in the percentage change in number of monthly drop seizures (the sum of all reported atonic, tonic and tonic-clonic seizures that were also deemed drop seizures (involving the entire body, trunk or head that led or could have led to a fall, injury, slumping in a chair or hitting the patient's head on a surface)) during the 14 week treatment period (which includes 2 weeks' dose titration) compared with the 4 week baseline observation period.

The first Phase 3 trial is an evaluation of Epidiolex at a dose of 20mg/kg per day over a 14 week treatment period. Originally expected to recruit 100 patients, this trial reached a total of 171 patients randomized and is expected to report top-line results in June 2016.

The second Phase 3 trial differs from the first Phase 3 LGS trial in that it includes two Epidiolex dose arms, at 20mg/kg and at 10mg/kg. Originally expected to recruit 150 patients, this trial reached a total of 225 patients randomized and is expected to report top-line results in the third quarter of 2016.

#### *TSC*

GW has recently commenced Phase 3 clinical development of Epidiolex in a third orphan pediatric epilepsy indication, TSC. The Company has received Orphan Drug Designation from FDA for this indication and the Phase 3 pivotal trial in approximately 200 children and adults with TSC is expected to report results in the second half of 2017.

At the 69th Annual Meeting of the American Epilepsy Society, safety and efficacy data on 10 patients diagnosed with TSC from the expanded access program were presented by Massachusetts General Hospital for Children (Geffrey et al) on Epidiolex treatment of refractory epilepsy in these patients. In this poster, there was a response rate of 50%, 50%, 40%, 60% and 66% at 2, 3, 6, 9, and 12 months of treatment with Epidiolex, respectively. Side effects were seen in five patients (50%) and most were resolved with anti-epileptic drug or CBD dose adjustment.

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### *New Drug Application (NDA)*

Following the success of the first Dravet syndrome Phase 3 trial, GW has commenced work on the Epidiolex NDA submission. GW has requested a pre-NDA meeting with the FDA to discuss a proposed Dravet syndrome NDA. In addition to pivotal efficacy data, the proposed NDA is expected to include data from approximately ten Phase 1 studies as well as safety data that will include over 1,000 patients from both the expanded access program & pivotal programs, including over 100 patients with one year or more of Epidiolex continuous exposure. The outcome of the pre-NDA meeting, together with results of the two LGS trials, will provide greater clarity on the optimal NDA submission strategy. Our expectation is that the submission is most likely to take place during the first half of 2017 and, subject to the outcome of the LGS trials, would include data supporting the approval of Epidiolex in both indications.

### *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, 98% of patients who have completed the treatment period have elected to enroll in the open label extension. The withdrawal rate in this open label extension is 10%.

### *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.

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

In parallel with the GW's formal clinical trial program, the FDA has granted 20 intermediate expanded access Investigational New Drug Applications (INDs) to independent physician investigators in the U.S to treat a total of 465 children and young adults suffering from intractable epilepsy with Epidiolex. In addition, the FDA has granted further INDs to treat 440 additional patients under expanded access programs supported by six U.S. states and for which GW is supplying Epidiolex. The FDA may authorize expanded access programs to facilitate access to investigational drugs for treatment use for patients with a serious or immediately life-threatening disease or condition who lack therapeutic alternatives. The FDA has also authorized to physicians twelve individual emergency INDs and three individual patient non-emergency INDs. As at 31 March 2016, over 400 patients were on treatment at 24 U.S. clinical sites.

Most recently, physician reports of clinical effect and safety data on the use of Epidiolex to treat epilepsy were presented at the American Academy of Neurology in April 2016. Included in these presentations were updates from the state programs from Alabama (Szaflarski *et al*) and Georgia (Park *et al*).

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In the Alabama study – 51 total patients (23 pediatric and 28 adults), over the 6-month duration of the study:

- 25 (49%) were responders at the last visit ( $\geq 50\%$  seizure reduction)
- Responder rates were similar in both pediatric and adult groups
- 18% withdrawal rate over 6-month study due to lack of efficacy or side effects
  - side effects - 4% (2 - diarrhea)
  - lack of efficacy – 14% (7)
- Two patients were seizure-free at the last assessment

In the Georgia study – 46 total pediatric patients (of which, 20 received at least 8-weeks treatment):

- 51% reduction in seizure frequency for all patients, 48% reduction in all types of major seizures (tonic, atonic, and generalized tonic clonic)
- 95% of patients experienced seizure frequency reduction from baseline
  - Statistical analyses were calculated for relevant median overall seizure frequency reduction from baseline
- Adverse events in 10% of patients that received at least 8-weeks treatment (n=2) included somnolence (n=1), ataxia (loss of full control of bodily movements; n=1), and vomiting (n=2). One patient withdrew primarily due to lack of efficacy. No related Serious Adverse Events (SAEs) were reported.

Overall, these results were consistent with overall results seen in the Epidiolex EAP.

#### *Intellectual Property*

In addition to orphan exclusivity, GW has been seeking to build exclusivity for Epidiolex through its patent portfolio. In 2015, GW was granted a patent from the U.S. Patent and Trademark Office protecting the use of CBD in the treatment of partial seizures, providing an exclusivity period until June 2030. In late 2015, GW also had a patent granted in the UK which claims the use of CBD in combination with certain standard anti-epileptic drugs in the treatment of epilepsy. Corresponding patent applications are being prosecuted in the U.S. and at the European Patent Office. Several additional CBD patent applications have also been filed.

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

GW is developing a second generation product candidate, GWP42006, which features the non-psychoactive cannabinoid CBDV as the primary cannabinoid. CBDV is distinct in chemical structure to CBD and has shown anti-seizure properties across a range of *in vitro* and *in vivo* models, demonstrating reduced seizures in animals consistent with anticonvulsant effects of cannabinoids reported in other models of acute seizure. GW has also evaluated CBDV in both general and syndromic pre-clinical models of autism spectrum disorders yielding promising signals on cognitive and social endpoints as well as repetitive behavior.

GW has completed a Phase 1 trial of GWP42006 by the oral and intravenous route in 66 healthy subjects. In this trial, GWP42006 was well tolerated even at the highest tested dose. There were no serious or severe adverse events, nor any withdrawals due to adverse events.

GW is pursuing multiple development programs for CBDV both within adult and childhood epilepsy and in childhood behavioral disorders.

