GW Pharmaceuticals plc Reports Financial Results and Operational Progress for the Second Quarter Ended June 30, 2019

August 6, 2019

- Epidiolex U.S. Q2 net sales of $68.4 million -
- Positive CHMP opinion clears way for an expected European approval in October -
- Conference call today at 4:30 p.m. EST -

CARLSBAD, Calif., Aug. 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 second quarter ended June 30, 2019.

“We are pleased to report a strong second quarter of sales of Epidiolex in the US, reflecting high demand by US patients, increased prescribing by healthcare providers, and ongoing progress in payor coverage determinations. With the recent positive Phase 3 trial in Tuberous Sclerosis Complex, we expect to submit an sNDA by the end of 2019 with the goal of expanding the Epidiolex label and market opportunity to include both children and adult patients with TSC, a highly treatment-resistant condition,” stated Justin Gover, GW’s Chief Executive Officer. “In Europe, we are pleased to have recently received the positive opinion from the CHMP which clears the way for an expected approval in October. Our European commercial organization is in place and will be ready to launch in the first European markets upon approval, making this important new treatment option available to deserving European patients.”

OPERATIONAL HIGHLIGHTS

- Epidiolex® (cannabidiol)
  - U.S. commercial update
    - Q2 Net sales of $68.4M; $101.9M net sales in the first half of 2019
    - Over 12,000 patients have received Epidiolex prescriptions since launch
    - Over 2,500 physicians have generated dispensed prescriptions since launch
    - Pharmacy distribution network delivering median time to fill a first prescription in approximately 2 weeks
    - Vast majority of patients who have received Epdiolex remain on therapy
    - Transition of 900 patients in expanded access program and open label extension to commercial product complete
  - Strong payor coverage
    - Approximately 93 percent of all Commercial, Medicaid and Medicare lives in the US have a coverage determination, of which 65% are PA to indication or less restrictive
  - European launch update
    - Positive CHMP opinion with European Commission approval expected in early October
    - Q4 launches expected in France, Germany and UK; Spain and Italy launches to follow in 2020
    - Early Access Program in Europe for Dravet syndrome and LGS patients now includes over 800 patients registered across 5 major EU countries
  - Manufacturing
    - Commercial manufacturing and supply chain running smoothly
    - Production capacity sufficient to meet expected demand in both U.S. and Europe
  - Clinical trials
    - Phase 3 trial in Rett Syndrome now recruiting
  - 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 expected
    - Key favorable patent grants by USPTO related to the use of CBD in epilepsy
      - 9 patents listed in “Orange Book” and align directly with Epidiolex FDA label
      - Patent expiry dates to 2035
    - Additional patent applications under review, including patents related to the use of Epidiolex in TSC and other indications

- Pipeline progress
  - Sativex® (nabiximols)
    - Initial U.S. target indication: Multiple Sclerosis spasticity
      - Clinical program expected to commence in Q4 to augment existing pivotal data package
      - No new oral anti-spasticity treatments developed in the field for over 20 years
      - Novel mechanism of action
    - Potential “pipeline in a product” with over 10 placebo-controlled trials already completed in other indications
  - CBDV
    - Potential both within field of autism and epilepsy
    - IND open for 30-patient open label study in autism expected to begin recruitment by the end of 2019
    - Investigator-led 100 patient placebo-controlled trial in autism spectrum disorder has commenced recruitment
    - Open label study in Rett syndrome and seizures ongoing
  - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
    - Phase 1 trial complete in healthy volunteers
    - Safety study in patients expected to commence in Q4
    - Orphan Drug and Fast Track Designations granted from FDA and EMA

FINANCIAL HIGHLIGHTS

- Revenue for the quarter ended June 30, 2019 was $72.0 million compared to $3.3 million for the quarter ended June 30, 2018
- Cash and cash equivalents at June 30, 2019 were $583.7 million compared to $591.5 million as of December 31, 2018
- Closed on sale of Rare Pediatric Priority Review Voucher in the quarter and recognized net proceeds of $104.1 million as a gain on the sale of an intangible asset
- Net income for the quarter ended June 30, 2019 was $79.7 million compared to a net loss of $84.0 million for the quarter ended June 30, 2018

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the quarter ending June 30, 2019 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: 51890.

