

# GW PHARMACEUTICALS PLC

## **FORM 6-K** (Report of Foreign Issuer)

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Industry	Biotechnology & Medical Research
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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**Form 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Month of November, 2017**

**Commission File Number: 001-35892**

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

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

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

Form 20-F  Form 40-F

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

Yes  No

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

Yes  No

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## **Other Events**

On October 30, 2017, GW Pharmaceuticals plc (the “Company”) issued a press release announcing that the Company and its U.S. subsidiary, Greenwich Biosciences, completed the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Epidiolex<sup>®</sup> (cannabidiol) as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome, two highly treatment-resistant forms of childhood-onset epilepsy. The press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein. The information in the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

## **Exhibits**

[99.1 Press release dated October 30, 2017](#)

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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: Company Secretary

Date: November 1, 2017

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**GW Pharmaceuticals and Its U.S. Subsidiary Greenwich Biosciences Completes Rolling New Drug Application Submission to U.S. Food and Drug Administration for Epidiolex<sup>®</sup> (cannabidiol) in the treatment of Lennox-Gastaut syndrome and Dravet syndrome**

**London, UK and Carlsbad, CA, 30 Oct 2017:** GW Pharmaceuticals plc (Nasdaq: GWPH, “GW” or “the Company”), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, along with its U.S. subsidiary Greenwich Biosciences, today announced it has completed the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Epidiolex<sup>®</sup> (cannabidiol) as adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome, two highly treatment-resistant forms of childhood-onset epilepsy.

GW has received Rare Pediatric Disease and Orphan Drug Designations from the FDA for Epidiolex in the treatment of both LGS and Dravet syndrome. Additionally, GW has received Fast Track Designation from the FDA for Epidiolex for the treatment of Dravet syndrome.

"The submission of the Epidiolex NDA is an important milestone for patients with LGS and Dravet syndrome in that a potential new treatment option is within sight for these very difficult to treat and devastating conditions," stated Justin Gover, CEO of GW Pharmaceuticals. "On behalf of all those patients, clinicians and GW employees who have supported the Epidiolex program, we are pleased to submit this promising therapy for FDA review and we look forward to working with the FDA throughout the review process. This regulatory submission is a demonstration of GW's commitment to developing innovative cannabinoid-based treatments that have the potential to address significant unmet medical needs."

The NDA for Epidiolex is supported by data from three Phase 3 safety and efficacy studies, each of which met their primary endpoint. Epidiolex was generally well tolerated in these trials. The NDA includes safety data on approximately 1,500 patients, with approximately 400 patients on continuous therapy for more than one year. Beyond pivotal safety and efficacy data, the NDA includes a comprehensive clinical pharmacology, pre-clinical and toxicology package. The CMC section of the NDA incorporates the Company's recently expanded UK manufacturing facilities.

The Company plans to file a Marketing Authorization Application (MAA) in Europe for Epidiolex in the near future.

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## **About Lennox-Gastaut Syndrome**

The onset of LGS typically occurs between ages of 3 to 5 years and can be caused by a number of conditions, including brain malformations, severe head injuries, central nervous system infections, and genetic neuro-degenerative or metabolic conditions. In up to 30 percent of patients, no cause can be found. Patients with LGS commonly have multiple seizure types including drop and convulsive seizures, which frequently lead to falls and injuries, and non-convulsive seizures. Resistance to anti-epileptic drugs (AEDs) is common in patients with LGS. Most children with LGS experience some degree of intellectual impairment, as well as developmental delays and aberrant behaviors.

## **About Dravet Syndrome**

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic encephalopathy frequently associated with genetic mutations in the SCN1A sodium channels. Onset of Dravet syndrome occurs typically during the first year of life in previously healthy and developmentally normal infants. Initial seizures are often body temperature related, severe, and long-lasting. Over time, patients with Dravet syndrome often develop multiple types of seizures, including tonic-clonic, myoclonic, and atypical absences and are prone to bouts of prolonged seizures including status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden unexpected death in epilepsy) is elevated in patients with Dravet syndrome. Additionally, the majority will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care. There are currently no FDA-approved treatments and nearly all patients continue to experience seizures and other medical needs throughout their lifetime.

## **About Epidiolex<sup>®</sup> (cannabidiol)**

Epidiolex, GW's lead cannabinoid product candidate is a pharmaceutical formulation of purified cannabidiol (CBD), which is in development for the treatment of several rare childhood-onset epilepsy disorders. GW has submitted a New Drug Application with the FDA for Epidiolex as adjunctive treatment for seizures associated with LGS and Dravet syndrome with an expected approval and launch in 2018. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex for the treatment of Dravet syndrome, LGS, TSC and IS. Additionally, GW has received Fast Track Designation from the FDA for the treatment of Dravet syndrome and conditional grant of rare pediatric disease designation by FDA. The Company has also received Orphan Designation from the European Medicines Agency, or EMA, for Epidiolex for the treatment of LGS and Dravet syndrome. GW is currently evaluating additional clinical development programs in other orphan seizure disorders including Phase 3 trials in Tuberous Sclerosis Complex and Infantile Spasms.

## **About GW Pharmaceuticals plc and Greenwich Biosciences**

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW, along with its U.S. subsidiary Greenwich Biosciences, is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex (cannabidiol), for which GW has submitted an NDA to the FDA for the adjunctive treatment of LGS and Dravet syndrome. The Company continues to evaluate Epidiolex in additional epilepsy conditions and currently has ongoing clinical trials in Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup> (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in 30 countries outside the United States. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioblastoma, 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 timing and outcomes of regulatory or intellectual property decisions, the relevance of GW products commercially available and in development, the clinical benefits of Epidiolex<sup>®</sup> (cannabidiol) and the safety profile and commercial potential of 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 and uncertainties related to the regulatory process, and the acceptance of Sativex, Epidiolex and other products by consumer and medical professionals. A further list and description of risks and uncertainties associated with an investment in GW can be found in GW's filings with the U.S. Securities and Exchange Commission, including the most recent Form 20-F filed on 5 December 2016. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. GW undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

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**Enquiries:**

**GW Pharmaceuticals plc**

Stephen Schultz, VP Investor Relations (U.S.)

917 280 2424 / 401 500 6570

**U.S. Media Enquiries:**

**Sam Brown Inc. Healthcare Communications**

Christy Curran

615 414 8668

Mike Beyer

312 961 2502

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