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- In epilepsy, GW is recruiting a Phase 2 study of GWP42006. This is a double blind, randomized, placebo-controlled two-part study to investigate the pharmacokinetics, followed by efficacy and safety of GWP42006 as add-on therapy in patients with inadequately controlled focal seizures. The first part of this trial has completed enrollment of 30 patients and the dose-ranging pharmacokinetic and safety data has been reviewed by an independent panel. Following this review, the placebo-controlled safety and efficacy part of the study is now about to commence and is expected to recruit 100 patients. Data from this part of the study is expected in the first quarter of 2017.
- In October 2015, GW announced that it had signed a Memorandum of Understanding (MOU) with the Government of New South Wales (NSW) in Australia to progress a research program for Epidiolex and CBDV in children with severe, drug resistant childhood epilepsy. As part of this agreement, GW expects an additional trial of GWP42006 to commence in children with treatment-resistant epilepsy.
- GW is conducting pre-clinical research into CBDV within the field of autism spectrum disorders (ASD). Many of the pediatric intractable epilepsy conditions within the Epidiolex Expanded Access Program share considerable overlap with ASD and these conditions often fall within the orphan disease space. Initial clinical observations from treating physicians suggest a potential role for cannabinoids in addressing problems associated with ASD such as deficits in cognition, behavior and communication. GW is working with investigators and early open-label clinical experience is expected to commence in the second half of 2016, with Phase 2 placebo-controlled trials expected to commence in the first quarter of 2017.

#### *CBDV Intellectual Property Portfolio*

In 2015, GW was granted a patent from the U.S. Patent and Trademark Office protecting the use of CBDV in the treatment of patients with epilepsy, providing an exclusivity period until March 2031. Several additional CBDV patents have also been filed.

#### **Epidiolex Manufacturing & Production**

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

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## **U.S. Commercial Organization**

GW's US commercial organization is based in GW's office at Carlsbad, CA and led by Julian Gangolli, GW's President of North America. Mr. Gangolli joined GW in June 2015 from Allergan, where he had previously held the same position. With the successful results from the first Dravet syndrome Phase 3 trial, plans for the U.S. commercial organization are now accelerating. GW currently has an experienced U.S. commercial leadership team in place, including executives with significant epilepsy industry expertise. The Company expects to implement a "high efficiency" commercial deployment model expected to include a dedicated sales force of approximately 50 to 60 sales professionals targeting approximately 4,000-5,000 U.S. physicians. This commercial organization will be defined by a high-touch patient, payor and physician communication, education and distribution model.

GW believes that the U.S. physician awareness and enthusiasm for a new therapeutic alternative is high, and that, if approved, Epidiolex would represent an entirely new class of anti-convulsant with a potentially differentiated side-effect profile and mechanism of action. GW also believes that there exists a significant unmet medical need for a new prescription option as over 70% of child-onset epilepsy patients are, or become, treatment resistant over time. Additionally, side effects of current anti-epilepsy drugs are dose dependent and at high doses can cause patient non-compliance and high drop-rates. Discussions with U.S. managed care providers are taking place to develop an economic rationale relative to those current anti-epilepsy drugs.

## **Other Orphan/Neurology Pipeline Programs**

### *Neonatal Hypoxic-Ischemic Encephalopathy (NHIE)*

NHIE is acute or sub-acute brain injury resulting from deprivation of oxygen during birth (hypoxia). GW estimates 6,500 to 12,000 cases of NHIE occur in the U.S. each year. Of these, 35% are expected to die in early life and 30% are expected to develop persistent neurologic disability. There are currently no FDA-approved medicines specifically indicated for NHIE.

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

### *Glioma*

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

GW has completed recruitment of 27 patients into a placebo-controlled Phase 1b/2a trial in recurrent GBM. This study first evaluated the safety of CBD:THC taken in combination with dose-intense temozolomide, and then initiated a placebo-controlled phase. Data from this trial is expected in the fourth quarter of 2016.

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## **Other Pipeline Programs**

### *Sativex in Cancer Pain*

Sativex is an oromucosal spray consisting of a formulated extract of the cannabis sativa plant that contains the principal cannabinoids delta-9-tetrahydrocannabinol, or THC, and CBD. Otsuka Pharmaceutical Co. Ltd, hold exclusive rights to commercialize Sativex in the U.S.

In 2015, GW and Otsuka completed a Phase 3 program in cancer pain. Whilst Sativex did not meet the primary endpoint in these trials, a pre-specified subgroup analysis of U.S. patients across the Phase 3 trials showed a statistically significant improvement for Sativex compared to placebo (n=248, p=0.02). GW and Otsuka have consulted with the FDA and received feedback that this analysis of U.S. patients would not be deemed pivotal. GW and Otsuka will now meet to discuss whether there are any next steps for Sativex in the U.S. within the scope of this partnership.

### *Sativex in Spasticity*

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

Sativex is also undergoing a Phase 2, 72-patient placebo-controlled trial in children with spasticity due to cerebral palsy. Results from this trial are expected in the fourth quarter of 2016.

### *Type 2 Diabetes*

GW is testing its product candidate GWP42004 in the treatment of type 2 diabetes. GWP42004 is an orally administered product which features plant-derived tetrahydrocannabivarin (THCV) as its active ingredient. THCV is distinct from THC and does not share its intoxicating psychoactive effects. Pre-clinical models have shown evidence of pancreatic islet cell protection, and an earlier small scale proof of concept study have shown GWP42004 to have promising effects on glucose and insulin status in patients with type 2 diabetes. A Phase 2b study is now complete which compares the efficacy, safety and tolerability of three doses of GWP42004 with placebo in a total of 200 patients. Data from this study is expected late in the second quarter or early in the third quarter of 2016.

### *Schizophrenia*

GW's product candidate, an oral formulation of GWP42003 (CBD), has shown notable anti-psychotic effects in accepted pre-clinical models of schizophrenia and 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.

## **Pre-clinical developments**

In addition to GW's extensive in-house research organization, the Company has established a global network of leading scientists in the cannabinoid field including 36 academic institutions in 9 countries. GW's proprietary cannabinoid product platform allows the Company to discover, develop and commercialize additional novel first-in-class cannabinoid products across a broad range of therapeutic areas of unmet need including autism spectrum disorders, Duchenne muscular dystrophy, glioma, ovarian and pancreatic cancers.

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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 2016, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and six months ended 31 March 2016 have been translated into U.S. dollars at the rate on 31 March 2016 of \$1.4365 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 principal factors affecting GW's profitability and operating cash flow are the amount and timing of GW funded research and development expenditure, the rate of growth of Sativex product revenues, the amount of development and approval milestone receipts from the Company's commercial partners.

Expenditure on research and development activities is 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 type-2 diabetes. GW refers to this as "GW funded research and development expenditure."

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

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

Net foreign exchange gains primarily result from unrealized gains 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.

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## Results of Operations

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

#### *Revenue*

Total revenue for the three months to 31 March 2016 was £2.6 million, compared to £6.4 million for the three months ended 31 March 2015. This decrease of £3.8 million is due to a £3.8 million reduction in research and development fees to £1.3 million for the three months ended 31 March 2016 from £5.1 million for the three months ended 31 March 2015. This reflects the impact of the conclusion of the Group's partner funded Sativex Phase 3 cancer pain clinical trials. This revenue stream is expected to conclude by 30 September 2016.

