

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 December, 2015

Commission File Number: 001-35892

GW PHARMACEUTICALS PLC

(Translation of registrant's name into English)

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

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

Form 20-F Form 40-F

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

Yes No

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

Yes No

Other Events

On December 24, 2015, GW Pharmaceuticals plc (the “Company”), issued a press release announcing that Epidiolex® (cannabidiol or CBD) data from the physician-led expanded access program in treatment-resistant epilepsy were published in *The Lancet Neurology*¹. The published paper reported that Epidiolex reduced seizure frequency across multiple drug-resistant epilepsy syndromes and seizure types and was generally well tolerated. The authors note that the administration of Epidiolex as an add-on treatment led to a clinically meaningful reduction in seizure frequency in many patients and had an adequate safety profile in this patient population with highly treatment-resistant epilepsies. The safety and tolerability profile of Epidiolex was favorable with only 3 percent of patients terminating therapy due to an adverse event. The authors noted that without a control group, the results regarding efficacy and safety should be interpreted cautiously. The *Lancet Neurology* paper provides a more expansive description of data previously presented at the American Academy of Neurology Annual Meeting in April 2015. Since that time, additional expanded access data, encompassing almost twice the number of patients, were presented as a late-breaking poster at the American Epilepsy Society Annual Meeting earlier this month². The press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.

Exhibits

99.1 Press release dated December 24, 2015

¹ Devinsky et al., Cannabidiol in Patients with Treatment Resistant Epilepsy: an open-label interventional trial, *Lancet Neurology* December 23, 2015.

² Devinsky et al, Epidiolex (Cannabidiol) in Treatment Resistant Epilepsy, American Epilepsy Society Annual Meeting, Poster, December 7, 2015.

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: December 28, 2015



The Lancet Neurology Publishes Data from the Epidiolex® Expanded Access Program in Children and Young Adults with Treatment-Resistant Epilepsy

London, UK; 24 December 2015: 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, today announced that Epidiolex® (cannabidiol or CBD) data from the physician-led expanded access program in treatment-resistant epilepsy were published in *The Lancet Neurology*¹.

The paper reports that patients taking Epidiolex showed reductions in seizure frequency across multiple drug-resistant epilepsy syndromes and seizure types and was generally well tolerated. The authors note that the administration of Epidiolex as an add-on treatment led to a clinically meaningful reduction in seizure frequency in many patients and had an adequate safety profile in this patient population with highly treatment-resistant epilepsies. The safety and tolerability profile of Epidiolex was favorable with only 3 percent of patients terminating therapy due to an adverse event. The authors note that without a control group, the results regarding efficacy and safety should be interpreted cautiously.

“We are pleased that *The Lancet Neurology* has chosen to report these promising data on a significant number of patients with very challenging forms of epilepsy,” said lead author Orrin Devinsky, M.D., of New York University Langone Medical Center’s Comprehensive Epilepsy Center. “These data reinforce and support the safety and efficacy we have shared in previous studies. Most importantly it is providing hope to the children and their families who have been living with debilitating seizures. Further study is needed before results can be confirmed and randomized controlled studies are now underway to help us better understand the effectiveness of the drug. We very much look forward to the results from these studies in 2016.”

The expanded access program is a non-placebo controlled “compassionate access” program carried out by individual investigators independent from GW. Patients enrolled in the expanded access program were some of the most treatment-resistant patients being treated at each of the epilepsy centers. Prior to participating in the expanded access program, many of these patients failed to achieve seizure control despite treatment with antiepileptic drugs, dietary therapies, surgical therapies, and vagus nerve stimulation. The median number of concomitant antiepileptic drugs at the start of the trial was three. Data in the paper is from 11 independent epilepsy centers in the U.S. 162 patients who had at least 12 weeks of follow-up after the first dose of cannabidiol were included in the safety and tolerability analysis, and 137 patients were included in the efficacy analysis. Of these 162 patients, there were 33 patients with Dravet syndrome and 31 patients with LGS. Dravet syndrome and LGS are two rare, extremely debilitating epilepsy syndromes that begin in infancy or early childhood. Ninety percent or more of people with Dravet Syndrome and LGS are considered treatment resistant.

The Lancet Neurology paper provides a more expansive description of data previously presented at the American Academy of Neurology Annual Meeting in April 2015. Since that time, additional expanded access data, encompassing almost twice the number of patients, was presented as a late-breaking poster at the American Epilepsy Society Annual Meeting earlier this month².

“We are pleased that these Epidiolex data were selected for publication in *The Lancet Neurology*. The treatment effect seen in this open label study of Epidiolex in our initial target indications of Dravet syndrome and Lennox-Gastaut syndrome shows consistency with other data disclosures, and also demonstrates the effect of Epidiolex across multiple drug-resistant epilepsy syndromes and seizure types,” stated Justin Gover, GW’s Chief Executive Officer. “GW’s Phase 3 pivotal safety and efficacy studies in Dravet syndrome and Lennox Gastaut Syndrome are now nearing completion and will provide the placebo-controlled efficacy and safety profile that patients and physicians have been calling for. We look forward to these results in 2016.”

