

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2020

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-35892

GW PHARMACEUTICALS PLC

(Exact name of Registrant as specified in its charter)

England and Wales
(State or other jurisdiction of
incorporation or organization)

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

Not Applicable
(I.R.S. Employer
Identification No.)

+44 1223 266800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
American Depositary Shares, each representing 12 Ordinary Shares, par value £0.001 per share	GWPH	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

As of October 29, 2020, 374,180,696 Ordinary Shares were outstanding including 363,572,688 Ordinary Shares held as American Depositary Shares, each representing twelve Ordinary Shares, par value of £0.001 per share and 10,608,008 Ordinary Shares.

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ITEM 1. FINANCIAL STATEMENTS

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
Assets		
Cash and cash equivalents	\$ 480,330	\$ 536,933
Accounts receivable, net	80,424	48,883
Inventory	115,036	85,528
Prepaid expenses and other current assets	44,485	28,292
Total current assets	<u>720,275</u>	<u>699,636</u>
Property, plant, and equipment, net	131,204	127,765
Operating lease assets	22,297	24,916
Intangible assets	5,564	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	18,123
Other assets	5,839	4,850
Total assets	<u>\$ 910,261</u>	<u>\$ 882,249</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 17,841	\$ 9,990
Accrued liabilities	114,898	99,374
Current tax liabilities	—	437
Other current liabilities	7,549	7,760
Total current liabilities	<u>140,288</u>	<u>117,561</u>
Long-term liabilities:		
Finance lease liabilities	5,219	5,573
Operating lease liabilities	19,607	21,650
Other liabilities	10,699	11,431
Total long-term liabilities	<u>35,525</u>	<u>38,654</u>
Total liabilities	<u>175,813</u>	<u>156,215</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 374,169,836 shares outstanding as of September 30, 2020; 371,068,436 shares outstanding as of December 31, 2019	575	570
Additional paid-in capital	1,672,237	1,632,046
Accumulated deficit	(866,940)	(837,959)
Accumulated other comprehensive loss	(71,424)	(68,623)
Total stockholders' equity	<u>734,448</u>	<u>726,034</u>
Total liabilities and stockholders' equity	<u>\$ 910,261</u>	<u>\$ 882,249</u>

See accompanying notes to these condensed consolidated financial statements.

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues				
Product net sales	\$ 136,846	\$ 90,849	\$ 378,608	\$ 201,312
Other revenue	207	122	375	944
Total revenues	<u>137,053</u>	<u>90,971</u>	<u>378,983</u>	<u>202,256</u>
Operating expenses				
Cost of product sales	7,635	8,150	27,112	19,901
Research and development	56,934	36,301	148,542	99,143
Selling, general and administrative	85,205	64,178	232,282	181,529
Total operating expenses	<u>149,774</u>	<u>108,629</u>	<u>407,936</u>	<u>300,573</u>
Loss from operations	(12,721)	(17,658)	(28,953)	(98,317)
Interest income	208	2,249	1,727	6,646
Interest expense	(269)	(272)	(850)	(805)
Other income	-	-	-	104,117
Foreign exchange (loss) gain	(1,796)	1,889	(430)	2,801
(Loss) income before income taxes	<u>(14,578)</u>	<u>(13,792)</u>	<u>(28,506)</u>	<u>14,442</u>
Income tax (benefit)expense	(2,390)	(35)	475	(1,485)
Net (loss) income	<u>\$ (12,188)</u>	<u>\$ (13,757)</u>	<u>\$ (28,981)</u>	<u>\$ 15,927</u>
Net (loss) income per share:				
Basic	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ 0.04</u>
Diluted	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ 0.04</u>
Weighted average shares outstanding:				
Basic	376,281	372,246	375,218	371,286
Diluted	376,281	372,246	375,218	376,985

See accompanying notes to these condensed consolidated financial statements.

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net (loss) income	\$ (12,188)	\$ (13,757)	\$ (28,981)	\$ 15,927
Foreign currency translation adjustments	12,962	(7,783)	(2,801)	(8,863)
Comprehensive (loss) income	<u>\$ 774</u>	<u>\$ (21,540)</u>	<u>\$ (31,782)</u>	<u>\$ 7,064</u>

See accompanying notes to these condensed consolidated financial statements.

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)
(unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	371,069	\$ 570	\$ 1,632,046	\$ (837,959)	\$ (68,623)	\$ 726,034
Issuance of common stock from exercise of stock options	1,493	3	—	—	—	3
Net loss	—	—	—	(7,965)	—	(7,965)
Share-based compensation	—	—	11,361	—	—	11,361
Other comprehensive loss	—	—	—	—	(14,428)	(14,428)
Balances at March 31, 2020	372,562	\$ 573	\$ 1,643,407	\$ (845,924)	\$ (83,051)	\$ 715,005
Issuance of common stock from exercise of stock options	1,147	2	—	—	—	2
Net loss	—	—	—	(8,828)	—	(8,828)
Common stock withheld for employee tax obligations	—	—	(1,223)	—	—	(1,223)
Share-based compensation	—	—	13,316	—	—	13,316
Other comprehensive loss	—	—	—	—	(1,335)	(1,335)
Balances at June 30, 2020	373,709	\$ 575	\$ 1,655,500	\$ (854,752)	\$ (84,386)	\$ 716,937
Issuance of common stock from exercise of stock options	460	—	1,572	—	—	1,572
Net loss	—	—	—	(12,188)	—	(12,188)
Common stock withheld for employee tax obligations	—	—	(604)	—	—	(604)
Share-based compensation	—	—	15,769	—	—	15,769
Other comprehensive income	—	—	—	—	12,962	12,962
Balances at September 30, 2020	374,169	\$ 575	\$ 1,672,237	\$ (866,940)	\$ (71,424)	\$ 734,448

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2018	366,617	\$ 564	\$ 1,581,144	\$ (828,940)	\$ (78,688)	\$ 674,080
Issuance of common stock from exercise of stock options	1,996	3	770	—	—	773
Net loss	—	—	—	(50,064)	—	(50,064)
Share-based compensation	—	—	11,142	—	—	11,142
Other comprehensive income	—	—	—	—	3,798	3,798
Balances at March 31, 2019	368,613	\$ 567	\$ 1,593,056	\$ (879,004)	\$ (74,890)	\$ 639,729
Issuance of common stock from exercise of stock options	2,008	3	2,102	—	—	2,105
Net income	—	—	—	79,748	—	79,748
Share-based compensation	—	—	12,188	—	—	12,188
Other comprehensive loss	—	—	—	—	(4,878)	(4,878)
Balances at June 30, 2019	370,621	\$ 570	\$ 1,607,346	\$ (799,256)	\$ (79,768)	\$ 728,892
Issuance of common stock from exercise of stock options	316	—	—	—	—	-
Net income	—	—	—	(13,757)	—	(13,757)
Share-based compensation	—	—	12,303	—	—	12,303
Other comprehensive loss	—	—	—	—	(7,783)	(7,783)
Balances at September 30, 2019	370,937	\$ 570	\$ 1,619,649	\$ (813,013)	\$ (87,551)	\$ 719,655

See accompanying notes to these condensed consolidated financial statements.

GW PHARMACEUTICALS PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>
Cash flows from operating activities		
Net loss	\$ (28,981)	\$ 15,927
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange gain	(132)	(418)
Share-based compensation	40,446	35,633
Depreciation and amortization	9,144	7,096
Gain from sale of priority review voucher	—	(104,117)
Other	27	39
Changes in operating assets and liabilities:		
Accounts receivable, net	(31,654)	(37,691)
Inventory	(31,184)	(37,561)
Prepaid expenses and other current assets	(8,466)	(14,869)
Other assets	2,369	2,968
Accounts payable	8,116	(1,161)
Current tax liabilities	(8,570)	(601)
Accrued liabilities	18,030	29,176
Other liabilities	(2,459)	(1,943)
Net cash used in operating activities	<u>(33,314)</u>	<u>(107,522)</u>
Cash flows from investing activities		
Proceeds from sale of priority review voucher	—	104,117
Additions to property, plant and equipment	(14,259)	(29,915)
Additions to capitalized software	(2,365)	(1,183)
Additions to intangible assets	(6,404)	—
Net cash (used) provided by investing activities	<u>(23,028)</u>	<u>73,019</u>
Cash flows from financing activities		
Proceeds from exercise of stock options	1,577	2,878
Payments in connection with common stock withheld for employee tax obligation	(1,827)	—
Payments on finance leases	(221)	(317)
Payments on landlord financing obligation	(430)	(404)
Net cash (used in) provided by financing activities	<u>(901)</u>	<u>2,157</u>
Effect of exchange rate changes on cash	640	(4,469)
Net decrease in cash and cash equivalents	(56,603)	(36,815)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	<u>\$ 480,330</u>	<u>\$ 554,682</u>
Supplemental disclosure of cash flow information:		
Income taxes paid	9,106	7,052
Interest paid	799	805
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	1,204	1,534
Right-of-use asset obtained in exchange for operating liabilities	507	—

See accompanying notes to these condensed consolidated financial statements.

Note 1: Business Overview

GW Pharmaceuticals plc and its subsidiaries (referred to herein as “we,” “us,” “our,” and the “Company”) is a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from our proprietary cannabinoid product platform in a broad range of disease areas. The Company is developing a portfolio of cannabinoid medicines, of which the lead product is *Epidiolex*[®], an oral medicine for the treatment of certain refractory childhood epilepsies.

The Company is a public limited company, which has American Depository Shares (ADSs) registered with the U.S. Securities and Exchange Commission (SEC) and has been listed on Nasdaq since May 1, 2013. The Company’s ADSs each represent twelve ordinary shares of GW Pharmaceuticals plc. The Company is incorporated and domiciled in the United Kingdom. The address of the Company’s registered office and principal place of business is Sovereign House, Vision Park, Histon, Cambridgeshire.

Note 2: Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual financial statements. In the Company’s opinion, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of the Company’s financial statements for interim periods.

The condensed consolidated balance sheet as of December 31, 2019 was derived from audited annual financial statements but does not include all annual disclosures required by U.S. GAAP. These interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2019 included in the Company’s Form 10-K. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the results to be expected for the full year or any other future periods.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the condensed consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. We have made estimates of the impact of COVID-19 within our financial statements and there may be changes to those estimates in future periods. Actual results may differ from these estimates.

Fair Value of Financial Instruments

The carrying values of the Company's financial instruments, consisting of cash and cash equivalents, trade receivables, interest and other receivables, and accounts payable and accrued liabilities, approximate fair value due to the relative short-term nature of these instruments.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for prompt payment discounts, chargebacks, and doubtful accounts. Allowances for prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. As of September 30, 2020, the allowance for doubtful accounts was \$0.5 million. At December 31, 2019, the allowance for doubtful accounts was \$0.3 million. No accounts were written off during the periods presented.

Inventory

Inventory is stated at the lower of cost or estimated net realizable value. The Company uses a combination of standard and actual costing methodologies to determine the cost basis for its inventories which approximates actual cost. Inventory is valued on a first-in, first-out basis. The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand, as well as product shelf life.