Other revenue streams, individually, did not change by a material amount.

#### *Cost of sales*

Cost of sales for the three months ended 31 March 2016 of £0.5 million is £0.1 million lower than the £0.6 million recorded in the three months ended 31 March 2015 due to a reduction in Sativex unit costs during the period.

#### *Research and development expenditure*

Total research and development expenditure for the three months ended 31 March 2016 of £25.7 million increased by £10.3 million compared to the £15.4 million incurred in the three months ended 31 March 2015.

Partner funded research and development expenditure decreased by £3.8 million to £1.3 million for the three months ended 31 March 2016 from £5.1 million for the three months ended 31 March 2015. This decrease reflects the conclusion and close out of the Sativex Phase 3 cancer pain clinical trials.

GW funded research and development expenditure increased by £14.3 million to £24.5 million for the three months ended 31 March 2016 from £10.2 million for the three months ended 31 March 2015. The increase is due to:

- £6.2 million increase in epilepsy and other GW funded clinical program costs - reflecting the costs associated with GW's continuing Dravet and Lennox-Gastaut syndrome Epidiolex studies, setting up a new Phase 3 study in Tuberous Sclerosis, costs of our other pipeline studies and costs of providing regulatory support and Epidiolex under the increasing number of patients supplied via FDA-authorized expanded access INDs.
  - £6.1 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.
  - £1.4 million increase in other 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 transition of clinical staff to GW funded activities from partner funded Sativex trials.
  - £0.6 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program.
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### *Sales, general and administrative expenses*

Sales, general and administrative expenses for the three months ended 31 March 2016 of £3.2 million decreased by £0.6 million compared to the £3.8 million incurred in the three months ended 31 March 2015. This net decrease reflects:

- A £1.0 million decrease in respect of pre-launch commercialization costs in the U.S. These costs follow discreet commercialization projects and the timing of these is such that a decrease in costs is observed from the comparative quarter.
- A £0.8 million decrease in the charge in respect of the provision for payroll taxes on unrealized staff share option gains.
- A £0.7 million increase in payroll costs driven by increased headcount within the Group's growing commercial operations
- A £0.3 million increase in respect of increased accountancy, audit and investor relation costs arising from GW's U.S. listing and Sarbanes-Oxley compliance.
- A £0.2 million increase in respect of property and travel costs, primarily to the U.S. by staff involved in the establishment of U.S. based operations.

### *Net foreign exchange gains*

Net foreign exchange gains for the three months ended 31 March 2016 was a gain of £4.5 million, an increase of £0.4 million compared to the £4.1 million gain recorded for the three months ended 31 March 2015. In both periods the gain 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 31 March 2016. The Sterling to U.S. dollar exchange rate has moved from 1.4776 at 31 December 2015 to 1.4365 at 31 March 2016. Dollar denominated cash deposits totalled \$215.8 million at 31 March 2016 and \$243.9 million at 31 December 2015.

### *Taxation*

Our tax credit was £5.4 million for the three months ended 31 March 2016, which represents an increase of £3.6 million compared to a £1.8 million credit recorded in the three months ended 31 March 2015.

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, GW Pharmaceuticals Inc.

In the three months ended 31 March 2015, GW recorded a tax credit of £1.8 million made up of the recognition of an accrued £1.8 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 three months ended 31 March 2015.

### *Loss*

The Group reported a loss after tax for the three months ended 31 March 2016 of £16.8 million compared with a loss after tax for the three months ended 31 March 2015 of £7.5 million.

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## Results of Operations

### *Comparison of the six months ended 31 March 2016 and 31 March 2015*

#### *Revenue*

Total revenue for the six months to 31 March 2016 was £6.3 million, compared to £14.3 million for the six months ended 31 March 2015. This decrease of £8.0 million is due to an £8.0 million decrease in research and development fees to £3.5 million for the six months ended 31 March 2016 compared to £11.5 million for the six months ended 31 March 2015. This decrease primarily reflects the conclusion of partner funded Sativex Phase 3 cancer pain trials. This revenue stream is expected to conclude by 30 September 2016.

#### *Cost of sales*

Cost of sales for the six months ended 31 March 2016 of £1.2 million was consistent with the £1.2 million recorded in the six months ended 31 March 2015. Sativex volume growth was offset by volume related reduction in per unit cost.

#### *Research and development expenditure*

Total research and development expenditure for the six months ended 31 March 2016 of £49.9 million increased by £19.4 million compared to the £30.5 million incurred in the six months ended 31 March 2015.

Partner funded research and development expenditure decreased by £8.1 million to £3.5 million for the six months ended 31 March 2016 from £11.6 million for the six months ended 31 March 2015. This decrease reflects the conclusion and close out of the Sativex Phase 3 cancer pain clinical trials compared to the previous period.

GW funded research and development expenditure increased by £27.5 million to £46.4 million for the six months ended 31 March 2016 from £18.9 million for the six months ended 31 March 2015. The increase is due to:

- £13.7 million increase in epilepsy and other GW funded clinical program costs - reflecting the costs associated with GW's continuing Dravet and Lennox-Gastaut syndrome Epidiolex studies, setting up new Phase 3 studies, costs of our other pipeline studies and costs of providing regulatory support and Epidiolex to an increasing number of patients under FDA-authorized expanded access INDs.
- £9.0 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 Sativex trials to the GW funded Epidiolex development program.
- £3.3 million increase in other 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 refocussing of assets on GW funded activities from partner funded projects.
- £1.5 million increase in costs of growing an increased volume of high CBD plant material for the Epidiolex development program.

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

Sales, general and administrative expenses for the six months ended 31 March 2016 of £6.9 million increased by £2.3 million compared to the £4.6 million incurred in the three months ended 31 March 2015. This net increase reflects:

- £1.6 million increase in payroll costs driven by increased headcount as we progress recruitment of our U.S.-based commercial team
  - A £0.4 million increase in respect of property and travel costs, primarily to the U.S. by staff involved in the establishment of U.S. based operations.
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- A £0.3 million increase in respect of increased accountancy, audit and investor relation costs arising from GW's U.S. listing and Sarbanes-Oxley compliance.

#### *Net foreign exchange gains*

Net foreign exchange gains for the six months ended 31 March 2016 was a gain of £8.1 million, a decrease of £0.1 million compared to the £8.2 million gain recorded for the six months ended 31 March 2015. In both periods the gain 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 31 March. The Sterling to U.S. dollar exchange rate has moved from 1.5127 at 30 September 2015 to 1.4365 at 31 March 2016. Dollar denominated cash deposits totalled \$215.8 million at 31 March 2016 and \$274.9 million at 30 September 2015.

#### *Taxation*

Our tax credit was £8.9 million for the six months ended 31 March 2016, which represents an increase of £6.1 million compared to a £2.8 million credit recorded in the six months ended 31 March 2015.

