



December 5, 2016

GW Pharmaceuticals plc Reports Fourth Quarter and Year-End 2016 Financial Results and Operational Progress

- Three Positive Phase 3 Epidiolex clinical trials reported in 2016 -
- NDA submission and launch preparation on track -
- Conference call today at 8:00 a.m. EST -

LONDON, Dec. 05, 2016 (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 fourth quarter and year-ended 30 September 2016.

"In 2016 GW has completed three positive Phase 3 trials for Epidiolex in patients with two different rare treatment resistant forms of childhood-onset epilepsy and we are making good progress towards an NDA submission. Our sights are now focused on Epidiolex approval and accelerating our preparations for a highly successful launch," stated Justin Gover, GW's Chief Executive Officer. "Our goal is to provide the children and their families suffering from these highly treatment-resistant forms of childhood-onset epilepsy with a much needed new prescription option as quickly as possible."

2016 OPERATIONAL HIGHLIGHTS

- ┆ Epidiolex[®] (CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and infantile spasms (IS)
 - ┆ Phase 3 trials:
 - ┆ Positive results in a pivotal Phase 3 Dravet syndrome trial
 - ┆ Positive results in two pivotal Phase 3 LGS trials
 - ┆ Positive data presented at the American Epilepsy Society Annual Meeting
 - ┆ Regulatory:
 - ┆ Positive Dravet syndrome pre-NDA meeting held with FDA in July 2016
 - ┆ Positive CMC pre-NDA meeting held with FDA in November 2016
 - ┆ NDA submission for both Dravet and LGS indications expected at end of H1 2017, just 3 years since opening of IND
 - ┆ Preparations advancing for EU regulatory submission in H2 2017
 - ┆ Manufacturing scale-up:
 - ┆ Manufacturing scale-up on track to deliver significant commercial launch inventory
 - ┆ Expanded access program and open label extension:
 - ┆ 98% of patients who complete Phase 3 trials have entered long term extension
 - ┆ Over 1,000 patients now on Epidiolex treatment
 - ┆ NDA submission to include safety data from over 1,500 patients and over 400 patients with 1 year or more continuous exposure
 - ┆ Withdrawal rate in long term studies approx 20%
 - ┆ Commercial:
 - ┆ US commercial team build underway and pre-launch preparations advancing well
 - ┆ EU commercial team now being established
 - ┆ Additional 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
- ┆ 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 mid-2017
 - ┆ CBDV pre-clinical research ongoing within field of autism spectrum disorders. Phase 2 trials expected to commence in Q3 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 December 2016
 - ┆ Orphan Drug and Fast Track Designations granted from FDA and EMA
- ┆ THC:CBD for the treatment of Recurrent Glioblastoma Multiforme (GBM)
 - ┆ Phase 1b/2a study completed — data expected Q1 2017
 - ┆ Orphan Drug Designation from FDA
- ┆ Sativex[®] Phase 2 study in children with spasticity due to cerebral palsy completed — data expected Q1 2017

FINANCIAL HIGHLIGHTS

- ┆ Revenue for the twelve months ended 30 September 2016 of £10.3 million (\$13.3 million) compared to £28.5 million for the twelve months ended 30 September 2015.
- ┆ Loss for the twelve months ended 30 September 2016 of £63.7 million (\$82.2 million) compared to £44.6 million for the twelve months ended 30 September 2015.
- ┆ Cash and cash equivalents at 30 September 2016 of £374.4 million (\$483.4 million) compared to £234.9 million as at 30 September 2015.

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the fourth quarter and year-end 2016 financial results today at 8:00 a.m.. 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 # 13650870.

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 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 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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Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 30 September 2016, the Condensed Consolidated Income Statement, Condensed Consolidated Statement of Comprehensive Income, Condensed Consolidated Statement of Changes in Equity and the Condensed Consolidated Cash Flow Statement for the three months and for the year ended 30 September 2016 have been translated into U.S. dollars at the rate on 30 September 2016 of \$1.29128 to £1.00. 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.