Our inventory production process includes the cultivation of botanical raw material. Because of the duration of the cultivation process, a portion of our inventory will not be sold within one year. Consistent with the practice in other industries that cultivate botanical raw materials, all inventory is classified as a current asset.

The Company capitalizes inventory costs associated with its products upon regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. Prior to FDA approval of Epidiolex, all costs related to the manufacturing of Epidiolex were charged to research and development expense in the period incurred.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity is entitled to in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers (Topic 606), the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Revenue for the Company's product sales has not been adjusted for the effects of a financing component as the Company expects, at contract inception, that the period between when the Company's transfers control of the product and when the Company receives payment will be one year or less. Product shipping and handling costs are included in cost of product sales.

In the United States, the Company sells Epidiolex to specialty pharmacies (SPs) and specialty distributors (SDs). The Company recognizes revenue from product sales upon receipt of product at the SPs and SDs, the date at which the control is transferred, net of the following allowances which are reflected either as a reduction to the related account receivable or as an accrued liability, depending on how the allowance is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the SPs and SDs based on a contractually fixed percentage of the wholesale acquisition cost (WAC), and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit, and contractual rebates with commercial payers. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or statutory requirements. The allowance for rebates is based on contracted or statutory discount rates and expected utilization by benefit plan participants. The Company's estimates for expected utilization of rebates is based on utilization data received from the SPs since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to the Company the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. The Company also incurs group purchasing organization fees for transactions through certain purchasing organizations. The Company estimates sales with these entities and accrues for anticipated chargebacks and organization fees, based on the applicable contractual terms. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages, shipment errors, and expiring product, provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and SDs and has the ability to control the amount of product that is sold to the SPs and SDs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

In September 2019, the Company announced that the European Commission (EC) approved the marketing authorization for Epidyolex (the trade name in Europe for Epidiolex) for use as adjunctive therapy of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older. The Company has launched Epidyolex in Germany and the U.K. and recognizes revenue from product sales in Europe upon delivery of the product, which is the point at which control of the goods is transferred to the customer. The Company recognizes revenue net of standard discounts and allowances, which are reflected as accrued liabilities.

The Company also sells Epidiolex in certain markets outside of the United States under early access programs that enable patients to receive the product prior to regulatory approval. Revenue under early access programs is generally recognized when the product is delivered.

The total amount deducted from gross sales for the allowances described above for the three and nine months ended September 30, 2020 was \$37.1 million and \$99.4 million, respectively. The total amount deducted from gross sales for the allowances described above for the three and nine months ended September 30, 2019 was \$18.6 million and \$40.7 million, respectively.

Sativex Product Net Sales

Sativex is sold outside of the United States for the treatment of spasticity due to multiple sclerosis, or MS, pursuant to license agreements with commercial partners and, beginning in the first quarter of 2020, directly to customers in the U.K.

Under the license agreements, the Company sells fully labeled Sativex vials to its commercial partners for a contractually agreed price, which is generally based on percentages of the commercial partners' in-market net selling price charged to end customers. Product net sales revenue related to Sativex shipments to commercial license partners is recognized when shipped, at which point the customer obtains control of the product.

In the U.K., the Company recognizes revenue from product sales of Sativex upon delivery of the product, which is the point at which control of the goods is transferred to the customer. The Company recognizes revenue net of standard discounts and allowances, which are reflected as accrued liabilities.

The Company also commercializes Sativex in Australia and New Zealand through a consignment relationship with a local distributor. Product net sales revenues related to Sativex sales in Australia and New Zealand are recognized when the product is sold through to the end customer.

Other Revenue

The Company's other revenue primarily consists of research and development fee revenue and variable consideration milestone payments related to the Sativex license agreements.

The research and development fee revenue is recognized at the time the underlying services are performed.

The Sativex license agreements contain provisions for the Company to earn variable consideration in the form of regulatory milestone payments, sales-based milestone payments, and royalty payments. The Company has no further performance obligations related to the regulatory milestone payments and these amounts are recognized in accordance with Topic 606 when receipt of these payments becomes probable and there is no significant risk of revenue reversal. Revenue related to the sales-based milestone payments and product royalty payments are subject to the sales-based royalty exception under Topic 606 and is recognized when the underlying sales are made.

Research and Development Expenses

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, internal and external costs associated with preclinical development, pre-commercialization manufacturing expenses, and clinical trials. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services provided and the invoices received from its external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. As actual costs become known, the Company adjusts its accruals accordingly.

Research and development expense is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government. Reimbursable research and development tax and expenditure credits were \$1.1 million and \$2.9 million for the three and nine months ended September 30, 2020, respectively, compared to \$0.7 million and \$2.2 million for the same periods in 2019.

Concentration Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, and accounts receivable. The Company's cash and cash equivalents balances are primarily in depository accounts and money market funds at major financial institutions in accordance with the Company's investment policy. The Company's investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of its investments to preserve principal and maintain liquidity. Further, the Company specifies credit quality standards for its customers that are designed to limit the Company's credit exposure to any single party.

Share-based Compensation

The Company recognizes share-based compensation expense for grants of stock options under the Company's Long-Term Incentive Plans to employees and non-employee members of the Company's board of directors based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. Expense related to awards with graded vesting is generally recognized over the vesting period using the accelerated attribution method.

Income Taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities along with net operating loss and tax credit carryovers. The Company records a valuation allowance against its deferred tax assets to reduce the net carrying value to an amount that it believes is more likely than not to be realized. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, respectively, in the period such determination is made.

Uncertain tax positions, for which management's assessment is that there is more than a 50% probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to certain recognition and measurement criteria. The Company re-evaluates uncertain tax positions and considers various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, and changes in facts or circumstances related to a tax position. The Company adjusts the level of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain positions. The Company recognizes interest and penalties related to income tax matters in income tax expense.

The UK Finance of Act 2020, originally introduced to Parliament as Finance Bill 2019-20, received Royal Assent from Her Majesty on July 22, 2020. As a result, the main UK corporate income tax rate remains at 19% rather than the previously enacted reduction to 17%. The Company is currently evaluating the legislation and the effect of this change on its deferred tax balances; however, given the full valuation allowance currently recorded, there will be no impact to the financial statements.

On March 27, 2020, the President of the United States signed the Coronavirus Aid Relief, and Economic Securities ("CARES") Act into law. The Act includes several significant provisions for corporations, including the usage of net operating losses, interest deductions and payroll benefits. The Company does not expect any material impact to the financial statements.

Recently Issued Accounting Standards

Accounting Standards Update (ASU) 2016-13, Measurement of Credit Losses on Financial Instruments:

In June 2016, the FASB issued ASU 2016-13, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim periods. We adopted this guidance as of January 1, 2020. Under the current expected credit loss model, we have adopted a provision matrix approach, utilizing historical loss rates based on the number of days past due, adjusted to reflect current economic conditions

and forecasts of future economic conditions. The adoption of ASU 2016-13 had an immaterial impact on the Company's interim unaudited condensed consolidated financial statements.

ASU 2019-12, Income Taxes: Simplifying the Accounting for Income Taxes:

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes, as part of its initiative to reduce complexity in accounting standards. The amendments in the ASU are effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption of the standard is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. We have not early adopted this ASU for 2020. The ASU is currently not expected to have a material impact on our interim unaudited condensed consolidated financial statements.

Note 3: Sativex License Agreements

The Company has entered into license agreements for Sativex with major pharmaceutical companies that provide the license partners with exclusive rights in a defined geographic territory to commercialize Sativex for all indications. The Company has retained the exclusive right to manufacture and supply Sativex to license partners on commercial supply terms for the duration of the commercial life of the product. In the first quarter of 2020, the Company reacquired the rights to commercialize Sativex in the U.K. from Bayer AG for approximately \$6.4 million. The Company capitalized the cost to reacquire the license as an intangible asset and will amortize the asset over its five-year estimated useful life.

In 2007, the Company entered into an exclusive license agreement with Otsuka Pharmaceutical Co., Ltd. (Otsuka) for the development and commercialization of Sativex in the United States. In December 2017, the Company entered into a mutual termination agreement with Otsuka to return the rights to develop and commercialize Sativex in the United States to the Company. As part of the termination agreement, the Company agreed to pay Otsuka a contingent future milestone payment of \$10 million if Sativex achieves FDA approval in the U.S. and a total of \$30 million of potential sales-based milestones if U.S. sales of Sativex reach certain thresholds. As of September 30, 2020, no amounts have been accrued related to the contingent payments because it is not probable that the milestones will be achieved.

Note 4: Fair Value Measurements

At September 30, 2020 and December 31, 2019, the Company's cash equivalents consisted of money market funds, which are classified as Level 1 within the fair value hierarchy defined by authoritative guidance.

Securities classified as Level 1 are valued using quoted market prices. The Company does not hold any securities classified as Level 2, which are securities valued using inputs that are either directly or indirectly observable, or Level 3, which are securities valued using unobservable inputs. The Company has not transferred any securities between the classification levels.

Note 5: Composition of Certain Balance Sheet Captions:

Inventory consisted of the following:

	<u>September 30,</u>	<u>December 31,</u>
	<u>2020</u>	<u>2019</u>
	(in thousands)	
Raw materials	\$ 2,239	\$ 1,976
Work in process	103,020	78,547
Finished goods	9,777	5,005
	<u>\$ 115,036</u>	<u>\$ 85,528</u>

Property, plant and equipment, net, consisted of the following:

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(in thousands)	
Buildings	\$ 15,033	\$ 4,725
Machinery and equipment	46,335	36,323
Leasehold improvements	47,519	42,744
Office and IT equipment	5,631	3,837
Construction-in-process	61,386	78,485
	<u>175,904</u>	<u>166,114</u>
Accumulated depreciation	(44,700)	(38,349)
	<u>\$ 131,204</u>	<u>\$ 127,765</u>

Depreciation of property, plant, and equipment was \$2.8 million and \$2.0 million for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, depreciation of property, plant, and equipment was \$7.1 million and \$6.2 million, respectively. The Company did not have any significant property, plant, or equipment write-offs in the three and nine months ended September 30, 2020 and 2019.

Accrued liabilities consisted of the following:

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(in thousands)	
Accrued compensation and benefits	\$ 28,665	\$ 25,469
Accrued vendor fees	25,447	29,731
Clinical trial accruals	12,598	10,382
Accrued growing fees	2,149	3,818
Accrued sales rebates and discounts	38,692	22,995
Other	7,347	6,979
	<u>\$ 114,898</u>	<u>\$ 99,374</u>

Other current liabilities consisted of the following:

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(in thousands)	
Finance lease liabilities	\$ 313	\$ 305
Operating lease liabilities	5,706	5,902
Landlord financing	616	595
Other	914	958
	<u>\$ 7,549</u>	<u>\$ 7,760</u>

Other liabilities consisted of the following:

	<u>September 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
	(in thousands)	
Landlord financing obligation	\$ 8,492	\$ 9,152
Other	2,207	2,279
	<u>\$ 10,699</u>	<u>\$ 11,431</u>

Note 6: Earnings Per Share

The computation of basic earnings per share (EPS) is based on the weighted-average number of our ordinary shares outstanding. For the purpose of this calculation, vested nominal strike-price options are considered ordinary shares outstanding. The computation of diluted EPS is based on the weighted-average number of ordinary shares outstanding and potentially dilutive common stock equivalents outstanding for the period, primarily shares that may be issued under the Company's stock option plans, determined using the treasury stock method.