In the six months ended 31 March 2016, GW recorded a tax credit 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, GW Pharmaceuticals Inc.

In the six months ended 31 March 2015, GW recorded a tax credit of £2.8 million made up of: (i) the recognition of an accrued £2.7 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 2015; (ii) the recognition of an additional £0.2 million of research and development tax credits in respect of the year ended 30 September 2014 in its principal research subsidiary, GW Research Limited, as part of the process for finalizing tax returns for that period and; (iii) recording of £0.1 million of deferred tax expense due to the fact that previously recognized losses have been utilized to offset profits earned in the six months ended 31 March 2015 by GW Pharma Limited.

#### *Loss*

The Group reported a loss after tax for the six months ended 31 March 2016 of £34.5 million compared with a loss after tax for the six months ended 31 March 2015 of £10.9 million.

### **Liquidity and Capital Resources**

#### *Cash Flow*

Net cash outflow from operating activities for the six months ended 31 March 2016 of £46.4 million was £32.1 million higher than the £14.3 million outflow from operating activities for the six months ended 31 March 2015, principally reflecting the increase in investment in Epidiolex and other pipeline research and development activities and the reduction in partner-funded research and development fee revenue from Otsuka.

Capital expenditure for the six months ended 31 March 2016 of £4.7 million, consisting primarily of ongoing upgrades to our cannabinoid extraction and Epidiolex manufacturing and growing facilities, was £5.5 million lower than the £10.2 million for the six months ended 31 March 2015 as the work approaches completion.

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Net cash flow from financing activities increased by £0.2 million to a £0.5 million inflow in the six months ended 31 March 2016 compared to a £0.3 million inflow for the six months ended 31 March 2015 due to an increase in proceeds on the exercise of employee share options.

As at 31 March 2016, GW had a closing cash position of £192.7 million compared to £234.9 million as at 30 September 2015.

#### *Property, plant and equipment*

Property, plant and equipment at 31 March 2016 increased by £5.7 million to £34.4 million from £28.7 million at 30 September 2015. This increase primarily reflects the upgrade and expansion of new cannabinoid extraction facilities and growing facilities for Epidiolex production.

#### *Inventories*

Inventories at 31 March 2016 decreased by £0.1 million to £4.7 million from £4.8 million at 30 September 2015. Inventories consist of finished goods, consumable items and work in progress and are stated net of a negligible realizable-value provision (30 September 2015: £0.1 million). During the six months ended 31 March 2016, the provision for inventories reduced by £0.1 million as a result of having utilized some of the Group's oldest work in progress in research and development.

#### *Trade receivables and other receivables*

Trade receivables and other receivables at 31 March 2016 increased by £0.5 million to £3.4 million from £2.9 million at 30 September 2015. This is due to an increase in Sativex shipments in March 2016 of £0.2 million, an increase in recoverable value added tax on expenditure of £0.2 million and a £0.1 million increase in prepaid rent as a result of the timing of rental invoices.

#### *Trade and other payables*

Current trade and other payables at 31 March 2016 increased by £5.6 million to £29.6 million from £24.0 million at 30 September 2015. This increase reflects a £5.6 million increase in trade payables and accruals as a result of the continued expansion of GW funded clinical trials and capital expenditure to grow the Group's manufacturing capability.

Non-current trade and other payables at 31 March 2016 increased by £0.3 million to £8.7 million from £8.4 million at 30 September 2015. This reflects a £0.3 million increase resulting from accrued interest on the finance facility provided by the Group's landlord for the cannabinoid extraction facility under construction during the period.

#### *Headcount*

Average headcount for the six months ended 31 March 2016 was 412 (31 March 2015: 320).

#### *Guidance*

Consistent with previous guidance, we expect capital expenditure associated with further expansion of our manufacturing and growing capacity of £13-15 million (\$20-23 million) for 2016. Having incurred capital expenditure in the first half of 2016 of £4.8 million (\$6.9 million) we now expect capital expenditure for the second half of 2016 in the range of £8-10 million (\$11-14 million).

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Having recorded a core cash outflow, before capital expenditure, of £37.4 million (\$53.7 million) for the first half of the year, we now expect a core operating cash outflow for the second half of the year to be in the range of £42-45 million (\$60-65 million).

## **RISKS AND UNCERTAINTIES**

A detailed analysis of the risks that the Group faces is set out in the Group's Annual Report on Form 20-F filed by the Company with the SEC on 7 December 2015. The following summary of key risks for the Group are as highlighted below:

### *Clinical*

- Clinical trials for our product candidates are expensive, time-consuming, uncertain and susceptible to change, delay or termination. Even if we completed Phase 3 clinical trials for a product candidate and these trials show positive results, there can be no assurance that a regulatory authority will approve that product candidate for any given indication.
- There is a high rate of failure for drug candidates proceeding through clinical trials. Until we obtain regulatory approval for a product other than Sativex, our future success will depend heavily on the continued successful commercialization of our only approved product, Sativex, which is currently being commercialized for MS spasticity outside the United States.
- Our expanded access studies are uncontrolled, carried out by individual physician investigators independent from GW, and not always conducted in strict compliance with Good Clinical Practices, all of which can lead to a treatment effect which may differ from one seen in placebo-controlled trials. Data from these studies provide only anecdotal evidence of efficacy for regulatory review, although they may provide supportive safety information for regulatory review. These studies contain no control or comparator group for reference and are not designed to be aggregated or reported as study results. Moreover, data from such small numbers of patients may be highly variable. Such information, including the statistical principles that the independent physician investigators have chosen to apply to the data, may not reliably predict data collected via systematic evaluation of the efficacy in company-sponsored clinical trials or evaluated via other statistical principles that may be applied in these trials. Reliance on such information may lead to Phase 2 and/or Phase 3 clinical trials that are not adequately designed to demonstrate efficacy and could delay or prevent GW's ability to seek approval of Epidiolex.

### *Regulatory & Legislative*

- Legislative or regulatory reform, including reform of the laws governing the use of marijuana for medicinal or recreational use, or of the health care system, in the United States and foreign jurisdictions may affect our ability to profitably sell our products, if approved.
- If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit the commercialization of our product candidates.
- Our ability to research, develop and commercialize our product candidates is dependent on our ability to maintain licenses relating to the cultivation, possession and supply of controlled substances.
- Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit our ability to sell Sativex and our product candidates.
- Epidiolex, Sativex and the other product candidates we are developing will be subject to controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition.

### *Orphan drug designation and intellectual property*

- In respect of our product candidates targeting rare indications, orphan drug exclusivity may afford limited protection, and if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our product candidates in those indications during that period of exclusivity. Even if we obtain orphan drug exclusivity for any of our product candidates this exclusivity may afford limited protection and may be lost if the FDA later determines that the request for designation was materially defective, or if we are unable to assure sufficient quantity of the drug. Further if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our product candidates in those indications during that period of exclusivity.
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- We may not be able to maintain and protect our proprietary technology and assets, which could impair our proprietary cannabinoid product platform and commercial opportunities and adversely affect our operating profits.
- If third parties claim that activities infringe upon their intellectual property, our operating profits could be adversely affected and/or we may be prevented from developing, manufacturing, importing, using or commercializing some or all of our products and product candidates in jurisdictions in which their intellectual property subsists.

