



## GW Pharmaceuticals plc Reports First Quarter 2020 Financial Results and Operational Progress

May 11, 2020

- Total revenue of \$120.6 million -  
- Total Epidiolex® net product sales of \$116.1 million -  
- Conference call today at 4:30 p.m. EDT -

LONDON and CARLSBAD, Calif., May 11, 2020 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq: GWPH), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, today announces financial results for the first quarter ended March 31, 2020.

"In the first quarter of 2020, we have seen continued strength of the Epidiolex brand in both the U.S. and Europe and remain confident about prospects for growth in the remainder of the year. Having been granted priority review by the FDA for our proposed label expansion to include TSC, our US commercial team is actively preparing for the launch of this indication in August," stated Justin Gover, GW's CEO. "In this current environment caused by COVID-19, we have been able to support the epilepsy community remotely and maintain production of Epidiolex, while taking necessary steps to maintain the wellbeing of our employees. Looking ahead, GW is well placed to emerge strongly from the COVID-19 crisis with significant growth prospects for Epidiolex in the US and Europe, important pipeline clinical trials ready to execute, a strong balance sheet, and an unparalleled leading position in cannabinoid science."

### FINANCIAL RESULTS

- Total revenue for the quarter ended March 31, 2020 was \$120.6 million compared to \$39.2 million for the quarter ended March 31, 2019
- Net loss for the quarter ended March 31, 2020 was \$8.0 million compared to a net loss of \$50.1 million for the quarter ended March 31, 2019
- Cash and cash equivalents at March 31, 2020 were \$500.9 million compared to \$536.9 million as of December 31, 2019

### OPERATIONAL HIGHLIGHTS

- Epidiolex (cannabidiol) progress:
  - Total Q1 net product sales of Epidiolex of \$116.1 million
  - U.S. commercial update
    - U.S. Epidiolex Q1 net product sales of \$106.1 million
    - August commercial launch planned for TSC indication; July 31 PDUFA date
    - Epidiolex descheduled by the DEA
    - Payer discussions focused on pending TSC approval and expanding coverage
  - European commercial update
    - Successful commercial launches in Germany and UK
    - Important pricing & reimbursement progress in Germany & Italy. Commercial launches in France, Spain and Italy on track for later this year
    - TSC EMA submission accepted for review
  - Clinical progress with additional indications to broaden addressable market
    - Phase 3 trial in Rett Syndrome (recruitment temporarily on hold)
    - Several new formulations of CBD advancing into additional Phase 1 studies in 2020, including modified oral solution and capsule
  - Strengthening commercial exclusivity
    - Orphan exclusivity in both the U.S. and EU
    - 10 granted patents listed in Orange Book with expiry dates to 2035, including 1 patent recently granted broadly covering use in LGS and Dravet syndrome
    - Epidiolex composition patent application in process
    - 1 new allowed patent covering seizure sub-type use in Dravet syndrome expected to grant in Q2 2020
    - TSC patent applications under review with initial grant expected in 2020
- Pipeline progress
  - Start of new clinical programs delayed until H2 2020 due to current COVID restrictions
  - Nabiximols (Sativex®) outside of the US
    - Multiple Sclerosis spasticity
      - US pivotal clinical program expected to commence in H2 2020 to augment existing data package

- 3 positive Phase 3 trials completed in Europe
      - Spinal cord injury spasticity - clinical program expected to commence in H2 2020
      - PTSD – clinical program expected to commence in H2 2020
  - Schizophrenia (GWP42003)
    - Phase 2b trial expected to commence H2 2020
  - CBDV in autism
    - 30-patient open label study in autism
    - Investigator-led 100 patient placebo-controlled trial in autism
    - Open label study in Rett syndrome and seizures
  - Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program commenced
    - Phase 1b safety study in patients continues to recruit due to emergency care environment
    - Orphan Drug and Fast Track Designations granted from FDA and EMA

#### Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast 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: 34479.

#### 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. The Company's lead product, EPIDIOLEX® (cannabidiol) oral solution, is commercialized in the U.S. by its U.S. subsidiary Greenwich Biosciences for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome in patients two years of age or older. This product has received approval in the European Union under the tradename EPIDYOLEX®. The Company has submitted applications in both the U.S. and Europe to expand the indication for Epidiolex to include seizures associated with Tuberous Sclerosis Complex (TSC), for which it has reported positive Phase 3 data, and is carrying out a Phase 3 trial in Rett syndrome. The Company has a deep pipeline of additional cannabinoid product candidates, in particular nabiximols, for which the Company is advancing multiple late-stage clinical programs in order to seek FDA approval in the treatment of spasticity associated with multiple sclerosis and spinal cord injury, as well as for the treatment of PTSD. The Company has additional cannabinoid product candidates in Phase 2 trials for autism and schizophrenia. For further information, please visit [www.gwpharm.com](http://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®/EPIDYOLEX® (cannabidiol) oral solution and Sativex® (nabiximols), and the safety profile and commercial potential of both medicines, and those associated with the COVID-19 pandemic, and those associated with the COVID-19 pandemic. 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 EPIDIOLEX®/EPIDYOLEX®, Sativex® 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.*