The Company incurred net losses for the three and nine months ended September 30, 2020 and therefore did not include potentially dilutive common stock equivalents in the computation of diluted net loss per share. For the three and nine months ended September 30, 2020, options totaling approximately 15.6 million ordinary shares were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive. For the three months ended September 30, 2019, options totaling approximately 14.7 million ordinary shares were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

The computations for basic and diluted EPS were as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net (loss) income for basic and diluted EPS	\$ (12,188)	\$ (13,757)	\$ (28,981)	\$ 15,927
	(in thousands, except per share amounts)			
Weighted-average shares for basic EPS	376,281	372,246	375,218	371,286
Effect of dilutive securities	—	—	—	5,699
Weighted-average shares for diluted EPS	376,281	372,246	375,218	376,985
Net (loss) income per share:				
Basic EPS	\$ (0.03)	\$ (0.04)	\$ (0.08)	\$ 0.04
Diluted EPS	\$ (0.03)	\$ (0.04)	\$ (0.08)	\$ 0.04

Note 7: Share-Based Compensation

Compensation expense for share-based awards is recognized over the requisite service period using the accelerated attribution method. An estimated forfeiture rate has been applied to unvested awards for the purpose of calculating compensation cost. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

The fair value of stock option awards is estimated using the Black-Scholes option-pricing model. The determination of fair value using the Black-Scholes model is affected by the Company's ADS price as well as assumptions regarding a number of complex and subjective variables, including expected ADS price volatility, risk-free interest rate, expected dividends and projected employee stock option exercise behaviors.

The Company estimates its stock price volatility using a combination of historical stock price volatility and the average implied volatility of options traded in the open market. The risk-free interest rate assumption is based on observed interest rates for the appropriate term of the Company's stock options. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future. The expected option life assumption is estimated using the simplified method prescribed by ASC Topic 718, *Compensation – Stock Compensation*, and is based on the mid-point between vest date and expiration date since the Company does not have sufficient exercise history to estimate expected option life of historical grants.

The table below summarizes the total share-based compensation expense included in the Company's statements of operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Research and development	\$ 3,101	\$ 2,384	\$ 8,026	\$ 7,225
Sales, general and administrative	11,760	9,101	29,929	26,289
	<u>\$ 14,861</u>	<u>\$ 11,485</u>	<u>\$ 37,955</u>	<u>\$ 33,514</u>

For the three months ended September 30, 2020 and 2019, \$0.9 million and \$0.8 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively. For the nine months ended September 30, 2020 and 2019, \$2.5 million and \$2.1 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively.

Note 8: Commitments and Contingencies

As of September 30, 2020, the Company was not a party to any material legal proceedings.

In 2007, the Company entered into a research collaboration agreement with Otsuka Pharmaceutical Co., Ltd., or Otsuka, which expired in June 2013. Otsuka has contacted the Company to assert that it is owed royalty payments under the agreement up to 2% of Epidiolex net sales. While the Company believes Otsuka's position is without merit, a meeting with Otsuka is expected to take place before the end of 2020. The Company cannot predict the outcome of this matter and cannot provide assurances that it will be successful, in whole or in part, in its efforts.

The Company is not aware of any other proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, the expected impact of COVID-19 on our business, any predictions, opinions, expectations, plans, strategies, objectives and any statements of assumptions underlying any of the foregoing relating to the company's current and future business and operations, including, but not limited to, financial matters, development activities, clinical trials and regulatory matters, manufacturing and supply operations, and product sales and demand. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect" and similar words are intended to identify estimates and forward-looking statements. Estimates and forward-looking statements speak only at the date they were made, and we undertake no obligation to update or to review any estimate and/or forward-looking statement because of new information, future events or other factors. Statements of past performance, efforts, or results about which inferences or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results; these statements can be identified by the use of words such as "preliminary," "initial," or other forms of these words or similar words or expressions or the negative thereof. These forward-looking statements are subject to substantial risks and uncertainties that could cause our results or future business, financial condition, results of operations or performance to differ materially from our historical results or experiences or those expressed or implied in any forward-looking statements contained in this report. These risks and uncertainties include, but are not limited to: those associated with the COVID-19 pandemic, clinical trial or commercial results or new product approvals and adoption; unpredictability of obtaining regulatory approval and successfully launching products; competitive dynamics; changes to reimbursement for the company's products; the company's success in developing new products and avoiding manufacturing and quality issues; the impact of currency exchange rates; the timing or results of research and development and clinical trials; unanticipated actions by the U.S. Food and Drug Administration and other regulatory agencies; unexpected litigation impacts or expenses; and other risks detailed under "Risk Factors" in this quarterly report on Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2019, as such risks and uncertainties may be amended, supplemented or superseded from time to time by subsequent reports on Forms 10-Q and 8-K we file with the Securities and Exchange Commission from time to time. These forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If we do update or correct one or more of these statements, investors and others should not conclude that we will make additional updates or corrections.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from our proprietary cannabinoid product platform in a broad range of disease areas. In over 20 years of operations, we have established a world leading position in the science, development, and commercialization of plant-derived cannabinoid therapeutics through our proven drug discovery and development processes, our intellectual property portfolio, and regulatory, manufacturing, and commercial expertise.

Our lead cannabinoid product is Epidiolex®, a pharmaceutical formulation comprising highly purified plant-derived cannabidiol (CBD) for which we retain global commercial rights. We initially launched Epidiolex in the U.S. in November 2018 for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome for patients two years of age and older. In July 2020, the U.S. Food and Drug Administration (FDA) expanded the approval of Epidiolex, adding a new indication of seizures associated with Tuberous Sclerosis Complex (TSC). The FDA also approved the expansion of all existing indications, LGS, Dravet syndrome and TSC, to patients one year of age and older. LGS and Dravet syndrome are severe childhood-onset, drug-resistant epilepsy syndromes. TSC is a rare genetic disorder that causes non-malignant tumors to form in many different organs that affects approximately 50,000 individuals in the United States and one million worldwide. We have received Orphan Drug Designation from the FDA and the Committee for Orphan Medical Products (COMP) for TSC (we previously received the same designations for LGS and Dravet syndrome).

Epidyolex® (the trade name in Europe for Epidiolex) was approved in September 2019 by the European Commission (EC) for use as adjunctive therapy of seizures associated with LGS or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older. We have launched Epidyolex in Germany and the U.K. and are planning launches in France, Italy, and Spain. In September 2020, Epidyolex was approved in Australia.

We continue to develop Epidiolex for additional indications. In March 2020, we applied for approval of Epidyolex for the treatment of TSC in Europe, which is currently under review by the European Medicines Agency. This filing follows our announcement of positive results from a Phase 3 trial in the use of Epidiolex to treat seizures associated with TSC.

Although we had begun to recruit patients for a clinical trial of Epidiolex in the treatment of Rett syndrome, we terminated this trial in November 2020 due to severe feasibility challenges arising from COVID-19. Within the field of epilepsy, we are committed to expanding the potential for Epidiolex and plan to commence an additional clinical program in 2021.

We have a deep pipeline of additional cannabinoid product candidates that includes compounds in Phase 1, Phase 2, and Phase 3 trials. Our most advanced pipeline asset is nabiximols, for which we have commenced the first of five clinical trials for the treatment of spasticity due to multiple sclerosis. The second is expected to commence in the fourth quarter of 2020, and the three others in the first half of 2021. We believe that any one of these studies could enable a new drug application submission with the FDA, potentially as early as 2021. We anticipate commercializing nabiximols in the U.S. using our in-house commercial organization. Nabiximols is already approved in over 25 countries outside the U.S. for the treatment of spasticity due to multiple sclerosis under the brand name Sativex®. We are advancing plans to commence an additional clinical program for nabiximols in spasticity due to spinal cord injury in 2021. We also plan on evaluating nabiximols for post-traumatic stress disorder, and the timing for a clinical trial in this condition will be assessed during 2021.

In addition to nabiximols, our pipeline includes cannabinoid product candidates for schizophrenia, autism spectrum disorder, various potential targets within neuropsychiatry, and Neonatal Hypoxic Ischemic Encephalopathy. Clinical trials for each of these indications are ongoing.

In the U.S., we have 13 patents for Epidiolex listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), 12 of which have an expiry to 2035, and we have seven years of orphan exclusivity. To date, the Company has been unable to agree on a proposed pediatric study request with FDA. We seek to further protect Epidiolex through the expansion of our patent portfolio. Our patent portfolio relating to the use of CBD in the treatment of epileptic encephalopathies includes over 70 distinct patent families that 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, we have obtained 17 patents from the U.S. Patent and Trademark Office, or USPTO, including claims for the use of CBD for the treatment of seizures in LGS and Dravet syndrome; seizure sub-types including convulsive, drop and atonic seizures associated with both LGS and Dravet syndrome; an oral composition of CBD; as well as the use of CBD with clobazam, and the teaching that dose adjustment may be needed when concomitantly prescribed. We filed patent applications in the U.S. and many jurisdictions worldwide based on promising data that we believe demonstrates that Epidiolex is more efficacious than synthetic CBD at the same concentration in a mouse model of seizures. Unlike synthetic CBD, Epidiolex comprises up to 2% of other cannabinoids. It would appear from this early data that the presence of these cannabinoids, albeit in small amounts, provides an additional benefit over CBD alone in an animal model of epilepsy. This patent, if granted, will have an expiry date of 2039. We continue to identify novel findings and submit patent applications resulting from the Epidiolex development program and we expect additional grants from these applications.

Impact of COVID-19 on our Business

In March 2020, the World Health Organization categorized the coronavirus disease 2019 (COVID-19) as a pandemic. COVID-19 continues to spread throughout the United States and other countries across the world, and the duration and severity of its effects are currently unknown. The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and U.S. and global financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain or treat it, its impact and the economic impact on local, regional, national and international markets.

To date, we have been able to continue to supply our products to our patients and license partners and currently do not anticipate any interruptions in supply. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our sales, expenses, manufacturing and clinical trials.

While we did not see a significant impact on our product net sales in the first nine months of 2020 from COVID-19, we are monitoring the demand for our products in light of the ongoing impact to health care systems in both the United States and Europe. In March, we suspended in-person interactions by our customer-facing personnel in healthcare settings and adjusted to virtually supporting healthcare professionals and patient care. We have since returned to limited in-person field contact where local conditions and clinic policies allow. We have seen and may continue to see a negative impact on growth of our product net sales from fewer patients visiting their healthcare provider to initiate, change or receive therapy.

