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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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**Form 6-K**

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REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Month of August, 2018

Commission File Number: 001-35892

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**GW PHARMACEUTICALS PLC**  
(Translation of registrant's name into English)

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Sovereign House  
Vision Park  
Histon  
Cambridge CB24 9BZ  
United Kingdom  
(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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## Other Events

On August 7, 2018, GW Pharmaceuticals plc (the “Company”) issued a press release announcing its third quarter 2018 financial results and operational progress and details of a conference call to be held at 4:30 p.m. EST on August 7, 2018 to discuss the results and operational progress. The Company’s unaudited condensed consolidated interim financial statements as of June 30, 2018 are attached as Exhibit 99.1 hereto and incorporated by reference herein. The Company’s Financial and Operational Results for the Third Quarter Ending June 30, 2018 are attached as Exhibit 99.2 hereto and incorporated by reference herein. The Company’s Management’s Discussion and Analysis of Financial Condition and Results of Operations is attached as Exhibit 99.3 hereto and incorporated by reference herein. Exhibits 99.1, 99.2 and 99.3 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3 (Registration Number 333-217329) and Form S-8 (Registration Numbers 333-204389 and 333-217328), and related Prospectuses, as such Registration Statements and Prospectuses may be amended from time to time and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished. The press release issued by the Company in connection with the earnings announcement is attached as Exhibit 99.4 hereto and is incorporated by reference herein. Exhibit 99.4 to this Report on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act.

### EXHIBIT INDEX

<u>Exhibit</u>	<u>Description of Exhibit</u>
99.1	GW Pharmaceuticals plc Unaudited Condensed Consolidated Interim Financial Statements as of June 30, 2018
99.2	GW Pharmaceuticals plc Financial and Operational Results for the Third Quarter Ending June 30, 2018
99.3	GW Pharmaceuticals plc Management’s Discussion and Analysis of Financial Condition and Results of Operations
99.4	GW Pharmaceuticals plc Press Release dated August 7, 2018

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**GW Pharmaceuticals plc**

By: /s/ Douglas B. Snyder

Name: Douglas B. Snyder

Title: Chief Legal Officer

Date: August 7, 2018

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## GW PHARMACEUTICALS PLC

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GW Pharmaceuticals plc  
Condensed consolidated income statement  
Three months ended 30 June 2018 and 2017

	Notes	30 June 2018 \$000's	30 June 2018 £000's	30 June 2017 £000's
<b>Revenue</b>	3	3,457	<b>2,623</b>	2,412
Cost of sales		(1,741)	<b>(1,321)</b>	(1,110)
Research and development expenditure		(24,503)	<b>(18,592)</b>	(27,936)
Sales, general and administrative expenses		(35,158)	<b>(26,677)</b>	(11,751)
Net foreign exchange gain/(loss)		21,825	<b>16,560</b>	(8,410)
<b>Operating loss</b>		(36,120)	<b>(27,407)</b>	(46,795)
Interest expense		(303)	<b>(230)</b>	(266)
Interest and other income		1,452	<b>1,102</b>	456
<b>Loss before tax</b>		(34,971)	<b>(26,535)</b>	(46,605)
Tax (expense)/benefit	4	(734)	<b>(557)</b>	6,247
<b>Loss for the period</b>		<b>(35,705)</b>	<b>(27,092)</b>	<b>(40,358)</b>
<b>Loss per share – basic and diluted</b>		(10.5c)	<b>(8.0p)</b>	(13.3p)
<b>Loss per ADS – basic and diluted<sup>(1)</sup></b>		(126.0c)	<b>(96.0p)</b>	(159.6p)
<b>Weighted average ordinary shares outstanding (in millions) – basic and diluted</b>			<b>338.6</b>	303.9

All activities relate to continuing operations.

<sup>(1)</sup> Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss  
For the three months ended 30 June 2018 and 2017

	30 June 2018 £000's	30 June 2017 £000's
<b>Loss for the period</b>	<b>(27,092)</b>	<b>(40,358)</b>
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange gain/(loss) on retranslation of foreign operations	959	(508)
<b>Other comprehensive gain/(loss) for the period</b>	<b>959</b>	<b>(508)</b>
<b>Total comprehensive loss for the period</b>	<b>(26,133)</b>	<b>(40,866)</b>

GW Pharmaceuticals plc  
Condensed consolidated income statement  
Nine months ended 30 June 2018 and 2017

	Notes	30 June 2018 \$000's	30 June 2018 £000's	30 June 2017 £000's
<b>Revenue</b>	3	14,154	10,740	6,095
Cost of sales		(4,440)	(3,369)	(2,512)
Research and development expenditure		(107,608)	(81,650)	(80,007)
Sales, general and administrative expenses		(81,321)	(61,704)	(27,725)
Net foreign exchange loss		(801)	(608)	(583)
<b>Operating loss</b>		(180,016)	(136,591)	(104,732)
Interest expense		(923)	(700)	(509)
Interest and other income		4,783	3,629	1,042
<b>Loss before tax</b>		(176,156)	(133,662)	(104,199)
Tax (expense)/benefit	4	(4,014)	(3,046)	13,878
<b>Loss for the period</b>		(180,170)	(136,708)	(90,321)
<b>Loss per share – basic and diluted</b>		(54.7c)	(41.5p)	(29.8p)
<b>Loss per ADS – basic and diluted<sup>(1)</sup></b>		(656.4c)	(498.0p)	(357.6p)
<b>Weighted average ordinary shares outstanding (in millions) – basic and diluted</b>			329.6	303.4

All activities relate to continuing operations.

<sup>(1)</sup> Each ADS represents 12 ordinary shares

Condensed consolidated statement of comprehensive loss  
For the nine months ended 30 June 2018 and 2017

	30 June 2018 £000's	30 June 2017 £000's
<b>Loss for the period</b>	(136,708)	(90,321)
<b>Items that may be reclassified subsequently to profit or loss</b>		
Exchange gain/(loss) on retranslation of foreign operations	19	(267)
<b>Other comprehensive gain/(loss) for the period</b>	19	(267)
<b>Total comprehensive loss for the period</b>	(136,689)	(90,588)

GW Pharmaceuticals plc  
Condensed consolidated statement of changes in equity  
Nine months ended 30 June 2018 and 2017

	Share capital £000's	Share premium account £000's	Other reserves £000's	Accumulated deficit £000's	Total £000's
<b>Balance at 1 October 2016</b>	302	556,477	19,538	(177,827)	398,490
Exercise of share options	2	88	-	-	90
Share-based payment transactions	-	-	-	8,141	8,141
Loss for the period	-	-	-	(90,321)	(90,321)
Deferred tax attributable to unrealized share option gains	-	-	-	(251)	(251)
Other comprehensive loss	-	-	(267)	-	(267)
<b>Balance at 30 June 2017</b>	<u>304</u>	<u>556,565</u>	<u>19,271</u>	<u>(260,258)</u>	<u>315,882</u>
<b>Balance at 1 October 2017</b>	304	556,570	18,822	(297,521)	278,175
Exercise of share options	2	-	-	-	2
Issue of share capital	33	223,037	-	-	223,070
Expense of new equity issue	-	(911)	-	-	(911)
Share-based payment transactions	-	-	-	15,742	15,742
Loss for the period	-	-	-	(136,708)	(136,708)
Deferred tax attributable to unrealized share option gains	-	-	-	2,202	2,202
Other comprehensive gain	-	-	19	-	19
<b>Balance at 30 June 2018</b>	<u>339</u>	<u>778,696</u>	<u>18,841</u>	<u>(416,285)</u>	<u>381,591</u>

GW Pharmaceuticals plc  
Condensed consolidated balance sheets  
As at 30 June 2018 and 30 September 2017

