GW PHARMACEUTICALS PLC

FORM 6-K
(Report of Foreign Issuer)

Filed 12/05/16 for the Period Ending 12/05/16

Telephone	44 1223 266800
CIK	0001351288
Symbol	GWPH
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare

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 December, 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 ☐

Other Events

On December 5, 2016, GW Pharmaceuticals plc (the "Company") issued a press release announcing its fourth quarter and year-end 2016 financial results and operational progress and details of a conference call to be held at 8:00 a.m. EST on December 5, 2016 to discuss the results. The press release is attached as Exhibit 99.1 and is incorporated by reference herein.

On December 5, 2016, the Company issued a press release announcing additional positive Epidiolex® (cannabidiol or CBD) Phase 3 data in poster presentations at the 70th Annual Meeting of the American Epilepsy Society. The press release is attached as Exhibit 99.2 and is incorporated by reference herein. The posters are also available from the Investors section of the Company's website.

The information contained in Exhibits 99.1 and 99.2 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

99.1	Press release dated December 5, 2016
99.2	Press release dated December 5, 2016

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: December 5, 2016

Exhibit 99.1

GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2016 Financial Results and Operational Progress

- Three Positive Phase 3 Epidiolex clinical trials reported in 2016 –
- NDA submission and launch preparation on track –
-Conference call today at 8:00 a.m. EST-

London, UK, 5 December 2016 : 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, announced financial results for the fourth quarter and year-ended 30 September 2016.

"In 2016 GW has completed three positive Phase 3 trials for Epidiolex in patients with two different rare treatment resistant forms of childhood-onset epilepsy and we are making good progress towards an NDA submission. Our sights are now focused on Epidiolex approval and accelerating our preparations for a highly successful launch," stated Justin Gover, GW's Chief Executive Officer. "Our goal is to provide the children and their families suffering from these highly treatment-resistant forms of childhood-onset epilepsy with a much needed new prescription option as quickly as possible."

2016 OPERATIONAL HIGHLIGHTS

- Epidiolex ® (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and infantile spasms (IS)
  - Phase 3 trials:
    - Positive results in a pivotal Phase 3 Dravet syndrome trial
    - Positive results in two pivotal Phase 3 LGS trials
    - Positive data presented at the American Epilepsy Society Annual Meeting
  - Regulatory:
    - Positive Dravet syndrome pre-NDA meeting held with FDA in July 2016
    - Positive CMC pre-NDA meeting held with FDA in November 2016
    - NDA submission for both Dravet and LGS indications expected at end of H1 2017, just 3 years since opening of IND
    - Preparations advancing for EU regulatory submission in H2 2017
  - Manufacturing scale-up:
    - Manufacturing scale-up on track to deliver significant commercial launch inventory
  - Expanded access program and open label extension:
    - 98% of patients who complete Phase 3 trials have entered long term extension
    - Over 1,000 patients now on Epidiolex treatment
    - NDA submission to include safey data from over 1,500 patients and over 400 patients with 1 year or more continuous exposure
    - Withdrawal rate in long term studies approx 20%
  - Commercial:
    - US commercial team build underway and pre-launch preparations advancing well
    - EU commercial team now being established

- Additional indications:
  - Phase 3 trial in TSC ongoing
  - Two part Phase 3 trial in IS commenced in December 2016
- Intellectual Property:
  - Patent portfolio being prosecuted with claims directed to the use of CBD in the treatment of epilepsy seizure subtypes and epilepsy syndromes

- Advanced clinical programs in multiple cannabinoid pipeline product candidates:
  - CBDV Phase 2 partial-onset epilepsy study in adults ongoing. Part A complete and Part B underway with data expected mid-2017
  - CBDV pre-clinical research ongoing within field of autism spectrum disorders. Phase 2 trials expected to commence in Q3 2017
    - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
  - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
    - Phase 1 trial commenced in December 2016
    - Orphan Drug and Fast Track Designations granted from FDA and EMA
  - THC:CBD for the treatment of Recurrent Glioblastoma Multiforme (GBM)
    - Phase 1b/2a study completed – data expected Q1 2017
    - Orphan Drug Designation from FDA
  - Sativex ® Phase 2 study in children with spasticity due to cerebral palsy completed – data expected Q1 2017

FINANCIAL HIGHLIGHTS

- Revenue for the twelve months ended 30 September 2016 of £10.3 million ($13.3 million) compared to £28.5 million for the twelve months ended 30 September 2015.