Throughout the COVID-19 pandemic, we have been able to continue operating our manufacturing facilities at normal levels through the implementation of strict safety measures. While we currently do not anticipate any interruptions in our manufacturing process, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our and/or our third-party suppliers' ability to manufacture our products.

While we are continuing the clinical trials we have underway in sites across the globe, we temporarily stopped enrolling new patients for existing trials in the second quarter of 2020. Enrollment of new patients in our trials has resumed, but COVID-19 precautions continue to directly and indirectly impact the timeline for some of our planned clinical trials and other research and development activities.

In the U.S. and the U.K., our office-based employees have been working from home since early March 2020, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories and manufacturing facilities.

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. *Risk Factors* included in this report.

Critical Accounting Estimates

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). These accounting principles require us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements.

For a discussion of our critical accounting estimates, please read Part II, Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the year ended December 31, 2019. There have been no material changes to the critical accounting estimates previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019.

Recent Accounting Pronouncements

The adoption of new accounting standards is discussed in Note 2 to our interim unaudited condensed consolidated financial statements.

Results of Operations

The following table summarizes the results of our operations for the three months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Increase/Decrease
	2020	2019	
(in thousands)			
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	\$ 136,846	\$ 90,849	\$ 45,997
Other revenue	207	122	85
Total revenues	137,053	90,971	46,082
Operating expenses:			
Cost of product sales	7,635	8,150	(515)
Research and development	56,934	36,301	20,633
Selling, general and administrative	85,205	64,178	21,027
Total operating expenses	149,774	108,629	41,145
Loss from operations	(12,721)	(17,658)	4,937
Interest income	208	2,249	(2,041)
Interest expense	(269)	(272)	3
Foreign exchange (loss) gain	(1,796)	1,889	(3,685)
Loss before income taxes	(14,578)	(13,792)	(786)
Income tax benefit	(2,390)	(35)	(2,355)
Net loss	\$ (12,188)	\$ (13,757)	\$ 1,569

The following table summarizes the results of our operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		Increase/Decrease
	2020	2019	
(in thousands, except per share amounts)			
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	\$ 378,608	\$ 201,312	\$ 177,296
Other revenue	375	944	(569)
Total revenues	378,983	202,256	176,727
Operating expenses:			
Cost of product sales	27,112	19,901	7,211
Research and development	148,542	99,143	49,399
Selling, general and administrative	232,282	181,529	50,753
Total operating expenses	407,936	300,573	107,363
Loss from operations	(28,953)	(98,317)	69,364
Interest income	1,727	6,646	(4,919)
Interest expense	(850)	(805)	(45)
Other income	—	104,117	(104,117)
Foreign exchange (loss) gain	(430)	2,801	(3,231)
(Loss) income before income taxes	(28,506)	14,442	(42,948)
Income tax expense (benefit)	475	(1,485)	1,960
Net (loss) income	\$ (28,981)	\$ 15,927	\$ (44,908)

Product net sales

Epidiolex, our treatment for certain severe childhood-onset, drug-resistant epilepsy syndromes, was launched in the United States in November 2018 and in certain European markets in late 2019. We also sell Epidiolex through certain early access programs outside of the United States. Sativex, our treatment for spasticity due to multiple sclerosis, is sold outside of the United States, primarily through license agreements with commercial partners. In March 2020, we reacquired the rights to sell Sativex in the U.K. and began to record direct sales in that market.

Product net sales for the three months ended September 30, 2020 consists of \$132.6 million in net sales of Epidiolex and \$4.3 million in net sales of Sativex. Product net sales for the three months ended September 30, 2019 consists of \$88.0 million in net sales of Epidiolex and \$2.8 million in net sales of Sativex. The \$46.1 million increase in product net sales for the three months ended September 30, 2020 compared to the three months ended September 30, 2019 was primarily due to the growth of U.S. Epidiolex revenue and the launch of Epidiolex in certain European markets.

Product net sales for the nine months ended September 30, 2020 consists of \$366.4 million in net sales of Epidiolex and \$12.2 million in net sales of Sativex. Product net sales for the nine months ended September 30, 2019 consists of \$191.9 million in net sales of Epidiolex and \$9.4 million in net sales of Sativex. The \$177.3 million increase in product net sales for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019 was primarily due to the growth of U.S. Epidiolex revenue and the launch of Epidiolex in certain European markets.

While we did not see a significant impact on our product net sales in the first nine months of 2020 from COVID-19, disruptions in health care systems in both the United States and Europe due to COVID-19 have impacted the rate of growth in new patient prescriptions for our products.

Other revenue

Other revenue for the three and nine months ended September 30, 2020 and 2019 consists of remaining development fees related to the Otsuka license agreement that was terminated in December 2017.

Cost of product sales

Cost of sales decreased \$0.6 million, or 6%, in the three months ended September 30, 2020 to \$7.6 million, or 6% of product net sales, compared to \$8.2 million, or 9% of product net sales in the three months ended September 30, 2019. The decrease in cost of sales in dollars and as a percentage of product net sales is primarily due to manufacturing efficiencies related to the significant period over period increase in Epidiolex unit volumes.

Cost of sales increased \$7.2 million or 36%, in the nine months ended September 30, 2020 to \$27.1 million, or 7% of product net sales, compared to \$19.9 million, or 10% of product net sales in the nine months ended September 30, 2019. The increase in cost of sales in dollars is primarily due to an increase in product net sales. The reduction in cost of sales as a percentage of product net sales is primarily due to manufacturing efficiencies related to the significant period over period increase in Epidiolex unit volumes and, to a lesser degree, the higher mix of Epidiolex sales as a percentage of total product net sales.

Research and development expenses

We believe that our future revenues and cash flows are most likely to be affected by the successful development and approval of our significant late-stage research and development candidates. As of September 30, 2020, we consider the following research and development projects to be our most significant late-stage product candidates:

- Epidyoex for the treatment of tuberous sclerosis complex (Europe)
- Nabiximols for spasticity associated with MS (United States)

In addition, our pipeline includes cannabinoid product candidates for schizophrenia, autism spectrum disorder, various potential targets within neuropsychiatry, and Neonatal Hypoxic Ischemic Encephalopathy.

In July 2020, the FDA expanded the approval of Epidiolex, adding a new indication of seizures associated with TSC and expanding existing indications to patients one year of age and older.

In March 2020, we applied for approval of TSC in Europe, which is currently under review by the European Medicines Agency.

In December 2017, we terminated our license agreement with Otsuka and we have reacquired full ownership of the development and commercialization rights to nabiximols in the United States. We expect to commence five clinical trials of nabiximols for the treatment of spasticity due to multiple sclerosis, two of which are expected to commence in the fourth quarter of 2020 and three of which are expected to commence in the first half of 2021.

Research and development expenses consist of internal and external costs to conduct our pre-clinical studies and clinical trials, payroll costs associated with employing our team of research and development staff, share-based payment expenses, property costs associated with leasing laboratory and office space to accommodate our research teams, costs of growing botanical raw material, costs of processing product for clinical trials, costs of consumables used in the conduct of our in-house research programs, payments for research work conducted by sub-contractors and sponsorship of work by our network of academic collaborative research scientists, costs associated with safety studies and costs associated with the development of Epidiolex, Sativex, and our other pipeline product candidates. Research and development expense is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government.

We track all research and development expenditures against detailed budgets but do not seek to allocate all research and development costs by individual project. The components of R&D expense for the three and nine months ended September 30, 2020 and 2019 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
External clinical trial expense				
Epidiolex	\$ 6,622	\$ 5,745	\$ 16,553	\$ 19,881
Nabiximols	5,663	2,255	7,076	2,857
Other programs	4,207	1,649	10,275	5,680
Total external clinical trial expense	16,492	9,649	33,904	28,418
Research and development tax and expense credits	(1,057)	(681)	(2,948)	(2,191)
Other internal research and development	41,499	27,333	117,586	72,916
Total research and development expense	<u>\$ 56,934</u>	<u>\$ 36,301</u>	<u>\$ 148,542</u>	<u>\$ 99,143</u>

Research and development expenses increased \$20.6 million, or 57%, to \$56.9 million for the three months ended September 30, 2020 compared to \$36.3 million for the same period in 2019, primarily due to an increase in internal costs and external clinical trial expenses for nabiximols, as well as increased costs for early stage development programs.

Research and development expenses increased \$49.4 million, or 50%, to \$148.5 million for the nine months ended September 30, 2020 compared to \$99.1 million for the same period in 2019, primarily due to an increase in internal costs and external clinical trial expenses for nabiximols, as well as increased costs for early stage development programs. These increases were partially offset by a reduction in expenses related to the Epidiolex open-label extension trial in the United States due to the transition of patients to commercial product in early 2019 and a reduction in other external clinical trial expenses related delays caused by the COVID-19 pandemic.

The COVID-19 pandemic impacted the timeline of some of our clinical trials and other research and development activities during the third quarter of 2020 and may cause further clinical trial delays in the remainder of 2020.

Sales, general and administrative expenses

Sales, general and administrative, or SG&A, expenses consist primarily of salaries and benefits related to our executive, commercial, and corporate support functions, expenses associated with our commercial activities, and other general administration expenses.

We expect that sales, general and administrative expenses will increase in the future as we expand our operating activities and continue to build our commercial team for continued commercialization of Epidiolex in Europe.

SG&A expenses increased \$21.0 million, or 33%, to \$85.2 million for the three months ended September 30, 2020 compared to \$64.2 million for the same period in 2019. The increase in SG&A expenses in 2020 was primarily due to an increase in employee-related expenses driven by the build-out of our commercial functions in Europe, an increase in expenses to support our launch of Epidiolex for the treatment of TSC in the United States, an increase in all of our corporate support functions, including information technology infrastructure, and, to a smaller degree, an increase in insurance expenses and legal fees. These increases were partially offset by a decrease in travel related expenses due to the impact of COVID-19.

SG&A expenses increased \$50.8 million, or 28%, to \$232.3 million for the nine months ended September 30, 2020 compared to \$181.5 million for the same period in 2019. The increase in SG&A expenses in the nine months ended September 30, 2020 was primarily due to the same factors discussed above with respect to the increase in SG&A expenses for the third quarter of 2020.

Interest income

Interest income decreased \$2.0 million for the three months ended September 30, 2020 to \$0.2 million compared to interest income of \$2.2 million for the same period in 2019. Due to uncertainties in the financial markets related to COVID-19, we transitioned a large portion of our cash equivalent balances to lower interest earning U.S. government securities money market funds from relatively higher interest rate bearing commercial money market funds in early 2020.

Interest income decreased \$4.9 million for the nine months ended September 30, 2020 to \$1.7 million compared to interest income of \$6.6 million for the same period in 2019. The decrease in interest income is primarily due to the same factor described above with regard to the decrease in interest income for the three months ended September 30, 2020.