	Notes	As at 30 June 2018	As at 30 June 2018	As at 30 September 2017
		£000's	£000's	£000's
<b>Non-current assets</b>				
Goodwill		6,866	5,210	5,210
Other intangible assets		2,855	2,166	1,049
Property, plant and equipment		65,768	49,903	43,666
Deferred tax asset		11,287	8,564	6,282
		<u>86,776</u>	<u>65,843</u>	<u>56,207</u>
<b>Current assets</b>				
Inventories	5	26,333	19,981	4,244
Taxation recoverable		2,499	1,896	20,072
Trade receivables and other assets		23,367	17,730	11,217
Cash and cash equivalents		440,190	334,005	241,175
		<u>492,389</u>	<u>373,612</u>	<u>276,708</u>
<b>Total assets</b>		<u>579,165</u>	<u>439,455</u>	<u>332,915</u>
<b>Current liabilities</b>				
Trade and other payables	6	(52,876)	(40,121)	(33,119)
Current tax liabilities		(2,558)	(1,941)	(838)
Obligations under finance leases		(282)	(214)	(205)
Deferred revenue		(1,074)	(815)	(2,307)
		<u>(56,790)</u>	<u>(43,091)</u>	<u>(36,469)</u>
<b>Non-current liabilities</b>				
Trade and other payables	6	(11,602)	(8,803)	(9,256)
Obligations under finance leases		(6,053)	(4,593)	(4,755)
Deferred revenue		(1,815)	(1,377)	(4,260)
<b>Total liabilities</b>		<u>(76,260)</u>	<u>(57,864)</u>	<u>(54,740)</u>
<b>Net assets</b>		<u>502,905</u>	<u>381,591</u>	<u>278,175</u>
<b>Equity</b>				
Share capital		447	339	304
Share premium account		1,026,255	778,696	556,570
Other reserves		24,831	18,841	18,822
Accumulated deficit		(548,628)	(416,285)	(297,521)
<b>Total equity</b>		<u>502,905</u>	<u>381,591</u>	<u>278,175</u>



GW Pharmaceuticals plc  
Condensed consolidated cash flow statements  
For the nine months ended 30 June 2018 and 2017

	Nine months ended 30 June 2018 \$000's	Nine months ended 30 June 2018 £000's	Nine months ended 30 June 2017 £000's
<b>Loss for the period</b>	(180,170)	(136,708)	(90,321)
Adjustments for:			
Interest and other income	(4,783)	(3,629)	(1,042)
Interest expense	923	700	509
Tax expense/(benefit)	4,014	3,046	(13,878)
Depreciation of property, plant and equipment	6,190	4,697	3,781
Impairment of property, plant and equipment	-	-	95
Reversal of impairment of property, plant and equipment	-	-	(216)
Amortization of intangible assets	480	364	168
Net foreign exchange losses	800	607	583
(Decrease)/increase in provision for inventories	(477)	(362)	80
Decrease in deferred signature fees	(4,169)	(3,163)	(1,097)
Share-based payment charge	20,743	15,742	8,141
Loss on disposal of property, plant and equipment	149	113	605
	(156,300)	(118,593)	(92,592)
(Increase)/decrease in inventories	(20,789)	(15,774)	52
Increase in trade receivables and other assets	(3,033)	(2,301)	(1,914)
Increase/(decrease) in trade and other payables and deferred revenue	9,305	7,061	(1,279)
Research and development tax credits received	26,509	20,114	21,679
Income taxes paid	(2,562)	(1,944)	(1,277)
<b>Net cash outflow from operating activities</b>	(146,870)	(111,437)	(75,331)
<b>Investing activities</b>			
Interest received	2,205	1,673	970
Purchases of property, plant and equipment	(22,399)	(16,996)	(12,989)
Purchase of intangible assets	(1,730)	(1,313)	(468)
<b>Net cash outflow from investing activities</b>	(21,924)	(16,636)	(12,487)
<b>Financing activities</b>			
Proceeds on exercise of share options	3	2	91
Proceeds of new equity issue	293,987	223,070	-
Expenses of new equity issue	(1,201)	(911)	(134)
Interest paid	(923)	(700)	(729)
Repayment of fit out funding	(384)	(291)	(748)
Repayment of obligations under finance leases	(202)	(153)	(160)
<b>Net cash inflow/(outflow) from financing activities</b>	291,280	221,017	(1,680)
Effect of foreign exchange rate changes on cash and cash equivalents	(144)	(114)	(810)
<b>Net increase/(decrease) in cash and cash equivalents</b>	122,342	92,830	(90,308)
Cash and cash equivalents at beginning of the period	317,848	241,175	374,392
<b>Cash and cash equivalents at end of the period</b>	440,190	334,005	284,084

## 1. Significant accounting policies

### Basis of preparation

These unaudited condensed consolidated interim financial statements for the three and nine month periods ended 30 June 2018 and 30 June 2017 of GW Pharmaceuticals plc and subsidiaries (collectively, the “Group”) have been prepared in accordance with International Accounting Standard 34 – “Interim Financial Reporting” (“IAS 34”), as issued by the International Accounting Standards Board (“IASB”) and as endorsed by the European Union. These statements were approved by the Board on 7 August 2018.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the IASB and as adopted by the European Union have been condensed or omitted as permitted by IAS 34. The balance sheet as at 30 September 2017 was derived from the audited financial statements.

The significant accounting policies and methods of computation adopted in the preparation of these condensed consolidated interim financial statements are consistent with those used in the preparation of the Group’s annual audited financial statements for the year ended 30 September 2017 in accordance with IFRS, as issued by the IASB and as adopted by the European Union. These condensed consolidated interim financial statements include all adjustments necessary to fairly state the results of the interim period and the Group believes that the disclosures are adequate to make the information presented not misleading. Interim results are not necessarily indicative of results to be expected for the full year.

The Group has not adopted early any standard, interpretation or amendment that was issued but is not yet effective.

Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 30 June 2018, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and nine months ended 30 June 2018 have been translated into U.S. dollars at the rate on 30 June 2018 of \$1.31792 to £1.0000. 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.

The Directors do not consider the business to be seasonal or cyclical.

### Going concern

At 30 June 2018 the Group had cash and cash equivalents of £334.0 million. The Directors have considered the financial position of the Group, its cash position and forecast cash flows for the 12-month period from the date of this report when considering going concern. They have also considered the Group’s key risks and uncertainties affecting the likely development of the business. In the light of this review, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for at least a 12-month period from the date of this report. Accordingly, they continue to adopt the going concern basis in preparing these financial statements.

## 2. Segmental Information

### Operating Segments

In accordance with IFRS 8 – “Operating Segments”, the chief operating decision maker (CODM), who is responsible for allocating resources and assessing performance of the Group, has been identified as a sub-group of the Executive Leadership Team (ELT), consisting of those members charged with executive management of the Group’s business activities.

During the first quarter of financial year ended 30 September 2018, the Group’s research and collaboration agreement with Otsuka Pharmaceuticals was terminated by mutual agreement. As part of this process, the rights to develop and commercialize Sativex in the United States were returned to the Group. As a result of this, the recognition of certain advance payments and deferred signature fee income balances in the Income Statement was accelerated on the basis that no further obligations remain to be fulfilled by the Group. The Group’s CODM considered that, following this termination, the nature of the Group’s operations has changed such that a review of operating segments was performed. The results of this identified that reporting a single operating segment has become appropriate, and reflects the Group’s strategy of discovering, developing and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. Accordingly, the information required under IFRS 8 “Operating Segments”, including the respective comparative information, has been presented for the single operating segment in Note 3 below.

The Group has licensing agreements for the commercialization of Sativex® with Almirall S.A. in Europe (excluding the United Kingdom) and Mexico, Bayer HealthCare AG in the United Kingdom and Canada, Neopharm Group in Israel, Emerge Health Pty. Ltd. in Australasia and Malaysia and Ipsen Biopharm Ltd. in Latin America (excluding Mexico and the Islands of the Caribbean). Revenues include product sales, royalties, license, collaboration and technical access fees, and development and approval milestone fees.