- Loss for the twelve months ended 30 September 2016 of £63.7 million ($82.2 million) compared to £44.6 million for the twelve months ended 30 September 2015.

- Cash and cash equivalents at 30 September 2016 of £374.4 million ($483.4 million) compared to £234.9 million as at 30 September 2015.

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the fourth quarter and year-end 2016 financial results today at 8:00 a.m.. To participate in the conference call, please dial 877-407-8133 (toll free from the U.S. and Canada) or 201-689-8040 (international). Investors may also access a live audio webcast of the call via the investor relations section of the Company's website at http://www.gwpharm.com . A replay of the call will also be available through the GW website shortly after the call and will remain available for 90 days. Replay Numbers: (toll free):1-877-481-4010, (international):1-919-882-2331. For both dial-in numbers please use conference ID # 13650870.

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, Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex ® , 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 glioma, schizophrenia and epilepsy. 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 clinical trials, the relevance of GW products commercially available and in development, the clinical benefits of Sativex® and Epidiolex® and the safety profile and commercial potential of Sativex and 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 of 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. 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.

Enquiries:
GW Pharmaceuticals plc
Stephen Schultz, VP Investor Relations 401 500 6570

Sam Brown (U.S. Media Enquiries)
Amanda Foley +44 20 7418 8900

Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 30 September 2016, the Condensed Consolidated Income Statement, Condensed Consolidated Statement of Comprehensive Income, Condensed Consolidated Statement of Changes in Equity and the Condensed Consolidated Cash Flow Statement for the three months and for the year ended 30 September 2016 have been translated into U.S. dollars at the rate on 30 September 2016 of $1.29128 to £1.00. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 30 September 2016

	Three months ended 30 September 2016 $000's	**Three months ended 30 September 2016 £000's**	Three months ended 30 September 2015 £000's
Revenue	2,156	**1,670**	5,595
Cost of sales	(1,006)	**(779)**	(683)
Research and development expenditure	(31,401)	**(24,318)**	(25,457)
Sales, general and administrative expenses	(9,645)	**(7,469)**	(4,988)
Net foreign exchange gain	8,099	**6,272**	6,874
Operating loss	(31,797)	**(24,624)**	(18,659)
Interest and other income	408	**316**	83
Interest expense	(155)	**(120)**	(15)
Loss before tax	(31,544)	**(24,428)**	(18,591)
Tax benefit	9,710	**7,520**	6,358
Loss for the period	(21,834)	**(16,908)**	(12,233)
Loss per share – basic and diluted	(7.4c)	**(5.7p)**	(4.7p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the three months ended 30 September 2016

	Three months ended 30 September 2016 £000's	Three months ended 30 September 2015 £000's
Loss for the period	**(16,908)**	(12,233)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	**183**	(51)
Other comprehensive gain/(loss) for the period	**183**	(51)
Total comprehensive loss for the period	**(16,725)**	(12,284)

GW Pharmaceuticals plc
Condensed consolidated income statement
Year ended 30 September 2016

	Year ended 30 September 2016 $000's	**Year ended 30 September 2016 £000's**	Year ended 30 September 2015 £000's
Revenue	13,320	**10,315**	28,540
Cost of sales	(3,511)	**(2,719)**	(2,618)
Research and development expenditure	(128,889)	**(99,815)**	(76,785)
Sales, general and administrative expenses	(25,747)	**(19,939)**	(12,569)
Net foreign exchange gain	32,993	**25,551**	6,202
Operating loss	(111,834)	**(86,607)**	(57,230)
Other income	785	**608**	244
Interest expense	(223)	**(173)**	(75)
Loss before tax	(111,272)	**(86,172)**	(57,061)
Tax benefit	29,073	**22,515**	12,498
Loss for the year	(82,199)	**(63,657)**	(44,563)
Loss per share – basic and diluted	(30.4c)	**(23.5p)**	(18.1p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the year ended 30 September 2016