GW Pharmaceuticals plc
Condensed consolidated income statement
Three months ended 30 September 2016

	Three months ended 30 September 2016 \$000's	Three months ended 30 September 2016 £000's	Three months ended 30 September 2015 £000's
Revenue	2,156	1,670	5,595
Cost of sales	(1,006)	(779)	(683)
Research and development expenditure	(31,401)	(24,318)	(25,457)
Sales, general and administrative expenses	(9,645)	(7,469)	(4,988)
Net foreign exchange gain	8,099	6,272	6,874
Operating loss	(31,797)	(24,624)	(18,659)
Interest and other income	408	316	83
Interest expense	(155)	(120)	(15)
Loss before tax	(31,544)	(24,428)	(18,591)
Tax benefit	9,710	7,520	6,358
Loss for the period	(21,834)	(16,908)	(12,233)
Loss per share — basic and diluted	(7.4c)	(5.7p)	(4.7p)

All activities relate to continuing operations.

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

	Three months ended 30 September 2016 £000's	Three months ended 30 September 2015 £000's
Loss for the period	(16,908)	(12,233)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	183	(51)
Other comprehensive gain/(loss) for the period	183	(51)
Total comprehensive loss for the period	(16,725)	(12,284)

GW Pharmaceuticals plc
Condensed consolidated income statement
Year ended 30 September 2016

	Year ended 30 September 2016 \$000's	Year ended 30 September 2016 £000's	Year ended 30 September 2015 £000's
Revenue	13,320	10,315	28,540
Cost of sales	(3,511)	(2,719)	(2,618)
Research and development expenditure	(128,889)	(99,815)	(76,785)
Sales, general and administrative expenses	(25,747)	(19,939)	(12,569)
Net foreign exchange gain	32,993	25,551	6,202
Operating loss	(111,834)	(86,607)	(57,230)
Other income	785	608	244
Interest expense	(223)	(173)	(75)
Loss before tax	(111,272)	(86,172)	(57,061)
Tax benefit	29,073	22,515	12,498
Loss for the year	(82,199)	(63,657)	(44,563)
Loss per share — basic and diluted	(30.4c)	(23.5p)	(18.1p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the year ended 30 September 2016

	Year ended 30 September 2016 £000's	Year ended 30 September 2015 £000's
Loss for the year	(63,657)	(44,563)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on translation of foreign operations	349	(71)
Other comprehensive gain/(loss) for the year	349	(71)
Total comprehensive loss for the year	(63,308)	(44,634)

GW Pharmaceuticals plc
Condensed consolidated statement of changes in equity
Year ended 30 September 2016

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total equity £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	—	(271)	—	—	(271)
Exercise of share options	2	1,183	—	—	1,185
Share-based payment transactions	—	—	—	2,488	2,488
Loss for the year	—	—	—	(44,563)	(44,563)
Deferred tax attributable to unrealized share option gains	—	—	—	84	84
Other comprehensive expense	—	—	(71)	—	(71)
Balance at 30 September 2015	261	349,275	19,189	(123,455)	245,270

Balance at 1 October 2015	261	349,275	19,189	(123,455)	245,270
Issue of share capital	39	206,512	—	—	206,551
Expense of new equity issue	—	(472)	—	—	(472)
Underwriters' contribution towards expenses of new equity issue	—	472	—	—	472
Exercise of share options	2	690	—	—	692
Share-based payment transactions	—	—	—	8,152	8,152
Loss for the year	—	—	—	(63,657)	(63,657)
Deferred tax attributable to unrealized share option gains	—	—	—	1,133	1,133
Other comprehensive expense	—	—	349	—	349
Balance at 30 September 2016	302	556,477	19,538	(177,827)	398,490

GW Pharmaceuticals plc
Condensed consolidated balance sheet
As at 30 September 2016