## 3. Revenue

Revenues arising from the Group’s activities during the period were as follows:

	<b>Three months ended 30 June 2018</b>	Three months ended 30 June 2017	<b>Nine months ended 30 June 2018</b>	Nine months ended 30 June 2017
	<b>£000’s</b>	£000’s	<b>£000’s</b>	£000’s
Product sales	<b>2,281</b>	1,790	<b>5,972</b>	4,427
Research and development fees	<b>138</b>	236	<b>1,494</b>	459
License, collaboration and technical access fees	<b>204</b>	276	<b>3,163</b>	1,099
Development milestones	-	110	<b>111</b>	110
	<b>2,623</b>	2,412	<b>10,740</b>	6,095

### 3. Revenue (continued)

Revenues from the Group's major customers, ranked according to the results of the nine month current period, are included within revenue as follows:

	<b>Three months ended 30 June 2018 £000's</b>	Three months ended 30 June 2017 £000's	<b>Nine months ended 30 June 2018 £000's</b>	Nine months ended 30 June 2017 £000's
Customer A	1,651	1,535	4,485	3,556
Customer B	137	306	4,042	668
Customer C	583	398	1,515	1,174
Customer D	101	114	323	121

Geographical analysis of revenue by destination of customer:

	<b>Three months ended 30 June 2018 £000's</b>	Three months ended 30 June 2017 £000's	<b>Nine months ended 30 June 2018 £000's</b>	Nine months ended 30 June 2017 £000's
UK	533	374	1,492	1,196
Europe (excluding UK)	1,651	1,528	4,484	3,846
United States	-	196	3,693	300
Canada	277	204	662	384
Asia	162	110	409	369
	<b>2,623</b>	<b>2,412</b>	<b>10,740</b>	<b>6,095</b>

### 4. Tax (expense)/benefit

	<b>Three months ended 30 June 2018 £000's</b>	Three months ended 30 June 2017 £000's	<b>Nine months ended 30 June 2018 £000's</b>	Nine months ended 30 June 2017 £000's
Current period research and development tax credit	-	(5,568)	-	(12,789)
Adjustments in respect of prior year tax credit	(26)	(541)	(82)	(732)
Deferred tax credit	(1,053)	(355)	(2,150)	(355)
Reclassification of amounts previously charged to equity	1,966	(251)	2,226	(251)
Current period tax (credit)/charge	(330)	468	3,052	249
Total charge/(credit) for the period	<b>557</b>	<b>(6,247)</b>	<b>3,046</b>	<b>(13,878)</b>

In the nine months ended 30 June 2018, the Group recognized the impact of The Tax Cuts and Jobs Act (the Act), which was signed into law on 22 December 2017, and thus enacted at this date.

#### 4. Tax (expense)/benefit (continued)

With effect from 1 October 2017, the Group is also no longer able to qualify tax credits in respect of the Small and Medium sized enterprises (SME) R&D relief under the Finance Act 2000. The Group now qualifies for the Research and Development Expenditure Credit (RDEC), available to large enterprises in the UK. An above-the-line RDEC credit of £0.4 million has been recorded within Interest and Other Income for the three months ended 30 June 2018 and £1.9 million within Interest and Other Income for the nine months ended 30 June 2018.

The carrying amount of deferred tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient future taxable profits will be available to allow all or part of the asset to be recovered.

#### 5. Inventories

	<b>30 June</b>	30 September
	<b>2018</b>	2017
	<b>£000's</b>	£000's
Raw materials	578	199
Work in progress	18,894	3,379
Finished goods	509	666
	<u>19,981</u>	<u>4,244</u>

Inventory is stated net of a provision for inventories, calculated in accordance with the Group's accounting policy. The movement in the provision for inventories is as follows:

	<b>£000's</b>
Opening balance – as at 1 October 2016	118
Write-down of inventories to net realizable value	136
Write off of inventories included in the provision	(169)
Reversal of write-down of inventories	(55)
<b>Closing balance as at 30 June 2017</b>	<b><u>30</u></b>
Opening balance – as at 1 October 2017	41
Write-down of inventories to net realizable value	17,140
Write off of inventories included in the provision	(162)
Reversal of write-down of inventories	(16,778)
<b>Closing balance as at 30 June 2018</b>	<b><u>241</u></b>

During the current period, and after notification by the FDA of the Group's successful submission of a New Drug Application, capitalization of Epidiolex-related plant material commenced. This inventory was subject to a full provision until FDA approval was received on 25 June 2018. We have determined that this presents clear evidence to indicate an increase in the net realizable value and therefore the provision can be reversed for the element of inventory expected to be fully commercialized.

**6. Trade and other payables**

	<b>30 June 2018 £000's</b>	30 September 2017 £000's
<b>Amounts falling due within one year</b>		
Other creditors and accruals	26,389	19,335
Trade payables	6,701	5,807
Clinical trial accruals	4,667	5,520
Other taxation and social security	1,934	2,032
Fit out funding	410	389
Onerous lease provision	20	36
	<u>40,121</u>	<u>33,119</u>
<b>Amounts falling due after one year</b>		
Fit out funding	7,646	7,957
Other creditors and accruals	1,157	1,288
Onerous lease provision	-	11
	<u>8,803</u>	<u>9,256</u>

Fit out funding represents £8.1 million (30 September 2017: £8.3 million) owed to the Group's landlord reflecting the liability to repay the £7.8 million of fit out funding received to fund the expansion and upgrades to manufacturing facilities and associated interest of £2.6 million (30 September 2017: £2.2 million), net of payments to date of £2.2 million (30 September 2017: £1.7 million).

**GW Pharmaceuticals plc**  
**(“GW” or “the Company” or “the Group”)**

**Financial and Operational Results for the Third Quarter Ending 30 June 2018**

**GW Overview**

GW was founded in 1998 and 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 has established the world leading position in the development of plant-derived cannabinoid therapeutics through its proven drug discovery and development processes, intellectual property portfolio and regulatory and manufacturing expertise.

The Company’s lead cannabinoid product is Epidiolex<sup>®</sup>, a pharmaceutical oral formulation of cannabidiol (CBD), for which GW retains global commercial rights. Epidiolex was approved by the FDA on June 25, 2018 for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome, each of which are severe infantile-onset, drug-resistant epilepsy syndromes. GW expects to make Epidiolex available to U.S. patients in Fall 2018, following re-scheduling which is expected to occur within 90 days of FDA approval. In Europe, the Company submitted an application to the European Medicines Agency (EMA) in December 2017 and expects an outcome of this review process in the first quarter of 2019. GW has received Orphan Drug Designation from the FDA for Epidiolex for seizures associated with LGS, Dravet syndrome and Tuberous Sclerosis Complex (TSC), GW has also received Orphan Designation from the EMA, for Epidiolex for Dravet syndrome, LGS, and TSC. The Company continues to develop Epidiolex for additional rare childhood-onset epilepsy disorders including TSC and in autism spectrum disorders (ASD).

Previously, GW developed the world’s first plant-derived cannabinoid prescription drug, Sativex<sup>®</sup> (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States. In the U.S., GW has full commercial rights to this product and plans to meet with the FDA in the second half of 2018 to discuss data from the completed Phase 3 trials in Europe and to determine a regulatory pathway in the U.S.

GW has a deep pipeline of additional cannabinoid product candidates focusing primarily on orphan childhood-onset neurologic conditions and oncology. The Company’s pipeline includes research in autism spectrum disorders, or ASD using both CBD and cannabidivarin, or CBDV. GW reported positive Phase 2 data for its CBD:THC product in the treatment of glioblastoma multiforme. GW has also reported positive Phase 2 data in schizophrenia. In addition, GW has received Orphan Drug Designation and Fast Track Designation from the FDA for intravenous CBD for the treatment of Neonatal Hypoxic Ischemic Encephalopathy, or NHIE, for which a Phase 1 study has been completed.

**Epidiolex (cannabidiol) Oral Solution**

Following an April 19, 2018 FDA Advisory Committee unanimous vote (13 to 0) in favor of supporting the approval, Epidiolex was approved by the FDA on June 25, 2018 for the treatment of seizures associated with LGS or Dravet syndrome, each of which are severe infantile-onset, drug-resistant epilepsy syndromes. Following the approval, the FDA confirmed orphan drug exclusivity for Epidiolex and granted GW a rare pediatric disease voucher.