#### *Manufacturing*

- Problems with scale up of our manufacturing process, failure to comply with manufacturing regulations or pass regulatory inspections, unexpected increases in our manufacturing costs, or delays in being able to ship product could harm our business, results of operations and financial condition; as could product recalls or inventory losses caused by unforeseen events, cold chain interruption and testing difficulties.

#### *Marketing and Commercialization*

- We are dependent on the success of our product candidates, none of which may receive regulatory approval or be successfully commercialized.
- Our product candidates, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue from new products.
- Counterfeit versions of our products could harm our business.
- As we market and commercialize our product candidates, our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- We expect to face intense competition, often from companies with greater resources and experience than we have.
- Sativex, Epidiolex and our other product candidates contain controlled substances, the use of which may generate public controversy around our business which could negatively impact the commercial success of any of our approved products or the future development of our product candidates.
- If the price for Sativex or any future approved products decreases or if governmental and other third-party payers do not provide adequate coverage and reimbursement levels our revenue and prospects for profitability will suffer.

#### *Safety*

- Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of our product candidates, or limit the scope of any approved label or market acceptance.

#### *Staffing and systems*

- We have recently grown our business and will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.
- As we continue to grow our business in terms of size and complexity we will need to adapt and change our internal controls and may identify material weaknesses in our internal control over financial reporting, which could result in our financial statements not being prepared properly.

#### *Funding*

- We have significant and increasing liquidity needs and may require additional funding.
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*Risk in Relation to the Use of Financial Instruments*

- The Group is exposed to a number of financial risks, including credit risk, liquidity risk, market price risk and exchange rate risk. It is the Group's policy that no speculative trading in financial instruments shall be undertaken, and as such the Group does not enter into contracts for complicated or compound financial instruments.

*Credit Risk*

- The Group's principal financial assets are cash and short-term cash equivalents. Risk is minimized through an investment policy restricting the investment of surplus cash to interest bearing deposits principally held with the major UK banking groups and with UK subsidiaries of banking groups with acceptable credit ratings.
- Trade receivables are concentrated to a small number of large customers with well-established relationships, where the risk and history of default is considered to be low.

*Liquidity Risk*

- This risk is minimized by placing surplus funds in a range of low risk cash deposits and short-term liquid investments for periods up to 90 days. This portfolio of deposits is managed to ensure that a rolling programme of maturity dates is managed in accordance with Group expenditure plans in order to ensure available liquid cash funds when required.

*Market Price Risk*

- Market price risk primarily comprises interest rate exposure risk, which is managed by maintaining a rolling programme of varying deposit maturity dates, up to a maximum of 90 days, on a breakable deposit basis. The majority of funds are deposited for terms of less than 90 days. This allows the Group to react to rate changes within a reasonable timeframe and to mitigate pricing risk accordingly.

*Exchange Rate Risk*

- The individual financial statements of each Group company are presented in the currency of the primary economic environment in which it operates (its functional currency). For the purpose of the consolidated financial statements, the results and financial position of each Group company are expressed in Pounds Sterling. However, during the year the Group had exposure to U.S. Dollars ("U.S.\$"), Euros ("€") and Canadian Dollars ("CAD"). The Group's policy is to maintain natural hedges, where possible, by matching revenue and receipts with expenditure. The Group continues to hold a large balance of U.S.\$, to match future anticipated U.S.\$ denominated expenditure on pre-launch activities and our clinical trials for Epidiolex.

*Overseas entity*

- As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and NASDAQ corporate governance rules and are permitted to file less information with the Securities and Exchange Commission than U.S. companies. This may limit the information available to holders of the ADSs.

GW continues to face a number of potential risks and uncertainties which could have a material impact on the Group's performance over the remaining six months of the financial year and could cause actual results to differ materially from expected and historical results.

The directors are satisfied that the Group has sufficient resources to continue in operation for the foreseeable future, a period of not less than 12 months from the date of this report. Accordingly, they continue to adopt the going concern basis in preparing the financial information for the three and six months ended 31 March 2016.

The directors do not consider that the principal risks and uncertainties have changed since the Annual Report on Form 20-F for the year ended 30 September 2015 was filed by the Group with the SEC on 7 December 2015.

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**Related party transactions**

The Group did not enter into any significant related party transactions during the period.

Justin Gover  
Chief Executive Officer

Adam George  
Chief Financial Officer



## **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 commercialized the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the United States. GW is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex® (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex. GW has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, type 2 diabetes, schizophrenia and epilepsy. For further information, please visit [www.gwpharm.com](http://www.gwpharm.com).*

## **Forward-looking statements**

*This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding financial performance, the timing of clinical trials, the 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. 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  
Condensed consolidated income statement  
Three months ended 31 March 2016

	Notes	Three months ended 31 March 2016 \$000's	Three months ended 31 March 2016 £000's	Three months ended 31 March 2015 £000's
<b>Revenue</b>	2	3,805	2,649	6,351
Cost of sales		(779)	(542)	(645)
Research and development expenditure	3	(36,988)	(25,749)	(15,362)
Sales, general and administrative expenses		(4,657)	(3,242)	(3,794)
Net foreign exchange gain		6,448	4,488	4,145
<b>Operating loss</b>		(32,171)	(22,396)	(9,305)
Interest income		188	131	71
Interest expense		(23)	(16)	(19)
<b>Loss before tax</b>		(32,006)	(22,281)	(9,253)
Tax benefit	4	7,827	5,449	1,754
<b>Loss for the period</b>		(24,179)	(16,832)	(7,499)
<b>Loss per share – basic and diluted</b>	5	(9.2c)	(6.4p)	(3.2p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss  
For the three months ended 31 March 2016

	Three months ended 31 March 2016 £000's	Three months ended 31 March 2015 £000's
<b>Loss for the period</b>	(16,832)	(7,499)
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange differences on retranslation of foreign operations	(46)	(30)
<b>Other comprehensive loss for the period</b>	(46)	(30)
<b>Total comprehensive loss for the period</b>	(16,878)	(7,529)



GW Pharmaceuticals plc  
Condensed consolidated income statement  
Six months ended 31 March 2016