	Year ended 30 September 2016 £000's	Year ended 30 September 2015 £000's
Loss for the year	**(63,657)**	(44,563)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	**349**	(71)
Other comprehensive gain/(loss) for the year	**349**	(71)
Total comprehensive loss for the year	**(63,308)**	(44,634)

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Year ended 30 September 2016

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total equity £000's
Balance at 1 October 2014	237	220,551	19,260	(81,464)	158,584
Issue of share capital	22	127,812	–	–	127,834
Expense of new equity issue	–	(271)	–	–	(271)
Exercise of share options	2	1,183	–	–	1,185
Share-based payment transactions	–	–	–	2,488	2,488
Loss for the year	–	–	–	(44,563)	(44,563)
Deferred tax attributable to unrealized share option gains	–	–	–	84	84
Other comprehensive expense	–	–	(71)	–	(71)
Balance at 30 September 2015	**261**	**349,275**	**19,189**	**(123,455)**	**245,270**
Balance at 1 October 2015	261	349,275	19,189	(123,455)	245,270
Issue of share capital	39	206,512	–	–	206,551
Expense of new equity issue	–	(472)	–	–	(472)
Underwriters' contribution towards expenses of new equity issue	–	472	–	–	472
Exercise of share options	2	690	–	–	692
Share-based payment transactions	–	–	–	8,152	8,152
Loss for the year	–	–	–	(63,657)	(63,657)
Deferred tax attributable to unrealized share option gains	–	–	–	1,133	1,133
Other comprehensive expense	–	–	349	–	349
Balance at 30 September 2016	**302**	**556,477**	**19,538**	**(177,827)**	**398,490**

GW Pharmaceuticals plc
Condensed consolidated balance sheet
As at 30 September 2016

	As at 30 September 2016 $000's	**As at 30 September 2016 £000's**	As at 30 September 2015 £000's
Non-current assets			
Intangible assets - goodwill	6,728	**5,210**	5,210
Other intangible assets	812	**629**	245
Property, plant and equipment	50,291	**38,947**	28,733
Deferred tax asset	5,001	**3,873**	418
	62,832	**48,659**	34,606
Current assets			
Inventories	5,485	**4,248**	4,756
Taxation recoverable	27,533	**21,322**	12,641
Trade receivables and other assets	5,883	**4,556**	2,873
Cash and cash equivalents	483,445	**374,392**	234,872
	522,346	**404,518**	255,142
Total assets	585,178	**453,177**	289,748
Current liabilities			
Trade and other payables	(40,249)	**(31,170)**	(24,022)
Current tax liabilities	(1,140)	**(883)**	(366)
Obligations under finance leases	(272)	**(211)**	(111)
Deferred revenue	(3,468)	**(2,686)**	(3,269)
	(45,129)	**(34,950)**	(27,768)
Non-current liabilities			
Trade and other payables	(12,168)	**(9,423)**	(8,445)
Obligations under finance leases	(6,403)	**(4,959)**	(1,540)
Deferred revenue	(6,915)	**(5,355)**	(6,725)
Total liabilities	(70,615)	**(54,687)**	(44,478)
Net assets	514,563	**398,490**	245,270
Equity			
Share capital	390	**302**	261
Share premium account	718,568	**556,477**	349,275
Other reserves	25,229	**19,538**	19,189
Accumulated deficit	(229,624)	**(177,827)**	(123,455)
Total equity	514,563	**398,490**	245,270

GW Pharmaceuticals plc
Condensed consolidated cash flow statement
As at 30 September 2016