Interest expense

Interest expense remained consistent for the three and nine months ended September 30, 2020 and 2019. Interest expense is primarily related to our finance lease liabilities.

Foreign currency exchange (loss) gain

Foreign currency exchange loss was \$1.8 million and \$0.4 million for the three and nine month periods ended September 30, 2020 compared to foreign currency exchange gains of \$1.9 million and \$2.8 million for the three and nine months ended September 30, 2019, respectively. Foreign currency exchange gains and losses are driven primarily by cash balances, accounts payable and intercompany balances denominated in a currency other than the transacting entity's functional currency. Our primary foreign currency exposure is the exchange rate between the British pound and the U.S. dollar.

Income tax expense (benefit)

The provision for income taxes is determined using an annual effective tax rate. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as expected utilization of research and development tax credits, valuation allowances against deferred tax assets, the recognition or derecognition of tax benefits related to uncertain tax positions, and changes in or the interpretation of tax laws in jurisdictions where we conduct business. Also, excess tax benefits and tax deficiencies related to future stock option exercises could result in fluctuations in our effective tax rate in future periods.

Income taxes arise in the United States due to our U.S. subsidiary generating taxable profits. We incur losses in the United Kingdom. Income tax benefit for the three months ended September 30, 2020 was \$2.4 million compared to an income tax benefit of less than \$0.1 million for the three months ended September 30, 2019. The increase in the income tax benefit was primarily due to a prior period true-up related to the company's deduction under IRC Section 250 for foreign-derived intangible income as a result of regulations being finalized in the quarter.

For the nine months ended September 30, 2020, income tax expense was \$0.5 million compared to an income tax benefit of \$1.5 million for the nine months ended September 30, 2019. The increase in income tax expense was primarily due to the impact of excess tax benefits and tax deficiencies for stock options and higher pre-tax income.

Liquidity and Capital Resources

In recent years, we have incurred significant net losses and negative cash flows from operations. We have largely funded our operations from issuances of equity securities, government expense and tax credits, and milestone payments from our out-license partners. Our cash flows may fluctuate, are difficult to forecast and will depend on many factors, including:

- the timing of achievement of future regulatory approvals and commercial launches in the United States and Europe;
- the extent to which we seek to retain development rights to our pipeline of new product candidates or whether we seek to out-license them to a partner who will fund future research and development expenditure in return for a right to share in future commercial revenue;
- the extent of success in our early pre-clinical and clinical stage research programs which will determine the amount of funding required to further the development of our product candidates;
- the terms and timing of new strategic collaborations;
- the number and characteristics of the product candidates that we seek to develop;
- the outcome, timing and cost of regulatory approvals of our product candidates;
- the costs involved in filing and prosecuting patent applications and enforcing and defending potential patent claims; and
- the costs of hiring additional skilled employees to support our continued growth.

We believe that our cash and cash equivalents as of September 30, 2020 of \$480.3 million will be sufficient to fund our operations, including currently anticipated research and development activities and planned capital expenditures, for the foreseeable future, including for at least the next 12 months.

Cash Flows

The following table summarizes the results of our cash flows for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,	
	2020	2019
Net cash used in operating activities	\$ (33,314)	\$ (107,522)
Net cash used in investing activities	(23,028)	73,019
Net cash (used in) provided by financing activities	(901)	2,157
Cash and cash equivalents at end of period	\$ 480,330	\$ 554,682

Operating activities

As of September 30, 2020, we had cash and cash equivalents totaling \$480.3 million compared to \$554.7 million as of September 30, 2019. Net cash used in operating activities decreased by \$74.2 million to \$33.3 million for the nine months ended September 30, 2020 compared to \$107.5 million for the nine months ended September 30, 2019. The decrease in cash used in operating activities is primarily attributable to a \$177.3 million increase in net product sales, partially offset by a \$7.2 million increase in cost of product sales, a \$50.8 million increase in SG&A expenses, \$49.4 million increase in research and development spend, and a \$7.8 million decrease in cash used to fund changes in net operating assets and liabilities.

Investing activities

Net cash used in investing activities was \$23.0 million for the nine months ended September 30, 2020 compared to net cash provided by investing activities of \$73.0 million for the nine months ended September 30, 2019. The cash used in investing activities as of September 30, 2020 included \$14.3 million in capital expenditures, primarily due to the continued expansion of our manufacturing facilities, and \$6.4 million used to reacquire the rights to commercialize Sativex in the U.K. from Bayer. The cash provided by investing operations in the nine months ended September 30, 2019 is primarily attributable to the cashed received on the sale of the priority review voucher of \$104.1 million, partially offset by \$29.9 million in additions to property, plant and equipment.

Financing activities

Net cash used in financing activities was \$0.9 million for the nine months ended September 30, 2020 compared to financing activities providing cash of \$2.2 million during the nine months ended September 30, 2019. The increase in cash used in financing activities is primarily attributable to payments made in connection with common stock withheld for employee tax obligations and a decrease in proceeds received from the exercise of stock options.

Contractual Obligations

There have been no significant changes to the disclosure of payments we have committed to make under our contractual obligations as summarized in our Annual Report on Form 10-K for the twelve months ended December 31, 2019, in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under the caption “Tabular Disclosure of Contractual Obligations.”

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business, which are principally limited to foreign currency exchange rate fluctuations, particularly between the British pound and the U.S. dollar, and credit risk. These risks are managed by maintaining an appropriate mix of cash deposits and securities in various currencies, placed with a variety of financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

We are exposed to interest rate risk on cash and cash equivalents. The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest in highly liquid and high-quality government and other debt securities. To minimize our exposure due to adverse shifts in interest rates, we invest in short-term securities. Due to the short holding period of our investments and the nature of our investments, we have concluded that we do not have a material financial market risk exposure.

Currency Risk

We are exposed to currency exchange rate risk because we operate in the United Kingdom, Europe, and the United States. Our manufacturing operations and a substantial portion of our research and development costs are incurred in our U.K.-based subsidiaries and are generally denominated in British pounds, which is also the functional currency of the U.K.-based subsidiaries. The functional currency of GW Pharmaceuticals plc and our U.S. subsidiary is the U.S. dollar. We do not use forward exchange contracts to manage currency exchange rate exposure.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by SEC Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls in the three months ended September 30, 2020 that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Item 1. Legal Proceedings

The Company was not a party to any material legal proceedings.

In 2007, we entered into a research collaboration agreement with Otsuka Pharmaceutical Co., Ltd., or Otsuka, which expired in June 2013. Otsuka has contacted us to assert that it is owed royalty payments under the agreement of up to 2% of Epidiolex net sales. While we believe Otsuka's position is without merit, we plan to meet with Otsuka before the end of 2020. We cannot predict the outcome of this matter and cannot provide assurances that we will be successful, in whole or in part, in our efforts.

We are not aware of any other proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

As of and for the period ended September 30, 2020, there have been no material changes from the risk factors previously disclosed by us in Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2019, except for the risk factors below, which have been updated:

Our business is subject to risks arising from epidemic diseases, such as the recent global outbreak of the COVID-19 coronavirus.

An epidemic or pandemic disease outbreak, including the recent COVID-19 outbreak, could cause significant disruption to our business operations or the operations of third-party suppliers and Contract Research Organizations upon whom we rely, as well as to our clinical trials, including as a result of significant restrictions or bans on travel where we conduct our clinical trials, as well as a diversion of healthcare resources away from the conduct of clinical trials. Such disruption could impede, delay, limit or prevent our employees and Contract Research Organizations from continuing research and development activities, the production, delivery or release of our product candidates to our clinical trial sites, as well as clinical trial investigators, patients or other critical staff from traveling to or otherwise continuing to participate in our clinical trials, and delay data collection and analysis and other related activities, any of which could impede, delay, limit or prevent completion of our ongoing clinical trials and preclinical studies or commencement of new clinical trials, and ultimately lead to the delay or denial of regulatory approval of our product candidates, which would seriously harm our operations and financial condition and increase our costs and expenses. Further, due to "shelter in place" orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members in the U.S. and U.K. excluding those necessary to maintain minimum basic operations. At this time, we are beginning to return to limited in-person field contact where local conditions and clinic policies allow. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

The COVID-19 outbreak could also potentially affect the operations of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned or completed clinical trials and ultimately of reviews and approvals of our product candidates. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to market our drugs effectively and raise capital when needed. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Our prospects are highly dependent on the successful commercialization of Epidiolex/Epidyolex, for which we received expanded approval in July 2020 from the FDA and approval in September 2019 from the EC. To the extent Epidiolex/Epidyolex is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our ADSs may decline.

In July 2020, the FDA expanded the approval of Epidiolex, adding a new indication of seizures associated with TSC and expanding all indications to patients one year of age and older. Epidiolex is now approved to treat seizures associated with LGS, Dravet syndrome, or TSC in patients one year of age and older. In September 2019, we received EC approval of the marketing authorization for Epidyolex. We have received Orphan Drug Designation

from the FDA for Epidiolex for seizures associated with LGS, Dravet syndrome and TSC. We also received Orphan Designation from the EMA's COMP for Epidiolex for Dravet syndrome, LGS and TSC, and the COMP reconfirmed the designation for LGS and Dravet syndrome upon the EC's approval. In Europe, Epidiolex has only been approved for use as adjunctive therapy of seizures associated with LGS or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older. We are focusing a significant portion of our activities and resources on Epidiolex, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize Epidiolex in the U.S. and Europe.

Successful commercialization of Epidiolex is subject to many risks. Prior to Epidiolex, we have only launched or commercialized one product, Sativex, outside of the U.S., and there is no guarantee that we will be able to continue to successfully commercialize Epidiolex for its approved indications. While we have established our commercial team and have hired our U.S. and European sales forces, we will need to continue to maintain and further develop the teams in order to successfully coordinate the commercialization of Epidiolex. Even if we are successful in maintaining and continuing to develop our commercial team, there are many factors that could cause the commercialization of Epidiolex to be unsuccessful, including a number of factors that are outside our control. Additionally, our revenues are concentrated on sales of Epidiolex in markets affected directly and indirectly by the COVID-19 pandemic.

Because no drug has previously been approved by the FDA for the treatment of seizures associated with Dravet syndrome prior to 2018, it is especially difficult to estimate the market potential of Epidiolex. The commercial success of Epidiolex depends on the extent to which patients and physicians accept and adopt Epidiolex as a treatment for LGS, Dravet syndrome, or TSC, and we do not know whether our or others' estimates in this regard will be accurate. We have limited information about how physicians, patients and payers will respond to the pricing of Epidiolex. Physicians may not prescribe Epidiolex and patients may be unwilling to use Epidiolex if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex in the market after launch, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex. Thus, significant uncertainty remains regarding the commercial potential of Epidiolex.

If the launch or commercialization of Epidiolex is unsuccessful or perceived as disappointing, our share price could decline significantly, and the long-term success of the product and the Company could be harmed.