	Notes	Six months ended 31 March 2016 \$000's	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
<b>Revenue</b>	2	9,073	<b>6,316</b>	14,317
Cost of sales		(1,765)	<b>(1,229)</b>	(1,214)
Research and development expenditure	3	(71,664)	<b>(49,888)</b>	(30,487)
Sales, general and administrative expenses		(9,864)	<b>(6,867)</b>	(4,597)
Net foreign exchange gain		11,618	<b>8,089</b>	8,179
<b>Operating loss</b>		(62,602)	<b>(43,579)</b>	(13,802)
Interest income		279	<b>194</b>	114
Interest expense		(50)	<b>(35)</b>	(39)
<b>Loss before tax</b>		(62,373)	<b>(43,420)</b>	(13,727)
Tax benefit	4	12,765	<b>8,886</b>	2,823
<b>Loss for the period</b>		(49,608)	<b>(34,534)</b>	(10,904)
<b>Loss per share – basic and diluted</b>	5	(18.9c)	<b>(13.2p)</b>	(4.6p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss  
For the six months ended 31 March 2016

	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
<b>Loss for the period</b>	<b>(34,534)</b>	(10,904)
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange differences on retranslation of foreign operations	<b>(99)</b>	(36)
<b>Other comprehensive loss for the period</b>	<b>(99)</b>	(36)
<b>Total comprehensive loss for the period</b>	<b>(34,633)</b>	(10,940)

GW Pharmaceuticals plc  
Condensed consolidated statement of changes in equity  
Six months ended 31 March 2016

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total £000's
<b>Balance at 1 October 2014</b>	237	220,551	19,260	(81,464)	158,584
Issue of share capital	-	59	-	-	59
Exercise of share options	-	379	-	-	379
Share-based payment transactions	-	-	-	806	806
Loss for the period	-	-	-	(10,904)	(10,904)
Other comprehensive loss	-	-	(36)	-	(36)
<b>Balance at 31 March 2015</b>	<b>237</b>	<b>220,989</b>	<b>19,224</b>	<b>(91,562)</b>	<b>148,888</b>
<b>Balance at 1 October 2015</b>	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)
<b>Balance at 31 March 2016</b>	<b>263</b>	<b>349,898</b>	<b>19,090</b>	<b>(154,821)</b>	<b>214,430</b>

GW Pharmaceuticals plc  
Condensed consolidated balance sheets  
As at 31 March 2016

	Notes	As at 31 March 2016 \$000's	As at 31 March 2016 £000's	As at 30 September 2015 £000's
<b>Non-current assets</b>				
Intangible assets - goodwill		7,484	5,210	5,210
Other intangible assets		418	291	245
Property, plant and equipment		49,439	34,416	28,733
Deferred tax asset	4	1,006	700	418
		<u>58,347</u>	<u>40,617</u>	<u>34,606</u>
<b>Current assets</b>				
Inventories	6	6,698	4,663	4,756
Taxation recoverable		31,415	21,869	12,641
Trade receivables and other assets	7	4,847	3,374	2,873
Cash and cash equivalents		276,791	192,684	234,872
		<u>319,751</u>	<u>222,590</u>	<u>255,142</u>
<b>Total assets</b>		<u>378,098</u>	<u>263,207</u>	<u>289,748</u>
<b>Current liabilities</b>				
Trade and other payables	8	(42,569)	(29,633)	(24,022)
Current tax liabilities		(122)	(85)	(366)
Obligations under finance leases	10	(164)	(114)	(111)
Deferred revenue	9	(3,792)	(2,640)	(3,269)
		<u>(46,647)</u>	<u>(32,472)</u>	<u>(27,768)</u>
<b>Non-current liabilities</b>				
Trade and other payables	8	(12,462)	(8,675)	(8,445)
Obligations under finance leases	10	(2,130)	(1,483)	(1,540)
Deferred revenue	9	(8,830)	(6,147)	(6,725)
<b>Total liabilities</b>		<u>(70,069)</u>	<u>(48,777)</u>	<u>(44,478)</u>
<b>Net assets</b>		<u>308,029</u>	<u>214,430</u>	<u>245,270</u>
<b>Equity</b>				
Share capital		378	263	261
Share premium account		502,628	349,898	349,275
Other reserves		27,423	19,090	19,189
Accumulated deficit		(222,400)	(154,821)	(123,455)
<b>Total equity</b>		<u>308,029</u>	<u>214,430</u>	<u>245,270</u>

GW Pharmaceuticals plc  
Condensed consolidated cash flow statements  
For the six months ended 31 March 2016

	Six months ended 31 March 2016 \$000's	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
<b>Loss for the period</b>	(49,608)	(34,534)	(10,904)
Adjustments for:			
Interest income	(279)	(194)	(114)
Interest expense	50	35	39
Tax benefit	(12,765)	(8,886)	(2,823)
Depreciation of property, plant and equipment	2,212	1,540	1,016
Amortisation of intangible assets	39	27	2
Net foreign exchange gains	(12,034)	(8,377)	(8,265)
(Decrease)/increase in provision for inventories	(66)	(45)	13
Loss on disposal of property, plant and equipment	-	-	1
Share-based payment charge	4,545	3,164	806
	(67,906)	(47,270)	(20,229)
Decrease in inventories	200	138	289
Increase in trade receivables and other assets	(715)	(498)	(904)
Increase in trade and other payables and deferred revenue	3,086	2,148	1,106
<b>Cash used in operations</b>	(65,335)	(45,482)	(19,738)
Income taxes paid	(1,284)	(894)	-
Research and development tax credits received	-	-	5,415
<b>Net cash outflow from operating activities</b>	(66,619)	(46,376)	(14,323)
<b>Investing activities</b>			
Interest received	267	186	113
Purchases of property, plant and equipment	(6,687)	(4,655)	(10,165)
Purchases of intangible assets	(214)	(149)	(59)
Proceeds from sales of property, plant and equipment	-	-	1
<b>Net cash outflow from investing activities</b>	(6,634)	(4,618)	(10,110)
<b>Financing activities</b>			
Proceeds on exercise of share options	898	625	379
Proceeds of new equity issue	-	-	59
Interest paid	(50)	(35)	(44)
Repayment of obligations under finance leases	(79)	(55)	(55)
<b>Net cash inflow from financing activities</b>	769	535	339
Effect of foreign exchange rate changes on cash and cash equivalents	11,881	8,271	8,235
<b>Net decrease in cash and cash equivalents</b>	(60,603)	(42,188)	(15,859)
Cash and cash equivalents at beginning of the period	337,394	234,872	164,491
<b>Cash and cash equivalents at end of the period</b>	276,791	192,684	148,632

## 1. Significant accounting policies

### Basis of preparation

These unaudited condensed consolidated interim financial statements for the three and six month periods ended 31 March 2016 and 31 March 2015 of GW Pharmaceuticals plc and subsidiaries (collectively, the "Group") have been prepared in accordance with International Accounting Standard 34 – "Interim Financial Reporting", as issued by the International Accounting Standards Board ("IASB") and as endorsed by the European Union. These statements were approved by the Board on 5 May 2016.

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 2015 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 2015 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.