	Year ended 30 September 2016 $000's	**Year ended 30 September 2016 £000's**	Year ended 30 September 2015 £000's
Loss for the year	(82,199)	**(63,657)**	(44,563)
Adjustments for:			
Other income	(785)	**(608)**	(244)
Interest expense	223	**173**	75
Tax benefit	(29,073)	**(22,515)**	(12,498)
Depreciation of property, plant and equipment	4,654	**3,605**	2,250
Impairment of property, plant and equipment	–	**–**	606
Amortization of intangible assets	80	**62**	52
Net foreign exchange gains	(32,993)	**(25,551)**	(6,282)
Increase in provision for inventories	93	**72**	33
Decrease in deferred signature fees	(1,511)	**(1,170)**	(1,250)
Share-based payment charge	10,527	**8,152**	2,478
Loss on disposal of property, plant and equipment	1	**1**	1
	(130,983)	**(101,436)**	(59,342)
Decrease/(increase) in inventories	563	**436**	(12)
Increase in trade receivables and other assets	(972)	**(753)**	(1,010)
Increase in trade and other payables and deferred revenue	6,148	**4,761**	8,478
Cash used in operations	(125,244)	**(96,992)**	(51,886)
Income taxes paid	(1,140)	**(883)**	–
Research and development tax credits received	17,150	**13,281**	5,415
Net cash outflow from operating activities	(109,234)	**(84,594)**	(46,471)
Investing activities			
Interest received	560	**434**	236
Purchases of property, plant and equipment	(11,206)	**(8,678)**	(17,915)
Purchase of intangible assets	(661)	**(512)**	(114)
Proceeds from sales of property, plant and equipment	–	**–**	2
Net cash outflow from investing activities	(11,307)	**(8,756)**	(17,791)
Financing activities			
Proceeds on exercise of share options	697	**540**	1,185
Proceeds of new equity issue	266,714	**206,550**	127,834
Expenses of new equity issue	(412)	**(319)**	(271)
Underwriters' contribution towards expenses of new equity issue	609	**472**	–
Interest paid	(89)	**(69)**	(74)
Repayments of advance funding	(310)	**(240)**	–
Repayments of obligations under finance leases	(164)	**(127)**	(255)
Net cash inflow from financing activities	267,045	**206,807**	128,419
Effect of foreign exchange rate changes on cash and cash equivalents	33,655	**26,063**	6,224
Net increase in cash and cash equivalents	180,159	**139,520**	70,381
Cash and cash equivalents at beginning of the year	303,286	**234,872**	164,491
Cash and cash equivalents at end of the year	483,445	**374,392**	234,872

Exhibit 99.2

GW Announces New Epidiolex ® (CBD) Positive Phase 3 Data in Dravet Syndrome and Lennox-Gastaut Syndrome
- Posters Presented at American Epilepsy Society Annual Meeting -
- New data includes key secondary efficacy endpoints -

London, UK, 5 Dec 2016: 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, announced additional positive Epidiolex ® (cannabidiol or CBD) Phase 3 data in poster presentations at the 70 th Annual Meeting of the American Epilepsy Society. These data are from the positive pivotal Phase 3 study of Epidiolex in Dravet syndrome and the first pivotal Phase 3 study of Epidiolex in Lennox-Gastaut syndrome (LGS),both reported earlier this year.

"We are pleased to present key findings from two pivotal Phase 3 studies of Epidiolex and believe these additional positive data reinforce the robust nature of the results achieved in two of the most difficult-to-treat epilepsy patient populations," stated Justin Gover, GW's Chief Executive Officer. "We are making very good progress toward a NDA submission to the FDA as well as preparations for commercial launch and look forward to the opportunity to make this important new medicine available to patients as quickly as possible."

Highlights of Findings in both Phase 3 studies:

- Each pivotal Phase 3 study achieved the primary endpoint demonstrating a statistically significant difference between Epidiolex and placebo in seizure frequency reduction during the 14 week treatment period.
- In the 12-week maintenance period (excluding the initial dose escalation), the treatment effect increased for patients receiving Epidiolex and showed a greater level of statistically significance compared with placebo.
- Caregivers of patients receiving Epidiolex were significantly more likely to report an improvement in overall condition,
- A consistent separation between Epidiolex and placebo across all response rates was seen. In the LGS study, the drop seizure responder analysis showed a statistically-significant separation between Epidiolex and placebo at the 50 percent seizure reduction threshold,
- Epidiolex efficacy was established relatively early in treatment.
- Epidiolex was generally well tolerated.

