



August 7, 2017

GW Pharmaceuticals plc Reports Fiscal Third Quarter 2017 Financial Results and Operational Progress

- Epidiolex[®] NDA submission process underway -
- Conference call today at 4:30 p.m. EDT -

LONDON and CARLSBAD, Calif., Aug. 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, announces financial results for the third quarter ended 30 June 2017.

"I am pleased to report the NDA submission process for Epidiolex is now underway with the final sections of the submission expected to be completed in October. With a clear view now towards our anticipated approval, we are making excellent progress with preparations to ensure a highly successful launch in 2018," stated Justin Gover, GW's Chief Executive Officer. "Following the recent publication of our first Phase 3 trial in *The New England Journal of Medicine*, we look forward to additional Epidiolex data publications and presentations in the second half of the year. In addition to Epidiolex, we continue to keep focus on our growing and innovative cannabinoid pipeline where we have advanced a number of additional exciting clinical programs."

OPERATIONAL HIGHLIGHTS

- Epidiolex (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and Infantile Spasms (IS)
 - i Regulatory progress:
 - NDA rolling submission for both Dravet and LGS indications underway. Pre-clinical module submitted; Clinical module submission in progress; CMC module submission expected in October
 - EMA pre-submission meetings held. Expected EU regulatory submission in Q4 2017
 - i Further clinical progress:
 - Phase 3 Dravet syndrome trial published in *The New England Journal of Medicine*
 - Quality of Life in Childhood Epilepsy published in *Epilepsia*
 - Phase 3 trial in Tuberous Sclerosis Complex ongoing
 - Part A of two-part Phase 3 trial in Infantile Spasms ongoing
 - Numerous abstracts submitted to American Epilepsy Society annual meeting
 - i Manufacturing scale-up on track to deliver significant projected commercial launch inventory:
 - Preparations on track for FDA GMP inspection anticipated in early 2018
 - i Expanded access program and open label extension:
 - Over 1,500 patients now exposed to Epidiolex treatment
 - 97 percent of patients who complete Phase 3 trials have entered long term extension
 - i Commercial progress:
 - U.S. pre-launch commercial leadership team in place
 - Full team of epilepsy specialist Medical and Scientific Liaisons (MSLs) in place with significant medical education initiatives underway and major presence at key target congresses
 - EU commercial team build-out underway and increasing presence at European congresses
 - i Strengthened Epidiolex exclusivity:
 - 14 distinct patent families in prosecution relating to the use of CBD in the treatment of epilepsy; decisions expected for several patents towards end 2017 and H1 2018
 - 6 patents published in the last quarter claiming various methods of treatment using CBD
 - i Life-cycle management:
 - Several new formulations of CBD in Phase 1 trials

- Progressed cannabinoid pipeline product candidates

- i CBDV Phase 2 partial-onset epilepsy study in adults fully enrolled. Data expected end 2017/early 2018
- i CBDV in field of autism spectrum disorders:
 - Expanded access IND granted by FDA for 10 patients with autism
 - Open label study in Rett syndrome and Phase 2 placebo-controlled trial in planning for H1 2018
 - Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
- i CBD:THC in Glioblastoma:
 - Positive survival data from Phase 2 study presented recently at ASCO; further follow-up demonstrates continued increased survival in the CBD:THC arm
- i Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program:
 - Phase 1 trial complete
 - Orphan Drug and Fast Track Designations granted from FDA and EMA

- Management appointments

- i Dr. Volker Knappertz appointed Chief Medical Officer
- i Douglas Snyder appointed Chief Legal Officer
- i Prof. Ben Whalley appointed as Director of Research

FINANCIAL HIGHLIGHTS

- Cash and cash equivalents at 30 June 2017 of £284.1 million (\$369.5 million) compared to £374.4 million as at 30 September 2016
- Revenue for the nine months ended 30 June 2017 of £6.1 million (\$7.9 million) compared to £8.6 million for the nine months ended 30 June 2016
- Loss for the nine months ended 30 June 2017 of £90.3 million (\$117.5 million) compared to £46.7 million for the nine months ended 30 June 2016

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 30 June 2017 of \$1.30081 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 third quarter 2017 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. For both dial-in numbers please use conference ID # 13667808 and PIN: 19259.