	As at 30 September 2016	As at 30 September 2016	As at 30 September 2015
Non-current assets	\$000's	£000's	£000's
Intangible assets - goodwill	6,728	5,210	5,210
Other intangible assets	812	629	245
Property, plant and equipment	50,291	38,947	28,733
Deferred tax asset	5,001	3,873	418
	62,832	48,659	34,606
Current assets			
Inventories	5,485	4,248	4,756
Taxation recoverable	27,533	21,322	12,641
Trade receivables and other assets	5,883	4,556	2,873
Cash and cash equivalents	483,445	374,392	234,872
	522,346	404,518	255,142
Total assets	585,178	453,177	289,748
Current liabilities			
Trade and other payables	(40,249)	(31,170)	(24,022)
Current tax liabilities	(1,140)	(883)	(366)
Obligations under finance leases	(272)	(211)	(111)
Deferred revenue	(3,468)	(2,686)	(3,269)
	(45,129)	(34,950)	(27,768)
Non-current liabilities			
Trade and other payables	(12,168)	(9,423)	(8,445)
Obligations under finance leases	(6,403)	(4,959)	(1,540)
Deferred revenue	(6,915)	(5,355)	(6,725)
Total liabilities	(70,615)	(54,687)	(44,478)
Net assets	514,563	398,490	245,270

Equity			
Share capital	390	302	261
Share premium account	718,568	556,477	349,275
Other reserves	25,229	19,538	19,189
Accumulated deficit	(229,624)	(177,827)	(123,455)
Total equity	514,563	398,490	245,270

GW Pharmaceuticals plc
Condensed consolidated cash flow statement
As at 30 September 2016

	Year ended 30 September 2016	Year ended 30 September 2016	Year ended 30 September 2015
	\$000's	£000's	£000's
Loss for the year	(82,199)	(63,657)	(44,563)
Adjustments for:			
Other income	(785)	(608)	(244)
Interest expense	223	173	75
Tax benefit	(29,073)	(22,515)	(12,498)
Depreciation of property, plant and equipment	4,654	3,605	2,250
Impairment of property, plant and equipment	—	—	606
Amortization of intangible assets	80	62	52
Net foreign exchange gains	(32,993)	(25,551)	(6,282)
Increase in provision for inventories	93	72	33
Decrease in deferred signature fees	(1,511)	(1,170)	(1,250)
Share-based payment charge	10,527	8,152	2,478
Loss on disposal of property, plant and equipment	1	1	1
	(130,983)	(101,436)	(59,342)
Decrease/(increase) in inventories	563	436	(12)
Increase in trade receivables and other assets	(972)	(753)	(1,010)
Increase in trade and other payables and deferred revenue	6,148	4,761	8,478
Cash used in operations	(125,244)	(96,992)	(51,886)
Income taxes paid	(1,140)	(883)	—
Research and development tax credits received	17,150	13,281	5,415
Net cash outflow from operating activities	(109,234)	(84,594)	(46,471)
Investing activities			
Interest received	560	434	236
Purchases of property, plant and equipment	(11,206)	(8,678)	(17,915)
Purchase of intangible assets	(661)	(512)	(114)
Proceeds from sales of property, plant and equipment	—	—	2
Net cash outflow from investing activities	(11,307)	(8,756)	(17,791)
Financing activities			
Proceeds on exercise of share options	697	540	1,185
Proceeds of new equity issue	266,714	206,550	127,834
Expenses of new equity issue	(412)	(319)	(271)
Underwriters' contribution towards expenses of new	609	472	—

equity issue			
Interest paid	(89)	(69)	(74)
Repayments of advance funding	(310)	(240)	—
Repayments of obligations under finance leases	(164)	(127)	(255)
Net cash inflow from financing activities	267,045	206,807	128,419
Effect of foreign exchange rate changes on cash and cash equivalents	33,655	26,063	6,224
Net increase in cash and cash equivalents	180,159	139,520	70,381
Cash and cash equivalents at beginning of the year	303,286	234,872	164,491
Cash and cash equivalents at end of the year	483,445	374,392	234,872