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### ***FDA Approval for LGS and Dravet Syndrome***

LGS is a form of epilepsy with multiple types of seizures, particularly tonic (stiffening) and predominantly drop seizures which were defined as atonic, tonic or tonic-clonic seizures involving the entire body, trunk or head that led or could have led to a fall, injury, slumping in a chair or hitting the patient's head on a surface. Seizures due to LGS are hard to control and they generally require life-long treatment as LGS usually persists into the adult years. Historically patients with LGS have had few effective treatment options. Intellectual and behavioral problems associated with LGS are common and add to the complexity of this syndrome and the difficulties in managing life with LGS. Drug resistance is one of the main features of LGS.

GW has reported results from two LGS Phase 3 pivotal studies, both achieving the primary endpoint of a median reduction in monthly drop seizures compared with placebo. The first study compared a single Epidiolex 20 mg/kg dose arm to placebo in 171 patients (p=0.0135) and the second compared both a 20 mg/kg and 10 mg/kg Epidiolex dose arm to placebo in 225 patients (p=0.0047 and p=0.0016 respectively). In January 2018, the single-dose LGS trial was published in *The Lancet* and in May 2018, the second multi-dose trial was published in *The New England Journal of Medicine*.

Dravet syndrome is a severe infantile-onset, genetic, drug-resistant epilepsy syndrome with a distinctive but complex electroclinical presentation. Onset of Dravet syndrome occurs during the first year of life with clonic seizures (jerking) and tonic-clonic (convulsive) seizures in previously healthy and developmentally normal infants. Prognosis is poor and death occurs before the age of 10 years in 3 out of 4 people (73 percent) with Sudden Unexpected Death in Epilepsy or SUDEP the likely cause in nearly half of those deaths. Patients develop intellectual disability and life-long ongoing seizures. There are currently no FDA-approved treatments specifically indicated for Dravet syndrome.

GW has reported results from the first Phase 3 pivotal efficacy and safety study in 120 patients, achieving the primary endpoint of a median reduction in monthly convulsive seizures compared with placebo (p=0.012). In May 2017, this trial was published in *The New England Journal of Medicine*.

Epidiolex demonstrated an acceptable safety profile in these Phase 3 pivotal trials. Across the Epidiolex development program, the most common reported adverse reactions that occurred in Epidiolex-treated patients were somnolence; decreased appetite; diarrhea; transaminase elevations; fatigue, malaise, and asthenia; rash; insomnia, sleep disorder and poor quality sleep; and infections. The Company's development program represents the only well-controlled clinical evaluation of a cannabinoid medication for patients with LGS and Dravet syndrome.

GW is conducting a second Phase 3 trial of Epidiolex in Dravet syndrome. This placebo-controlled trial differs from the first Phase 3 trial in that it includes two Epidiolex dose arms, at 20 mg/kg per day and at 10 mg/kg per day. Enrollment is complete in this trial at 186 patients with data expected in the fourth quarter of 2018.

### ***Open Label Extension***

All patients in the randomized controlled clinical trials who completed the treatment period were eligible to enroll in a long-term open label extension trial. 95 percent of patients who have completed the pivotal treatment period have elected to enroll in the open label extension.

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### ***Epidiolex EU Regulatory***

In Europe, GW has submitted a marketing authorization application in December 2017 for both the Dravet syndrome and LGS indications. This application has been validated by the EMA and the outcome is expected in first quarter of 2019.

GW has received Orphan Designation from the EMA for Epidiolex for Dravet syndrome, LGS, and TSC.

### ***Epidiolex Follow-On Target Indication:TSC***

TSC is a genetic disorder that causes developmental changes in the nervous system and skin, as well as the formation of non-malignant tumors in multiple organ systems, primarily in the brain, eyes, heart, kidney, skin and lungs. The most common symptom of TSC is epilepsy, which occurs in 75 to 90 percent of patients, about 70 percent of whom experience seizure onset in their first year of life. There are significant co-morbidities associated with TSC including cognitive impairment, autism spectrum disorders and neurobehavioral disorders.

A number of patients with TSC have been treated with Epidiolex in the expanded access program. Treatment experience in 18 TSC patients with refractory epilepsy from the Massachusetts General Hospital for Children enrolled in the expanded access program has been published in *Epilepsia* (Hess *et al* - 2016). The findings from this study suggest that cannabidiol may be an effective and well-tolerated treatment option for patients with refractory seizures in TSC.

GW is progressing a Phase 3 trial of Epidiolex in patients with TSC. This dose-ranging trial is a 16-week comparison of Epidiolex versus placebo which is expected to recruit a total of approximately 200 patients, aged one to 65 years, to assess the safety and efficacy of Epidiolex as an adjunctive anti-epileptic treatment. The primary measure of this trial is the percentage change from baseline in seizure frequency during the treatment period. Primary endpoint seizure types include focal motor seizures with or without impairment of consciousness or awareness and generalized convulsive seizures. Data from this trial is expected in the first half of 2019. Subject to positive results, GW would expect to submit a supplemental NDA (sNDA) for Epidiolex in TSC in the second half of 2019.

### ***Epidiolex Manufacturing***

GW manufactures Epidiolex through utilization of in-house and external third-party facilities for various steps in the production process. The Company has expanded various parts of the production process both in-house and with external third parties in readiness for commercial launch. As part of the NDA review, the FDA inspections of the Company's manufacturing facilities were successfully completed and did not result in any Form 483 observations. GW is continuing to expand its Epidiolex manufacturing capacity in anticipation of post-U.S. launch and EU demand.

### ***Epidiolex Commercialization***

#### ***U.S. Commercial Operation Status***

In the U.S., GW's commercial organization operates under the name, Greenwich Biosciences, Inc.

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With Epidiolex approved by the FDA and as the Company awaits DEA rescheduling, the U.S. commercial team now has completed the build-out of an experienced commercial organization consisting of sales, medical affairs and marketing and market access/payor teams. The U.S. sales team includes two National Directors and eight Regional Managers plus 66 Neurology Account Managers that will target approximately 5,000 physicians who may treat patients with LGS or Dravet syndrome. The Company had a dramatic response to these available commercial positions and feels that the current team is drawn from the best qualified and most experienced professionals from the epilepsy and rare disease industry.

In advance of U.S. product launch, the Company has set a list price per 100 mL bottle of \$1,235. Based on anticipated dosing and patient weight assumptions, we believe that this translates to a weighted average gross price in the first year of \$32,500, which is in line with other branded anti-epileptic drugs used to treat these conditions. Our general pricing approach has been discussed with the payor community who appears supportive of the rationale that Epidiolex should be priced in line with the other branded anti-seizure therapies prescribed for these intractable patients. The analyses of the direct cost burden associated with LGS and Dravet syndrome in the U.S. showed a substantial cost burden for both conditions and further highlights the need for this new therapeutic option. A comprehensive patient support program is in development to help provide resources which may lower patients' out-of-pocket costs, or provide product at no cost to eligible patients.

Preparations with the payor community have been active and detailed reviews with major payors have been completed. This activity, which includes individual one on one and advisory board interactions with a wide variety of payors and insurance programs, including most of the larger commercial and state/federal payors, is designed to gather insights ahead of commercial launch. A number of one-on-one meetings have also taken place with payors and Pharmacy Benefit Managers, or PBM's and with Centers for Medicare & Medicaid Services, or CMS. Given the significant pediatric population that may likely try Epidiolex, CMS will be an important payor. To date, the Greenwich team have presented to plans that cover over 80% of commercial covered lives in the U.S. The Company believes that this advance work has generated a meaningful level of understanding that the Company feels is encouraging regarding formulary coverage and reimbursement decision making.

The Company has now finalized the U.S. supply chain platform which will employ a closed model distribution network of Specialty Pharmacy Providers (SPP's). These providers range from those that have retail distribution in all 50 States, in addition to a Medicaid dedicated SPP and other SPP's that have a large pharmacy benefit network for SPP distribution for the majority of the insurers in the U.S. These SPPs will process the prescription initiated in the physician's office and ship directly to the patient or caregiver. The Company is also employing a central "Hub" that offers the optional support of benefit verification, SPP selection, and prior-authorization management as and when needed.