The expanded FDA approval for the use of Epidiolex and the EC approval of Epidiolex subject us to ongoing obligations and continued regulatory review, which may result in significant additional expense. If we do not meet those ongoing obligations, we could be subject to significant penalties, including market withdrawal and/or civil or criminal penalties. Additionally, our other product candidates, if approved, could be subject to labeling and other restrictions and we may be subject to penalties (including market withdrawal) if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

The FDA's and EC's approvals and other regulatory approvals for any of our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the approved product candidate. With respect to the FDA's and EMA's approvals of Epidiolex, we are subject to certain post-marketing requirements. Failure to comply with these post-marketing requirements could result in withdrawal of our marketing approval for Epidiolex and/or other civil or criminal penalties. In addition, with respect to Epidiolex, and any product candidate that the FDA, EMA or a comparable foreign regulatory authority approves, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practices, or GMPs, with Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval, and with Good Laboratory Practices, or GLPs, for any nonclinical studies.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, mandatory safety labeling changes or product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or suspension or revocation of product approvals;
- imposition of risk evaluation and mitigation strategies, or REMS;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and EC's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any of our product candidates or future indications for currently approved products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we could lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We are dependent on the success of our product candidates, some of which may not receive regulatory approval or be successfully commercialized.

Our success will depend on our ability to successfully commercialize our product pipeline, including commercialization of Epidiolex, nabiximols and our other cannabinoid product candidates. While we have received U.S. regulatory approval for the treatment of seizures associated with LGS, Dravet syndrome, or TSC in patients one year of age and older and EMA regulatory approval for the use of Epidiolex for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older, we are evaluating Epidiolex for the treatment of other conditions such as additional rare childhood-onset epilepsy disorders. Epidiolex may never receive regulatory approval for the treatment of any other indications in the U.S. or elsewhere. Even if completed Phase 3 clinical trials and/or ongoing or future Phase 3 clinical trials show positive results, there can be no assurance that the FDA, EMA or any other regulatory authority will approve Epidiolex for any additional indications or that any other product candidate will receive approval.

Our ability to successfully commercialize Epidiolex, nabiximols and our other product candidates will depend on, among other things, our ability to:

- successfully complete pre-clinical and other nonclinical studies and clinical trials, including assessment of abuse potential;
- demonstrate to the FDA, EMA and similar foreign regulatory authorities that the efficacy of Epidiolex, nabiximols or any other product candidates in clinical trials can be attributed to the investigative product and not exclusively to its interaction with concomitant medications. It is possible that FDA may convene an advisory committee of external experts to consider any of our other drug candidates, and the course and outcome of meetings with these advisory committees can be hard to predict;
- receive regulatory approvals from the FDA, EMA and similar foreign regulatory authorities;
- produce, through a validated process, in manufacturing facilities inspected and approved by regulatory authorities, including the FDA and EMA, sufficiently large quantities of the product candidate, and the related Botanical Drug Substances, or BDSs, to permit successful commercialization;

- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates, or otherwise establish collaborations with third parties for the commercialization of our product candidates;
- obtain reimbursement from payers such as government health care programs and insurance companies and other third-party payers, as well as achieve commercially attractive levels of pricing;
- secure acceptance of our product candidates from physicians, health care payers, patients and the medical community;
- create positive publicity surrounding our product candidates;
- manage our spending as costs and expenses increase due to clinical trials and commercialization; and
- obtain and enforce sufficient intellectual property for our product candidates.

Our failure or delay with respect to any of the factors above could have a material adverse effect on our business, results of operations and financial condition.

We have limited marketing experience, and have only recently established our sales force, distribution and reimbursement capabilities, and we may not be able to successfully commercialize Epidiolex, or any of our product candidates if they are approved in the future.

Our ability to generate revenues ultimately depends on our ability to sell our approved products and secure adequate third-party reimbursement. We currently have limited experience in marketing and selling our products. Our product Sativex is currently approved and sold through marketing partners in a number of countries outside of the U.S. for treatment of MS spasticity. Epidiolex for the treatment of seizures associated with LGS, Dravet syndrome, or TSC in patients one year of age and older is our only product approved for sale in the U.S., and Epidyolex was approved for sale in Europe in September 2019. We have only had commercialization experience in the U.S. since November 2018, and are only now building the commercial organization in Europe.

The commercial success of Epidiolex and nabiximols depends on a number of factors beyond our control, including the willingness of physicians to prescribe Epidiolex and nabiximols to patients, payers' willingness and ability to pay for the drug, the level of pricing achieved, patients' response to Epidiolex and nabiximols and the ability of our marketing partners to generate sales. We have experienced an impact on our sales and marketing activities due to widespread restrictions on in-person meetings with healthcare professionals. During the first and second quarters of 2020, our sales force in the U.S and Europe. was unable to meet in-person with doctors starting in the second half of March. At this time, we are beginning to return to limited in-person field contact where local conditions and clinic policies allow. As a result of the lower number of in-person meetings with prescribers and restrictions on patient movements due to government-mandated work-from-home or shelter-in-place policies, the rate of new prescriptions for Epidiolex may slow, which may impact our financial results.

There can be no guarantee that we will be able to establish or maintain the personnel, systems, arrangements and capabilities necessary to successfully commercialize Epidiolex, nabiximols or any product candidate approved by the FDA and EMA in the future. If we fail to establish or maintain successful marketing, sales and reimbursement capabilities or fail to enter into successful marketing arrangements with third parties, our product revenues may suffer.

We expect to face intense competition, often from companies with greater resources and experience than we have.

The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we have. Some of these competitors and potential competitors have more experience than we have in the development of pharmaceutical products, including

validation procedures and regulatory matters. In addition, Epidiolex and nabiximols compete with, and our product candidates, if successfully developed, will compete with, product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than we or our collaboration partners have. Zogenix, Inc. received regulatory approval from the FDA for low-dose fenfluramine (Fintepla) in Dravet syndrome in June 2020. Ovid Therapeutics Inc./Takeda Pharmaceutical Company Limited and Marinus Pharmaceuticals, Inc. are developing therapies for treating Developmental and Epileptic Encephalopathies (includes Dravet and LGS). Biocodex received regulatory approval from the FDA for the drug Stiripentol (Diacomit) for the treatment of Dravet syndrome in September 2018. Other companies, including those with greater resources than us may announce similar plans in the future. In addition, there are non-FDA approved CBD preparations being made available from companies in the medical marijuana industry, which might attempt to compete with Epidiolex. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of Epidiolex, nabiximols and our other product candidates require import and export licenses. In the U.S., the FDA, U.S. Customs and Border Protection and the DEA, and in the U.K., the Home Office, and in other countries, similar regulatory authorities regulate the import and export of pharmaceutical products that contain controlled substances, including Epidiolex, nabiximols and our other product candidates. Specifically, the import and export process requires the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of Epidiolex, nabiximols and our product candidates may be held up in transit due to other factors such as the COVID-19 pandemic, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in a partial or total loss of revenue from one or more shipments of Epidiolex, nabiximols or our other product candidates. A partial or total loss of revenue from one or more shipments of Epidiolex, nabiximols or our other product candidates could have a material adverse effect on our business, results of operations and financial condition.

Business interruptions could delay us in the process of developing our product candidates and could disrupt our product sales.

Loss of our manufacturing facilities, our growing facilities, stored inventory or laboratory facilities through fire, theft or other causes, or loss of our botanical raw material due to pathogenic infection or other causes, and interruptions to our operations from a health epidemic such as COVID-19, which could cause interruption of, or delays in receiving, supplies due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, which could have an adverse effect on our ability to meet demand for Epidiolex or nabiximols or to continue product development activities and to conduct our business. Failure to supply our partners with commercial product may lead to adverse consequences, including the right of partners to take over responsibility for product supply. We currently have insurance coverage to compensate us for business interruptions; however, to the extent such insurance covers pandemic-related losses, it may prove insufficient to fully compensate us for the damage to our business resulting from any significant property or casualty loss to our inventory or facilities.

We have significant and increasing liquidity needs and may require additional funding.

Our operations have consumed substantial amounts of cash since inception. As of September 30, 2020, we reported a net operating cash outflow of \$33.3 million and a net cash outflow from investing activities of \$23.0 million.

Research and development, sales, general and administrative expenses and cash used for operations will continue to be significant and may increase substantially in the future in connection with new research and development initiatives and continued product commercialization efforts. We may need to raise additional capital to fund our operations, continue to conduct clinical trials to support potential regulatory approval of marketing applications and to fund commercialization of our products.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the timing of FDA approval, if any, and approvals in international markets of our product candidates, if at all;
- the timing and amount of revenue from sales of our products, or revenue from grants or other sources;
- the rate of progress and cost of our clinical trials and other product development programs;
- costs of establishing or outsourcing sales, marketing and distribution capabilities;
- costs and timing of completion of expanded in-house manufacturing facilities as well as any outsourced growing and commercial manufacturing supply arrangements for our product candidates;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs of operating as a U.S. public company;
- the effect of competing technological and market developments;
- personnel, facilities and equipment requirements;
- general economic, industry and market conditions other events or factors, many of which are beyond our control, such as the recent COVID-19 outbreak; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

While we expect to fund our future capital requirements from a number of sources including existing cash balances, future cash flows from operations and the proceeds from further public offerings, we cannot assure you that any of these funding sources will be available to us on favorable terms, or at all. Further, even if we can raise funds from all of the above sources, the amounts raised may not be sufficient to meet our future capital requirements.

Operating results may vary significantly in future periods.

Our quarterly revenues, expenses and operating results have fluctuated in the past and are likely to fluctuate significantly in the future. Our financial results are unpredictable and may fluctuate, for among other reasons, due to:

- commercial sales of Epidiolex and Sativex;
- our achievement of product development objectives and milestones;
- clinical trial enrollment and expenses;
- research and development expenses;
- changes in insurance coverage of our patients;
- business interruptions resulting from geopolitical actions, including war and terrorism, health epidemics such as COVID-19, or natural disasters including earthquakes, typhoons, floods and fires; and
- timing and nature of contract manufacturing and contract research payments.

A high portion of our costs are predetermined on an annual basis, due in part to our significant research and development costs. Thus, small declines in revenue could disproportionately affect financial results in a quarter. Because of these factors, our financial results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our share price to decline.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business.

Separately, in response to COVID-19, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Product recalls or inventory losses caused by unforeseen events, cold chain interruption and testing difficulties may adversely affect our operating results and financial condition.

Epidiolex, nabiximols and our product candidates are manufactured and distributed using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture of our products, subjects us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. Some of our products must be stored and transported at temperatures within a certain range, which is known as "strict cold chain" storage and transportation. Further, we may experience production and distribution difficulties due to resource constraints or as a result of natural disasters, unstable political environments, or public health epidemics such as the recent COVID-19 outbreak. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches.

The United Kingdom's withdrawal from the European Union could lead to increased market volatility, which could adversely impact the market price of our ADSs and make it more difficult for us to do business in Europe or have other adverse effects on our business.