Treatment effect data analysis used in this publication mainly focuses on monthly seizure frequency calculated over the entire 12-week treatment period (including a 4-week dose titration period) compared to monthly seizure frequency during a 4-week baseline observation period. This calculation is similar to the approach being utilized in calculating the U.S. Food and Drug Administration’s (FDA) recommended primary efficacy endpoint in GW’s Phase 3 pivotal trials, which compares percent change in the monthly seizure frequency over the entire 14-week treatment period (including a 2-week dose titration period) to monthly seizure frequency during the 4-week baseline observation period.

Highlights from the publication of particular relevance to GW’s pivotal trials program in Dravet syndrome and LGS include:

- Dravet syndrome: median reduction in monthly motor (i.e. convulsive) seizures was 49.8% (n=32). 50% of Dravet syndrome patients had a 50% or greater reduction in monthly motor seizures. During the last 4 weeks of therapy, 13% (n=4) were free of motor seizures; these patients were also free of all other seizure types. In Dravet syndrome patients who experienced them at baseline, there was a median 69.2% reduction in monthly tonic seizures (n=6), 46.7% reduction in monthly tonic-clonic seizures (n=29), and 83.3% reduction in non-motor focal seizures (n=10).
 - LGS: median 68.8% reduction in average monthly atonic seizures (n=14). During the last 4 weeks of therapy, 21% (n=3) were atonic seizure free and 3% (n=1) were totally seizure free. In LGS patients who experienced them at baseline, there was a median 36.8% reduction in motor seizures (n=30) and 44% reduction in tonic seizures (n=21).
 - Adverse events occurred in 79% of all patients treated with cannabidiol (n=162). Adverse events reported in greater than 10% of patients were somnolence (25%), decreased appetite (19%), diarrhea (19%), fatigue (13%) and convulsion (11%). Most adverse events were mild or moderate and transient. Five patients (3%) discontinued treatment due to an adverse event.
 - Serious adverse events were reported in 48 patients (30%), including one death, regarded as unrelated to CBD. Serious adverse events which were deemed possibly related to CBD occurred in 20 patients.
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GW Pivotal Trials Program

GW is conducting two Phase 3 trials in Dravet syndrome and two Phase 3 trials in LGS. GW also expects to commence Phase 3 clinical development of Epidiolex in Tuberous Sclerosis Complex (TSC) in early 2016.

For Dravet syndrome, GW expects to report top-line results from the Phase 2/3 pivotal safety and efficacy study in the first quarter of 2016 and results from the second Phase 3 trial around mid-2016. The primary measure of efficacy in both trials will be 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 compared with the 4 week baseline observation period.

For LGS, GW expects to report top-line results from both Phase 3 trials in the second quarter of 2016. 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 compared with the 4 week baseline observation period.

The use of either "mean" or "median" analyses is determined during a blinded analysis of the data – the mean is employed if the data are parametric and the median is employed if the data are non-parametric (which is the case for the expanded access program and has historically been the case in many pediatric epilepsy trials).

Reference:

1. Devinsky et al., Cannabidiol in Patients with Treatment Resistant Epilepsy: an open-label interventional trial, Lancet Neurology December 23, 2015
2. Devinsky et al, Epidiolex (Cannabidiol) in Treatment Resistant Epilepsy, American Epilepsy Society Annual Meeting, Poster, December 7, 2015

Note Regarding Expanded Access Studies

The expanded access studies we currently support are uncontrolled, carried out by individual investigators independent from us, and not typically conducted in strict compliance with Good Clinical Practices, all of which can lead to a treatment effect which may differ from that in placebo-controlled trials. These studies provide only anecdotal evidence of efficacy for regulatory review. These studies contain no control or comparator group for reference and these patient data are not designed to be aggregated or reported as study results. Moreover, data from such small numbers of patients may be highly variable. Information obtained from these studies, including the statistical principles that the independent 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 those trials. Reliance on such information to design our clinical trials may lead to Phase 2 and 3 trials that are not adequately designed to demonstrate efficacy and could delay or prevent our ability to seek approval of Epidiolex. Expanded access programs provide supportive safety information for regulatory review. Physicians conducting these studies may use Epidiolex in a manner inconsistent with the protocol, including in children with conditions beyond those being studied in GW-sponsored trials. Any adverse events or reactions experienced by subjects in the expanded access program may be attributed to Epidiolex and may limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

Forward-looking statements

This news release may contain forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding the therapeutic benefit, safety profile and commercial value of the company's investigational drug Epidiolex®, the development and commercialization of Epidiolex, plans and objectives for product development, plans and objectives for present and future clinical trials and results of such trials, plans and objectives for regulatory approval. 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 the 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, uncertainties and other risks 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.

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 and Lennox-Gastaut syndrome and which is also expected to enter Phase 3 clinical trials in the treatment of Tuberous Sclerosis Complex. GW has a deep pipeline of additional cannabinoid product candidates which includes Sativex in Phase 3 clinical development as a potential treatment of pain associated with advanced cancer, as well as compounds in Phase 1 and 2 trials for glioma, type 2 diabetes, and schizophrenia. For further information, please visit www.gwpharm.com.

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