



May 5, 2016

GW Pharmaceuticals plc Reports Second Quarter and Half-Year 2016 Financial Results and Operational Progress

- Positive Phase 3 Epidiolex pivotal trial in Dravet syndrome -
- Initial LGS Phase 3 pivotal data expected in June -
- Conference call today at 9:00 a.m. EDT, 2:00 p.m. BST -

LONDON, May 05, 2016 (GLOBE NEWSWIRE) -- GW Pharmaceuticals plc (NASDAQ:GWPH) (AIM:GWP) (AIM: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 and half-year ended 31 March 2016.

"Following positive results in our first Phase 3 trial of Epidiolex in Dravet syndrome, GW is now entering an exciting new chapter as we start to prepare the Company's first NDA submission to the FDA and step up plans for Epidiolex commercialization," stated Justin Gover, GW's Chief Executive Officer. "The robust data from this first Phase 3 trial in Dravet syndrome provides additional confidence for future clinical trials of Epidiolex and we look forward to results from our Phase 3 trials in Lennox-Gastaut syndrome in the near future. In addition, we continue to expand our research through exploring further indications for Epidiolex as well as ongoing Phase 2 clinical programs for a number of our pipeline candidates."

RECENT OPERATIONAL HIGHLIGHTS

- ┆ Epidiolex[®] (CBD) orphan epilepsy program:
 - ┆ Company sponsored Phase 3 development programs in Dravet syndrome, Lennox-Gastaut syndrome (LGS) and Tuberous Sclerosis Complex (TSC)
 - ┆ Positive results in first Phase 3 Dravet syndrome trial
 - ┆ Full publication of trial results expected in Q4 2016
 - ┆ Second Phase 3 Dravet syndrome trial ongoing
 - ┆ Pre-NDA meeting with FDA requested
 - ┆ Two LGS Phase 3 trials fully enrolled; Data from first trial expected in June
 - ┆ 98% transition rate of eligible patients from pivotal Phase 3 trials to long term open label extension
 - ┆ Phase 3 TSC trial commenced, Orphan Drug Designation received from FDA
 - ┆ Additional clinical development for Epidiolex expected to commence in H2 2016
 - ┆ Expanded access program:
 - ┆ Recent updates at the American Academy of Neurology (AAN) Annual Meeting showing consistent treatment effect and safety profile in state-sponsored clinical programs from Alabama and Georgia
 - ┆ Over 900 children and young adults authorized for treatment by FDA under Expanded Access Treatment INDs and 6 U.S. State programs
- ┆ 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 Q1 2017
 - ┆ CBDV pre-clinical research ongoing within field of autism spectrum disorders. Initial clinical evaluation is expected to commence in H2 2016, with Phase 2 trials expected to commence in Q1 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
 - ┆ THCV Phase 2 study in type-2 diabetes completed - data expected in Q2/3 2016
 - ┆ THC:CBD Phase 1b/2a study for the treatment of Recurrent Glioblastoma Multiforme (GBM) fully enrolled with data expected in Q4 2016
 - ┆ Orphan Drug Designation granted from FDA and EMA
 - ┆ Sativex[®] Phase 2 study in spasticity due to cerebral palsy ongoing with data expected Q4 2016
- ┆ Pre-clinical progress addressing a number of areas of unmet need including autism spectrum disorders, Duchenne muscular dystrophy, glioma, ovarian and pancreatic cancers

FINANCIAL HIGHLIGHTS

- 1 Cash and cash equivalents at 31 March 2016 of £192.7 million (\$276.8 million) compared to £234.9 million as at 30 September 2015
- 1 Revenue for the six months ended 31 March 2016 of £6.3 million (\$9.1 million) compared to £14.3 million for the six months ended 31 March 2015. This decrease primarily reflects the expected reduction in R&D fees associated with the conclusion of partner funded Sativex Phase 3 cancer pain trials
- 1 Loss for the six months ended 31 March 2016 of £34.5 million (\$49.6 million) compared to £10.9 million for the six months ended 31 March 2015

Conference Call and Webcast Information

GW Pharmaceuticals will host a conference call and webcast to discuss the second quarter and half-year 2016 financial results today at 9:00 a.m. EDT / 2:00 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 # 13636232.

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, Lennox-Gastaut syndrome and Tuberous Sclerosis Complex. GW has a deep pipeline of additional cannabinoid product candidates which includes compounds in Phase 1 and 2 trials for glioma, type 2 diabetes, 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 31 March 2016

	Three months ended 31 March 2016 \$000's	Three months ended 31 March 2016 £000's	Three months ended 31 March 2015 £000's
Revenue	3,805	2,649	6,351
Cost of sales	(779)	(542)	(645)
Research and development expenditure	(36,988)	(25,749)	(15,362)
Sales, general and administrative expenses	(4,657)	(3,242)	(3,794)
Net foreign exchange gain	6,448	4,488	4,145
Operating loss	(32,171)	(22,396)	(9,305)
Interest income	188	131	71
Interest expense	(23)	(16)	(19)
Loss before tax	(32,006)	(22,281)	(9,253)
Tax benefit	7,827	5,449	1,754
Loss for the period	(24,179)	(16,832)	(7,499)
Loss per share - basic and diluted	(9.2c)	(6.4p)	(3.2p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the three months ended 31 March 2016

	Three months ended 31 March 2016 £000's	Three months ended 31 March 2015 £000's
Loss for the period	(16,832)	(7,499)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on retranslation of foreign operations	(46)	(30)
Other comprehensive loss for the period	(46)	(30)
Total comprehensive loss for the period	(16,878)	(7,529)

