



February 7, 2017

GW Pharmaceuticals plc Reports First Quarter 2017 Financial Results and Operational Progress

- Epidiolex[®] NDA submission and launch preparation on track -
- New Positive Phase 2 glioma data further demonstrates value of cannabinoid pipeline -
- Conference call today at 8:30 a.m. EST -

LONDON, Feb. 07, 2017 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ:GWPH) (GW, the Company or the Group), a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform, announced financial results for the first quarter ended 31 December 2016.

"As we look forward to 2017, our primary focus is on completing the Epidiolex NDA, which we expect to submit to the FDA in the middle of this year. With three positive Phase 3 trials delivered in 2016, we remain confident in the prospects for Epidiolex's approval and are accelerating our preparations for a highly successful launch," stated Justin Gover, GW's Chief Executive Officer. "Beyond Epidiolex, the value of GW's cannabinoid platform is further illustrated by promising new clinical data in the field of oncology and we continue to advance a number of additional clinical programs that will yield data this year."

OPERATIONAL HIGHLIGHTS

- Epidiolex[®] (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and infantile spasms (IS)
 - Regulatory:
 - NDA submission for both Dravet and LGS indications expected mid 2017
 - Preparations advancing for expected EU regulatory submission in H2 2017
 - Clinical:
 - Positive results in a pivotal Phase 3 Dravet syndrome trial and in two pivotal Phase 3 LGS trials
 - Substantial new data presented at the American Epilepsy Society Annual Meeting in December 2016
 - Manufacturing scale-up on track to deliver significant commercial launch inventory
 - Pre-NDA CMC meeting held with FDA in November 2016
 - Successful UK regulatory GMP inspection of GW manufacturing facility in December 2016. On track for FDA GMP inspection anticipated in H2 2017
 - Expanded access program and open label extension:
 - Over 1,200 patients now on Epidiolex treatment
 - 97 percent of patients who complete Phase 3 trials have entered long term extension
 - Commercial:
 - US commercial team build well underway and pre-launch preparations advancing well
 - EU commercial team now being established
 - Follow-on indications:
 - Phase 3 trial in TSC ongoing
 - Two part Phase 3 trial in IS commenced in December 2016
 - Intellectual Property:
 - Patent portfolio being prosecuted with claims directed to the use of CBD in the treatment of epilepsy seizure subtypes and epilepsy syndromes
- THC:CBD for Glioma
 - Positive Phase 2 placebo-controlled data in Recurrent Glioblastoma Multiforme (GBM) (see separate announcement issued today)
 - Orphan Drug Designation from FDA and EMA
 - Multiple relevant patents granted or in process
- Other cannabinoid pipeline product candidates:
 - CBDV Phase 2 partial-onset epilepsy study in adults ongoing. Part A complete and Part B underway with data expected H2 2017
 - CBDV pre-clinical research ongoing within field of autism spectrum disorders. Phase 2 trials expected to commence in H2 2017
 - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome

- Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
 - Phase 1 trial commenced in October 2016
 - Orphan Drug and Fast Track Designations granted from FDA and EMA

FINANCIAL HIGHLIGHTS

- Revenue for the three months ended 31 December 2016 of £2.1 million (\$2.5 million) compared to £3.7 million for the three months ended 31 December 2015
- Loss for the three months ended 31 December 2016 of £15.6 million (\$19.3 million) compared to £17.7 million for the three months ended 31 December 2015
- Cash and cash equivalents at 31 December 2016 of £360.2 million (\$444.6 million) compared to £374.4 million as at 30 September 2016

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 31 December 2016 of \$1.23429 to £1. These translations should not be considered representations that any such amounts have been, could have been or could be converted into U.S. dollars at that or any other exchange rate as at that or any other date.

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the first quarter 2017 financial results today at 8:30 a.m 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, (international):1-919-882-2331. For both dial-in numbers please use conference ID # 13654672.

About GW Pharmaceuticals plc

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 is advancing an orphan drug program in the field of childhood epilepsy with a focus on Epidiolex[®] (cannabidiol), which is in Phase 3 clinical development for the treatment of Dravet syndrome, Lennox-Gastaut syndrome, Tuberous Sclerosis Complex and Infantile Spasms. GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex[®], which is approved for the treatment of spasticity due to multiple sclerosis in 31 countries outside the United States. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, schizophrenia and epilepsy. 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 Sativex[®] and Epidiolex[®] and the safety profile and commercial potential of Sativex and 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 of 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 20-F filed on 5 December 2016. 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.

GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 31 December 2016 and 2015

	Three months ended 31 December 2016 \$000's	Three months ended 31 December 2016 £000's	Three months ended 31 December 2015 £000's
Revenue	2,538	2,056	3,667
Cost of sales	(883)	(715)	(687)
Research and development expenditure	(30,751)	(24,914)	(24,139)
Sales, general and administrative expenses	(8,250)	(6,684)	(3,625)
Net foreign exchange gain	14,583	11,815	3,601
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Operating loss	(22,763)	(18,442)	(21,183)
Interest income	337	273	63
Interest expense	(111)	(90)	(19)
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Loss before tax	(22,537)	(18,259)	(21,139)
Tax benefit	3,287	2,663	3,437
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Loss for the period	(19,250)	(15,596)	(17,702)
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Loss per share — basic and diluted	(6.4c)	(5.2p)	(6.8p)
Loss per ADS — basic and diluted⁽¹⁾	(76.8c)	(62.4p)	(81.6p)
Weighted average ordinary shares outstanding (in millions) — basic and diluted		302.7	261.4

All activities relate to continuing operations.