“These placebo-controlled studies demonstrate that Epidiolex provides clinically meaningful reductions in seizure frequency together with an acceptable safety and tolerability profile”, stated Orrin Devinsky, M.D., of New York University Langone Medical Center’s Comprehensive Epilepsy Center and Principal Investigator of the Dravet syndrome trial. “The epilepsy community has been eagerly anticipating the presentation of this high quality scientific data from the Epidiolex program at the American Epilepsy Society. My colleagues and I are excited at the future prospect of prescribing an appropriately standardized and tested pharmaceutical formulation of cannabidiol.”

“Dravet syndrome and Lennox-Gastaut syndrome are diagnosed in early childhood and represent some of the most difficult types of epilepsy to treat. Nearly all patients continue to have uncontrolled seizures and other medical needs throughout their lifetime. These trial results show that Epidiolex offers much needed new hope for children and their families,” stated Elizabeth Thiele, MD, PhD, Director of Pediatric Epilepsy at the Massachusetts General Hospital, Professor of Neurology at the Harvard Medical School and Principal Investigator of the LGS trial. “I very much look forward to the day when Epidiolex is available as a new prescription option for my patients.”

The studies represented in the posters are the first randomized, double-blind, placebo-controlled studies to investigate the efficacy and safety of CBD added to concomitant antiepileptic drug (AED) therapy in Dravet syndrome and LGS. The following are links to the posters presented:

Phase 3 Trial in Lennox-Gastaut syndrome (click to access)
Phase 3 Trial in Dravet syndrome (Part A) (click to access)
Phase 3 Trial in Dravet syndrome (Part B) (click to access)
Copies of these posters will also be available on GW’s corporate website in the Investor Relations section under presentations.

About Lennox-Gastaut Syndrome

The peak 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 inherited 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 non-convulsive, convulsive and drop seizures, which frequently lead to falls and injuries. Drug resistance is one of the main features of LGS. Most children with LGS experience some degree of impaired intellectual functioning, as well as developmental delays and behavioral disturbances. It is estimated that there are approximately 14,000-18,500 patients with LGS in the United States and 23,000-31,000 patients with LGS in Europe.

About Dravet Syndrome

Dravet syndrome is a severe infantile-onset and highly treatment-resistant epileptic syndrome frequently associated with a genetic mutation in sodium channels. Onset of Dravet syndrome occurs during the first year of life in previously healthy and developmentally normal infants. Initial seizures are often temperature related, severe, and long-lasting. Over time, people with Dravet syndrome can develop multiple types of seizures, including tonic-clonic, myoclonic, and atypical absences and are prone to bouts of prolonged seizures called status epilepticus, which can be life threatening. Risk of premature death including SUDEP (sudden expected death in epilepsy) is elevated in people 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 have uncontrolled seizures and other medical needs throughout their lifetime.

About Epidiolex

Epidiolex, GW's lead cannabinoid product candidate, is a liquid formulation 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 has the ability to treat seizures in acute animal models of epilepsy with significantly fewer side effects than existing anti-epileptic drugs. To date, GW has received Orphan Drug Designation from the FDA for Epidiolex in the treatment of both Dravet syndrome and Lennox-Gastaut syndrome. 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 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, Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex®, 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 glioma, schizophrenia and epilepsy. In the United States, GW is operating as Greenwich Biosciences Inc. For further information, please visit www.gwpharm.com.

Forward-looking statements

This news release may contain forward-looking statements that reflect GWs 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 Sativex®, 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.

