
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
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the Month of September, 2018

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):

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):

Other Events

On September 27, 2018, GW Pharmaceuticals plc along with its U.S. subsidiary, Greenwich Biosciences, announced that EPIDIOLEX[®] (cannabidiol) oral solution has been transferred to Schedule V, the lowest restriction classification, by the U.S. Drug Enforcement Administration. The press release is attached as Exhibit 99.1 hereto and is hereby 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, or incorporated by reference in any filing under the Securities Act of 1933, as amended unless expressly set forth by specific reference in such a filing.

Exhibits

99.1 Press release dated September 27, 2018

SIGNATURES

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

GW Pharmaceuticals plc

By: /s/ Douglas B. Snyder
Name: Douglas B. Snyder
Title: Chief Legal Officer

Date: September 27, 2018



GW Pharmaceuticals plc and its U.S. Subsidiary Greenwich Biosciences Announce the DEA has Rescheduled EPIDIOLEX® (cannabidiol) Oral Solution to Schedule V

- Product expected to be available within six weeks -

London, UK, Carlsbad, CA, 27 September, 2018: GW Pharmaceuticals plc (Nasdaq: GWPH, “GW,” “the Company” or “the Group”), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, along with its U.S. subsidiary Greenwich Biosciences, announced today that EPIDIOLEX® (cannabidiol) oral solution has been transferred to Schedule V, the lowest restriction classification, by the U.S. Drug Enforcement Administration (DEA). EPIDIOLEX, which was approved by the U.S. Food and Drug Administration (FDA) on June 25, 2018 for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older, is the first prescription pharmaceutical formulation of highly-purified, plant-derived cannabidiol (CBD), a cannabinoid lacking the high associated with marijuana, and the first in a new category of anti-epileptic drugs (AEDs).

“We are pleased that the DEA has placed EPIDIOLEX in the lowest restriction Schedule, because it will help ensure that patients with LGS and Dravet syndrome, two of the most debilitating forms of epilepsy, can access this important new treatment option through their physicians,” said Justin Gover, GW’s Chief Executive Officer. “With this final step in the regulatory process completed, we are working hard to make EPIDIOLEX available within the next six weeks as we know there is excitement for a standardized version of cannabidiol that has undergone the rigor of controlled clinical trials and been approved by the FDA.”

With this decision, the product label for EPIDIOLEX will be finalized. The Company’s development program represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with LGS and Dravet syndrome. Both diseases, which develop in childhood, are rare, severe forms of epilepsy that are notoriously treatment-resistant.^{1,2} Most patients with LGS and Dravet syndrome require multiple seizure medications and the majority are resistant to currently approved AEDs.^{2,3,4} The day-to-day impact of these conditions is significant with high rates of early mortality.^{5,6} The Company anticipates making EPIDIOLEX available within the next six weeks. Availability is primarily dependent on the time involved in obtaining the required Schedule V licenses for the U.S. distributor and importer.

¹ LGS Foundation. About Lennox-Gastaut Syndrome. Available at <http://www.lgsfoundation.org/aboutlgs>. Accessed May 7, 2018.

² Dravet C. The core Dravet syndrome phenotype. *Epilepsia*. 2011;52(Suppl. 2):3–9.

³ Epilepsy Foundation. Lennox-Gastaut Syndrome. Available at <http://www.epilepsy.com/learn/types-epilepsy-syndromes/lennox-gastaut-syndrome-lgs>. Accessed May 7, 2018.

⁴ Epilepsy Foundation. Dravet syndrome. Available at <https://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome>. Accessed May 7, 2018.

⁵ Cooper MS, Mcintosh A, Crompton DE, et al. Mortality in Dravet syndrome. *Epilepsy Res*. 2016;128:43-47.

⁶ Trevathan, E. Infantile Spasms and Lennox-Gastaut Syndrome. *Journal of child neurology* 17, 2S9-2S22 (2002).

Medicines in Schedule V have a proven medical use and low potential for abuse. DEA's decision to move EPIDIOLEX to Schedule V was based on non-clinical and clinical data that evaluated the medicine's potential for abuse and applies only to CBD products approved by the FDA. Other, non-FDA-approved CBD preparations remain in Schedule I. Some examples of Schedule V drugs are cough preparations such as Robitussin AC, and a number of commonly prescribed anti-epilepsy drugs such as VIMPAT (lacosamide), BRIVIACT (brivaracetam), and Lyrica (pregabalin).

The most common adverse reactions that occurred in EPIDIOLEX-treated patients were somnolence, decreased appetite, diarrhea, transaminase elevations, fatigue, malaise, and asthenia, rash, insomnia, sleep disorder and poor-quality sleep, and infections. The medicine will be marketed in the United States by Greenwich Biosciences, the U.S. subsidiary of GW Pharmaceuticals plc. More information, including the final product label, can be found at Epidiolex.com.

About EPIDIOLEX[®] (cannabidiol) oral solution

EPIDIOLEX, the first prescription, plant-derived cannabinoid medicine in the United States and the first in a new class of anti-epileptic medications, is a pharmaceutical formulation of highly-purified cannabidiol (CBD) now FDA-approved for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. GW has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for EPIDIOLEX with an expected decision date in the first quarter of 2019. GW has received Orphan Drug Designation from the FDA for EPIDIOLEX for the treatment of tuberous sclerosis complex (TSC). The Company has also received Orphan Designation from the European Medicines Agency, or EMA, for EPIDIOLEX for the treatment of LGS, Dravet syndrome, and TSC. GW is currently conducting an additional Phase 3 clinical development program in the treatment of seizures associated with TSC.

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

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, has received U.S. FDA approval for EPIDIOLEX (cannabidiol) oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. The Company has submitted a regulatory application in Europe for the adjunctive treatment of seizures associated with LGS and Dravet syndrome. The company continues to evaluate EPIDIOLEX in additional rare epilepsy conditions and currently has an ongoing clinical trial in tuberous sclerosis complex (TSC). GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex[®] (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States and for which the company is now planning a U.S. Phase 3 trial. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for epilepsy, glioblastoma, and schizophrenia. For further information, please visit www.gwpharm.com.

Forward-looking statements

This news release contains forward-looking statements that reflect GW's current expectations regarding future events, including statements regarding financial performance, the timing of commercial launch of EPIDIOLEX, 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 (cannabidiol) oral solution 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. An additional 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 4 December 2017. 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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