GW Pharmaceuticals plc Reports Financial Results and Operational Progress for the First Quarter Ended March 31, 2019

May 6, 2019

- Epidiolex U.S. Q1 net sales of $33.5m -
- Positive Phase 3 pivotal results in Tuberous Sclerosis Complex, sNDA submission expected in Q4 2019 -
- Conference call today at 4:30 p.m. EDT -

CARLSBAD, Calif., May 06, 2019 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the science, development and commercialization of cannabinoid prescription medicines, announces financial results for the first quarter ended March 31, 2019.

“We are pleased to report a strong launch of Epidiolex in the US and continue to be encouraged by the level of support for this medicine from patients, caregivers and healthcare professionals. As the first and only plant-derived CBD medicine approved by the FDA, Epidiolex offers a novel treatment option for patients with Lennox-Gastaut Syndrome and Dravet syndrome, two highly treatment-resistant forms of childhood-onset epilepsy”, stated Justin Gover, GW’s Chief Executive Officer. “In addition, we are delighted to report today positive results from a Phase 3 trial in patients with seizures associated with Tuberous Sclerosis Complex, and are excited at the prospect of expanding the use of Epidiolex to these high need patients in the future.”

OPERATIONAL HIGHLIGHTS

- Darren Cline appointed U.S. Chief Commercial Officer
- Epidiolex® (cannabidiol)
  - U.S. commercial update
    - Q1 Net sales of $33.5m
    - Over 7,600 patients have received Epidiolex prescriptions since launch
    - Over 1,900 physicians have generated dispensed prescriptions since launch
    - Pharmacy distribution network now includes over 145 distribution points
    - Approximately 75 percent of 900 patients in expanded access program and open label extension now transitioned to commercial product. Remaining patients expected to transition by end of Q2.
  - Rapid and encouraging payor coverage decisions
    - Over 90 percent of all U.S. lives now covered – 65 percent of which have either Prior Authorization (PA) to indication or less restrictive
    - New commercial coverage determination recently announced by United HealthCare, OptumRx and Prime Therapeutics
    - 99 percent of State Fee-for-Service Medicaid lives now have a coverage determination with 67 percent of covered lives having either PA to indication or less restrictive
      - 7 States covering Epidiolex without restrictions
    - Approximately 90 percent of Managed Medicaid lives have a coverage determination with 40 percent having a PA to indication or less restrictive
  - Target physician coverage
    - The sales organization has to date interacted with about 70 percent of the over 5,000 target healthcare professionals including all Level 3 and 4 epilepsy centers
  - European regulatory and pre-launch progress
    - CHMP opinion expected mid-2019
    - Launches expected in major five European markets by end of 2019
  - Manufacturing
    - Commercial manufacturing and supply chain running smoothly
    - Production capacity sufficient to meet expected demand in both U.S. and Europe
  - Clinical trials
    - Positive results in Phase 3 trial in Tuberous Sclerosis Complex
      - Primary efficacy measure achieved with both Epidiolex doses compared to placebo
      - sNDA submission expected in Q4 2019
    - IND open for pivotal Phase 3 trial in Rett Syndrome with expected start in Q2 2019
  - Life-cycle management
    - Several new formulations of CBD in development including modified oral solution, capsule and intravenous

formulation
        - PK data expected in 2019
    - Exclusivity
        - 7 years of orphan exclusivity confirmed by FDA, plus 6-month pediatric extension expected. 10 years of orphan exclusivity in Europe plus 2 year pediatric extension
        - Key favorable patent grants by USPTO related to the use of CBD in epilepsy
            - Patents align directly with new Epidiolex FDA label and listed in “Orange Book”
            - Patent expiry dates to 2035
        - Additional patent applications under review, including patents related to the use of Epidiolex in TSC
- Pipeline progress
    - Sativex® (nabiximols)
        - FDA meeting in December 2018 resulted in regulatory pathway in the U.S.
            - Initial U.S. target indication: Multiple Sclerosis spasticity
            - Single Phase 3 pivotal study expect to commence in Q4 2019
        - Over 10 placebo-controlled trials already completed in other indications, representing significant U.S. lifecycle management opportunities
    - CBDV
        - Initial data from 5 patient expanded access program in patients with seizures and autism presented at American Epilepsy Society Annual Meeting suggest that CBDV is well tolerated and has potential as an AED/behavioral/cognitive medicine in the autism/epilepsy population
        - Company sponsored IND open for 30-patient open label study in autism
        - Investigator-led 100 patient placebo-controlled trial in autism spectrum disorder has commenced recruitment
        - Open label study in Rett syndrome and seizures has commenced

