



GW Pharmaceuticals plc Reports Third Quarter 2020 Financial Results and Operational Progress

November 3, 2020

- Total revenue increased 51 percent to \$137.1 million –
- Epidiolex for seizures associated with TSC launched in the U.S. -
- Nabiximols Phase 3 program in MS spasticity now recruiting -
- Conference call today at 8:30 a.m. EST -

LONDON and CARLSBAD, Calif., Nov. 03, 2020 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (Nasdaq: GWPH), a world leader in the science, development, and commercialization of cannabinoid prescription medicines, today announced financial results and operating progress for the third quarter ended September 30, 2020.

"We are pleased to report strong revenue growth in the 3rd quarter despite the challenges presented by COVID-19. Epidiolex meets a serious unmet need within the field of epilepsy and we expect the product to demonstrate continued strong growth in the months and years ahead. The recent expanded indication for the treatment of seizures associated with TSC has been very well received by patients, clinicians and payers," stated Justin Gover, GW's Chief Executive Officer. "We have also now commenced the pivotal Phase 3 program for nabiximols in the treatment of multiple sclerosis spasticity, which provides multiple opportunities for an NDA submission, including as early as next year. Beyond nabiximols, we are advancing several clinical-stage pipeline candidates, including the recent start of a Phase 2 trial in schizophrenia."

FINANCIAL RESULTS

- Total revenue for the quarter ended September 30, 2020 was \$137.1 million compared to \$91.0 million for the quarter ended September 30, 2019
- Total revenue for the first nine months of 2020 of \$378.6 million compared to \$202.3 million in the prior year period
- Net loss for the quarter ended September 30, 2020 was \$12.2 million compared to net loss of \$13.8 million for the quarter ended September 30, 2019
- Cash and cash equivalents at September 30, 2020 were \$480.3 million

OPERATIONAL HIGHLIGHTS

- Epidiolex (cannabidiol) progress:
 - Total Q3 net product sales of Epidiolex of \$132.6 million
 - U.S. commercial update
 - U.S. Epidiolex Q3 net product sales of \$121.6 million
 - TSC indication launched with high prescriber awareness and near universal payer coverage
 - Expanded payer coverage
 - 85 million lives with no/broad prior authorization (+47% year-to-date)
 - Ex-U.S. commercial update
 - Ex-U.S. Epidiolex Q3 net product sales of \$11.0 million
 - UK pricing and reimbursement in place. Progress in Germany, France, Italy and Spain
 - TSC EMA submission under review
 - Epidiolex approved in Australia
 - Strengthening commercial exclusivity
 - Orphan exclusivity in both the U.S. and EU
 - 13 patents listed in Orange Book, 12 of which expire in 2035
 - Patents include formulation and method of use
 - Epidiolex composition patent application in process
 - Two further Orange Book listable patents to be allowed or granted by Q1 2021
- Nabiximols development program:
 - First Phase 3 MS Spasticity trial underway
 - Phase 3 placebo-controlled spasm frequency study (N=450)
- MS Spasticity trials due to commence
 - Phase 3 placebo-controlled muscle tone studies:
 - N=52; Expected start Q4 2020 (subject to COVID)
 - N=190; Expected start: Q1 2021
 - N=36 (nabiximols responders); Expected start: Q1 2021
 - Additional Phase 3 placebo-controlled spasm frequency study (N=200) in nabiximols responders expected start Q2