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 and has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP). The company continues to evaluate EPIDIOLEX in additional rare conditions including Tuberous Sclerosis Complex (TSC) and Rett 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, autism, 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)

	June 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 583,683	$ 591,497
Accounts receivable, net	32,113	4,192
Inventory	60,042	33,030
Prepaid expenses and other current assets	21,693	17,903
Total current assets	697,531	646,622
Property, plant, and equipment, net	107,332	90,832
Operating lease assets	18,739	—
Goodwill	6,959	6,959
Deferred tax assets	8,726	8,720
Other assets	3,490	2,935
Total assets	$ 842,777	$ 756,068
Liabilities and stockholders' equity		
Accounts payable	$ 11,757	$ 9,796
Accrued liabilities	66,434	52,477
Current tax liabilities	—	2,384
Other current liabilities	5,757	1,559
Total current liabilities	83,948	66,216
Long-term liabilities:		
Finance lease liabilities	5,536	5,690
Operating lease liabilities	15,139	—
Other liabilities	9,262	10,082
Total long-term liabilities	29,937	15,772
Total liabilities	113,885	81,988
Commitments and contingencies		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 370,621,184 shares outstanding as of June 30, 2019; 366,616,688 shares outstanding as of December 31, 2018	570	564
Additional paid-in capital	1,607,346	1,581,144
Accumulated deficit	(799,256)	(828,940)
Accumulated other comprehensive loss	(79,768)	(78,688)
Total stockholders' equity	728,892	674,080
Total liabilities and stockholders' equity	$ 842,777	$ 756,068

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

	Three Months Ended June 30,	Six Months Ended June 30,

	2019	2018	2019	2018
Revenues				
Product net sales	$ 71,489	$ 3,094	$ 110,463	$ 5,906
Other revenue	549	190	822	419
Total revenues	72,038	3,284	111,285	6,325
Operating expenses				
Cost of product sales	6,620	1,791	11,751	3,416
Research and development	32,467	45,113	62,842	88,598
Selling, general and administrative	62,273	37,786	117,351	63,959
Total operating expenses	101,360	84,690	191,944	155,973
Loss from operations	(29,322)	(81,406)	(80,659)	(149,648)
Interest income	2,310	999	4,397	1,758
Interest expense	(268)	(313)	(533)	(638)
Other income	104,117	—	104,117	—
Foreign exchange gain (loss)	2,026	(3,660)	912	(4,300)
Income (loss) before income taxes	78,863	(84,380)	28,234	(152,828)
Income tax (benefit) expense	(885)	(369)	(1,450)	644
Net income (loss)	$ 79,748	$ (84,011)	$ 29,684	$ (153,472)
Net income (loss) per share:				
Basic	$ 0.21	$ (0.25)	$ 0.08	$ (0.45)
Diluted	$ 0.21	$ (0.25)	$ 0.08	$ (0.45)
Weighted average shares outstanding:				
Basic	371,712	340,457	370,776	340,355
Diluted	377,435	340,457	376,674	340,355

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

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities		
Net income (loss)	$ 29,684	$ (153,472)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Foreign exchange loss	882	3,930
Share-based compensation	23,330	16,426
Depreciation and amortization	4,808	4,720
Deferred income taxes	—	1,407
Gain from sale of priority review voucher	(104,117)	-
Other	21	148
Changes in operating assets and liabilities:		
Accounts receivable, net	(27,924)	(423)
Inventory	(27,070)	2,501
Prepaid expenses and other current assets	(6,819)	22,139
Other assets	1,542	(249)
Accounts payable	3,488	3,156

Current tax liabilities	619	(3,458)
Accrued liabilities	13,887	3,599
Other liabilities	(2,192)	1,265
Net cash used in operating activities	(89,861)	(98,311)
Cash flows from investing activities		
Proceeds from sale of priority review voucher	104,117	-
Additions to property, plant and equipment	(22,515)	(14,675)
Additions to capitalized software	(1,017)	(983)
Net cash provided by (used in) investing activities	80,585	(15,658)
Cash flows from financing activities		
Proceeds from exercise of stock options	2,878	2
Payments on finance leases	(250)	(143)
Payments on landlord financing obligation	(273)	(271)
Net cash provided by (used in) financing activities	2,355	(412)
Effect of exchange rate changes on cash	(893)	(4,906)
Net decrease in cash and cash equivalents	(7,814)	(119,287)
Cash and cash equivalents at beginning of period	591,497	559,227
Cash and cash equivalents at end of period	$ 583,683	$ 439,940