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), for which GW has commenced a rolling NDA submission with the FDA for the treatment of Dravet syndrome and Lennox-Gastaut syndrome. The Company continues to evaluate Epidiolex in additional epilepsy conditions and currently has ongoing Phase 3 clinical trials in 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 30 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 30 June 2017

	30 June 2017	30 June 2017	30 June 2016
	\$000's	£000's	£000's
Revenue	3,138	2,412	2,329
Cost of sales	(1,444)	(1,110)	(711)
Research and development expenditure	(36,339)	(27,936)	(25,609)
Sales, general and administrative expenses	(15,286)	(11,751)	(5,603)
Net foreign exchange (loss) / gain	(10,940)	(8,410)	11,190
Operating loss	(60,871)	(46,795)	(18,404)
Interest income	593	456	98
Interest expense	(346)	(266)	(18)
Loss before tax	(60,624)	(46,605)	(18,324)
Tax benefit	8,126	6,247	6,109
Loss for the period	(52,498)	(40,358)	(12,215)
Loss per share — basic and diluted	(17.3c)	(13.3p)	(4.6p)
Loss per ADS — basic and diluted⁽¹⁾	(207.6c)	(159.6p)	(55.2p)
Weighted average ordinary shares outstanding (in millions) — basic and diluted		303.9	262.9

All activities relate to continuing operations.

(1) Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the three months ended 30 June 2017

	30 June 2017	30 June 2016
	£000's	£000's
Loss for the period	(40,358)	(12,215)
Items that may be reclassified subsequently to profit or loss		
Exchange (loss)/gain on retranslation of foreign operations	(508)	266
Other comprehensive (loss)/gain for the period	(508)	266

Total comprehensive loss for the period **(40,866)** (11,949)

GW Pharmaceuticals plc
Condensed consolidated income statement
Nine months ended 30 June 2017

	30 June 2017 \$000's	30 June 2017 £000's	30 June 2016 £000's
Revenue	7,928	6,095	8,645
Cost of sales	(3,268)	(2,512)	(1,940)
Research and development expenditure	(104,074)	(80,007)	(75,497)
Sales, general and administrative expenses	(36,065)	(27,725)	(12,470)
Net foreign exchange (loss) / gain	(757)	(583)	19,279
Operating loss	(136,236)	(104,732)	(61,983)
Interest income	1,355	1,042	292
Interest expense	(662)	(509)	(53)
Loss before tax	(135,543)	(104,199)	(61,744)
Tax benefit	18,053	13,878	14,995
Loss for the period	(117,490)	(90,321)	(46,749)
Loss per share — basic and diluted	(38.7c)	(29.8p)	(17.8p)
Loss per ADS — basic and diluted⁽¹⁾	(464.4c)	(357.6p)	(213.6p)
Weighted average ordinary shares outstanding (in millions) — basic and diluted		303.4	262.3

All activities relate to continuing operations.

⁽¹⁾ Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the nine months ended 30 June 2017

	30 June 2017 £000's	30 June 2016 £000's
Loss for the period	(90,321)	(46,749)
Items that may be reclassified subsequently to profit or loss		
Exchange (loss)/gain on retranslation of foreign operations	(267)	166
Other comprehensive (loss)/gain for the period	(267)	166
Total comprehensive loss for the period	(90,588)	(46,583)

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Nine months ended 30 June 2017

	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	633	-	-	635
Share-based payment transactions	-	-	-	5,900	5,900
Loss for the period	-	-	-	(46,749)	(46,749)
Deferred tax attributable to unrealized share option gains	-	-	-	366	366
Other comprehensive gain	-	-	166	-	166
Balance at 30 June 2016	263	349,908	19,355	(163,938)	205,588

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	-	-	-	8,141	8,141
Loss for the period	-	-	-	(90,321)	(90,321)
Deferred tax attributable to unrealized share option gains	-	-	-	(251)	(251)
Other comprehensive loss	-	-	(267)	-	(267)
Balance at 30 June 2017	304	556,565	19,271	(260,258)	315,882