The Company has also expanded its Medical Information team to include an innovative, in-house support center for both caregivers and providers. The Company believes this level of direct support is an important offering that can provide high-quality, consistent information in an empathetic manner during the launch and post-launch phases. This team will be tasked with responding quickly, consistently, and accurately to medical inquiries and optimize the customer experience. This center will also align with the Physician Hub and Specialty Pharmacy network for as seamless customer experience.

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The Epidiolex U.S. marketing team have now concluded a comprehensive program of physician and patient audience research. This includes research conducted in the last month on physician response to the approved label. Importantly, this research confirms that the approved label appears to have been received well in terms of efficacy description, dosing instructions and understanding of safety profile. Some of the important findings from this research includes:

- Physicians universally characterized Epidiolex as first in a new class of anti-epileptic drug,
- Physicians suggested the FDA approval would ensure quality control and consistency and saw little reason to consider non-FDA approved CBD products,
- Many physicians positioned Epidiolex as an early adjunctive option, and,
- Physicians expect that the high level of caregiver awareness and interest will be a driver in adoption.

The U.S. marketing team has also been carrying out numerous education initiatives with one such example being the launch of two important educational websites, one focused on both the physician and patient communities located at [CannabinoidClinical.com](http://CannabinoidClinical.com) and the other for the patient communities located at [Takeonepilepsy.com](http://Takeonepilepsy.com).

Approximately 1,200 patients from the expanded access program and open label extension from the pivotal trials are currently receiving Epidiolex in the form of clinical research product. The Company will embark on a systematic program to help ensure these patients access to commercial product, and most importantly to ensure continuity of treatment. As such, the Company will be focusing initially on new patients with immediate need of Epidiolex prescriptions, and over time, likely by mid-2019, begin working with physicians to commence migration of these existing patients to commercial product.

The Company will continue to disseminate important scientific data from the Epidiolex clinical program through data presentations at important medical congresses. These presentations are integral to the efficient education of treating physicians and for payors as they determine reimbursement policy. The Company believes there is significant expectation and anticipation for Epidiolex due to the level of awareness in both the patient/caregiver and physician communities, and that its pre-launch initiatives to date and those planned for launch, will support demand for the product in the LGS and Dravet communities.

#### ***Europe Commercial Operation Status***

The Company continues to make good organizational progress towards the commercialization of Epidiolex in Europe. We continue to expect an outcome to the EMA regulatory review in Q1 2019 and are planning for launches in the five major European markets in 2019. An experienced and epilepsy disease expert GW commercial leadership team is now fully recruited and in place. This team is focused on progressing the necessary pricing and reimbursement, medical and pre-commercial activities required to deliver a successful Europe launch. In particular significant progress is now being made on building out the local country organizations in the five major European markets. This first wave of local recruitment is very much focused on leadership and specifically medical staff. Medical affairs activities are progressing well with national advisory boards now completed in all the major markets and significant presence and data exposure at key European and National Congresses.

#### **Epidiolex Intellectual Property**

In addition to seven years of orphan exclusivity plus the expected six-month pediatric extension, GW seeks to protect Epidiolex through the expansion of its patent portfolio. GW's patent portfolio relating to the use of CBD in the treatment of epilepsy includes 21 distinct patent families which are either granted or filed. Most of the patent families in this portfolio claim the use of CBD in the treatment of particular childhood epilepsy syndromes, seizure sub-types and interactions with other concomitantly dosed anti-seizure drugs. To date, this has resulted in eight patents granted by the United States Patent and Trademark Office (USPTO) including claims which include the use of CBD for the treatment of convulsive seizures associated with both LGS and Dravet syndrome, as well as the use of CBD with clobazam and the teaching that dose adjustment may be needed when concomitantly prescribed. Some of these patents are directly aligned with the Epidiolex label and will be listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). These patents have expiry to 2035. The Company continues to identify novel findings and submit patent applications resulting from the Epidiolex development program and expects additional grants from these applications.

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## **Cannabidiol Formulation Development**

In addition to the initial launch formulation, GW continues to develop additional formulations of CBD as part of its life cycle management plan. As well as developing an improved oral solution, the Company is developing a capsule to provide more convenient administration, particularly for adults and older children across our target indications. An intravenous formulation is also under development, which is intended to provide short-term replacement or emergency therapy for patients unable to take the oral solution while hospitalized.

## **Pipeline Beyond Epidiolex for Treatment-Resistant Epilepsy**

### ***Sativex<sup>®</sup> (nabiximols) in the U.S.***

Sativex is an oromucosal spray of a formulated extract that contains the principal cannabinoids CBD and THC in a 1:1 ratio (as well as specific minor cannabinoids and other non-cannabinoids). GW has received regulatory approval for Sativex in MS spasticity in 28 countries outside the US. The product is marketed outside the US via marketing partners.

In December 2017, GW reacquired full ownership from a former licensing partner of the U.S. development and commercialization rights to Sativex, which enables GW to develop, seek approval for, and commercialize Sativex in the United States.

GW expects to meet with the FDA in the second half of 2018 in order to determine the most efficient regulatory pathway to achieve a NDA for Sativex in the U.S. for the treatment of MS spasticity. The Company has already completed three positive Phase 3 trials in Europe for Sativex in MS spasticity.

Beyond an initial target US indication of MS spasticity, GW believes that Sativex has significant additional market potential through the development of additional follow-on indications. To date, GW has completed over 20 randomized, placebo-controlled trials of Sativex. As such, we believe that Sativex is a product with several late stage lifecycle opportunities.

### ***Autism Spectrum Disorders (ASDs)***

Many of the childhood-onset intractable epilepsy conditions within the Epidiolex expanded access program share considerable overlap with ASDs and these conditions often fall within the orphan disease space. Initial clinical observations from treating physicians suggest a potential role for cannabinoids in addressing problems associated with ASDs such as deficits in cognition, behavior, and communication.

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GW has evaluated the cannabinoids CBD and CBDV in both general and syndromic pre-clinical models of ASDs yielding promising signals on cognitive and social functioning endpoints as well as repetitive behaviors. These animal models include both genetically determined and chemically-induced models of neurobehavioral abnormalities, and include Rett syndrome and Fragile X syndrome among others.

#### ***Epidiolex for Rett Syndrome***

GW is expanding its clinical evaluation in Rett Syndrome to now include Epidiolex. The Company believes, based on promising pre-clinical data and observations from the Company's pivotal and expanded access studies, that CBD offers potential in treating ASDs and considers that Epidiolex offers the most rapid development path for patients that suffer from this very challenging condition. GW expects to submit an IND with the FDA in the fourth quarter of 2018 for a pivotal placebo-controlled, multi-dose trial in children with Rett syndrome.

#### ***CBDV (cannabidivarin) Development Program***

In addition to Epidiolex, GW is working on various clinical initiatives for CBDV within the field of ASDs and has received Orphan Drug Designation from the FDA in the treatment of Rett syndrome.

CBDV has shown anti-epileptic properties across a range of *in vitro* and *in vivo* models of epilepsy. In pre-clinical studies, CBDV was also found to provide additional efficacy when combined with drugs currently used to control epilepsy. CBDV looks to be differentiated from CBD in four key ways: efficacy profile in seizure models, metabolic profile, pharmacological profile and differing physico-chemical characteristics.

A physician-led expanded access IND to treat seizures associated with autism has been granted by FDA in 10 patients and at this date, five patients have commenced treatment with initial data presentation expected at the AES Annual Meeting. In addition, an investigator led proof of principle 100-patient placebo-controlled trial in ASD is due to commence in the third quarter of 2018 and an open-label proof of principle study in Sydney, Australia evaluating CBDV in children with Rett syndrome and seizures in 30 patients.

#### ***Oncology***

Beginning in 2007, GW has conducted substantial pre-clinical oncologic research on several cannabinoids in models of various forms of cancer including brain, lung, breast, pancreatic, melanoma, ovarian, gastric, renal, prostate and bladder.

