



August 9, 2016

GW Pharmaceuticals plc Reports Third Quarter 2016 Financial Results and Operational Progress

- Positive Phase 3 Epidiolex pivotal trial in Lennox-Gastaut Syndrome (LGS) -
- Positive FDA pre-NDA meeting - NDA for Dravet syndrome and LGS on track for H1 2017 submission -
- Conference call today at 8:30 a.m. EDT, 1:30 p.m. BST -

LONDON, Aug. 09, 2016 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ:GWPH) (AIM:GWP) (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 third quarter ended 30 June 2016.

"We have now reported two positive Phase 3 trials for Epidiolex and are on track for an NDA filing that includes both the Dravet syndrome and Lennox-Gastaut Syndrome indications. We believe that these Phase 3 data show that Epidiolex has the potential to provide a robust and clinically meaningful reduction in seizures in these highly treatment-resistant populations together with an acceptable safety and tolerability profile," stated Justin Gover, GW's Chief Executive Officer. "Our recent successful financing has provided GW with the necessary capital to move forward with confidence in preparing to execute a highly successful launch."

RECENT OPERATIONAL HIGHLIGHTS

- ┆ Epidiolex[®] (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and infantile spasms (IS)
 - ┆ Phase 3 development programs:
 - ┆ Positive results in first Phase 3 Dravet syndrome trial
 - ┆ Positive results in first Phase 3 LGS trial
 - ┆ Data presentations expected at upcoming American Epilepsy Society Annual Meeting in December
 - ┆ Positive Dravet syndrome Pre-NDA meeting held with FDA
 - ┆ NDA on track for H1 2017 submission for both Dravet and LGS indications
 - ┆ Data from second LGS trial expected at end of Q3
 - ┆ Second Phase 3 Dravet syndrome trial ongoing
 - ┆ Phase 3 trial in TSC ongoing
 - ┆ Phase 3 trial in IS to commence in Q4 2016
 - ┆ Expanded access program and open label extension:
 - ┆ Over 1,000 patients now on Epidiolex treatment under Expanded Access Treatment INDs, U.S. State programs, and open label extension trial
- ┆ Advanced clinical programs in multiple cannabinoid pipeline product candidates:
 - ┆ CBDV Phase 2 partial-onset epilepsy study in adults ongoing. Part A complete and Part B underway with data expected H1 2017
 - ┆ CBDV pre-clinical research ongoing within field of autism spectrum disorders. Initial open-label clinical evaluation expected to commence in H2 2016, with Phase 2 trials expected to commence in H1 2017
 - ┆ Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD Phase 1 clinical program expected to commence in Q4 2016
 - ┆ Orphan Drug and Fast Track Designations granted from FDA and EMA
 - ┆ THC:CBD Phase 1b/2a study for the treatment of Recurrent Glioblastoma Multiforme (GBM) fully enrolled with data expected in Q4 2016
 - ┆ Sativex[®] Phase 2 study in children with spasticity due to cerebral palsy fully enrolled with data expected Q4 2016
 - ┆ THCV Phase 2 study in type 2 diabetes completed, primary endpoint not achieved

FINANCIAL HIGHLIGHTS

- ┆ Loss for the nine months ended 30 June 2016 of £46.7 million (\$62.2 million) compared to £32.3 million for the nine months ended 30 June 2015. This increased loss primarily reflects investment in the Epidiolex Phase 3 pivotal trials program.

- 1 Cash and cash equivalents at 30 June 2016 of £191.2 million (\$254.3 million) compared to £234.9 million as at 30 September 2015. Subsequently in July 2016 a follow-on offering raised total net proceeds after expenses of \$273.1 million (£206.4 million).

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the third quarter 2016 financial results today at 8:30 a.m. EDT / 1:30 p.m. BST. 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):1-877-660-6853, (international):1-201-612-7415. For both dial-in numbers please use conference ID # 13642862.

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 commercialized the world's first plant-derived cannabinoid prescription drug, Sativex®, which is approved for the treatment of spasticity due to multiple sclerosis in 28 countries outside the United States. 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 and Lennox-Gastaut syndrome and which is also expected to enter Phase 3 clinical trials in the treatment of Tuberous Sclerosis Complex. GW 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 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. 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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GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 30 June 2016

	Notes	30 June 2016 \$000's	30 June 2016 £000's	30 June 2015 £000's
Revenue	2	3,097	2,329	8,629

Cost of sales		(946)	(711)	(721)
Research and development expenditure	3	(34,058)	(25,609)	(20,841)
Sales, general and administrative expenses		(7,452)	(5,603)	(2,984)
Net foreign exchange gain/(loss)		14,883	11,190	(8,851)
Operating loss		(24,476)	(18,404)	(24,768)
Interest income		130	98	46
Interest expense		(24)	(18)	(21)
Loss before tax		(24,370)	(18,324)	(24,743)
Tax benefit	4	8,125	6,109	3,318
Loss for the period		(16,245)	(12,215)	(21,425)
Loss per share — basic and diluted	5	(6.1c)	(4.6p)	(8.5p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the three months ended 30 June 2016

	30 June	30 June
	2016	2015
	£000's	£000's
Loss for the period	(12,215)	(21,425)
Items that may be reclassified subsequently to profit or loss		
Exchange gain on retranslation of foreign operations	266	16
Other comprehensive gain for the period	266	16
Total comprehensive loss for the period	(11,949)	(21,409)

GW Pharmaceuticals plc
Condensed consolidated income statement
Nine months ended 30 June 2016