GW Pharmaceuticals plc
Condensed consolidated income statement
Six months ended 31 March 2016

	Six months ended 31 March 2016 \$000's	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
Revenue	9,073	6,316	14,317
Cost of sales	(1,765)	(1,229)	(1,214)
Research and development expenditure	(71,664)	(49,888)	(30,487)
Sales, general and administrative expenses	(9,864)	(6,867)	(4,597)
Net foreign exchange gain	11,618	8,089	8,179
Operating loss	(62,602)	(43,579)	(13,802)
Interest income	279	194	114

Interest expense	(50)	(35)	(39)
Loss before tax	(62,373)	(43,420)	(13,727)
Tax benefit	12,765	8,886	2,823
Loss for the period	(49,608)	(34,534)	(10,904)
Loss per share - basic and diluted	(18.9c)	(13.2p)	(4.6p)

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss
For the six months ended 31 March 2016

	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
Loss for the period	(34,534)	(10,904)
Items that may be reclassified subsequently to profit or loss		
Exchange differences on retranslation of foreign operations	(99)	(36)
Other comprehensive loss for the period	(99)	(36)
Total comprehensive loss for the period	(34,633)	(10,940)

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Condensed consolidated statement of changes in equity
Six months ended 31 March 2016

	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 2014	237	220,551	19,260	(81,464)	158,584
Issue of share capital	-	59	-	-	59
Exercise of share options	-	379	-	-	379
Share-based payment transactions	-	-	-	806	806
Loss for the period	-	-	-	(10,904)	(10,904)
Other comprehensive loss	-	-	(36)	-	(36)
Balance at 31 March 2015	237	220,989	19,224	(91,562)	148,888
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

GW Pharmaceuticals plc
Condensed consolidated balance sheets
As at 31 March 2016

	As at 31 March 2016	As at 31 March 2016	As at 30 September 2015
	\$000's	£000's	£000's
Non-current assets			
Intangible assets - goodwill	7,484	5,210	5,210
Other intangible assets	418	291	245
Property, plant and equipment	49,439	34,416	28,733
Deferred tax asset	1,006	700	418
	58,347	40,617	34,606
Current assets			
Inventories	6,698	4,663	4,756
Taxation recoverable	31,415	21,869	12,641
Trade receivables and other assets	4,847	3,374	2,873
Cash and cash equivalents	276,791	192,684	234,872
	319,751	222,590	255,142
Total assets	378,098	263,207	289,748
Current liabilities			
Trade and other payables	(42,569)	(29,633)	(24,022)
Current tax liabilities	(122)	(85)	(366)
Obligations under finance leases	(164)	(114)	(111)
Deferred revenue	(3,792)	(2,640)	(3,269)
	(46,647)	(32,472)	(27,768)
Non-current liabilities			
Trade and other payables	(12,462)	(8,675)	(8,445)
Obligations under finance leases	(2,130)	(1,483)	(1,540)
Deferred revenue	(8,830)	(6,147)	(6,725)
Total liabilities	(70,069)	(48,777)	(44,478)
Net assets	308,029	214,430	245,270
Equity			
Share capital	378	263	261
Share premium account	502,628	349,898	349,275
Other reserves	27,423	19,090	19,189
Accumulated deficit	(222,400)	(154,821)	(123,455)
Total equity	308,029	214,430	245,270

GW Pharmaceuticals plc
Condensed consolidated cash flow statements
For the six months ended 31 March 2016

	Six months ended 31 March 2016 \$000's	Six months ended 31 March 2016 £000's	Six months ended 31 March 2015 £000's
Loss for the period	(49,608)	(34,534)	(10,904)
Adjustments for:			
Interest income	(279)	(194)	(114)
Interest expense	50	35	39
Tax benefit	(12,765)	(8,886)	(2,823)
Depreciation of property, plant and equipment	2,212	1,540	1,016
Amortisation of intangible assets	39	27	2
Net foreign exchange gains	(12,034)	(8,377)	(8,265)
(Decrease)/increase in provision for inventories	(66)	(45)	13
Loss on disposal of property, plant and equipment	-	-	1
Share-based payment charge	4,545	3,164	806
	(67,906)	(47,270)	(20,229)
Decrease in inventories	200	138	289
Increase in trade receivables and other assets	(715)	(498)	(904)
Increase in trade and other payables and deferred revenue	3,086	2,148	1,106
	(65,335)	(45,482)	(19,738)
Cash used in operations	(65,335)	(45,482)	(19,738)
Income taxes paid	(1,284)	(894)	-
Research and development tax credits received	-	-	5,415
	(66,619)	(46,376)	(14,323)
Investing activities			
Interest received	267	186	113
Purchases of property, plant and equipment	(6,687)	(4,655)	(10,165)
Purchases of intangible assets	(214)	(149)	(59)
Proceeds from sales of property, plant and equipment	-	-	1
	(6,634)	(4,618)	(10,110)
Financing activities			
Proceeds on exercise of share options	898	625	379
Proceeds of new equity issue	-	-	59
Interest paid	(50)	(35)	(44)
Repayment of obligations under finance leases	(79)	(55)	(55)
	769	535	339
Net cash inflow from financing activities	769	535	339
Effect of foreign exchange rate changes on cash and cash equivalents	11,881	8,271	8,235
	(60,603)	(42,188)	(15,859)
Net decrease in cash and cash equivalents	(60,603)	(42,188)	(15,859)
Cash and cash equivalents at beginning of the period	337,394	234,872	164,491
	276,791	192,684	148,632
Cash and cash equivalents at end of the period	276,791	192,684	148,632