In February 2017, GW completed a placebo-controlled Phase 2 study of a combination of CBD and THC in 21 patients with recurrent glioblastoma multiforme, or GBM, the most common and most aggressive brain cancer. This study evaluated a number of safety and exploratory efficacy endpoints and showed that patients with documented recurrent glioblastoma treated with CBD:THC as add-on therapy to dose-intense temozolomide had an 83 percent one-year survival compared with 44 percent for patients on placebo (plus dose-intense temozolomide) ( $p=0.042$ ). Median survival time for the CBD:THC group was greater than 662 days compared with 369 days in the placebo group. Two year survival was 50 percent for patients treated with CBD:THC +TMZ versus 22 percent for patients treated with placebo + TMZ. Median survival time for the CBD:THC group was greater than 662 days compared with 369 days in the placebo group. In this study, CBD:THC was generally well tolerated. The results from this Phase 2 study were presented in a poster at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The Company has received Orphan Drug Designation from both FDA and EMA for its product for the treatment of glioblastoma.

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GW believes that the signals of efficacy demonstrated in this study further reinforce the potential role of cannabinoids in the field of oncology. GW is now conducting molecular genetic analysis of patient glioblastoma tumor tissue as well as analysis of imaging and clinical parameters to optimize the design and probability of success of a future glioblastoma study.

GW's portfolio of intellectual property related to the use of cannabinoids in oncology includes a number of issued patents and pending applications in both the U.S. and Europe. This portfolio is designed to protect the use of various cannabinoids individually or in combination, in the treatment of a variety of oncology-specific disorders and product formulations.

#### ***Neonatal Hypoxic-Ischemic Encephalopathy (NHIE)***

NHIE is acute or sub-acute brain injury resulting from deprivation of oxygen during birth (hypoxia). GW estimates 6,500 to 12,000 cases of NHIE occur in the U.S. each year. Of these, 35 percent are expected to die in early life and 30 percent are expected to develop persistent neurologic disability. There are currently no FDA-approved medicines specifically indicated for NHIE.

GW has received Orphan Drug Designation and Fast Track Designation from the FDA for CBD for the treatment of NHIE. GW has also received Orphan Drug Designation from the EMA for CBD for the treatment of perinatal asphyxia, an alternate term that describes the same condition. Under an IND, GW has completed a Phase 1 trial of GWP42003 in healthy volunteers for an intravenous CBD formulation in the treatment of NHIE. GW plans to consult with FDA on the most appropriate design for an efficacy and safety study in neonates.

#### ***Schizophrenia***

GW's cannabinoids have shown notable anti-psychotic effects in pre-clinical models of schizophrenia and in September 2015, GW announced positive top line results from an exploratory Phase 2a placebo-controlled clinical trial of CBD in 88 patients with schizophrenia who had previously failed to respond adequately to first line anti-psychotic medications. GW is evaluating appropriate next steps regarding product development in schizophrenia with future research likely focused on pediatric orphan neuropsychiatric indications.

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS**

The following discussion and analysis should be read in conjunction with the condensed consolidated financial information contained herein, which has been prepared in accordance with International Accounting Standard 34, Interim Financial Reporting. GW presents its condensed consolidated financial information in pounds sterling.

*Solely for the convenience of the reader, unless otherwise indicated, all pound sterling amounts stated in the Condensed Consolidated Balance Sheet as at 30 June 2018, the Condensed Consolidated Income Statement and the Condensed Consolidated Cash Flow Statement for the three and nine months ended 30 June 2018 have been translated into U.S. dollars at the rate on 30 June 2018 of \$1.31792 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.*

**Overview**

GW generates revenue from Sativex product sales, license fees, collaboration fees, technical access fees, development and approval milestone fees, research and development fees and royalties. The accounting policies that GW applies in recognizing these revenues are set out in detail in the Group's Annual Report as filed with SEC on Form 20-F on 4 December 2017.

Expenditure on research and development activities is recognized as an expense in the period in which the expense is incurred. GW incurs research and development expenditures that are funded from GW's own cash resources. This typically relates to core research and development spend on the Company's staff and research facilities plus spend on the Epidiolex development program and certain pipeline product trials.

Sales, general and administrative expenses consist primarily of salaries, employer payroll taxes and benefits related to GW's executive, finance, business development and support functions. Other sales, general and administrative expenses include costs associated with managing commercial activities and the costs of compliance with the day-to-day requirements of being a listed public company on NASDAQ in the U.S., including insurance, general administration overhead, investor relations, legal and professional fees, audit fees and fees for taxation services.

Net foreign exchange gains/losses primarily result from unrealized gains/losses on translating the Group's U.S. dollar denominated cash deposits to pounds sterling at the closing U.S. dollar to pounds sterling exchange rate.

As a UK resident Group with operations in the U.S., GW is subject to both UK and U.S. corporate taxation. GW's tax recognized represents the sum of the tax currently payable or recoverable, and deferred tax. Deferred tax assets are recognized only to the extent that it is probable that taxable profits will be available against which deductible temporary differences can be utilized.

**Results of Operations:**

***Comparison of the three months ended 30 June 2018 and 30 June 2017***

*Revenue*

Total revenue for the three months ended 30 June 2018 was £2.6 million, compared to £2.4 million for the three months ended 30 June 2017. This increase of £0.2 million primarily comprises:

- £0.5 million increase in Sativex product sales revenues to £2.3 million for the three months ended 30 June 2018 compared to £1.8 million for the three months ended 30 June 2017. In-market sales volumes sold by GW's commercial partners for the three months ended 30 June 2018 were 23% higher than the three months ended 30 June 2017. Sales volumes to partners increased by 21% over the same period, primarily due to increased shipments to Germany, offset in part by a decrease in sales price

- £0.1 million decrease in research and development fees to £0.1 million for the three months ended 30 June 2018 from £0.2 million for the three months ended 30 June 2017. This reflects the impact of the termination of the Group's partner-funded Sativex Phase 3 program in December 2017
- £0.1 million decrease in license, collaboration and technical access fees
- £0.1 million decrease in development & approval milestones

#### *Cost of sales*

Cost of sales for the three months ended 30 June 2018 of £1.3 million represents a £0.2 million increase over the £1.1 million recorded in the three months ended 30 June 2017 and is in line with the increase in shipments of Sativex to commercial partners.

#### *Research and development expenditure*

Total research and development expenditure for the three months ended 30 June 2018 of £18.6 million decreased by £9.3 million compared to the £27.9 million incurred in the three months ended 30 June 2017.

- £7.8 million decrease in the expense recognised in the income statement for growing high CBD plant material for Epidiolex, as a result of the commencement of capitalisation of such costs into inventory
- £3.7 million decrease in research and development costs as a result of the reversal of the Epidiolex inventory provision recorded upon FDA approval on 25 June 2018
- £2.2 million increase in clinical trial and consultancy costs associated with the epilepsy development program. The increase is largely due to staff and employment-related expenses linked to increased global headcount associated with the Group's Epidiolex NDA process and ongoing EMA filing reviews, pipeline and Epidiolex clinical development programs

#### *Sales, general and administrative expenses*

Sales, general and administrative expenses for the three months ended 30 June 2018 of £26.7 million increased by £14.9 million compared to the £11.8 million incurred in the three months ended 30 June 2017. This increase is due to:

- £7.6 million increase in payroll costs driven by increased headcount within the Group's expanding commercial operations in the U.S. and Europe
- £5.6 million increase in U.S. pre-launch commercialization, marketing and consultancy costs
- £1.0 million increase in respect of property and travel costs, primarily due to the expansion of U.S. based operations
- £0.7 million increase in corporate overhead costs such as legal, insurance, investor relations and professional fees

#### *Net foreign exchange gains / (losses)*

Net foreign exchange gain for the three months ended 30 June 2018 was £16.6 million, compared to a £8.4 million loss recorded for the three months ended 30 June 2017. In both periods the exchange movement recognized relates to the remeasurement of the Group's US dollar denominated cash deposits to pounds sterling at the closing U.S. dollar to Sterling exchange rate at 30 June. The Sterling to U.S. dollar exchange rate has moved from 1.40495 at 31 March 2018 to 1.31792 at 30 June 2018. Dollar denominated cash deposits totalled \$447.7 million at 31 March 2018 and \$360.0 million at 30 June 2018.