Enquiries:

GW Pharmaceuticals plc
Stephen Schultz, VP Investor Relations (U.S.) 917 280 2424 / 401 500 6570

Sam Brown, Inc.
Amanda Foley 610-725-0725 / 610-585-9400

Cannabidiol (CBD) Significantly Reduces Drop Seizure Frequency in Lennox-Gastaut Syndrome (LGS): Results of a Multi-center, Randomized, Double-blind, Placebo-controlled Trial (GWPCARE4)

SUMMARY

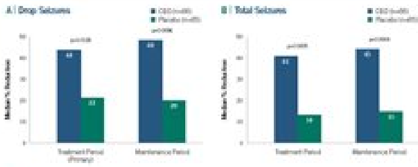
- The trial met its primary endpoint, demonstrating that CBD (20 mg/kg/day), as an add-on to standard of care, produced significantly greater reductions in drop seizures vs. placebo in patients with Lennox-Gastaut Syndrome (LGS).
- CBD resulted in significantly greater reductions in total seizure and non-drop seizure frequency vs. placebo.
- CBD patients/caregivers were significantly more likely than patients taking placebo to report an improvement in overall condition as measured on the Subject/Caregiver Global Impression of Change (S/CGIC) scale.
- CBD resulted in more adverse events than placebo, but it was generally well tolerated.

INTRODUCTION

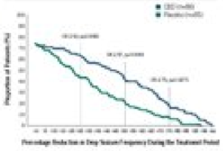
Patient disposition and baseline demographics

EFFICACY RESULTS

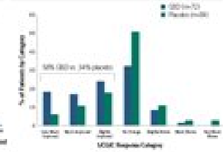
Percentage change from baseline in drop and total seizure frequency



Drop seizure responder rates



Subject/caregiver global impression of change from baseline at last visit



SAFETY RESULTS

Summary of treatment-emergent adverse events (TEAEs)

Laboratory investigations

METHODS

GREENWICH

A Dose Ranging Safety and Pharmacokinetic Study of Cannabidiol (CBD) in Children With Dravet Syndrome (GWPCARE1)

SUMMARY

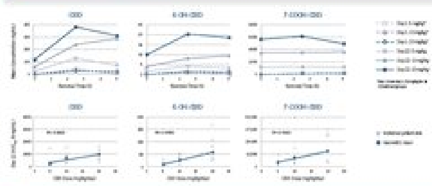
- Exposure to CBD and its metabolites increased in a dose-proportional manner; 7-COOH-CBD was the major circulating metabolite.
- N-desmethylclobazam (N-CLB) levels increased in patients on CBD, except for those on concomitant stiripentol, which may reflect prior saturated inhibition of CYP2C19 enzyme by stiripentol.
- There was no demonstrable effect on other antiepileptic drugs (AEDs) tested (valproic acid, topiramate, stiripentol, or levetiracetam).
- CBD resulted in more adverse events than placebo, but it was generally well tolerated at all doses examined.
- 20 mg/kg/day was approved by the Data Safety Monitoring Committee for further investigation.

