



December 4, 2017

## GW Pharmaceuticals plc Reports Fiscal Fourth Quarter 2017 and Year-End Financial Results and Operational Progress

**- Epidiolex<sup>®</sup> (cannabidiol) NDA Submitted to FDA -**  
**- Conference call today at 7:30 a.m. EST -**

LONDON and CARLSBAD, Calif., Dec. 04, 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 fourth quarter and year-ended 30 September 2017.

"With the Epidiolex NDA for Dravet syndrome and Lennox-Gastaut syndrome submitted, we have entered a very exciting period for GW and look forward to working with the FDA to support its review process. With a decision on the NDA anticipated in mid 2018, we believe we are making excellent progress with preparations to ensure a highly successful US launch if Epidiolex is approved," stated Justin Gover, GW's Chief Executive Officer. "We also expect to submit a European regulatory application for Epidiolex for these indications in late 2017 and are now building a European commercial presence to prepare for a potential future launch. During 2017, a substantial body of positive clinical data on Epidiolex was published and presented, including a landmark publication in *The New England Journal of Medicine*, as well as a wide range of important data presentations and posters at the American Academy of Neurology and American Epilepsy Society annual meetings. Beyond Epidiolex, as a world leader in the field of cannabinoid science, we continue to advance a number of additional exciting pipeline clinical programs."

### OPERATIONAL HIGHLIGHTS

• Epidiolex (cannabidiol or CBD) orphan epilepsy program in Dravet syndrome, Lennox-Gastaut Syndrome (LGS), Tuberous Sclerosis Complex (TSC) and Infantile Spasms (IS)

Regulatory:

- New Drug Application (NDA) submitted to the FDA for both Dravet syndrome and LGS indications
- NDA acceptance decision anticipated at end of December 2017
- If priority review status granted, PDUFA date expected mid 2018
- European regulatory submission expected in late 2017

Clinical data:

- Phase 3 Dravet syndrome trial published in *The New England Journal of Medicine*
- Phase 3 LGS trial accepted by a top tier journal and publication expected in early 2018
- Over 25 posters presented at American Epilepsy Society Annual Meeting relating to Epidiolex

Clinical trials

- Phase 3 trial in TSC ongoing with data expected H2 2018
- Second Phase 3 trial in Dravet syndrome enrollment complete with data expected H2 2018
- Part A of two-part Phase 2/3 trial in IS underway. Data expected in Q1 2018

Manufacturing

- Recently expanded UK manufacturing facility included in NDA submission
- Preparations on track for FDA GMP pre-approval inspection

Expanded access program and open label extension:

- Overall, greater than 1,700 patients now exposed to Epidiolex treatment
- Over 97 percent of patients who completed Phase 3 trials have entered the company-sponsored long term extension study

Commercial and medical affairs:

- U.S. launch preparations on track. Full medical affairs team in place, including 15 epilepsy specialist Medical Science Liaisons (MSLs)
- Active discussions ongoing with a wide variety of payors and insurance programs
- European commercial build-out underway

Life-cycle management

- Several new formulations of CBD in development including improved liquid formulations, a solid dose form and an intravenous formulation

- i Intellectual property
  - Portfolio of intellectual property relating to the use of CBD in epilepsy being prosecuted
  - We expect USPTO to reach a determination on whether to allow a number of pending applications in H1 2018
- i CBDV Phase 2 partial-onset epilepsy trial in adults fully enrolled with data expected Q1 2018
- i CBDV in Autism Spectrum Disorders
  - Expanded access IND granted by FDA for 10 patients with autism underway
  - Investigator-led 100 patient placebo-controlled trial in autism due to commence in H1 2018
  - Open label study in Rett syndrome and Phase 2 placebo-controlled trial expected to be initiated in 2018
  - Orphan Drug Designation from FDA for CBDV in the treatment of Rett syndrome
- i Sativex
  - Late stage negotiations for the return of U.S. development and commercialization rights
- i CBD:THC in Glioblastoma
  - Plans being developed on a pivotal clinical development program for CBD:THC in glioblastoma
- i Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
  - Phase 1 trial in healthy volunteers complete
  - Orphan Drug Designation from FDA and EMA; Fast Track Designation granted from FDA

## FINANCIAL HIGHLIGHTS

- i Revenue for the twelve months ended 30 September 2017 of £8.2 million (\$11.0 million) compared to £10.3 million for the twelve months ended 30 September 2016.
- i Loss for the twelve months ended 30 September 2017 of £131.7 million (\$175.9 million) compared to £63.7 million for the twelve months ended 30 September 2016.
- i Cash and cash equivalents at 30 September 2017 of £241.2 million (\$322.2 million) compared to £374.4 million as at 30 September 2016.

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 30 September 2017 of \$1.33577 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 fourth quarter and year end 30 September 2017 financial results today at 7:30 am 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 or 919-882-2331 (international). For both dial-in numbers please use conference ID # 13674049.

