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): November 26, 2018

GW PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

England and Wales	**001-35892**	**N/A**
(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)

CB24 9BZ
(Zip Code)

+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 under any of the following provisions (see General Instruction A.2. below):

☐ 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))

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 Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On November 26, 2018, GW Pharmaceuticals plc (the "Company" or "GW"), announced positive top-line results of the second randomized, double-blind, placebo-controlled Phase 3 clinical trial of EPIDIOLEX® (cannabidiol or CBD) CV in the treatment of seizures associated with Dravet syndrome, a rare and severe form of childhood-onset epilepsy. In this trial, EPIDIOLEX, when added to the patient's current treatment, achieved the primary endpoint of reduction in convulsive seizures for both dose levels (10 mg/kg per day and 20 mg/kg per day) with high statistical significance compared to placebo. Both EPIDIOLEX doses also demonstrated statistically significant improvements on all key secondary endpoints.

Patients aged 2-18 years with a confirmed diagnosis of drug-resistant Dravet syndrome currently uncontrolled on one or more concomitant anti-epileptic drugs (AEDs) were eligible to participate in this Phase 3, randomized, double-blind placebo-controlled trial. The trial randomized 199 patients into three arms, where EPIDIOLEX 20 mg/kg/day (n=67), EPIDIOLEX 10 mg/kg/day (n=67) or placebo (n=65) was added to current AED treatment. On average, patients were taking three AEDs, having previously tried and discontinued on average, four other AEDs. The average age of trial participants was nine years (range 2-18). The median baseline convulsive seizure frequency per month was 12 and the median baseline total seizure frequency per month was 35.

The primary endpoint of the study was the change in convulsive seizure frequency over the 14-week treatment period(2-week titration followed by 12-week maintenance at the target dose) compared to baseline. During the treatment period, patients taking EPIDIOLEX 20 mg/kg/day demonstrated a 46 percent reduction in convulsive seizures while patients taking EPIDIOLEX 10 mg/kg/day achieved a reduction of 49 percent, compared to a 27 percent reduction in patients taking placebo (p=0.0299 and p=0.0095 respectively). Results from the key secondary efficacy endpoints (reduction in total seizures, ≥50% responder analysis, and Caregiver Global Impression of Change) also showed statistical significance of both dose groups of EPIDIOLEX compared to placebo. In the EPIDIOLEX 20 mg/kg/day group, 49 percent of patients achieved a 50 percent or greater reduction in convulsive seizures from baseline over the treatment period, compared to 44 percent of patients taking EPIDIOLEX 10 mg/kg/day, and 26 percent of patients taking placebo (p=0.0069 and p=0.0332 respectively).

The currently available safety data from this trial are consistent with the previous Phase 3 clinical trials. As described in the US prescribing information, the most common adverse reactions in patients receiving EPIDIOLEX (≥10% and greater than placebo) include somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor-quality sleep; and infections.

Detailed findings from this clinical trial will be reported at a future medical conference and subsequently published in a medical journal.

The EPIDIOLEX clinical development program now includes four randomized, controlled Phase 3 clinical trials in Lennox-Gastaut Syndrome and Dravet syndrome (N=715) and an open-label extension study. The three previously completed Phase 3 studies have been published in The New England Journal of Medicine, and the Lancet. EPIDIOLEX represents the only development program of a plant-derived cannabinoid medication leading to FDA approval.

Forward-Looking Statements

This report 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 current report on Form 8-K filed on October 1, 2018. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated November 26, 2018, "GW Pharmaceuticals Announces Second Positive Phase 3 Pivotal Trial for EPIDIOLEX® (cannabidiol) oral solution CV in Patients with Dravet Syndrome."