The information for the period ended 30 September 2015 does not constitute statutory accounts as defined in section 434 of the Companies Act 2006.

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 2016, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and six months ended 31 March 2016 have been translated into U.S. dollars at the rate on 31 March 2016 of \$1.4365 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 2016 the Group had cash and cash equivalents of £192.7 million. The Directors have considered the financial position of the Group, its cash position and forecast cash flows for the 12-month period from the date of this report when considering going concern. They have also considered the Group's key risks and uncertainties affecting the likely development of the business. In the light of this review, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for at least a 12-month period from the date of this report. Accordingly, they continue to adopt the going concern basis in preparing these financial statements.

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## 2. Segmental Information

### *Operating Segments*

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

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

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

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

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**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 <sup>1</sup> £'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 and 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)
<b>Segmental result</b>	<b>838</b>	<b>(318)</b>	<b>(23,575)</b>	<b>(23,055)</b>	<b>(587)</b>	<b>(23,642)</b>
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						<b>(16,832)</b>

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

**Segmental revenues and results**

For the Three Months Ended 31 March 2015

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs <sup>1</sup> £'000	Consolidated £'000
Revenue:						
Product sales	870	-	-	870	-	870
Research and development fees	-	5,027	111	5,138	-	5,138
License, collaboration and technical access fees	343	-	-	343	-	343
<b>Total revenue</b>	<b>1,213</b>	<b>5,027</b>	<b>111</b>	<b>6,351</b>		<b>6,351</b>
Cost of sales	(645)	-	-	(645)	-	(645)
Research and development expenditure	(43)	(6,098)	(8,734)	(14,875)	(487)	(15,362)
<b>Segmental result</b>	<b>525</b>	<b>(1,071)</b>	<b>(8,623)</b>	<b>(9,169)</b>	<b>(487)</b>	<b>(9,656)</b>
Sales, general and administrative expenses						(3,794)
Net foreign exchange gain						4,145
Operating loss						(9,305)
Interest income						71
Interest expense						(19)
Loss before tax						(9,253)
Tax benefit						1,754
Loss for the period						<b>(7,499)</b>

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



**Segmental revenues and results**  
For the Six Months Ended 31 March 2016

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs <sup>1</sup> £'000	Consolidated £'000
<b>Revenue:</b>						
Product sales	2,197	-	-	2,197	-	2,197
Research and development fees	-	3,341	185	3,526	-	3,526
License, collaboration and technical access fees	593	-	-	593	-	593
<b>Total revenue</b>	<b>2,790</b>	<b>3,341</b>	<b>185</b>	<b>6,316</b>	<b>-</b>	<b>6,316</b>
Cost of sales	(1,229)	-	-	(1,229)	-	(1,229)
Research and development expenditure	-	(4,061)	(44,831)	(48,892)	(996)	(49,888)
<b>Segmental result</b>	<b>1,561</b>	<b>(720)</b>	<b>(44,646)</b>	<b>(43,805)</b>	<b>(996)</b>	<b>(44,801)</b>
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
<b>Loss for the period</b>						<b>(34,534)</b>

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

**Segmental revenues and results**  
For the Six Months Ended 31 March 2015

	Commercial £'000	Sativex R&D £'000	Pipeline R&D £'000	Total reportable segments £'000	Unallocated costs <sup>1</sup> £'000	Consolidated £'000
<b>Revenue:</b>						
Product sales	1,960	-	-	1,960	-	1,960
Research and development fees	-	11,319	234	11,553	-	11,553
License, collaboration and technical access fees	707	-	-	707	-	707
Development and approval milestones	97	-	-	97	-	97
Total revenue	2,764	11,319	234	14,317	-	14,317
Cost of sales	(1,214)	-	-	(1,214)	-	(1,214)
Research and development expenditure	(12)	(13,386)	(16,412)	(29,810)	(677)	(30,487)
<b>Segmental result</b>	<b>1,538</b>	<b>(2,067)</b>	<b>(16,178)</b>	<b>(16,707)</b>	<b>(677)</b>	<b>(17,384)</b>
Sales, general and administrative expenses						(4,597)
Net foreign exchange gain						8,179
Operating loss						(13,802)
Interest income						114
Interest expense						(39)
Loss before tax						(13,727)
Tax benefit						2,823
Loss for the period						<b>(10,904)</b>

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

## 2. Segmental Information (continued)

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

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Three months ended 31 March 2016	<b>70</b>	<b>1,181</b>	<b>88</b>	<b>1,339</b>
Three months ended 31 March 2015	70	5,027	115	5,212
Six months ended 31 March 2016	<b>140</b>	<b>3,341</b>	<b>185</b>	<b>3,666</b>
Six months ended 31 March 2015	140	11,319	237	11,696

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

	Commercial £'000	Sativex R&D £000's	Pipeline R&D £000's	Total £000's
Three months ended 31 March 2016	<b>843</b>	-	-	<b>843</b>
Three months ended 31 March 2015	584	-	-	584
Six months ended 31 March 2016	<b>1,786</b>	-	-	<b>1,786</b>
Six months ended 31 March 2015	1,449	-	-	1,449

### Geographical analysis of revenue by destination of customer

	Three months ended 31 March 2016 £000's	Three months ended 31 March 2015 £000's	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
UK	240	276	466	628
Europe (excluding UK)	908	667	1,880	1,623
United States	1,250	5,097	3,481	11,459
Canada	163	196	304	370
Asia	88	115	185	237
	<b>2,649</b>	<b>6,351</b>	<b>6,316</b>	<b>14,317</b>

### 3. Research and development expenditure

	<b>Three months ended 31 March 2016 £000's</b>	Three months ended 31 March 2015 £000's	<b>Six months ended 31 March 2016 £000's</b>	Six months ended 31 March 2015 £000's
GW funded research and development	24,480	10,224	46,362	18,934
Development partner funded research and development	1,269	5,138	3,526	11,553
<b>Total</b>	<b>25,749</b>	<b>15,362</b>	<b>49,888</b>	<b>30,487</b>

### 4. Tax benefit

	<b>Three months ended 31 March 2016 £000's</b>	Three months ended 31 March 2015 £000's	<b>Six months ended 31 March 2016 £000's</b>	Six months ended 31 March 2015 £000's
Current period research and development tax credit	(4,946)	(1,801)	(8,586)	(2,727)
Adjustments in respect of prior year tax credit	(640)	-	(591)	(165)
Current period utilization of deferred tax assets	-	47	-	69
Current period tax charge	137	-	291	-
<b>Total credit for the period</b>	<b>(5,449)</b>	<b>(1,754)</b>	<b>(8,886)</b>	<b>(2,823)</b>

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 2016 and 2015, the Group recognized the full 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.

