GW Pharmaceuticals plc Reports Fiscal Fourth Quarter and Year-End 2018 Financial Results and Operational Progress

November 27, 2018

- Epidiolex® (cannabidiol) oral solution (CV), first FDA-approved plant-derived cannabinoid medicine launched in the U.S. -
- Conference call today at 4:30 p.m. EST -

LONDON and CARLSBAD, Calif., Nov. 27, 2018 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the development and commercialization of cannabinoid prescription medicines, announces financial results for the fourth quarter and year ended 30 September 2018.

"We are proud to have recently launched Epidiolex, the first and only FDA-approved plant-derived cannabinoid medicine and a much needed new treatment option for patients with LGS and Dravet syndrome, two of the most difficult-to-treat forms of childhood-onset epilepsy. We are pleased with both the response of the medical community to the product launch and with the coverage decisions made to date by insurance providers, and we are committed to ensuring that appropriate patients can access treatment," stated Justin Gover, GW's Chief Executive Officer. "We also announced positive results from an additional Phase 3 trial in Dravet syndrome, further reinforcing the potential for Epidiolex to produce clinically meaningful seizure reductions in this patient population. The recent U.S. launch of Epidiolex introduces a new chapter for GW as a commercial-stage company and reinforces our world leadership in cannabinoid science. We fully expect to maintain this leadership as we leverage the potential of our cannabinoid product pipeline to meet unmet needs of patients across a range of therapeutic areas."

OPERATIONAL HIGHLIGHTS

- Epidiolex
  - Commercial:
    - Epidiolex launched on November 1st in the U.S. and now available by prescription
    - Sales organization actively engaging with clinicians
      - Awareness and interest high amongst patients and physicians
      - Physician education programs providing strong support for initial introduction into clinics
      - Patient and clinician websites active pre and post-launch
      - Epidiolex demand coming from both major centers of excellence and local epilepsy clinics
    - Active engagement with U.S. payors ongoing
      - Epidiolex now covered on growing number of formularies
    - U.S. supply chain distribution network operational and filling prescriptions
    - Commercial footprint in place in 5 major European markets in preparation for 2019 European launches
  - Regulatory:
    - DEA rescheduled Epidiolex to Schedule V
      - Scheduling decision specific to FDA approved CBD
    - European submission under review by the EMA with decision expected in Q1 2019
  - Clinical trials
    - Positive results in second Dravet syndrome Phase 3 trial
      - Primary endpoint achieved in both Epidiolex doses (10 mg/kg/day and 20 mg/kg/day) compared to placebo
      - Both Epidiolex doses also demonstrated statistically significant improvements versus placebo in all key secondary endpoints
    - Phase 3 trial in Tuberous Sclerosis Complex fully recruited with data expected H1 2019
      - sNDA submission expected in H2 2019
    - IND submitted for pivotal Rett Syndrome study with expected start in H1 2019.
  - Manufacturing
    - Commercial Epidiolex product shipments to the U.S. ongoing and sufficient to meet expected demand
    - Continued investment in expanded facilities to meet anticipated long-term demand
  - Expanded access program and open label extension:
    - Approximately 1,000 patients in these programs to be transitioned to commercial product during first half of 2019
  - Life-cycle management
    - Several new formulations of CBD in development including capsule and modified oral solution
  - Exclusivity

        - 7-year orphan exclusivity confirmed by FDA, 6-month pediatric extension expected
        - Key favorable patent grants by USPTO related to the use of CBD in epilepsy, including claims for the treatment of relevant seizure types associated with LGS and Dravet syndrome, as well as the use of CBD with clobazam
            - Includes two new patents related to the treatment of drop seizures
            - Patents align directly with new Epidiolex FDA label and listed in Orange Book
            - Patent expiry dates to 2035
        - Additional patent applications under review and being filed as new data is generated
- Pipeline progress
    - Sativex® (nabiximols)
        - Initial U.S. target indication: Multiple Sclerosis spasticity
            - Three positive Phase 3 trials completed in Europe
            - FDA meeting expected in December to determine optimal regulatory pathway in the U.S
        - U.S. development and commercialization rights wholly owned by GW
        - Over 10 placebo-controlled trials already completed in other indications, representing significant U.S. lifecycle management opportunities
    - CBDV
        - 10-patient investigator-initiated expanded access program for seizures associated with autism underway
            - Initial data on 5 patients to be presented at American Epilepsy Society Annual Meeting shows encouraging signals on seizures and autism-related outcomes
        - Investigator-led 100 patient placebo-controlled trial in autism spectrum disorder due to commence in Q4 2018
        - Open label study in Rett syndrome and seizures due to commence Q1 2019
    - CBD:THC in Glioblastoma
        - Phase 2 study showed significant increase in median survival for patients taking CBD:THC of 662 days compared to 369 days on placebo
        - Orphan Drug Designation from both FDA and EMA for CBD:THC to treat glioblastoma
    - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
        - Phase 1 trial complete
        - Orphan Drug and Fast Track Designations granted from FDA and EMA
        - Phase 2 trial expected to start in H1 2019

FINANCIAL HIGHLIGHTS (U.S. GAAP)

- Cash and cash equivalents at September 30, 2018 were $354.9 million compared to $322.2 million as of September 30, 2017
- Revenue for the year ended September 30, 2018 was $12.7 million compared to $8.6 million for the year ended September 30, 2017
- Net loss for the year ended September 30, 2018 was $295.2 million compared to $170.5 million for the year ended September 30, 2017
- October equity financing resulted in net proceeds of $324.2 million

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the fourth quarter year-end 2018 financial results today at 4:30 pm EST. 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 or 919-882-2331 (international). For both dial-in numbers please use conference Replay ID: 41034.