		30 June	30 June	30 June
	Notes	2016	2016	2015
		\$000's	£000's	£000's
Revenue	2	11,497	8,645	22,945
Cost of sales		(2,580)	(1,940)	(1,935)
Research and development expenditure	3	(100,406)	(75,497)	(51,328)
Sales, general and administrative expenses		(16,584)	(12,470)	(7,581)
Net foreign exchange gain/(loss)		25,640	19,279	(672)
Operating loss		(82,433)	(61,983)	(38,571)
Interest income		388	292	161
Interest expense		(70)	(53)	(60)
Loss before tax		(82,115)	(61,744)	(38,470)
Tax benefit	4	19,942	14,995	6,140
Loss for the period		(62,173)	(46,749)	(32,330)
Loss per share — basic and diluted	5	(23.7c)	(17.8p)	(13.4p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the nine months ended 30 June 2016

	30 June	30 June
	2016	2015
	£000's	£000's
Loss for the period	(46,749)	(32,330)
Items that may be reclassified subsequently to profit or loss		
Exchange gain/(loss) on retranslation of foreign operations	166	(20)
Other comprehensive gain/(loss) for the period	166	(20)
Total comprehensive loss for the period	(46,583)	(32,350)

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Nine months ended 30 June 2016

	Share capital	Share premium	Other reserves	Accumulated deficit	Total
	£000's	£000's	£000's	£000's	£000's
Balance at 1 October 2014	237	220,551	19,260	(81,464)	158,584
Issue of share capital	22	127,812	-	-	127,834
Expense of new equity issue	-	(307)	-	-	(307)
Exercise of share options	2	1,139	-	-	1,141
Share-based payment transactions	-	-	-	1,161	1,161
Loss for the period	-	-	-	(32,330)	(32,330)
Other comprehensive loss	-	-	(20)	-	(20)
Balance at 30 June 2015	261	349,195	19,240	(112,633)	256,063
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

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 30 June 2016

	As at 30 June 2016	As at 30 June 2016	As at 30 September 2015
	\$000's	£000's	£000's
Non-current assets			
Goodwill	6,929	5,210	5,210
Other intangible assets	749	563	245
Property, plant and equipment	51,266	38,548	28,733
Deferred tax asset	2,506	1,884	418

		61,450	46,205	34,606
Current assets				
Inventories	6	5,955	4,478	4,756
Taxation recoverable		18,912	14,220	12,641
Trade receivables and other assets	7	5,204	3,913	2,873
Cash and cash equivalents		254,252	191,177	234,872
		284,323	213,788	255,142
Total assets		345,773	259,993	289,748
Current liabilities				
Trade and other payables	8	(43,514)	(32,719)	(24,022)
Current tax liabilities		-	-	(366)
Obligations under finance leases	10	(153)	(115)	(111)
Deferred revenue	9	(3,028)	(2,277)	(3,269)
		(46,695)	(35,111)	(27,768)
Non-current liabilities				
Trade and other payables	8	(11,211)	(8,430)	(8,445)
Obligations under finance leases	10	(6,658)	(5,006)	(1,540)
Deferred revenue	9	(7,791)	(5,858)	(6,725)
Total liabilities		(72,355)	(54,405)	(44,478)
Net assets		273,418	205,588	245,270
Equity				
Share capital		350	263	261
Share premium account		465,353	349,908	349,275
Other reserves		25,741	19,355	19,189
Accumulated deficit		(218,026)	(163,938)	(123,455)
Total equity		273,418	205,588	245,270

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the nine months ended 30 June 2016

	Nine months ended 30 June 2016 \$000's	Nine months ended 30 June 2016 £000's	Nine months ended 30 June 2015 £000's
Loss for the period	(62,173)	(46,749)	(32,330)
Adjustments for:			
Interest income	(388)	(292)	(161)
Interest expense	70	53	60
Tax benefit	(19,942)	(14,995)	(6,140)
Depreciation of property, plant and equipment	3,359	2,526	1,670
Amortization of intangible assets	56	42	2
Net foreign exchange (gains)/losses	(25,777)	(19,382)	672

(Decrease)/increase in provision for inventories	(60)	(45)	13
Profit on disposal of property, plant and equipment	-	-	(1)
Share-based payment charge	7,847	5,900	1,166
	(97,008)	(72,942)	(35,049)
Decrease in inventories	430	323	-
Decrease/(Increase) in trade receivables and other assets	76	57	(171)
Increase in trade and other payables and deferred revenue	4,354	3,274	5,715
Cash used in operations	(92,148)	(69,288)	(29,505)
Income taxes paid	(1,529)	(1,150)	-
Research and development tax credits received	17,663	13,281	5,415
Net cash outflow from operating activities	(76,014)	(57,157)	(24,090)
Investing activities			
Interest received	386	290	154
Purchases of property, plant and equipment	(8,319)	(6,255)	(14,136)
Purchase of intangible assets	(483)	(363)	(59)
Proceeds from sales of property, plant and equipment	-	-	2
Net cash outflow from investing activities	(8,416)	(6,328)	(14,039)
Financing activities			
Proceeds on exercise of share options	845	635	1,141
Proceeds of new equity issue	-	-	127,834
Expenses of new equity issue	-	-	(307)
Interest paid	(70)	(53)	(63)
Repayment of fit out funding	(319)	(240)	-
Capital element of finance leases	(130)	(98)	(228)
Net cash inflow from financing activities	326	244	128,377
Effect of foreign exchange rate changes on cash and cash equivalents	25,993	19,546	(691)
Net (decrease)/increase in cash and cash equivalents	(58,111)	(43,695)	89,557
Cash and cash equivalents at beginning of the period	312,363	234,872	164,491
Cash and cash equivalents at end of the period	254,252	191,177	254,048