

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 June, 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 June 21, 2016, GW Pharmaceuticals plc (the “Company”) announced that it has selected infantile spasms (IS) as the fourth target indication for its Epidiolex orphan pediatric epilepsy development program and that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for Epidiolex (cannabidiol or CBD) for the treatment of IS. The Company expects to commence a two-part pivotal Phase 3 study in the fourth quarter of 2016. 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 June 21, 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: June 21, 2016

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**GW Pharmaceuticals Announces New Planned Epidiolex (Cannabidiol or CBD)  
Development Program in Infantile Spasms (IS)  
- Orphan Drug Designation Granted from FDA for Epidiolex for the Treatment of IS –  
- Phase 3 Trial Expected to Commence in Q4 2016 -**

**London, UK, 21 June 2016:** GW Pharmaceuticals plc (Nasdaq: GWPH, AIM: GWP, “GW” or “the Company”), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, today announced that the Company has selected infantile spasms (IS) as the fourth target indication for its Epidiolex orphan pediatric epilepsy development program. In addition, the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for Epidiolex (cannabidiol or CBD) for the treatment of IS. GW expects to commence a two-part pivotal Phase 3 study in the fourth quarter of 2016.

Epidiolex is already being developed in three other orphan indications within the field of pediatric epilepsy – Dravet syndrome, Lennox-Gastaut syndrome (LGS) and Tuberous Sclerosis Complex (TSC). In March 2016, GW announced positive results from the first Phase 3 trial in Dravet syndrome. Results of the first Phase 3 trial in LGS are expected in June 2016.

“We are pleased to add infantile spasms as a fourth target indication for Epidiolex, demonstrating GW’s ongoing commitment to addressing the significant unmet medical need within the field of pediatric epilepsy,” stated Justin Gover, CEO of GW Pharmaceuticals. “Currently, there are limited treatment options for children suffering from infantile spasms and outcomes for patients with the disorder include higher mortality, ongoing development of additional seizure disorders as the patient matures, and often severe cognitive and developmental delay.”

An infantile spasm is a specific type of seizure seen in an epilepsy syndrome of infancy and childhood known as West Syndrome. The onset of infantile spasms usually occur in the first year of life, typically between 4-8 months of age. The condition constitutes 2 percent of childhood epilepsies and 25 percent of epilepsies with onset in the first year of life. There are approximately 2,000 to 4,000 new cases in the United States each year. The long-term overall prognosis for patients with infantile spasms is poor. Cognitive and developmental delay is severe in 70 percent of patients, often with psychiatric problems such as autistic features or hyperactivity. It has been found that 50-70 percent of patients develop other seizure types and that 18 to 50 percent will develop Lennox-Gastaut syndrome or some other form of symptomatic generalized epilepsy.

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## About Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition - generally a disease or condition that affects fewer than 200,000 individuals in the U.S. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is typically entitled to a seven-year exclusive marketing period for that drug and use except under a few exceptions.

## About Infantile Spasms

According to the National Institute of Neurological Disorders and Stroke, an infantile spasm (IS) is a specific type of seizure seen in an epilepsy syndrome of infancy and childhood known as West Syndrome. West Syndrome is characterized by infantile spasms, developmental regression, and a specific pattern on electroencephalography (EEG) testing called hypsarrhythmia (chaotic brain waves). The onset of infantile spasms is usually in the first year of life, typically between 4-8 months of age. The seizures primarily consist of a sudden bending forward of the body with stiffening of the arms and legs; some children arch their backs as they extend their arms and legs. Spasms tend to occur upon awakening or after feeding, and often occur in clusters of up to 100 spasms at a time. Infants may have dozens of clusters and several hundred spasms per day. Infantile spasms usually stop by age five, but may be replaced by other seizure types. Many underlying disorders, such as birth injury, metabolic disorders, and genetic disorders can give rise to spasms, making it important to identify the underlying cause. In some children, no cause can be found.

## About Epidiolex

Epidiolex, GW's lead cannabinoid product candidate, is an oral solution of pure plant-derived CBD, which is in development for the treatment of a number of rare pediatric epilepsy disorders. GW has conducted extensive pre-clinical research of CBD in epilepsy since 2007. This research has shown that CBD has significant anti-epileptiform and anticonvulsant activity using a variety of *in vitro* and *in vivo* models and reduced seizures in acute animal models of epilepsy with significantly fewer side effects than comparator anti-epileptic drugs. To date, GW has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for Epidiolex in the treatment of Dravet syndrome, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex. Additionally, GW has received Fast Track Designation from the FDA and Orphan Designation from the European Medicines Agency for Epidiolex for the treatment of Dravet syndrome. GW is currently evaluating additional clinical development programs in other orphan pediatric seizure disorders.

## About GW Pharmaceuticals plc

Founded in 1998, GW is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. GW is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex® (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex. GW previously 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 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).

To obtain information about this clinical trial or eligibility criteria, the treating physician should contact: [medicaldirector@gwpharm.com](mailto:medicaldirector@gwpharm.com)

## References:

- 1: <http://www.ninds.nih.gov/disorders/infantilepasms/infantilepasms.htm>
  - 2: <http://emedicine.medscape.com/article/1176431-overview>
  - 3: <http://infantilepasmsproject.org/>
  - 4: <http://www.epilepsy.com/learn/types-epilepsy-syndromes/infantile-spasms-vests-syndrome>
  - 5: <http://misc.medscape.com/pi/iphone/medscapeapp/html/A1176431-business.html>
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**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 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.*

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