FINANCIAL HIGHLIGHTS

- Cash and cash equivalents at March 31, 2019 were $521.7 million compared to $591.5 million as of December 31, 2018
- Revenue for the quarter ended March 31, 2019 was $39.2 million compared to $3.0 million for the quarter ended March 31, 2018
- Net loss for the quarter ended March 31, 2019 was $50.1 million compared to $69.5 million for the quarter ended March 31, 2018
- Closed transaction to sell Rare Pediatric Disease Priority Review Voucher for $105 million on April 5, 2019. The sale will be reflected in our Q2 2019 results

Conference Call and Webcast Information
GW Pharmaceuticals will host a conference call and webcast to discuss the quarter ending March 31, 2019 financial results today at 4:30 pm EDT. 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: 47716.

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 and which is now available by prescription in the U.S. 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 including Tuberous Sclerosis Complex (TSC) andRett syndrome. 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 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 Sativex (nabiximols) and the safety profile and commercial potential of EPIDIOLEX and Sativex. 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 most recent Form 10-KT filed on 26 February 2019. 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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GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 521,669	$ 591,497
Accounts receivable, net	19,251	4,192
Inventory	48,559	33,030
Prepaid expenses and other current assets	19,389	17,903
Total current assets	608,868	646,622
Property, plant, and equipment, net	102,029	90,832
Operating lease assets	20,077	—
Goodwill	6,959	6,959
Deferred tax assets	8,584	8,720
Other assets	3,040	2,935
Total assets	$ 749,557	$ 756,068
Liabilities and stockholders' equity		
Accounts payable	$ 10,794	$ 9,796
Accrued liabilities	59,782	52,477
Current tax liabilities	1,730	2,384
Other current liabilities	5,651	1,559
Total current liabilities	77,957	66,216
Long-term liabilities:		
Finance lease liabilities	5,801	5,690
Operating lease liabilities	16,374	—
Other liabilities	9,696	10,082
Total long-term liabilities	31,871	15,772
Total liabilities	109,828	81,988
Commitments and contingencies		
Stockholders' equity:		
Ordinary shares par value £0.001; 368,613,440 shares outstanding as of March 31, 2019; 366,616,688 shares outstanding as of December 31, 2018	567	564
Additional paid-in capital	1,593,056	1,581,144
Accumulated deficit	(879,004)	(828,940)
Accumulated other comprehensive loss	(74,890)	(78,688)
Total stockholders' equity	639,729	674,080
Total liabilities and stockholders' equity	$ 749,557	$ 756,068

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Revenues		
Product net sales	$ 38,974	$ 2,812
Other revenue	273	229
Total revenues	39,247	3,041
Operating expenses		
Cost of product sales	5,131	1,625
Research and development	30,375	43,485
Selling, general and administrative	55,078	26,173
Total operating expenses	90,584	71,283
Loss from operations	(51,337)	(68,242)
Interest income	2,087	759
Interest expense	(265)	(325)
Foreign exchange loss	(1,114)	(640)
Loss before income taxes	(50,629)	(68,448)
Income tax (benefit) expense	(565)	1,013
Net loss	$ (50,064)	$ (69,461)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.20)
Weighted average common shares outstanding, basic and diluted	369,823	340,252

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (50,064)	$ (69,461)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange loss	797	873
Stock-based compensation	11,142	6,859
Depreciation and amortization	2,417	2,307
Deferred income taxes	—	2,128
Changes in operating assets and liabilities:		
Accounts receivable, net	(14,998)	(320)
Inventory	(14,295)	672
Prepaid expenses and other current assets	(874)	(492)
Other assets	659	(3)
Accounts payable	1,998	652
Current tax liabilities	(654)	(2,684)
Accrued liabilities	6,328	(7,005)
Other current liabilities	191	1,103
Long-term liabilities	(1,029)	(30)
Net cash used in operating activities	(58,382)	(65,401)
Cash flows from investing activities		
Additions to property, plant and equipment	(12,087)	(6,056)
Additions to capitalized software	(199)	(338)
Net cash used in investing activities	(12,286)	(6,394)
Cash flows from financing activities		
Proceeds from exercise of stock options	773	1
Payments on finance leases	(179)	(72)
Payments on landlord financing obligation	(138)	(137)
Net cash provided by (used in) financing activities	456	(208)

Effect of exchange rate changes on cash	384	11
Net increase (decrease) in cash and cash equivalents	(69,828)	(71,992)
Cash and cash equivalents at beginning of period	591,497	559,227
Cash and cash equivalents at end of period	$ 521,669	$ 487,235