The United Kingdom officially left the European Union as a member state on January 31, 2020 and now has third country status. There now follows a transitional period during which the U.K. and the EU will attempt to conclude a free trade agreement (the "Transitional Period"). During the Transitional Period, the U.K. will abide by all EU laws and regulations. In the event that the U.K. and the EU cannot agree to the terms of such a free trade agreement, the Transitional Period will end on the December 31, 2020 unless an extension to this date is agreed. The UK did not request an extension to the negotiating period by the deadline of June 30, 2020, and the U.K. government has reiterated its intention to conclude a free trade agreement before the end of 2020 and its intention to refuse any request from the EU to extend the current Transitional Period. In the event that no free trade agreement is reached by the end of 2020, it is likely that cross-border trade between the United Kingdom and the EU will revert to world trade organization terms. Our distribution model in the EU with the marketing authorization and a hub in the Netherlands has been designed to mitigate the impact of this on our business as much as possible. In addition, if no free trade agreement can be reached and the United Kingdom leaves the European Union with no free trade agreement, there will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as in relation to the regulatory process in Europe. As a result of this uncertainty, financial markets could experience volatility which could adversely affect the market price of our ADSs. We may also face new regulatory costs and challenges that could have a material adverse effect on our operations. In this regard, the EMA has already issued a notice reminding marketing authorization holders of centrally authorized medicinal products for human and veterinary use of certain legal requirements that need to be considered as part of Brexit, such as the requirement for the marketing authorization holder of a product centrally approved by the European Commission to be established in the European Union, and the requirement for some activities relating to centrally approved products, such as batch release and pharmacovigilance, to be performed in the European Union. As a result of the foregoing developments, and in the absence of any clear indication that any agreed form of a free trade agreement will contain a contrary requirement, we have taken steps to establish a network of subsidiary undertakings in the major European markets and have established pharmacovigilance and batch release operations in the European Union. Depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business worldwide more difficult. In addition, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue it could cause volatility in our financial results.

Item 6. Exhibits

The following exhibits are either provided with this Quarterly Report on Form 10-Q or are incorporated herein by reference:

Exhibit Number	Description
3.1*	<u>Substituted Articles of Association of GW Pharmaceuticals plc (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K filed with the SEC on November 29, 2018).</u>
10.1**	<u>Letter of Appointment by and between GW Pharmaceuticals plc and David Gryska, dated September 9, 2020.</u>
31.1**	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2**	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1**	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Previously filed.

** Filed herewith.

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

Date: November 4, 2020

By: /s/ Justin Gover
Name: Justin Gover
Title: Chief Executive Officer

Date: November 4, 2020

By: /s/ Scott Giacobello
Name: Scott Giacobello
Title: Chief Financial Officer



9 September 2020

David Gyska

Dear David

GW Pharmaceuticals plc (the "Company")

I am writing to record the terms of your appointment as a non-executive Director of, GW Pharmaceuticals plc ("**GW**"). These terms will take effect on 9th September 2020 and will continue until terminated by either party giving to the other not less than 3 months' prior written notice or as provided for in paragraph 1 below.

1. Appointment

- (a) Your appointment as a non-executive Director of GW is subject to the Articles of Association of GW. Your appointment as a Director will be subject to the usual rules requiring your appointment and re-appointment to be approved by shareholders. Your appointment as a non-executive Director will automatically terminate without any entitlement to compensation if you:
 - (i) are removed from office by a resolution of the shareholders;
 - (ii) are not re-elected to office; or
 - (iii) cease to be a director by reason of your vacating office pursuant to any provision of the Company's Articles of Association.

 - (b) The Company may terminate your appointment with immediate effect if you:
 - (i) commit any act, whether or not in the course of your duties for the Company, which tends to bring you or the Company or Group into disrepute;
 - (ii) commit a material breach of your obligations under this letter;
 - (iii) commit any serious or repeated breach or non-observance of your obligations to the Company (which include an obligation not to breach your duties to the Company, whether statutory, fiduciary or common law);
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- (iv) are declared bankrupt or have made an arrangement with, or for the benefit of, your creditors, or if a county court administration order is made against you under the County Court Act 1984;
 - (v) are convicted of any arrestable criminal offence (other than an offence under road traffic legislation in the UK or elsewhere for which a fine or non-custodial penalty is imposed);
 - (vi) are unavailable to perform your duties under your appointment for 6 months consecutively or in aggregate in any period of one year; or
 - (vii) you are disqualified from holding office as a Company director.
- (c) During any period of notice in accordance with this agreement, the Company may at its absolute discretion ask you not to attend any Board or General meetings or to perform any other services on its behalf.
- (d) Non-executive directors on the GW Board are typically expected to serve two three-year terms but you may be invited by the Company to serve for an additional period on the Board. Any term renewal is subject to Board review and GW AGM re-election. Notwithstanding any mutual expectation, there is no right to re-nomination by the Board, either annually or after any three-year period.
- (e) Upon the ending of your appointment for any reason, you will resign in writing from your statutory office as Director of the Company at the request of the Company, without any claim for compensation (other than for accrued and unpaid fees due under this letter), from all directorships and other offices held by you in the Company and any other member of the Group and from all trusteeships held by you of any pension scheme or other trusts established by any member of the Group. Should you fail to do so, you irrevocably appoint any member of the Board as your attorney in your name and on your behalf to sign any documents and take such other steps as are necessary to give effect to those resignations.

2. Time commitment

- (a) You will be expected to devote such time as is necessary for the proper performance of your duties, and you should be prepared to spend at least 12 days per annum attending meetings representing the Company business interests. You are expected to attend GW Board Meetings as and when they are held. In connection with attendance at the meetings, you will exercise such functions that are specifically delegated to you from time to time by the Board.
 - (b) You will also be required to sit on the Audit Committee of the GW Board.
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- (c) We expect this role to involve your attendance at a minimum of five GW Board meetings, and six Audit Committee meetings per annum. Unless urgent and unavoidable circumstances prevent you from doing so, it is expected that you will attend these meetings.
- (d) Additional time may be required, on an ad-hoc basis, to attend meetings to deal with certain GW Board and sub-committee matters as they arise. The nature of the role makes it impossible to be specific about the maximum time commitment, and there is always the possibility of additional time commitment in respect of preparation time and ad hoc matters which may arise from time to time, and particularly when the Company is undergoing a period of increased activity. At certain times, it may be necessary to convene additional GW Board, committee or shareholder meetings.
- (e) In accepting this role you are deemed to undertake that you have sufficient time available to commit to the proper performance of this role. Prior to acceptance of the role you will be required to provide to the Company Secretary details of your other Board appointments and significant commitments with a broad indication of the time involved and will be required to update the Company Secretary from time to time of any changes to these commitments.

3. Remuneration and expenses

- (a) Your fee for participation will be \$60,000 per annum and will be subject to any deduction required by law. This will be paid monthly in arrears in equal instalments. You are not eligible for any other benefits.

Your fee as a member of the Audit Committee will be \$10,000 per annum

Additional fees may be payable in future if you are asked to become a member of the other Board sub-committees or if you are asked to take up the role of Chair of any of these committees.

- (b) Your fees will be reviewed from time to time by the GW Board. It is our current practice to review these fees at the end of each calendar year although such review does not imply nor guarantee any increase.
 - (c) You will not be entitled to participate in any Group pension scheme.
 - (d) You will not be entitled to any other fees or benefits except as provided for in this letter, nor on termination will you be entitled to any compensation for loss of office except such fees as may have accrued to the date of termination (if any).
 - (e) You will be eligible to participate in the GW Pharmaceuticals Long Term Incentive Plan. Grants of equity based incentives under the terms of this scheme are made at the discretion of the Board, usually on an annual basis.
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- (f) You will be reimbursed for all reasonable out-of-pocket expenses properly incurred by you on Company business, including costs associated with you attending UK Board, Committee and General Meetings. Reimbursement would include the reasonable cost of obtaining legal advice, if circumstances should arise where it was necessary for you to seek such advice separately, about your responsibilities as a non-executive director of the Company although you should initially raise any such concerns with the Chairman of the Company. This advice should be obtained, and reimbursement will only be made, in accordance with any formal procedure for directors to take independent professional advice adopted from time to time by the Company and a copy of the current version will be supplied to you. Claims for reimbursement should be accompanied by evidence of expenditure.

4. Insurance

The Company will, at its expense, provide you with director's and officer's liability insurance, subject to the provisions governing such insurance and on such terms as the Board may from time to time decide (including but not limited to terms relating to the level of cover, deductibles, caps, exclusions and aggregate limits) and subject to the obtaining of insurance at reasonable rates of premium. No undertaking is given regarding the continuation of this insurance, other than that you will be covered for as long as it remains in place for the directors of the Company. A copy of the current policy is available upon request from the Company Secretary. The risks covered and time limitations are subject to the terms of the policy as amended from time to time. Insurance cover will not extend to loss due to fraud, dishonesty, wilful default or criminal behaviour.

5. Duties

- (a) You will be expected to perform your duties, whether statutory, fiduciary or common-law, faithfully, efficiently and diligently to a standard commensurate with both the functions of your role and your knowledge, skills and experience.
- (b) You will exercise your powers in your role as a non-executive director having regard to relevant obligations under prevailing law and regulation, including the Companies Act 2006. You are also required to comply with the requirements of the U.S. Securities and Exchange Commission and Nasdaq, including the independence standards set forth in Rule 10A-3(b) of the Securities Exchange Act of 1934, as amended and the independence and audit committee qualification requirements set forth under Rule 5605 of the Nasdaq Listing Rules.
- (c) You will be advised by the Company Secretary where these differ from requirements in the UK.
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(d) You will have particular regard to the general duties of directors as set out in Part 10, Chapter 2 of the Companies Act 2006, including the duty to promote the success of the company:

"A director of a company must act in the way he considers, in good faith, would be most likely to promote the success of the company for the benefit of its members as a whole, and in doing so have regard (amongst other matters) to -

- (a) *the likely consequences of any decision in the long term,*
- (b) *the interests of the company's employees,*
- (c) *the need to foster the company's business relationships with suppliers, customers and others,*
- (d) *the impact of the company's operations on the community and the environment,*
- (e) *the desirability of the company maintaining a reputation for high standards of business conduct, and*
- (f) *the need to act fairly as between members of the company."*

(e) In your role as non-executive director you will be required to:

- constructively challenge and help develop proposals on strategy;
 - scrutinise the performance of management in meeting agreed goals and objectives and monitor the reporting of performance;
 - satisfy yourself on the integrity of financial information and that financial controls and systems of risk management are robust and defensible;
 - satisfy yourself that the company is in substantial compliance with relevant laws and regulations
 - take opportunities such as attendance at general and other meetings, to understand shareholder concerns and to meet with key customers and members of the workforce from all levels of the organisation to have an understanding of the business and its relationships with significant stakeholders;
 - determine appropriate levels of remuneration of executive directors and have a prime role in appointing and, where necessary, removing executive directors, and in succession planning;
-

- devote time to developing and refreshing your knowledge and skills;
 - uphold high standards of integrity and probity and support me and the other directors in instilling the appropriate culture, values and behaviours in the boardroom and beyond;
 - insist on receiving high-quality information sufficiently in advance of board meetings; and
 - take into account the views of shareholders and other stakeholders where appropriate.
- (f) You will be required to exercise relevant powers under, and abide by, GW's Articles of Association.
- (g) You will be required to exercise your powers as a director in accordance with GW's policies and procedures.
- (h) You will disclose any direct or indirect interest which you may have in any matter being considered at a board meeting or committee meeting and, save as permitted under the Articles of Association, you will not vote on any resolution of the Board, or of one of its committees, on any matter where you have any direct or indirect interest.
- (i) You will notify the Chairman immediately if you become aware of any matter which may be prejudicial to the interests of the Company, or may affect your fitness to hold office as a company director, or which may affect the fitness of any of your fellow directors (or proposed directors) to hold office as a company director.
- (j) You will immediately report to the Chairman your own wrongdoing or the wrongdoing or proposed wrongdoing of any employee or director of which you become aware.
- (k) Unless specifically authorised to do so by the Board, you will not enter into any legal or other commitment or contract on behalf of the Company.