## 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 or CBD), for which GW has completed a rolling NDA submission with the FDA for the adjunctive treatment of LGS and Dravet 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<sup>®</sup>, which is approved for the treatment of spasticity due to multiple sclerosis in numerous 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 glioblastoma, schizophrenia and epilepsy. For further information, please visit [www.gwpharm.com](http://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 4 December 2017. 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.*

**Enquiries:**

**GW Pharmaceuticals plc**

Stephen Schultz, VP Investor Relations 401 500 6570

**FTI (UK Media Enquiries)**

Ben Atwell +44 (0) 203 727 1030

**Sam Brown (U.S. Media Enquiries)**

Mike Beyer 312 961 2502

*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 2017, the Condensed Consolidated Income Statement, Condensed Consolidated Statement of Comprehensive Loss, 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 2017 have been translated into U.S. dollars at the rate on 30 September 2017 of \$1.33577 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 2017

	Three months ended 30 September 2017 \$000's	Three months ended 30 September 2017 £000's	Three months ended 30 September 2016 £000's
<b>Revenue</b>	2,863	2,143	1,670
Cost of sales	(1,375)	(1,029)	(779)
Research and development expenditure	(41,705)	(31,221)	(24,318)
Sales, general and administrative expenses	(18,666)	(13,974)	(7,469)
Net foreign exchange (loss)/gain	(5,960)	(4,462)	6,272
<b>Operating loss</b>	(64,843)	(48,543)	(24,624)
Interest expense	(315)	(236)	(120)
Interest and other income	767	574	316
<b>Loss before tax</b>	(64,391)	(48,205)	(24,428)
Tax benefit	9,134	6,838	7,520
<b>Loss for the period</b>	(55,257)	(41,367)	(16,908)
<b>Loss per share — basic and diluted</b>	(18.2c)	(13.6p)	(5.7p)

All activities relate to continuing operations.

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

	Three months ended 30 September 2017 £000's	Three months ended 30 September 2016 £000's
<b>Loss for the period</b>	<b>(41,367)</b>	<b>(16,908)</b>
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange differences on translation of foreign operations	(449)	183
<b>Other comprehensive (loss)/gain for the period</b>	<b>(449)</b>	<b>183</b>
<b>Total comprehensive loss for the period</b>	<b>(41,816)</b>	<b>(16,725)</b>

GW Pharmaceuticals plc  
Condensed consolidated income statement  
Year ended 30 September 2017

	Year ended 30 September 2017 \$000's	Year ended 30 September 2017 £000's	Year ended 30 September 2016 £000's
<b>Revenue</b>	11,004	8,238	10,315
Cost of sales	(4,730)	(3,541)	(2,719)
Research and development expenditure	(148,576)	(111,229)	(99,815)
Sales, general and administrative expenses	(55,700)	(41,699)	(19,939)
Net foreign exchange (loss)/gain	(6,739)	(5,045)	25,551
<b>Operating loss</b>	<b>(204,741)</b>	<b>(153,276)</b>	<b>(86,607)</b>
Interest expense	(995)	(745)	(173)
Interest and other income	2,159	1,616	608
<b>Loss before tax</b>	<b>(203,577)</b>	<b>(152,405)</b>	<b>(86,172)</b>
Tax benefit	27,673	20,717	22,515
<b>Loss for the year</b>	<b>(175,904)</b>	<b>(131,688)</b>	<b>(63,657)</b>
<b>Loss per share — basic and diluted</b>	<b>(57.9c)</b>	<b>(43.4p)</b>	<b>(23.5p)</b>

All activities relate to continuing operations.

Condensed consolidated statement of comprehensive loss  
For the year ended 30 September 2017

	Year ended 30 September 2017 £000's	Year ended 30 September 2016 £000's
<b>Loss for the year</b>	<b>(131,688)</b>	<b>(63,657)</b>
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange differences on translation of foreign operations	(716)	349
<b>Other comprehensive (loss)/gain for the year</b>	<b>(716)</b>	<b>349</b>
<b>Total comprehensive loss for the year</b>	<b>(132,404)</b>	<b>(63,308)</b>

GW Pharmaceuticals plc  
Condensed consolidated statement of changes in equity  
Year ended 30 September 2017

	Called-up share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total equity £000's
<b>Balance at 1 October 2015</b>	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 gain	—	—	349	—	349
<b>Balance at 30 September 2016</b>	<b>302</b>	<b>556,477</b>	<b>19,538</b>	<b>(177,827 )</b>	<b>398,490</b>

<b>Balance at 1 October 2016</b>	302	556,477	19,538	(177,827 )	398,490
Exercise of share options	2	93	—	—	95
Share-based payment transactions	—	—	—	11,860	11,860
Loss for the year	—	—	—	(131,688 )	(131,688)
Deferred tax attributable to unrealized share option gains	—	—	—	134	134
Other comprehensive loss	—	—	(716 )	—	(716 )
<b>Balance at 30 September 2017</b>	<b>304</b>	<b>556,570</b>	<b>18,822</b>	<b>(297,521 )</b>	<b>278,175</b>