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### *Taxation*

The tax expense was £0.6 million for the three months ended 30 June 2018. This represents a decrease of £6.8 million compared to a £6.2 million benefit recorded in the three months ended 30 June 2017.

In the three months ended 30 June 2018, GW recorded a tax charge of £0.6 million in respect of its US subsidiary Greenwich Biosciences, Inc. With effect from 1 October 2017, the Group is also no longer able to qualify for tax credits in respect of the Small and Medium sized enterprises (SME) R&D relief under the UK Finance Act 2000. The Group now qualifies for the reduced above-the-line Research and Development Expenditure Credit (RDEC), available to large enterprises in the UK. A £0.4 million benefit is therefore recorded within Interest and Other Income for the three months ended 30 June 2018.

In the three months ended 30 June 2017, GW recorded a tax benefit of £6.2 million comprising: (i) the recognition of an accrued £5.6 million research and development tax credit claimable by GW Research Limited in respect of research and development expenditure incurred in the three months ended 30 June 2017; and (ii) the recognition of an additional £0.6 million of research and development tax credits in respect of the year ended 30 September 2016 as part of the process for finalising tax returns for that period.

### *Loss*

The Group reported a loss after tax for the three months ended 30 June 2018 of £27.1 million compared with a loss after tax for the three months ended 30 June 2017 of £40.4 million.

### **Results of Operations:**

#### ***Comparison of the nine months ended 30 June 2018 and 30 June 2017:***

### *Revenue*

Total revenue for the nine months ended 30 June 2018 was £10.7 million, compared to £6.1 million for the nine months ended 30 June 2017. This increase of £4.6 million comprises:

- £2.1 million increase in license collaboration and technical access fees to £3.2 million for the nine months ended 30 June 2018 compared to £1.1 million for the nine months ended 30 June 2017. This increase is due to the mutually-agreed termination of the Group's Sativex research and collaboration agreement with Otsuka Pharmaceuticals during the first quarter, which led to the accelerated recognition of certain deferred income balances
- £1.5 million increase in Sativex product sales revenues to £5.9 million for the nine months ended 30 June 2018 compared to £4.4 million for the nine months ended 30 June 2017. In-market sales volumes sold by GW's commercial partners for the nine months ended 30 June 2018 were 27% higher than the nine months ended 30 June 2017. Sales volumes to partners increased by 38% over the same period, due primarily to increased shipments to Germany
- £1.0 million increase in research and development fees to £1.5 million for the nine months ended 30 June 2018 compared to £0.5 million for the nine months ended 30 June 2017 also reflecting the impact of the termination of the Group's Sativex research and collaboration agreement

### *Cost of sales*

Cost of sales for the nine months ended 30 June 2018 of £3.4 million is an increase of £0.9 million compared to the £2.5 million recorded in the nine months ended 30 June 2017. This is a result of the increase in shipments of Sativex to commercial partners.

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### *Research and development expenditure*

Total research and development expenditure for the nine months ended 30 June 2018 of £81.7 million increased by £1.7 million compared to the £80.0 million incurred in the nine months ended 30 June 2017. This increase is due to:

- £7.3 million increase in clinical trial and consultancy costs associated with the epilepsy development program. The increase is largely due to staff and employment-related expenses linked to increased global headcount combined with consultancy and clinical trial costs associated with the Group's Epidiolex NDA process and ongoing EMA filing reviews, pipeline and Epidiolex clinical development programs
- £5.6 million decrease in the expense recognised in the income statement for growing high CBD plant material for Epidiolex, as a result of the commencement of capitalisation of such costs into inventory

### *Sales, general and administrative expenses*

Sales, general and administrative expenses for the nine months ended 30 June 2018 of £61.7 million increased by £34.0 million compared to the £27.7 million incurred in the nine months ended 30 June 2017. This increase is due to:

- £15.9 million increase in payroll costs driven by increased headcount within the Group's expanding U.S. and European commercial operations
- £13.6 million increase in marketing costs arising from the Group's preparations for U.S. commercial launch
- £2.8 million increase in property and travel costs, primarily due to the expansion of U.S. based operations
- £1.7 million increase in corporate overhead costs such as legal, insurance, investor relations and professional fees

### *Net foreign exchange gains / (losses)*

Net foreign exchange loss for the nine months ended 30 June 2018 was £0.6 million, consistent with a £0.6 million loss recorded for the nine months ended 30 June 2017. In both periods the exchange movement recognized relates to the remeasurement of the Group's US dollar denominated cash deposits to pounds sterling at the closing US dollar to Sterling exchange rate at 30 June. The Sterling to U.S. dollar exchange rate has moved from 1.40495 at 30 September 2017 to 1.31792 at 30 June 2018. Dollar denominated cash deposits totalled \$242.0 million at 30 September 2017 and \$360.0 m million at 30 June 2018.

### *Taxation*

The tax expense was £3.0 million for the nine months ended 30 June 2018, which represents a decrease of £16.9 million compared to a £13.9 million benefit recorded in the nine months ended 30 June 2017.

In the nine months ended 30 June 2018, GW recorded a tax expense of £3.0 million in respect of the Group's U.S. subsidiary Greenwich Biosciences, Inc. due primarily to the revaluation of certain deferred tax balances following the signing into law of the Tax Cuts and Jobs Act in December 2017. With effect from 1 October 2017, the Group is also no longer able to qualify for tax credits in respect of the Small and Medium sized enterprises (SME) R&D relief under the UK Finance Act 2000. The Group now qualifies for the reduced above-the-line Research and Development Expenditure Credit (RDEC), available to large enterprises in the UK. A £1.9 million benefit is therefore recorded within Interest and Other Income for the nine months ended 30 June 2018.

In the nine months ended 30 June 2017, GW recorded a tax benefit of £13.9 million comprising: (i) the recognition of an accrued £12.8 million research and development tax credit claimable by GW Research Limited in respect of the research and development expenditure incurred in the nine months ended 30 June 2017; (ii) the recognition of an additional £0.7 million of research and development tax credits in respect of the year ended 30 September 2016 as part of the process for finalising UK and US tax returns for that period; and (iii) the recording of £0.4 million of tax benefit in respect of an additional deferred tax asset recognised on timing differences for Greenwich Biosciences, Inc.

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### *Loss*

The Group reported a loss after tax for the nine months ended 30 June 2018 of £136.7 million compared with a loss after tax for the nine months ended 30 June 2017 of £90.3 million.

### **Liquidity and Capital Resources**

#### *Cash Flow*

Net cash outflow from operating activities for the nine months ended 30 June 2018 of £111.4 million was £36.1 million higher than the £75.3 million outflow from operating activities for the nine months ended 30 June 2017, principally reflecting the progress with the Epidiolex regulatory submissions, the scale up in operations in anticipation of the commercial release of Epidiolex and increased headcount.

Capital expenditure for the nine months ended 30 June 2018 of £18.3 million was £4.8 million higher than the £13.5 million for the nine months ended 30 June 2017 reflecting ongoing investment efforts in the Group's Epidiolex production and processing capacity.

Net cash flow from financing activities increased by £222.7 million to a £221.0 million inflow in the nine months ended 30 June 2018 compared to a £1.7 million outflow for the nine months ended 30 June 2017 due to the completion of a successful equity fundraising in December 2017.

As at 30 June 2018, GW had a closing cash position of £334.0 million compared to £241.2 million as at 30 September 2017.

#### *Property, plant and equipment*

Property, plant and equipment at 30 June 2018 increased by £6.2 million to £49.9 million from £43.7 million at 30 September 2017 reflecting the continued investment in increasing the Group's Epidiolex growing and production capacity.

#### *Inventories*

Inventories at 30 June 2018 increased by £15.8 million to £20.0 million from £4.2 million at 30 September 2017. Inventories consist of Epidiolex and Sativex finished goods, consumable items and work in progress and are stated net of a £0.2 million realizable value provision (30 September 2017: £0.1 million).