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Cash and cash equivalents	\$ 480,330	\$ 536,933
Accounts receivable, net	80,424	48,883
Inventory	115,036	85,528
Prepaid expenses and other current assets	44,485	28,292
Total current assets	<u>720,275</u>	<u>699,636</u>
Property, plant, and equipment, net	131,204	127,765
Operating lease assets	22,297	24,916
Intangible assets	5,564	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	18,123
Other assets	5,839	4,850
Total assets	<u>\$ 910,261</u>	<u>\$ 882,249</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 17,841	\$ 9,990
Accrued liabilities	114,898	99,374
Current tax liabilities	—	437
Other current liabilities	7,549	7,760
Total current liabilities	<u>140,288</u>	<u>117,561</u>
Long-term liabilities:		
Finance lease liabilities	5,219	5,573
Operating lease liabilities	19,607	21,650
Other liabilities	10,699	11,431
Total long-term liabilities	<u>35,525</u>	<u>38,654</u>
Total liabilities	<u>175,813</u>	<u>156,215</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001;		
374,169,836 shares outstanding as of September 30, 2020;		
371,068,436 shares outstanding as of December 31, 2019	575	570
Additional paid-in capital	1,672,237	1,632,046
Accumulated deficit	(866,940)	(837,959)
Accumulated other comprehensive loss	(71,424)	(68,623)
Total stockholders' equity	<u>734,448</u>	<u>726,034</u>
Total liabilities and stockholders' equity	<u>\$ 910,261</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>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenues				
Product net sales	\$ 136,846	\$ 90,849	\$ 378,608	\$ 201,312
Other revenue	207	122	375	944
Total revenues	<u>137,053</u>	<u>90,971</u>	<u>378,983</u>	<u>202,256</u>
Operating expenses				
Cost of product sales	7,635	8,150	27,112	19,901
Research and development	56,934	36,301	148,542	99,143
Selling, general and administrative	85,205	64,178	232,282	181,529
Total operating expenses	<u>149,774</u>	<u>108,629</u>	<u>407,936</u>	<u>300,573</u>

Loss from operations	(12,721)	(17,658)	(28,953)	(98,317)
Interest income	208	2,249	1,727	6,646
Interest expense	(269)	(272)	(850)	(805)
Other income	-	-	-	104,117
Foreign exchange (loss) gain	(1,796)	1,889	(430)	2,801
(Loss) income before income taxes	(14,578)	(13,792)	(28,506)	14,442
Income tax (benefit)expense	(2,390)	(35)	475	(1,485)
Net (loss) income	<u>\$ (12,188)</u>	<u>\$ (13,757)</u>	<u>\$ (28,981)</u>	<u>\$ 15,927</u>
Net (loss) income per share:				
Basic	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ 0.04</u>
Diluted	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ 0.04</u>
Weighted average shares outstanding:				
Basic	376,281	372,246	375,218	371,286
Diluted	376,281	372,246	375,218	376,985

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

	<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Cash flows from operating activities		
Net loss	\$ (28,981)	\$ 15,927
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange (gain) loss	(132)	(418)
Share-based compensation	40,446	35,633
Depreciation and amortization	9,144	7,096
Gain from sale of priority review voucher	—	(104,117)
Other	27	39
Changes in operating assets and liabilities:		
Accounts receivable, net	(31,654)	(37,691)
Inventory	(31,184)	(37,561)
Prepaid expenses and other current assets	(8,466)	(14,869)
Other assets	2,369	2,968
Accounts payable	8,116	(1,161)
Current tax liabilities	(8,570)	(601)
Accrued liabilities	18,030	29,176
Other liabilities	(2,459)	(1,943)
Net cash used in operating activities	<u>(33,314)</u>	<u>(107,522)</u>
Cash flows from investing activities		
Proceeds from sale of priority review voucher	—	104,117
Additions to property, plant and equipment	(14,259)	(29,915)
Additions to capitalized software	(2,365)	(1,183)
Additions to intangible assets	(6,404)	—
Net cash (used) provided by in investing activities	<u>(23,028)</u>	<u>73,019</u>
Cash flows from financing activities		
Proceeds from exercise of stock options	1,577	2,878
Payments in connection with common stock withheld for employee tax obligation	(1,827)	—
Payments on finance leases	(221)	(317)
Payments on landlord financing obligation	(430)	(404)
Net cash (used in) provided by financing activities	<u>(901)</u>	<u>2,157</u>
Effect of exchange rate changes on cash	640	(4,469)
Net decrease in cash and cash equivalents	(56,603)	(36,815)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	<u>\$ 480,330</u>	<u>\$ 554,682</u>
Supplemental disclosure of cash flow information:		

Income taxes paid	9,106	7,052
Interest paid	530	805
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	1,204	1,534
Right-of-use asset obtained in exchange for operating liabilities	507	—