GW Pharmaceuticals plc  
Condensed consolidated statement of changes in equity  
Year ended 30 September 2017

	As at 30 September 2017	As at 30 September 2017	As at 30 September 2016
	\$000's	£000's	£000's
<b>Non-current assets</b>			
Intangible assets - goodwill	6,959	5,210	5,210
Other intangible assets	1,401	1,049	629
Property, plant and equipment	58,328	43,666	38,947
Deferred tax asset	8,391	6,282	3,873
	75,079	56,207	48,659
<b>Current assets</b>			
Inventories	5,669	4,244	4,248
Taxation recoverable	26,812	20,072	21,322
Trade receivables and other assets	14,983	11,217	4,556
Cash and cash equivalents	322,154	241,175	374,392
	369,618	276,708	404,518
<b>Total assets</b>	444,697	332,915	453,177

<b>Current liabilities</b>			
Trade and other payables	(44,238 )	(33,119 )	(31,170 )
Current tax liabilities	(1,119 )	(838 )	(883 )
Obligations under finance leases	(274 )	(205 )	(211 )
Deferred revenue	(3,082 )	(2,307 )	(2,686 )
	(48,713 )	(36,469 )	(34,950 )
<b>Non-current liabilities</b>			
Trade and other payables	(12,364 )	(9,256 )	(9,423 )
Obligations under finance leases	(6,352 )	(4,755 )	(4,959 )
Deferred revenue	(5,690 )	(4,260 )	(5,355 )
<b>Total liabilities</b>	(73,119 )	(54,740 )	(54,687 )
<b>Net assets</b>	371,578	278,175	398,490
<b>Equity</b>			
Share capital	406	304	302
Share premium account	743,450	556,570	556,477
Other reserves	25,145	18,822	19,538
Accumulated deficit	(397,423 )	(297,521 )	(177,827 )
<b>Total equity</b>	371,578	278,175	398,490

GW Pharmaceuticals plc  
Condensed consolidated cash flow statement  
As at 30 September 2017

	Year ended 30 September 2017 \$000's	Year ended 30 September 2017 £000's	Year ended 30 September 2016 £000's
<b>Loss for the year</b>	(175,904 )	(131,688 )	(63,657 )
Adjustments for:			
Interest and other income	(2,159 )	(1,616 )	(608 )
Interest expense	995	745	173
Tax benefit	(27,672 )	(20,717 )	(22,515 )
Depreciation of property, plant and equipment	7,048	5,276	3,605
Impairment of property, plant and equipment	848	635	—
Reversal of impairment of property, plant and equipment	(289 )	(216 )	—
Amortization of intangible assets	328	245	62
Net foreign exchange losses/(gains)	6,739	5,045	(25,551 )
Increase in provision for inventories	134	100	72
Decrease in deferred signature fees	(1,830 )	(1,370 )	(1,170 )
Share-based payment charge	15,842	11,860	8,152
Loss on disposal of property, plant and equipment	779	582	1
	(175,142 )	(131,119 )	(101,436 )
(Increase)/decrease in inventories	(128 )	(96 )	436
Increase in trade receivables and other assets	(3,643 )	(2,728 )	(753 )
Increase in trade and other payables and deferred revenue	5,760	4,312	4,761
<b>Cash used in operations</b>	(173,153 )	(129,631 )	(96,992 )

Income taxes paid	(3,064 )	(2,293 )	(883 )
Research and development tax credits received	28,958	21,679	13,281
<b>Net cash outflow from operating activities</b>	<b>(147,259 )</b>	<b>(110,245 )</b>	<b>(84,594 )</b>
<b>Investing activities</b>			
Interest received	1,914	1,433	434
Purchases of property, plant and equipment	(21,451 )	(16,059 )	(8,678 )
Purchase of intangible assets	(850 )	(636 )	(512 )
<b>Net cash outflow from investing activities</b>	<b>(20,387 )</b>	<b>(15,262 )</b>	<b>(8,756 )</b>
<b>Financing activities</b>			
Proceeds on exercise of share options	128	96	540
Proceeds of new equity issue	—	—	206,550
Expenses of new equity issue	(179 )	(134 )	(319 )
Underwriters' contribution towards expenses of new equity issue	—	—	472
Interest paid	(1,289 )	(965 )	(69 )
Repayments of fit out funding	(1,123 )	(841 )	(240 )
Repayments of obligations under finance leases	(279 )	(209 )	(127 )
<b>Net cash (outflow)/inflow from financing activities</b>	<b>(2,742 )</b>	<b>(2,053 )</b>	<b>206,807</b>
Effect of foreign exchange rate changes on cash and cash equivalents	(7,560 )	(5,657 )	26,063
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(177,948 )</b>	<b>(133,217 )</b>	<b>139,520</b>
Cash and cash equivalents at beginning of the year	500,102	374,392	234,872
<b>Cash and cash equivalents at end of the year</b>	<b>322,154</b>	<b>241,175</b>	<b>374,392</b>