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: November 26, 2018

Exhibit 99.1

GW Pharmaceuticals Announces Second Positive Phase 3 Pivotal Trial for EPIDIOLEX® (cannabidiol) oral solution CV in Patients with Dravet Syndrome

- Primary endpoint achieved with both EPIDIOLEX doses compared to placebo -

- Today's data represents the fourth positive Phase 3 pivotal trial for EPIDIOLEX in Dravet syndrome and Lennox-Gastaut Syndrome -

- EPIDIOLEX recently launched in the US and is now available by prescription -

London, Nov. 26, 2018 (GLOBE NEWSWIRE): 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, announces positive top-line results of the second randomized, double-blind, placebo-controlled Phase 3 clinical trial of EPIDIOLEX® (cannabidiol or CBD) CV in the treatment of seizures associated with Dravet syndrome, a rare and severe form of childhood-onset epilepsy. In this trial, EPIDIOLEX, when added to the patient's current treatment, achieved the primary endpoint of reduction in convulsive seizures for both dose levels (10 mg/kg per day and 20 mg/kg per day) with high statistical significance compared to placebo. Both EPIDIOLEX doses also demonstrated statistically significant improvements on all key secondary endpoints.

"The positive outcome in this second trial of EPIDIOLEX in patients with Dravet syndrome further reinforces the effectiveness of this newly available medicine in this particularly difficult to treat, childhood-onset epilepsy," stated Ian Miller, M.D., Director, Epilepsy and Neurophysiology Program at Nicklaus Children's Hospital in Miami, FL and principal investigator of the trial. "The totality of data from the controlled clinical trials completed for EPIDIOLEX have shown clinically meaningful seizure reductions and a consistent safety and tolerability profile. I am excited that this recently approved and important new treatment option is now available for my patients."

"The positive results from this trial follow the recent FDA approval, DEA rescheduling and U.S. launch of EPIDIOLEX for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut Syndrome in patients two years and older. These data show an effective dose range in Dravet syndrome that is consistent with our FDA approved label, and which allows for dosing flexibility to address individual patient needs," stated Justin Gover, GW's CEO. "We are proud to have recently launched EPIDIOLEX, the first FDA-approved plant-derived cannabinoid medicine and are excited about its potential to help the lives of patients and their families."

“This new important EPIDIOLEX data is good news for the Dravet syndrome community and offers further scientific evidence for this newly available therapy,” said Mary Anne Meskis, Executive Director of the Dravet Syndrome Foundation. “As the first FDA-approved medicine for patients with Dravet syndrome, EPIDIOLEX offers hope to individuals who previously had few options available to effectively control their seizures.”

“The positive results from this latest EPIDIOLEX clinical trial are very encouraging for those living with intractable seizures caused by LGS and Dravet syndrome, two extremely difficult treatment-resistant forms of epilepsy,” said Philip M. Gattone, president and CEO of the Epilepsy Foundation. “This trial increases the body of scientific evidence to support the only FDA-approved cannabidiol therapy and provides hope to the most vulnerable individuals in our epilepsy community who are trying to gain better seizure control. We thank GW and all our partners who invest in a better tomorrow for people with epilepsy.”

Trial Overview and Results

Patients aged 2-18 years with a confirmed diagnosis of drug-resistant Dravet syndrome currently uncontrolled on one or more concomitant anti-epileptic drugs (AEDs) were eligible to participate in this Phase 3, randomized, double-blind placebo-controlled trial. The trial randomized 199 patients into three arms, where EPIDIOLEX 20 mg/kg/day (n=67), EPIDIOLEX 10 mg/kg/day (n=67) or placebo (n=65) was added to current AED treatment. On average, patients were taking three AEDs, having previously tried and discontinued on average, four other AEDs. The average age of trial participants was nine years (range 2-18). The median baseline convulsive seizure frequency per month was 12 and the median baseline total seizure frequency per month was 35.

The primary endpoint of the study was the change in convulsive seizure frequency over the 14-week treatment period (2-week titration followed by 12-week maintenance at the target dose) compared to baseline. During the treatment period, patients taking EPIDIOLEX 20 mg/kg/day demonstrated a 46 percent reduction in convulsive seizures while patients taking EPIDIOLEX 10 mg/kg/day achieved a reduction of 49 percent, compared to a 27 percent reduction in patients taking placebo ($p=0.0299$ and $p=0.0095$ respectively). Results from the key secondary efficacy endpoints (reduction in total seizures, $\geq 50\%$ responder analysis, and Caregiver Global Impression of Change) also showed statistical significance of both dose groups of EPIDIOLEX compared to placebo. In the EPIDIOLEX 20 mg/kg/day group, 49 percent of patients achieved a 50 percent or greater reduction in convulsive seizures from baseline over the treatment period, compared to 44 percent of patients taking EPIDIOLEX 10 mg/kg/day, and 26 percent of patients taking placebo ($p=0.0069$ and $p=0.0332$ respectively).