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.

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.

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 (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. 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, including the current report on Form 8K filed on 1 October, 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.

Enquiries:

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

U.S. Media Enquiries:
Sam Brown Inc. Healthcare Communications
Christy Curran 615 414 8668
Mike Beyer 312 961 2502

EU Media Enquiries:
FTI Consulting
Ben Atwell/Andrew Ward +44 (0) 203 727 1000

GW PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended September 30,	
	2018	**2017**
Revenues		
Product net sales	$ 2,343	$ 2,368
Other revenue	77	82
Total revenues	2,420	2,450
Operating expenses		
Cost of product sales	1,399	1,344
Research and development	28,943	30,149
Selling, general and administrative	52,685	19,371
Total operating expenses	83,027	50,864
Loss from operations	(80,607)	(48,414)
Interest income, net	986	440
Foreign exchange (loss) gain	(823)	(5,201)
Loss before income taxes	(80,444)	(53,175)
Income tax expense (benefit)	(565)	678
Net loss	$ (79,879)	$ (53,853)
Net loss per common share, basic and diluted	$ (0.23)	$ (0.18)
Weighted average common shares outstanding, basic and diluted	341,302	306,263

GW PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,	
	2018	**2017**
Revenues		
Product net sales	$ 10,469	$ 7,957
Other revenue	2,268	672
Total revenues	12,737	8,629
Operating expenses		

Cost of product sales	5,986	4,521
Research and development	153,736	112,249
Selling, general and administrative	141,818	58,020
Total operating expenses	301,540	174,790
Loss from operations	(288,803)	(166,161)
Interest income, net	2,396	1,112
Foreign exchange (loss) gain	(4,963)	(6,442)
Loss before income taxes	(291,370)	(171,491)
Income tax expense (benefit)	3,797	(1,032)
Net loss	$ (295,167)	$ (170,459)
Net loss per common share, basic and diluted	$ (0.88)	$ (0.56)
Weighted average common shares outstanding, basic and diluted	333,936	305,826

GW PHARMACEUTICALS PLC
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30,	
	2018	**2017**
Assets		
Cash and cash equivalents	$ 354,913	$ 322,154
Accounts receivable, net	2,122	1,367
Inventory	19,061	5,669
Prepaid expenses and other current assets	14,615	35,392
Total current assets	390,711	364,582
Property and equipment, net	82,381	63,175
Goodwill	6,959	6,959
Deferred tax assets	7,334	6,805
Other assets	3,150	1,401
Total assets	$ 490,535	$ 442,922
Liabilities and stockholders' equity		
Accounts payable	$ 9,741	$ 7,757
Accrued liabilities	46,739	33,656
Current tax liabilities	1,385	1,119
Other current liabilities	804	2,377
Total current liabilities	58,669	44,909
Long-term liabilities		
Capital lease liabilities	1,535	1,741
Build-to-suit financing obligation	4,378	4,611
Other liabilities	10,794	10,838
Total long-term liabilities	16,707	17,190
Total liabilities	75,376	62,099
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Ordinary shares par value £0.001; 340,246,840 and 304,439,740 shares issued as of September 30, 2018 and 2017, respectively	530	482
Additional paid-in capital	1,246,857	916,726
Accumulated deficit	(757,034)	(461,867)

Accumulated other comprehensive (loss) income	(75,194)	(74,518)
Total stockholders' equity	415,159	380,823
Total liabilities and stockholders' equity	$ 490,535	$ 442,922

GW PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended September 30,	
	2018	**2017**
Cash flows from operating activities		
Net loss	$ (295,167)	(170,459)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	31,627	15,479
Depreciation and amortization	9,290	7,054
Loss on disposal of assets	241	1,554
Changes in operating assets and liabilities:		
Accounts receivable, net	(804)	(277)
Inventory	(13,646)	5
Prepaid expenses and other current assets	19,406	(3,191)
Other assets	(564)	-
Accounts payable	2,238	3,171
Income taxes	(263)	(3,713)
Accrued liabilities	16,507	1,253
Other current liabilities	(1,546)	(11)
Long-term liabilities	813	161
Net cash used in operating activities	(231,868)	(148,974)
Cash flows from investing activities		
Additions to property, plant and equipment	(31,362)	(19,285)
Additions to capitalized software	(2,042)	(812)
Proceeds from disposal of property, plant and equipment	517	-
Net cash used in investing activities	(32,887)	(20,097)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares, net of issuance costs	297,931	-
Proceeds from exercise of stock options	621	122
Payments on build-to-suit financing obligation	(113)	(105)
Payments on capital leases	(163)	(156)
Payments on landlord financing obligation	(522)	(1,074)
Net cash provided by (used in) financing activities	297,754	(1,213)
Effect of exchange rate changes on cash	(240)	8,993
Net increase (decrease) in cash and cash equivalents	32,759	(161,291)
Cash and cash equivalents at beginning of period	322,154	483,445
Cash and cash equivalents at end of period	$ 354,913	322,154

Source: GW Pharmaceuticals plc