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	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Cash and cash equivalents	\$ 500,935	\$ 536,933
Accounts receivable, net	62,209	48,883
Inventory	89,056	85,528
Prepaid expenses and other current assets	20,546	28,292
Total current assets	<u>672,746</u>	<u>699,636</u>
Property, plant, and equipment, net	122,882	127,765
Operating lease assets	23,199	24,916
Intangible assets	5,951	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	18,123
Other assets	4,517	4,850
Total assets	<u>\$ 854,377</u>	<u>\$ 882,249</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 18,345	\$ 9,990
Accrued liabilities	77,479	99,374
Current tax liabilities	998	437
Other current liabilities	6,650	7,760
Total current liabilities	<u>103,472</u>	<u>117,561</u>
Long-term liabilities:		
Finance lease liabilities	5,157	5,573
Operating lease liabilities	20,028	21,650
Other liabilities	10,715	11,431
Total long-term liabilities	<u>35,900</u>	<u>38,654</u>
Total liabilities	<u>139,372</u>	<u>156,215</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 372,562,088 shares outstanding as of March 31, 2020; 371,068,436 shares outstanding as of December 31, 2019	573	570
Additional paid-in capital	1,643,407	1,632,046
Accumulated deficit	(845,924)	(837,959)
Accumulated other comprehensive loss	(83,051)	(68,623)
Total stockholders' equity	<u>715,005</u>	<u>726,034</u>
Total liabilities and stockholders' equity	<u>\$ 854,377</u>	<u>\$ 882,249</u>

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

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2020</u>	<u>2019</u>
<b>Revenues</b>		
Product net sales	\$ 120,532	\$ 38,974
Other revenue	101	273
Total revenues	<u>120,633</u>	<u>39,247</u>
<b>Operating expenses</b>		
Cost of product sales	10,769	5,131
Research and development	45,874	30,375
Selling, general and administrative	71,183	55,078
Total operating expenses	<u>127,826</u>	<u>90,584</u>
Loss from operations	(7,193)	(51,337)
Interest income	1,269	2,087
Interest expense	(284)	(265)
Foreign exchange loss	(20)	(1,114)
Loss before income taxes	<u>(6,228)</u>	<u>(50,629)</u>

Income tax expense (benefit)	1,737	(565)
Net loss	<u>\$ (7,965)</u>	<u>\$ (50,064)</u>
Net loss per share:		
Basic	<u>\$ (0.02)</u>	<u>\$ (0.14)</u>
Diluted	<u>\$ (0.02)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding:		
Basic	373,831	369,823
Diluted	373,831	369,823

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

	<b>Three Months Ended March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (7,965)	\$ (50,064)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Foreign exchange loss	60	797
Share-based compensation	11,361	11,142
Depreciation and amortization	2,656	2,417
Other	27	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(13,630)	(14,998)
Inventory	(8,928)	(14,295)
Prepaid expenses and other current assets	5,377	(874)
Other assets	885	659
Accounts payable	8,585	1,998
Current tax liabilities	1,726	(654)
Accrued liabilities	(16,953)	6,328
Other liabilities	(1,799)	(838)
Net cash used in operating activities	<u>(18,598)</u>	<u>(58,382)</u>
<b>Cash flows from investing activities</b>		
Additions to property, plant and equipment	(6,361)	(12,087)
Additions to capitalized software	(535)	(199)
Additions to intangible assets	(6,404)	—
Net cash used in investing activities	<u>(13,300)</u>	<u>(12,286)</u>
<b>Cash flows from financing activities</b>		
Proceeds from exercise of stock options	3	773
Payments on finance leases	(73)	(179)
Payments on landlord financing obligation	(143)	(138)
Net cash (used in) provided by financing activities	<u>(213)</u>	<u>456</u>
Effect of exchange rate changes on cash	(3,887)	384
Net decrease in cash and cash equivalents	(35,998)	(69,828)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	<u>\$ 500,935</u>	<u>\$ 521,669</u>
<b>Supplemental disclosure of cash flow information:</b>		
Income taxes paid	10	88
Interest paid	285	265
<b>Supplemental disclosure of noncash information:</b>		
Property and equipment purchases in accounts payable and accrued liabilities	1,661	714
Right-of-use asset obtained in exchange for operating liabilities	275	—