UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 23, 2019

GW PHARMACEUTICALS PLC
(Exact name of registrant as specified in its charter)

England and Wales	001-35892	00-0000000
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Sovereign House, Vision Park Chivers Way, Histon Cambridge, CB24 9BZ United Kingdom
(Address of Principal Executive Offices, including Zip Code)

Telephone: +44 1223 266 800
(Registrant's Telephone Number, Including Area Code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing 12 Ordinary Shares, par value £0.001 per share	**GWPH**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section13(a) of the Exchange Act ☐

Item 7.01 Regulation FD Disclosure.

On September 23, 2019, GW Pharmaceuticals plc (the "Company") issued a press release announcing that the European Commission (EC) has approved the marketing authorization for EPIDYOLEX® (cannabidiol) for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older. The approval paves the way for the launch of the medicine across Europe. The press release is furnished as Exhibit 99.1 hereto and incorporated by reference herein.

The information contained in Item 7.01 of this Form 8-K, including Exhibit 99.1 furnished herewith, 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 made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by the Company by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated September 23, 2019.
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document

SIGNATURE

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

Date: September 23, 2019

GW PHARMACEUTICALS PLC

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

Exhibit 99.1

GW Pharmaceuticals receives European Commission approval for EPIDYOLEX® (cannabidiol) for the treatment of seizures in patients with two rare, severe forms of childhood-onset epilepsy

Cannabidiol oral solution is the first plant-derived cannabis-based medicine to be approved by the European Medicines Agency (EMA)

Cannabidiol oral solution contains highly purified, plant-derived cannabidiol (CBD), a cannabinoid lacking the "high" associated with cannabis

LONDON and CARLSBAD, Calif., September 23, 2019 – GW Pharmaceuticals plc (Nasdaq: GWPH) ("GW", "the Company" or "the Group"), world leader in discovering, developing and commercialising cannabinoid prescription medicines, today announces that the European Commission (EC) has approved the marketing authorisation for EPIDYOLEX® for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome, in conjunction with clobazam, for patients 2 years of age and older. The approval paves the way for the launch of the medicine across Europe.

"The approval of EPIDYOLEX® marks a significant milestone, offering patients and their families the first in a new class of epilepsy medicines and the first and only EMA-approved CBD medicine to treat two severe and life-threatening forms of childhood-onset epilepsy," said Justin Gover, GW's Chief Executive Officer. "This approval is the culmination of many years of dedication and collaboration between GW, physicians and the epilepsy community. We believe patients and physicians deserve access to rigorously tested and evaluated cannabis-based medicines, manufactured to the highest standards and approved by medicines regulators, and we are delighted to be the first to offer this solution to the epilepsy community."

The approval of cannabidiol oral solution is based on results from four randomised, controlled Phase 3 trials. These studies incorporate data from more than 714 patients with either LGS or Dravet syndrome, two rare forms of epilepsy with high morbidity and mortality rates, which place a significant burden on families and caregivers. Many patients with LGS or Dravet syndrome have multiple seizures per day, which puts them at ongoing risk of falls and injury. Despite current anti-epileptic drug treatment, both of these severe forms of epilepsy remain highly treatment-resistant.[1,2,3]

"The approval of cannabidiol oral solution is an important milestone for patients and families whose lives are significantly impacted by these rare, complex and life-long forms of epilepsy," said Isabella Brambilla, Chairman, Dravet Syndrome European Federation. "We are very happy that patients will now have access to a much-needed, new treatment option, and one routed through a rigorous clinical trials programme and licensed by the EMA."

"LGS and Dravet syndrome are two of the most severe and difficult-to-treat forms of childhood-onset epilepsy, with few patients achieving adequate seizure control," said Professor Elinor Ben-Menachem, University of Goteborg, Sahlgren Academy and Hospital in Sweden. "The EMA approval of EPIDYOLEX® will bring hope to patients and families, with the potential to better control seizures and improve quality of life."

When added to other anti-epileptic therapies, EPIDYOLEX® significantly reduced the frequency of seizures in patients with LGS and Dravet syndrome. The most common adverse reactions that occurred in patients treated with the medicine were somnolence, decreased appetite, diarrhoea, pyrexia, fatigue and vomiting. GW's development programme represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with LGS and Dravet syndrome.

GW's cannabidiol oral solution was approved by the U.S. Food and Drug Administration (FDA) in June 2018 under the trade name EPIDIOLEX® for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age or older.

The EC decision is valid in all 28 countries of the European Union, alongside Norway, Iceland and Liechtenstein.

1. Bourgeois, B. F., Douglass, L. M. and Sankar, R. (2014), Lennox-Gastaut syndrome: A consensus approach to differential diagnosis. Epilepsia, 55: 4-9. Doi:10.1111/epi.12567.

2. Arzimanoglou A, French J, Blume WT, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Lancet Neurol. 2009;8(1):82-93.

3. Dravet C. The core Dravet syndrome phenotype. Epilepsia. 2011;52 Suppl 2:3-9.

ADDITIONAL INFORMATION

About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

Founded in 1998, GW is a UK-based global biopharmaceutical company focused on discovering, developing and commercialising novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. In June 2018 GW, along with its U.S. subsidiary Greenwich Biosciences, received U.S. FDA approval for EPIDIOLEX® (cannabidiol) for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. GW developed the world's first plant-derived cannabinoid prescription medicine, Sativex® (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in more than 25 countries around the world. The Company has a deep pipeline of additional cannabinoid product candidates, which includes compounds in Phase 1, 2 and 3 trials for epilepsy, autism, glioblastoma and schizophrenia.

About EPIDIOLEX®/EPIDYOLEX® (cannabidiol)

EPIDIOLEX®/EPIDYOLEX® (cannabidiol) oral solution, the first prescription, plant-derived cannabis-based medicine approved by the FDA for use in the U.S., is an oral solution which contains highly purified cannabidiol (CBD). The medicine is for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older and is the first in a new class of anti-epileptic medications with a novel mechanism of action. EPIDYOLEX® received a positive opinion from the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in July 2019 and the European Commission (EC) granted the marketing authorisation on 19 September 2019 for adjunctive use in conjunction with clobazam. The medicine was granted an Orphan Drug Designation from the EMA for the treatment of seizures associated with LGS, Dravet syndrome, and Tuberous Sclerosis Complex (TSC).

About Dravet syndrome

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic encephalopathy frequently associated with genetic mutations in the sodium channel gene *SCN1A*. 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 of patients will develop moderate to severe intellectual and development disabilities and require lifelong supervision and care.

About Lennox-Gastaut syndrome (LGS)

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 patients with LGS experience some degree of intellectual impairment, as well as developmental delays and aberrant behaviours.

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®/EPIDYOLEX® (cannabidiol) oral solution and Sativex® (nabiximols), and the safety profile and commercial potential of both medicines. 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 EPIDIOLEX®/EPIDYOLEX®, Sativex® 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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