The currently available safety data from this trial are consistent with the previous Phase 3 clinical trials. As described in the US prescribing information, the most common adverse reactions in patients receiving EPIDIOLEX (≥10% and greater than placebo) include somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor-quality sleep; and infections.

Detailed findings from this clinical trial will be reported at a future medical conference and subsequently published in a medical journal.

The EPIDIOLEX clinical development program now includes four randomized, controlled Phase 3 clinical trials in Lennox-Gastaut Syndrome and Dravet syndrome (N=715) and an open-label extension study. The three previously completed Phase 3 studies have been published in *The New England Journal of Medicine*, and the *Lancet*. EPIDIOLEX represents the only development program of a plant-derived cannabinoid medication leading to FDA approval.

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.

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 seizures associated with tuberous sclerosis complex (TSC). The Company has also received Orphan Designation from the EMA for EPIDIOLEX for the treatment of seizures associated with LGS, Dravet syndrome, and TSC. GW is currently conducting an additional Phase 3 clinical trial in the treatment of seizures associated with TSC.

Important Safety Information

CONTRAINDICATION: HYPERSENSITIVITY

EPIDIOLEX (cannabidiol) oral solution is contraindicated in patients with a history of hypersensitivity to cannabidiol or any ingredients in the product.

WARNINGS & PRECAUTIONS

Hepatocellular Injury:

EPIDIOLEX can cause dose-related transaminase elevations. Concomitant use of valproate and elevated transaminase levels at baseline increase this risk. Transaminase and bilirubin levels should be obtained prior to starting treatment, at one, three, and six months after initiation of treatment, and periodically thereafter, or as clinically indicated. Resolution of transaminase elevations occurred with discontinuation of EPIDIOLEX, reduction of EPIDIOLEX and/or concomitant valproate, or without dose reduction. For patients with elevated transaminase levels, consider dose reduction or discontinuation of EPIDIOLEX or concomitant medications known to affect the liver (e.g., valproate or clobazam). Dose adjustment and slower dose titration is recommended in patients with moderate or severe hepatic impairment. Consider not initiating EPIDIOLEX in patients with evidence of significant liver injury.

Somnolence and Sedation:

EPIDIOLEX can cause somnolence and sedation that generally occurs early in treatment and may diminish over time; these effects occur more commonly in patients using clobazam and may be potentiated by other CNS depressants.

Suicidal Behavior and Ideation:

Antiepileptic drugs (AEDs), including EPIDIOLEX, increase the risk of suicidal thoughts or behavior. Inform patients, caregivers, and families of the risk and advise to monitor and report any signs of depression, suicidal thoughts or behavior, or unusual changes in mood or behavior. If these symptoms occur, consider if they are related to the AED or the underlying illness.

Withdrawal of Antiepileptic Drugs:

As with most AEDs, EPIDIOLEX should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

Adverse Reactions:

The most common adverse reactions in patients receiving EPIDIOLEX (≥10% and greater than placebo) include somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor-quality sleep; and infections. Hematologic abnormalities were also observed.

Pregnancy:

EPIDIOLEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Encourage women who are taking EPIDIOLEX during pregnancy to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry.

Drug Interactions:

Moderate or strong inhibitors or inducers of CYP3A4 and CYP2C19 may affect EPIDIOLEX exposure. EPIDIOLEX may affect exposure to CYP2C19 substrates (e.g., clobazam, diazepam) or others. Concomitant use of EPIDIOLEX and valproate increases the incidence of liver enzyme elevations. Dosage adjustment of EPIDIOLEX or other concomitant medications may be necessary.

Drug Abuse:

EPIDIOLEX is a Schedule V controlled substance and has a low potential for abuse.

Indications:

EPIDIOLEX (cannabidiol) oral solution is indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years of age and older.

Please refer to the EPIDIOLEX full Prescribing Information for additional important information.

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 current report on Form 8-K filed on October 1, 2018. 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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