



May 9, 2017

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

- Epidiolex[®] NDA submission expected mid-year -
- New data in Lennox-Gastaut syndrome presented at the American Academy of Neurology -
- Conference call today at 4:30 p.m. EDT-

LONDON, May 09, 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 second quarter ended 31 March 2017.

"Our primary focus is on the submission of the Epidiolex NDA, which is expected in the middle of this year. Based on the efficacy and safety profile, we are confident in the prospects for an Epidiolex approval and continue to expand the commercial organization in preparation for a highly successful launch," stated Justin Gover, GW's Chief Executive Officer. "Beyond Epidiolex, we continue to advance 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)
 - | Regulatory:
 - NDA submission for both Dravet and LGS indications expected mid-2017
 - Expected EU regulatory submission in H2 2017
 - Rare pediatric disease designation conditionally granted by FDA - pre-cursor to priority review voucher
 - Orphan Designation granted by European Medicines Agency (EMA) in the treatment of LGS
 - | Clinical:
 - New Phase 3 LGS data presented at the American Academy of Neurology (AAN) Annual Meeting in April 2017
 - 3 podium presentations at AAN
 - Phase 3 Dravet syndrome trial accepted for publication in high status journal with publication expected in Q2
 - Phase 3 trial in Tuberous Sclerosis Complex ongoing
 - Part A of two-part Phase 3 trial in infantile spasms underway
 - | Management Update:
 - Scott Giacobello appointed as Chief Financial Officer
 - Adam George appointed as Managing Director - UK
 - | Manufacturing scale-up on track to deliver significant commercial launch inventory:
 - Pre-NDA CMC meeting held with FDA in November 2016
 - Successful UK regulatory Good Manufacturing Practice (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 1,500 patients now exposed to Epidiolex treatment
 - 97 percent of patients who complete Phase 3 trials have entered long term extension
 - | Commercial:
 - U.S. commercial team build well underway and pre-launch preparations advancing well
 - EU commercial team now being established
 - | Intellectual Property
 - 13 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
- Other cannabinoid pipeline product candidates:
 - | CBDV Phase 2 partial-onset epilepsy study in adults fully enrolled. Data expected Q4 2017
 - | CBDV in field of autism spectrum disorders
 - Expanded access IND granted by FDA for 10 patients with autism
 - Open label study in Rett syndrome to commence Q4 2017 and Phase 2 placebo-controlled trial in planning for Q1

2018

- Orphan Drug Designation from FDA for CBDV for the treatment of Rett syndrome
- | Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
 - Phase 1 trial complete. Phase 2 protocol discussions with FDA in H2 2017
 - Orphan Drug and Fast Track Designations granted from FDA and EMA
- | THC:CBD for Glioma
 - Positive Phase 2 placebo-controlled data in Recurrent Glioblastoma Multiforme (GBM)
 - Abstract accepted at ASCO
 - Orphan Drug Designation from FDA and EMA

FINANCIAL HIGHLIGHTS

- | Cash and cash equivalents at 31 March 2017 of £306.3 million (\$383.9 million) compared to £374.4 million as at 30 September 2016
- | Revenue for the six months ended 31 March 2017 of £3.7 million (\$4.6 million) compared to £6.3 million for the six months ended 31 March 2016
- | Loss for the six months ended 31 March 2017 of £50.0 million (\$62.6 million) compared to £34.5 million for the six months ended 31 March 2016

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 31 March 2017 of \$1.25331 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 second quarter 2017 financial results today at 4:30 pm EDT. To participate in the conference call, please dial 800-860-2442 (toll free from the U.S. and Canada) or 412-858-4600 (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 # 13661781.

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.

Three months ended 31 March 2017

	Three months ended 31 March 2017 \$000's	Three months ended 31 March 2017 £000's	Three months ended 31 March 2016 £000's
Revenue	2,039	1,627	2,649
Cost of sales	(861)	(687)	(542)
Research and development expenditure	(34,036)	(27,157)	(25,749)
Sales, general and administrative expenses	(11,643)	(9,290)	(3,242)
Net foreign exchange (loss) / gain	(4,998)	(3,988)	4,488
Operating loss	(49,499)	(39,495)	(22,396)
Interest income	392	313	131
Interest expense	(192)	(153)	(16)
Loss before tax	(49,299)	(39,335)	(22,281)
Tax benefit	6,226	4,968	5,449
Loss for the period	(43,073)	(34,367)	(16,832)
Loss per share - basic and diluted	(14.2c)	(11.3p)	(6.4p)
Loss per ADS - basic and diluted⁽¹⁾	(170.4c)	(135.6p)	(76.8p)
Weighted average ordinary shares outstanding (in millions) - basic and diluted		303.7	262.6

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 March 2017

	Three months ended 31 March 2017 £000's	Three months ended 31 March 2016 £000's
Loss for the period	(34,367)	(16,832)
Items that may be reclassified subsequently to profit or loss		
Exchange loss on retranslation of foreign operations	(177)	(46)
Other comprehensive loss for the period	(177)	(46)
Total comprehensive loss for the period	(34,544)	(16,878)

GW Pharmaceuticals plc
Condensed consolidated income statement
Six months ended 31 March 2017

	Six months ended 31 March 2017 \$000's	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Revenue	4,616	3,683	6,316
Cost of sales	(1,757)	(1,402)	(1,229)
Research and development expenditure	(65,261)	(52,071)	(49,888)
Sales, general and administrative expenses	(20,020)	(15,974)	(6,867)

Net foreign exchange gain	9,810	7,827	8,089
Operating loss	(72,612)	(57,937)	(43,579)
Interest income	734	586	194
Interest expense	(305)	(243)	(35)
Loss before tax	(72,183)	(57,594)	(43,420)
Tax benefit	9,564	7,631	8,886
Loss for the period	(62,619)	(49,963)	(34,534)
Loss per share - basic and diluted	(20.7c)	(16.5p)	(13.2p)
Loss per ADS - basic and diluted ⁽¹⁾	(248.4c)	(198.0p)	(158.4p)
Weighted average ordinary shares outstanding (in millions) - basic and diluted		303.2	262.0

All activities relate to continuing operations.