(1) Each ADS represents 12 ordinary shares.

Condensed consolidated statement of comprehensive loss
For the three months ended 31 December 2016 and 2015

	Three months ended 31 December 2016 £000's	Three months ended 31 December 2015 £000's
Loss for the period	(15,596)	(17,702)
Items that may be reclassified subsequently to profit or loss		
Exchange gain/(loss) on retranslation of foreign operations	418	(53)
Other comprehensive gain/(loss) for the period	418	(53)
Total comprehensive loss for the period	(15,178)	(17,755)

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Three months ended 31 December 2016 and 2015

	Share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total £000's
Balance at 1 October 2015	261	349,275	19,189	(123,455)	245,270
Exercise of share options	2	562	-	-	564
Share-based payment transactions	-	-	-	1,306	1,306

Loss for the period	-	-	-	(17,702)	(17,702)
Deferred tax attributable to unrealized share option gains	-	-	-	(74)	(74)
Other comprehensive loss	-	-	(53)	-	(53)
Balance at 31 December 2015	263	349,837	19,136	(139,925)	229,311
Balance at 1 October 2016	302	556,477	19,538	(177,827)	398,490
Exercise of share options	2	88	-	-	90
Share-based payment transactions	-	-	-	2,166	2,166
Loss for the period	-	-	-	(15,596)	(15,596)
Deferred tax attributable to unrealized share option gains	-	-	-	(255)	(255)
Other comprehensive income	-	-	418	-	418
Balance at 31 December 2016	304	556,565	19,956	(191,512)	385,313

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 31 December 2016 and 30 September 2016

	As at 31 December 2016 \$000's	As at 31 December 2016 £000's	As at 30 September 2016 £000's
Non-current assets			
Intangible assets - goodwill	6,431	5,210	5,210
Other intangible assets	1,206	977	629
Property, plant and equipment	46,647	37,792	38,947
Deferred tax asset	5,351	4,335	3,873
	59,635	48,314	48,659
Current assets			
Inventories	5,722	4,636	4,248
Taxation recoverable	29,272	23,716	21,322
Trade receivables and other assets	8,488	6,877	4,556
Cash and cash equivalents	444,649	360,247	374,392
	488,131	395,476	404,518
Assets held for sale	1,122	909	-
Total assets	548,888	444,699	453,177
Current liabilities			
Trade and other payables	(45,093)	(36,534)	(31,170)
Current tax liabilities	(909)	(736)	(883)
Obligations under finance leases	(204)	(165)	(211)
Deferred revenue	(3,096)	(2,508)	(2,686)
	(49,302)	(39,943)	(34,950)
Non-current liabilities			
Trade and other payables	(11,667)	(9,452)	(9,423)
Obligations under finance leases	(6,060)	(4,910)	(4,959)
Deferred revenue	(6,271)	(5,081)	(5,355)

Total liabilities	(73,300)	(59,386)	(54,687)
Net assets	475,588	385,313	398,490
Equity			
Share capital	375	304	302
Share premium account	686,963	556,565	556,477
Other reserves	24,631	19,956	19,538
Accumulated deficit	(236,381)	(191,512)	(177,827)
Total equity	475,588	385,313	398,490

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the three months ended 31 December 2016 and 2015

	Three months ended 31 December 2016 \$000's	Three months ended 31 December 2016 £000's	Three months ended 31 December 2015 £000's
Loss for the period	(19,250)	(15,596)	(17,702)
Adjustments for:			
Interest income	(337)	(273)	(63)
Interest expense	111	90	19
Tax benefit	(3,287)	(2,663)	(3,437)
Depreciation of property, plant and equipment	1,307	1,059	736
Impairment of property, plant and equipment	117	95	-
Amortization of intangible assets	22	18	14
Net foreign exchange gains	(14,583)	(11,815)	(3,762)
Increase in provision for inventories	35	28	7
Decrease in deferred signature fees	(530)	(429)	(289)
Share-based payment charge	2,673	2,166	1,306
Loss on disposal of property, plant and equipment	687	557	-
	(33,035)	(26,763)	(23,171)
(Increase)/decrease in inventories	(513)	(416)	56
Increase in trade receivables and other assets	(2,436)	(1,974)	(2,401)
Increase in trade and other payables and deferred revenue	6,929	5,613	7,931
Income taxes paid	(555)	(450)	(366)
Net cash outflow from operating activities	(29,610)	(23,990)	(17,951)
Investing activities			
Interest received	170	138	70
Purchases of property, plant and equipment	(1,698)	(1,376)	(1,782)
Purchases of intangible assets	(272)	(220)	(119)
Net cash outflow from investing activities	(1,800)	(1,458)	(1,831)
Financing activities			
Proceeds on exercise of share options	111	90	564
Expenses of new equity issue	(165)	(134)	-
Interest paid	(305)	(247)	(20)
Repayments of fit out funding	(696)	(564)	-

Repayments of obligations under finance leases	(117)	(95)	(26)
Net cash (outflow)/inflow from financing activities	(1,172)	(950)	518
Effect of foreign exchange rate changes on cash and cash equivalents	15,123	12,253	3,705
Net decrease in cash and cash equivalents	(17,459)	(14,145)	(15,559)
Cash and cash equivalents at beginning of the period	462,108	374,392	234,872
Cash and cash equivalents at end of the period	444,649	360,247	219,313

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