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 30 June 2017

	As at 30 June 2017	As at 30 June 2017	As at 30 September 2016
	\$000's	£000's	£000's
Non-current assets			
Goodwill	6,777	5,210	5,210
Other intangible assets	1,232	947	629
Property, plant and equipment	53,122	40,838	38,947
Deferred tax asset	6,944	5,338	3,873
	68,075	52,333	48,659
Current assets			
Inventories	5,354	4,116	4,248
Taxation recoverable	16,860	12,961	21,322
Trade receivables and other assets	12,926	9,937	4,556
Cash and cash equivalents	369,539	284,084	374,392
	404,679	311,098	404,518
Assets held for sale	1,182	909	-
Total assets	473,936	364,340	453,177
Current liabilities			
Trade and other payables	(34,652)	(26,639)	(31,170)
Current tax liabilities	(1,131)	(870)	(883)
Obligations under finance leases	(263)	(202)	(211)
Deferred revenue	(3,007)	(2,312)	(2,686)
	(39,053)	(30,023)	(34,950)
Non-current liabilities			
Trade and other payables	(11,830)	(9,094)	(9,423)

Obligations under finance leases	(6,253)	(4,807)	(4,959)
Deferred revenue	(5,898)	(4,534)	(5,355)
Total liabilities	(63,034)	(48,458)	(54,687)
Net assets	410,902	315,882	398,490
Equity			
Share capital	395	304	302
Share premium account	723,985	556,565	556,477
Other reserves	25,068	19,271	19,538
Accumulated deficit	(338,546)	(260,258)	(177,827)
Total equity	410,902	315,882	398,490

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the nine months ended 30 June 2017

	Nine months ended 30 June 2017 \$000's	Nine months ended 30 June 2017 £000's	Nine months ended 30 June 2016 £000's
Loss for the period	(117,490)	(90,321)	(46,749)
Adjustments for:			
Interest income	(1,355)	(1,042)	(292)
Interest expense	662	509	53
Tax benefit	(18,053)	(13,878)	(14,995)
Depreciation of property, plant and equipment	4,918	3,781	2,526
Impairment of property, plant and equipment	124	95	-
Reversal of impairment of property, plant and equipment	(281)	(216)	-
Amortization of intangible assets	219	168	42
Net foreign exchange losses/(gains)	758	583	(19,382)
Increase/(decrease) in provision for inventories	104	80	(45)
Decrease in deferred signature fees	(1,427)	(1,097)	(881)
Share-based payment charge	10,590	8,141	5,900
Loss on disposal of property, plant and equipment	787	605	-
	(120,444)	(92,592)	(73,823)
Decrease in inventories	68	52	323
(Increase)/decrease in trade receivables and other assets	(2,490)	(1,914)	57
(Decrease)/increase in trade and other payables and deferred revenue	(1,664)	(1,279)	4,155
Cash used in operations	(124,530)	(95,733)	(69,288)
Income taxes paid	(1,661)	(1,277)	(1,150)
Research and development tax credits received	28,200	21,679	13,281
Net cash outflow from operating activities	(97,991)	(75,331)	(57,157)
Investing activities			
Interest received	1,262	970	290
Purchases of property, plant and equipment	(16,896)	(12,989)	(6,255)

Purchase of intangible assets	(609)	(468)	(363)
Net cash outflow from investing activities	(16,243)	(12,487)	(6,328)
Financing activities			
Proceeds on exercise of share options	118	91	635
Expenses of new equity issue	(174)	(134)	-
Interest paid	(948)	(729)	(53)
Repayment of fit out funding	(973)	(748)	(240)
Repayment of obligations under finance leases	(208)	(160)	(98)
Net cash (outflow)/inflow from financing activities	(2,185)	(1,680)	244
Effect of foreign exchange rate changes on cash and cash equivalents	(1,053)	(810)	19,546
Net decrease in cash and cash equivalents	(117,472)	(90,308)	(43,695)
Cash and cash equivalents at beginning of the period	487,011	374,392	234,872
Cash and cash equivalents at end of the period	369,539	284,084	191,177

Enquiries:

GW Pharmaceuticals plc
Stephen Schultz, VP Investor Relations
401 500 6570

Sam Brown (U.S. Media Enquiries)
Christy Curran
615 414 8668