6. Outside interests

During your appointment you may not, without the prior approval of the Board, accept a directorship of a company or provide your services to anyone who is a competitor of the Group. The Board's agreement will not be given if such appointment or involvement would conflict with or is likely to interfere with this appointment. It is the parties understanding that the definition of a competitor shall be restricted to a project, business or activity, directly or indirectly, involving cannabinoid research. Please let the Company Secretary have a list of your current commitments for our records and keep him updated in that respect.

7. Conflicts of interests

- 7.1 You are under a duty to avoid any situation in which you have, or can have, a direct or indirect interest that conflicts, or possibly may conflict, with the interests of the Company. This applies in particular to the exploitation of any property, information or opportunity (regardless of whether the Company could take advantage of that property, information or opportunity).
- 7.2 It is nevertheless acknowledged that you may wish to have business interests other than those of the Company.
- 7.3 You have declared to the Board that there is no situation in which you have, or could have, a direct or indirect interest that conflicts, or possibly may conflict, with the interests of the Company (a “**Conflict Situation**”).
- 7.4 You confirm that you will disclose to the Chairman in writing immediately upon your becoming aware of anything which might reasonably be expected to lead to a Conflict Situation or to any change in an existing Conflict Situation that has been authorised.
- 7.5 You confirm that you will not, and you will take reasonable steps to ensure that none of your Connected Persons will, without the prior authority of the Board, accept any other appointment or enter into any other transaction or arrangement which might reasonably be expected to lead to a Conflict Situation. The Board is entitled, at its discretion, to give or withhold its authority for any Conflict Situation on any such terms and conditions as it may decide.
- 7.6 You confirm that you will comply with all terms and conditions of any authority granted to you by the Board or otherwise for any Conflict Situation.

8. Confidentiality

You should not, during your appointment (except in the proper performance of your duties and then only to those who need to know such information) or after it has ceased (except as required by law or which has entered into the public domain other than as a result of your unauthorised disclosure), disclose to any person, company or other organisation or use otherwise than for the benefit of the Group any confidential information or trade secrets concerning its business. This includes but is not limited to:

- (a) corporate and marketing strategy, acquisition and investment proposals, business development and plans, maturing business opportunities, sales reports and research results;
 - (b) business contacts, lists of customers and suppliers and details of contracts with customers and suppliers and their current or future requirements;
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- (c) budgets, financial plans and management accounts, trading statements and other financial reports and information;
- (d) unpublished price sensitive information about the Group;
- (e) confidential details as to the design of the Company's or Group's inventions or developments relating to future products whether or not in the case of documents or other written materials whether or not marked as confidential; and
- (f) any document marked "confidential" and any information which by its nature is commercially sensitive.

9. Compliance

- (a) You are expected to comply with the Company's Articles of Association, the City Code on Takeovers and Mergers, as applicable, relevant stock exchange rules and regulations and the Company's relevant internal codes. In particular during your appointment you will comply, and will procure, so far as you are able, that your spouse or Civil Partner and dependent children (if any) or any trust in which you or your spouse or Civil Partner may be concerned or interested as trustee or beneficiary, comply with any code of conduct relating to securities transactions by directors and specified employees adopted by the Company from time to time.
- (b) You will promptly give the Company such information as the Company or any member of the Group may require to enable it to comply with its legal and regulatory obligations whether to any securities or investment exchange or regulatory or governmental body to which any member of the Group is, from time to time, subject or howsoever arising.

10. Return of Company property

When your appointment ends, you should, unless otherwise agreed in writing, immediately return all documents and other property belonging to any member of the Group and which may be in your possession or under your control. No copies (including electronic copies) should be retained by you or by anyone on your behalf.

11. Data protection

Personal data

Processing of personal data and our policies

- (a) Information relating to an individual (or from which an individual may be identified) is called "personal data".
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- (b) In processing personal data, the Company is required to comply with the law on data protection. To help achieve this, data privacy policies have been adopted. Copies may be found on our GW Connect Intranet. You must read these and comply with them in carrying out your role. If you are unclear how the policies apply or, more generally, what you need to do to comply with the law on data protection, speak to the Chairman in the first instance who may direct your query as appropriate.

Data protection principles

- (c) In complying with the law on data protection, the Company is required to comply with what are known as data protection principles. In performing your role and carrying out your responsibilities, you must do your best to ensure that the Company complies with these principles.
- (d) A key element of the data protection principles is the duty to ensure that data is processed securely and protected against unauthorised or unlawful processing or loss. Key elements include the following:
- (i) You must ensure that laptops, memory sticks, phones and other mobile devices are password protected and encrypted. You must not take such devices outside the office without encryption. You must take care of them and keep them secure.
 - (ii) You must use strong passwords, changing them regularly and not sharing them with unauthorised colleagues;
 - (iii) You must not access other individuals' personal data unless in the course of your work;

Data breach – and urgent notification

- (e) If you discover a data breach, you **must** notify the Chairman and the CIO/Chief Legal Officer immediately – and if possible, within one hour. Depending on context, you may then need to provide further information on the circumstances of the breach.
- (f) A data breach occurs when there is destruction, loss, alteration or unauthorised disclosure of or access to personal data which is being held, stored, transmitted or processed in any way. For example, there is a data breach if our servers are hacked or if you lose a laptop or USB stick or send an email to the wrong person by mistake.
- (g) Failure to notify a breach or to provide information as set out above will be treated seriously and disciplinary action may be taken.
- (h) Further information regarding how the Company handles data breach is available on our GW Connect Intranet site.
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Why the Company processes personal data

(i) For information on the nature of the data processed, why it is processed, the legal basis for processing and related matters, please refer to the Privacy Notice which may be found on our GW Connect Intranet site. In summary:

(i) Personal data is processed relating to you for the purposes of the Company business including management, administrative, employment and legal purposes.

(j) The summary above is for information only. Consent is not, in general, relied upon as a legal basis for processing. Agreeing the terms of this Agreement will not constitute your giving consent to the processing of your data.

(k) The Company reserves the right to amend the policy and protocol documents referred to above from time to time.

12. Non-compete

By countersignature of this letter and in consideration for the fees payable to you under this letter, you agree you will not (except with prior written consent of the GW Board) directly or indirectly do or attempt to, for the period of 12 months immediately after the termination of your office, to any material extent, undertake, carry on or be employed, engaged or interested in any capacity in the supply or proposed supply of Competitive Services within the Territory. For the purposes of this paragraph, "Competitive Services" means any business connected to the marketing, sales or distribution, or development or proposed development of pharmaceuticals from cannabinoids which is competitive with the Company's or GW, or GW Pharma's businesses; and "Territory" means England, Wales, Scotland and/or Northern Ireland and any other country, or, in the United States, any state, which the Company or any member of the Group is operating or planning to operate a competitive business at the end of your appointment.

13. Rights of third parties

The Contracts (Rights of Third Parties) Act 1999 shall not apply to this letter. No person other than you and the Company shall have any rights under this letter and the terms of this letter shall not be enforceable by any person other than you and the Company.

14. Status

As a non-executive Director you are an office-holder, not an employee of the Company. You warrant that you are not subject to any restrictions which prevent you from holding office as a director or from fulfilling any of the obligations set out in this letter.

15. Miscellaneous

(a) For the purpose of this letter:

the "**Board**" shall mean the board of directors of the Company as constituted from time to time;

"**Civil Partner**" means a civil partner as defined by the Civil Partnership Act 2004;

"**Connected Person**" means any person connected with a director as defined in section 252 Companies Act 2006; and

the "**Group**" means any of the following from time to time: the Company, its subsidiaries and subsidiary undertakings and any holding company or parent undertaking of the Company and all other subsidiaries and subsidiary undertakings of any holding company or parent undertaking of the Company, where "holding company", "parent undertaking", "subsidiary" and "subsidiary undertaking" have the meanings given to them in the Companies Act 2006.

(b) Your appointment with the Company and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) will be governed by and construed in accordance with the law of England and Wales. You and the Company irrevocably agree that the courts of England and Wales will have non-exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this appointment or its subject matter or formation (including non-contractual disputes or claims).

(c) This letter constitutes the entire terms and conditions of your appointment. No variation or addition to this letter and no waiver of any provision of it will be valid unless in writing and signed by or on behalf of both parties. You agree that you will have no remedies in respect of any representation or warranty (whether made innocently or negligently) that is not set out in this letter and you will not have any claim for innocent or negligent misrepresentation based on any statement in this letter.

(d) No variation or modification of this letter will be effective unless it is in writing and signed by you and the Company (or respective authorised representatives).

I would ask you to countersign the enclosed copy of this letter to confirm the basis of your appointment with the Company and to show acceptance of the terms of this letter by executing it as a deed.

I look forward to working with you to the general benefit of our shareholders.

Yours sincerely

/s/ Geoffrey Guy

Geoffrey Guy

Chairman, GW Pharmaceuticals plc

**Certification of Principal Executive Officer
Pursuant to Exchange Act Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Justin Gover, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GW Pharmaceuticals plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the registrant's audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2020

/s/ Justin Gover

Justin Gover
Chief Executive Officer and Director
(Principal Executive Officer)

**Certification of Principal Financial Officer
Pursuant to Exchange Act Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002**

I, Scott Giacobello, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GW Pharmaceuticals plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the registrant's audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 4, 2020

/s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(Principal Financial and Accounting Officer)

**Certification of Principal Executive Officer
Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Justin Gover, the Chief Executive Officer of GW Pharmaceuticals plc (the "Company") hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the three-month period ended September 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 4, 2020

/s/ Justin Gover

Justin Gover

Chief Executive Officer and Director
(Principal Executive Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Certification of Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Scott Giacobello, the Chief Financial Officer of GW Pharmaceuticals plc (the "Company") hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the three-month period ended September 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 4, 2020

/s/ Scott Giacobello

Scott Giacobello
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference to any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.