⁽¹⁾ Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss
For the six months ended 31 March 2017

	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Loss for the period	(49,963)	(34,534)
Items that may be reclassified subsequently to profit or loss		
Exchange gain/(loss) on retranslation of foreign operations	241	(99)
Other comprehensive gain/(loss) for the period	241	(99)
Total comprehensive loss for the period	(49,722)	(34,633)

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Condensed consolidated statement of changes in equity
Six months ended 31 March 2017

	Called-up 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	623	-	-	625
Share-based payment transactions	-	-	-	3,164	3,164
Loss for the period	-	-	-	(34,534)	(34,534)
Deferred tax attributable to unrealized share option gains	-	-	-	4	4
Other comprehensive loss	-	-	(99)	-	(99)
Balance at 31 March 2016	263	349,898	19,090	(154,821)	214,430
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	-	-	-	4,768	4,768

Loss for the period	-	-	-	(49,963)	(49,963)
Deferred tax attributable to unrealized share option gains	-	-	-	595	595
Other comprehensive income	-	-	241	-	241
Balance at 31 March 2017	304	556,565	19,779	(222,427)	354,221

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 31 March 2017

	As at 31 March 2017 \$000's	As at 31 March 2017 £000's	As at 30 September 2016 £000's
Non-current assets			
Intangible assets - goodwill	6,530	5,210	5,210
Other intangible assets	1,271	1,014	629
Property, plant and equipment	50,873	40,591	38,947
Deferred tax asset	6,340	5,059	3,873
	65,014	51,874	48,659
Current assets			
Inventories	5,819	4,643	4,248
Taxation recoverable	35,773	28,543	21,322
Trade receivables and other assets	9,069	7,236	4,556
Cash and cash equivalents	383,870	306,285	374,392
	434,531	346,707	404,518
Assets held for sale	1,139	909	-
Total assets	500,684	399,490	453,177
Current liabilities			
Trade and other payables	(28,841)	(23,013)	(31,170)
Current tax liabilities	(192)	(153)	(883)
Obligations under finance leases	(287)	(229)	(211)
Deferred revenue	(3,056)	(2,438)	(2,686)
	(32,376)	(25,833)	(34,950)
Non-current liabilities			
Trade and other payables	(12,245)	(9,770)	(9,423)
Obligations under finance leases	(6,089)	(4,858)	(4,959)
Deferred revenue	(6,026)	(4,808)	(5,355)
Total liabilities	(56,736)	(45,269)	(54,687)
Net assets	443,948	354,221	398,490
Equity			
Share capital	381	304	302
Share premium account	697,548	556,565	556,477
Other reserves	24,789	19,779	19,538
Accumulated deficit	(278,770)	(222,427)	(177,827)
Total equity	443,948	354,221	398,490

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the six months ended 31 March 2017

	Six months ended 31 March 2017 \$000's	Six months ended 31 March 2017 £000's	Six months ended 31 March 2016 £000's
Loss for the period	(62,619)	(49,963)	(34,534)
Adjustments for:			
Interest income	(734)	(586)	(194)
Interest expense	305	243	35
Tax benefit	(9,564)	(7,631)	(8,886)
Depreciation of property, plant and equipment	2,895	2,310	1,540
Impairment of property, plant and equipment	119	95	-
Reversal of impairment of property, plant and equipment	(271)	(216)	-
Amortization of intangible assets	109	87	27
Net foreign exchange gains	(9,810)	(7,827)	(8,377)
Increase/(decrease) in provision for inventories	59	47	(45)
Decrease in deferred signature fees	(1,031)	(823)	(592)
Share-based payment charge	5,976	4,768	3,164
Loss on disposal of property, plant and equipment	707	564	-
	(73,859)	(58,932)	(47,862)
(Increase)/decrease in inventories	(554)	(442)	138
Increase in trade receivables and other assets	(2,089)	(1,667)	(498)
(Decrease)/increase in trade and other payables and deferred revenue	(5,148)	(4,108)	2,740
Income taxes paid	(1,038)	(828)	(894)
Net cash outflow from operating activities	(82,688)	(65,977)	(46,376)
Investing activities			
Interest received	548	437	186
Purchases of property, plant and equipment	(11,274)	(8,995)	(4,655)
Purchases of intangible assets	(536)	(428)	(149)
Net cash outflow from investing activities	(11,262)	(8,986)	(4,618)
Financing activities			
Proceeds on exercise of share options	113	90	625
Expenses of new equity issue	(168)	(134)	-
Interest paid	(579)	(462)	(35)
Repayments of fit out funding	(822)	(656)	-
Repayment of obligations under finance leases	(103)	(82)	(55)
Net cash (outflow)/inflow from financing activities	(1,559)	(1,244)	535
Effect of foreign exchange rate changes on cash and cash equivalents	10,150	8,100	8,271
Net decrease in cash and cash equivalents	(85,359)	(68,107)	(42,188)
Cash and cash equivalents at beginning of the period	469,229	374,392	234,872
Cash and cash equivalents at end of the period	383,870	306,285	192,684

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