During the nine months ended 30 June 2018, after notification by the FDA of the Group's successful submission of a New Drug Application, capitalization of Epidiolex inventory commenced. Gross inventories and a provision of £17.0 million were recognized during the period. This inventory was subject to full provision until the FDA approval process had made sufficient progress to give confidence of the recoverability of the inventory. On 25 June 2018, the Group received FDA approval for Epidiolex in the United States. As a result of this, in accordance with IFRS accounting standards, £16.8 million of the inventory provision held against Epidiolex material was reversed.

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#### *Trade receivables and other assets*

Trade receivables and other assets at 30 June 2018 increased by £6.5 million to £17.7 million from £11.2 million at 30 September 2017. This is primarily due to an increase in deposits paid for capital assets which have not yet been delivered to the Group.

#### *Trade and other payables*

Current trade and other payables at 30 June 2018 increased by £7.0 million to £40.1 million from £33.1 million at 30 September 2017. This increase primarily reflects an increase in other creditors and accruals relating to operational scale up and employee-related costs.

Non-current trade and other payables at 30 June 2018 decreased by £0.5 million to £8.8 million compared with £9.3 million at 30 September 2017.

#### *Headcount*

Average headcount for the nine months ended 30 June 2018 was 618 (30 June 2017: 519).

#### *Guidance*

Consistent with previous guidance, we expect total cash outflows for the second half of the year to be in the range of \$120 to \$140 million (£90 million to £105 million), which includes capital expenditure of \$10 million to \$20 million related to manufacturing expansion.

#### *Foreign Private Issuer Status*

As highlighted in our financial results for the three and six months to March 31, 2018, we no longer qualify as a foreign private issuer.

Effective October 1, 2018, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects, and which must be filed more promptly, than the forms available to a foreign private issuer, and we will be required to comply with the disclosure and procedural requirements under Section 14 of the Securities Exchange Act of 1934, as amended, applicable to soliciting proxies. Our next Annual Report for the year ended September 30, 2018 will be filed as a domestic issuer, on Form 10-K. The consolidated financial statements included on Form 10-K will be presented in U.S. dollars and in accordance with accounting principles generally accepted in the United States (U.S. GAAP). Accordingly, we have appointed the U.S. firm of Deloitte & Touche LLP as principal auditor for the consolidated financial statements as of and for the year ended September 30, 2018. In prior periods, the UK firm of Deloitte LLP served as principal auditor for our consolidated financial statements.

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**GW Pharmaceuticals plc Reports Fiscal Third Quarter 2018 Financial Results and Operational Progress**

**- Epidiolex® (cannabidiol) oral solution approved by FDA and on track to be launched in Fall –  
- Conference call today at 4:30 p.m. EST -**

**London, UK, Carlsbad, CA, 7 August 2018:** GW Pharmaceuticals plc (NASDAQ: GWPH, GW, the Company or the Group), the world leader in the development and commercialization of cannabinoid prescription medicines, announces financial results for the third quarter ended 30 June 2018.

“The recent FDA approval of Epidiolex represents a major medical advance for patients with Lennox-Gastaut Syndrome and Dravet syndrome. We anticipate rescheduling to be completed within 90 days of FDA approval and for product launch to take place in the Fall”, stated Justin Gover, GW’s Chief Executive Officer. “In preparation for launch, we have now completed the hiring of our US sales organization and are engaged with patient organizations, physicians and managed care organizations/payors. This approval has been a transformative event for GW, not only opening a new chapter as a commercial-stage company, but also validating and reinforcing our world leadership in cannabinoid science, and the potential of our product pipeline.”

**OPERATIONAL HIGHLIGHTS**

- Epidiolex (cannabidiol)
    - Regulatory:
      - FDA approval for the treatment of seizures associated with LGS or Dravet syndrome
      - Epidiolex rescheduling expected within 90 days of FDA approval
      - European submission under review by the EMA with decision expected in Q1 2019
      - FDA issuance of a priority review voucher (PRV) for Epidiolex.
    - Manufacturing
      - Commercial product being manufactured and prepared for shipping to the U.S.
      - Continued investment in expanded facilities to meet anticipated long-term demand
    - Commercial:
      - U.S. sales organization fully recruited comprising two national directors, eight regional managers plus 66 Neurology Account Managers
      - Active engagement with U.S. payors ongoing with clinical presentations to plans that cover over 80% of covered lives in the U.S.
      - U.S. supply chain platform in place which will employ a closed model distribution network of five Specialty Pharmacy Providers (SPP’s)
      - Commercial footprint in place in 5 major European markets in readiness for 2019 European launches
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- o Epilepsy Clinical trials
    - Three Phase 3 clinical trials published - two in *The New England Journal of Medicine* and one in *The Lancet*
    - Phase 3 trial in Tuberous Sclerosis Complex ongoing with data expected H1 2019
  - o Autism
    - Decision to expand target indications for Epidiolex beyond epilepsy to autism. IND expected to be submitted for pivotal Rett Syndrome study in Q4 18.
  - o Expanded access program and open label extension:
    - Over 2,000 patients now have been exposed to Epidiolex treatment
  - o Life-cycle management
    - Several new formulations of CBD in development including modified oral solution, capsule and an intravenous formulation
  - o Exclusivity
    - 7-year orphan exclusivity confirmed by FDA, 6-month pediatric extension expected
    - Key favorable patent grants by USPTO related to the use of CBD in epilepsy, including claims for the treatment of relevant seizure types associated with LGS and Dravet syndrome, as well as the use of CBD with clobazam
      - Patents align directly with new Epidiolex FDA label and to be listed in Orange Book
      - Patent expiry dates to [2035]
    - Additional patent applications under review and being filed as new data is generated
  - Pipeline progress
    - o Sativex® (nabiximols)
      - US development and commercialization rights wholly owned by GW
      - Initial U.S. target indication: Multiple Sclerosis spasticity. Three positive Phase 3 trials completed in Europe
      - Plans to meet with FDA in H2 18 to determine MS spasticity regulatory pathway in the U.S.
      - Over 20 placebo-controlled trials already completed in other indications, representing significant US lifecycle management opportunities
    - o CBDV
      - 10-patient investigator-initiated expanded access program for seizures associated with autism underway
      - Investigator-led 100 patient placebo-controlled trial in autism spectrum disorder due to commence in Q3 18
      - Open label study in Rett syndrome and seizures due to commence Q3 18
    - o CBD:THC in Glioblastoma
      - Recent data presented from the Phase 2 study showed significant increase in median survival for patients taking CBD:THC of 662 days compared to 369 days on placebo
      - Pivotal clinical development program plans under development
      - Orphan Drug Designation from both FDA and EMA for CBD:THC to treat glioblastoma
    - o Neonatal Hypoxic-Ischemic Encephalopathy (NHIE) intravenous CBD program
      - Phase 1 trial complete
      - Orphan Drug and Fast Track Designations granted from FDA and EMA
      - Phase 2 trial in planning
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## FINANCIAL HIGHLIGHTS

- Cash and cash equivalents at 30 June 2018 of £334.0 million (\$440.2 million) compared to £241.2 million as at 30 September 2017
- Revenue for the nine months ended 30 June 2018 of £10.7 million (\$14.2 million) compared to £6.1 million for the nine months ended 30 June 2017
- Loss for the nine months ended 30 June 2018 of £136.7 million (\$180.2 million) compared to £90.3 million for the nine months ended 30 June 2017

Solely for the convenience of the reader, the above balances have been translated into U.S. dollars at the rate on 30 June 2018 of \$1.31792 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 third quarter 2018 financial results today at 4:30 pm 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 Replay ID: 35897.

## About GW Pharmaceuticals plc and Greenwich Biosciences, Inc.

Founded in 1998, GW is the world leader in the development and commercialization of cannabinoid prescription medicines. The Company's lead product, EPIDIOLEX® (cannabidiol) oral solution, received U.S. FDA approval in June 2018 and is under review by European regulators. Previously, GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex® (nabiximols) in Europe and is now advancing plans to develop this medicine in the US. The Company has a deep pipeline of additional cannabinoid product candidates which includes compounds in development for epilepsy, autism, glioblastoma, and schizophrenia. 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 EPIDIOLEX (cannabidiol) oral solution and the safety profile and commercial potential of 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 and 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.*

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