## 5. Loss per share

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

	<b>Three months ended 31 March 2016</b>	Three months ended 31 March 2015	<b>Six months ended 31 March 2016</b>	Six months ended 31 March 2015
	<b>£000's</b>	£000's	<b>£000's</b>	£000's
Loss for the period	<b>(16,832)</b>	(7,499)	<b>(34,534)</b>	(10,904)
		Number of shares		
	<b>Three months ended 31 March 2016</b>	Three months ended 31 March 2015	<b>Six months ended 31 March 2016</b>	Six months ended 31 March 2015
	<b>Million</b>	Million	<b>Million</b>	Million
Weighted average number of ordinary shares	<b>262.6</b>	237.1	<b>262.0</b>	236.9
Less: ESOP trust ordinary shares <sup>(1)</sup>	-	-	-	-
Weighted average number of ordinary shares for purposes of basic earnings per share	<b>262.6</b>	237.1	<b>262.0</b>	236.9
Effect of potentially dilutive shares arising from share options and warrants <sup>(2)</sup>	-	-	-	-
Weighted average number of ordinary shares for purposes of diluted earnings per share	<b>262.6</b>	237.1	262.0	236.9
Loss per share—basic	<b>(6.4p)</b>	(3.2p)	<b>(13.2p)</b>	(4.6p)
Loss per share—diluted	<b>(6.4p)</b>	(3.2p)	<b>(13.2p)</b>	(4.6p)

- (1) As at 31 March 2016, 33,054 ordinary shares (31 March 2015: 34,706 ordinary shares) were held in the ESOP trust. The financial effect is less than £0.1 million for each of the three and six month periods ended 31 March, and consequently these have not been presented above.
- (2) The impact of 5.5 million and 5.8 million antidilutive share options have been excluded from the diluted loss per share calculation for the three and six months ended 31 March 2016 (7.7 million and 7.6 million antidilutive share options for the three and six months ended 31 March 2015).

**6. Inventories**

	<b>31 March</b>	30 September
	<b>2016</b>	2015
	<b>£000's</b>	£000's
Raw materials	<b>290</b>	317
Work in progress	<b>3,615</b>	3,686
Finished goods	<b>758</b>	753
	<b>4,663</b>	4,756

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

	<b>£000's</b>
Opening balance – as at 1 October 2015	<b>66</b>
Write-down of inventories	<b>9</b>
Write off of inventories included in the provision	<b>(19)</b>
Reversal of write-down of inventories	<b>(54)</b>
<b>Closing balance as at 31 March 2016</b>	<b>2</b>

	<b>£000's</b>
Opening balance – as at 1 October 2014	<b>351</b>
Write-down of inventories	<b>79</b>
Write off of inventories included in the provision	<b>(298)</b>
Reversal of write-down of inventories	<b>(66)</b>
<b>Closing balance as at 31 March 2015</b>	<b>66</b>

The reversal of write-down of inventories in the six months to 31 March 2015 was as a result of an increased level of production, reducing the level of work in progress expected to expire before use.

The reversal of write-down of inventories in the six months to 31 March 2016 was as a result of updated forecasts that indicate materials previously allocated to research and development activities are now expected to be utilized in commercial activities.

Inventories with a carrying value of £3.3 million are considered to be recoverable after more than one year from the condensed consolidated balance sheet date, but within the Group's normal operating cycle (30 September 2015: £2.7 million).

**7. Trade receivables and other assets**

	<b>31 March</b>	30 September
	<b>2016</b>	2015
	<b>£000's</b>	£000's
<b>Amounts falling due within one year</b>		
Trade receivables	493	373
Other receivables	1,249	956
Prepayments and accrued income	1,632	1,544
	<b>3,374</b>	<b>2,873</b>

**8. Trade and other payables**

	<b>31 March</b>	30 September
	<b>2016</b>	2015
	<b>£000's</b>	£000's
<b>Amounts falling due within one year</b>		
Other creditors and accruals	12,580	10,714
Clinical trial accruals	10,148	8,374
Trade payables	5,826	3,795
Fit out funding	434	348
Other taxation and social security	645	791
	<b>29,633</b>	<b>24,022</b>
<b>Amounts falling due after one year</b>		
Fit out funding	8,675	8,445
	<b>38,308</b>	<b>32,467</b>

Fit out funding represents £9.1 million (30 September 2015: £8.8 million) owed to the Group's landlord reflecting the liability to repay the £7.8 million of fit out funding received to fund the expansion and upgrades to manufacturing facilities and associated accrued interest of £1.3 million (30 September 2015: £1.0 million). This is expected to be repaid upon the completion of construction, currently expected to be during the third quarter of the year ending 30 September 2016, over a 15-year term. The Group has estimated that £0.4 million (30 September 2015: £0.4 million) will be due within one year and the remaining £8.7 million (30 September 2015: £8.4 million) is due after one year.

## 9. Deferred revenue

	<b>31 March</b>	30 September
	<b>2016</b>	2015
	<b>£000's</b>	£000's
<b>Amounts falling due within one year</b>		
Deferred license, collaboration and technical access fee income	1,245	1,260
Advance research and development fees	1,395	2,009
	<u>2,640</u>	<u>3,269</u>
<b>Amounts falling due after one year</b>		
Deferred license, collaboration and technical access fee income	6,147	6,725

Deferred revenues result mainly from the unamortized portion of up-front license fees received in 2005 of £12.0 million from Almirall S.A. and collaboration and technical access fees from other Sativex licensees.

Advance research and development fees represent amounts received from Otsuka for activities to be carried out on behalf of Otsuka. These amounts will be recognized as revenue in future periods as the services are rendered.

## 10. Amounts payable under finance leases

	<b>Minimum lease payments</b>	
	<b>31 March</b>	30 September
	<b>2016</b>	2015
	<b>£000's</b>	£000's
<b>Amounts payable under finance leases:</b>		
Within one year	176	176
In the second to fifth years inclusive	703	703
After five years	1,119	1,206
	<u>1,998</u>	<u>2,085</u>
Less: future finance charges	(401)	(434)
Present value of lease obligations	<u>1,597</u>	<u>1,651</u>

	<b>Present value of minimum lease payments</b>	
	<b>31 March</b>	30 September
	<b>2016</b>	2015
	<b>£000's</b>	£000's
<b>Amounts payable under finance leases:</b>		
Amounts due for settlement within 12 months	114	111
Amounts due for settlement after 12 months	1,483	1,540
	<u>1,597</u>	<u>1,651</u>

At as 31 March 2016, the weighted average lease term remaining is 11.6 years (30 September 2015: 12.1 years). All lease obligations are denominated in sterling.



#### **11. Contingent liabilities**

As at 31 March 2016 certain fees associated with ongoing capital expenditure have been estimated. The final fees payable are expected to be agreed and paid when construction is completed, scheduled for the third quarter of the year ending 30 September 2016. The Group estimates that there is a possible contingent liability for incremental fees of up to £0.4 million (30 September 2015: £0.4 million) of capital expenditure.

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