INTRODUCTION

Patient disposition and baseline demographics

PHARMACOKINETIC RESULTS

Plasma pharmacokinetics of CBD and metabolites



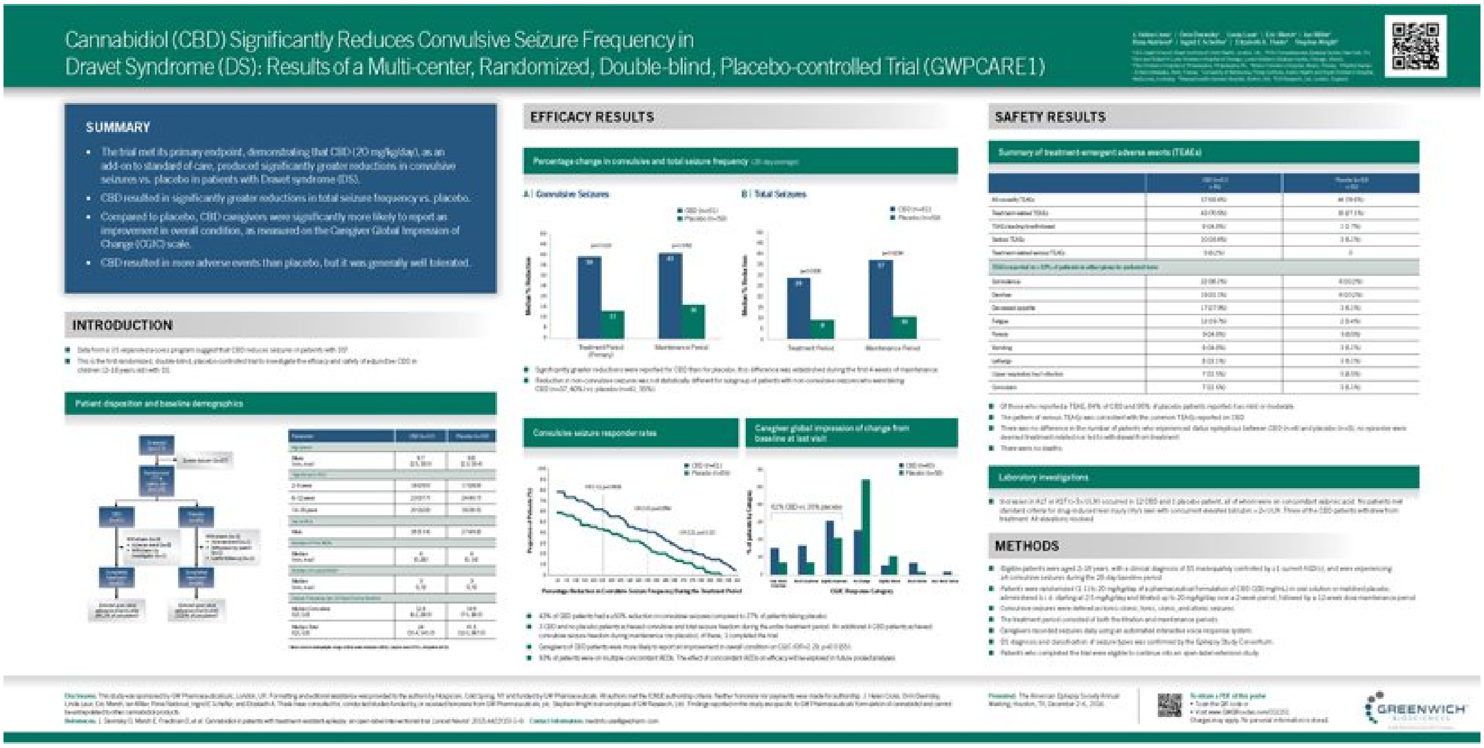
Mean percentage change in plasma concentrations of CLB, N-CLB, and valproic acid at Day 22

SAFETY RESULTS

Treatment-emergent adverse events (TEAEs)

All-causality TEAEs	8 (80)	5 (63)	7 (70)	6 (86)
Treatment-related TEAEs	6 (60)	3 (38)	6 (60)	1 (14)
TEAEs leading to withdrawal	0	1 (13)	1 (11)	0
Serious TEAEs	1 (10)	2 (25)	1 (10)	1 (14)
Treatment-related serious TEAEs	1 (10)	1 (13)	0	0
Somnolence	2 (20)	3 (38)	0	1 (14)
Pyrexia	3 (30)	3 (38)	0	0
Decreased appetite	0	1 (13)	4 (40)	0
Sedation	2 (20)	0	2 (20)	0

METHODS


Cannabidiol (CBD) Significantly Reduces Convulsive Seizure Frequency in
Dravet Syndrome (DS): Results of a Multi-center, Randomized, Double-blind, Placebo-controlled Trial (GWPCARE1)
SUMMARY
The trial met its primary endpoint, demonstrating that CBD (20 mg/kg/day), as an add-on to standard of care, produced significantly greater reductions in convulsive seizures vs. placebo in patients with Dravet syndrome (DS).
CBD resulted in significantly greater reductions in total seizure frequency vs. placebo.
Compared to placebo, CBD caregivers were significantly more likely to report an improvement in overall condition, as measured on the Caregiver Global Impression of Change (CGIC) scale.
CBD resulted in more adverse events than placebo, but it was generally well tolerated.
INTRODUCTION
Patient disposition and baseline demographics
EFFICACY RESULTS
Percentage change in convulsive and total seizure frequency
A | Convulsive Seizures
B | Total Seizures
Convulsive seizure responder rates
Caregiver global impression of change from baseline at last visit
SAFETY RESULTS
Summary of treatment-emergent adverse events (TEAEs)
Laboratory investigations
METHODS
GREENWICH