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, 2019

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)**	**Not Applicable** **(I.R.S. Employer Identification No.)**
Sovereign House, Vision Park **Chivers Way, Histon** **Cambridge, CB24 9BZ** **United Kingdom** **(Address of principal executive offices)**	**+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		Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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 31, 2019, 370,958,132 shares were outstanding including 356,415,948 shares held as American Depositary Shares, each representing twelve Ordinary Shares, par value of £0.001 per share and 14,542,096 Ordinary Shares.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 554,682	$ 591,497
Accounts receivable, net	41,818	4,192
Inventory	69,288	33,030
Prepaid expenses and other current assets	32,196	17,903
Total current assets	697,984	646,622
Property, plant, and equipment, net	110,161	90,832
Operating lease assets	20,438	—
Goodwill	6,959	6,959
Deferred tax assets	8,425	8,720
Other assets	3,884	2,935
Total assets	$ 847,851	$ 756,068
Liabilities and stockholders' equity		
Accounts payable	$ 6,934	$ 9,796
Accrued liabilities	81,704	52,477
Current tax liabilities	—	2,384
Other current liabilities	6,627	1,559
Total current liabilities	95,265	66,216
Long-term liabilities:		
Finance lease liabilities	5,297	5,690
Operating lease liabilities	17,007	—
Other liabilities	10,627	10,082
Total long-term liabilities	32,931	15,772
Total liabilities	128,196	81,988
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 370,937,744 shares outstanding as of September 30, 2019; 366,616,688 shares outstanding as of December 31, 2018	570	564
Additional paid-in capital	1,619,649	1,581,144
Accumulated deficit	(813,013)	(828,940)
Accumulated other comprehensive loss	(87,551)	(78,688)
Total stockholders' equity	719,655	674,080
Total liabilities and stockholders' equity	$ 847,851	$ 756,068

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,	
	2019	2018	2019	2018
Revenues				
Product net sales	$ 90,849	$ 2,343	$ 201,312	$ 8,249
Other revenue	122	77	944	496
Total revenues	90,971	2,420	202,256	8,745
Operating expenses				
Cost of product sales	8,150	1,399	19,901	4,815
Research and development	36,301	28,943	99,143	117,541
Selling, general and administrative	64,178	52,685	181,529	116,644
Total operating expenses	108,629	83,027	300,573	239,000
Loss from operations	(17,658)	(80,607)	(98,317)	(230,255)
Interest income	2,249	1,283	6,646	3,041
Interest expense	(272)	(297)	(805)	(935)
Other income	—	—	104,117	—
Foreign exchange gain (loss)	1,889	(823)	2,801	(5,123)
(Loss) income before income taxes	(13,792)	(80,444)	14,442	(233,272)
Income tax (benefit) expense	(35)	(565)	(1,485)	79
Net (loss) income	$ (13,757)	$ (79,879)	$ 15,927	$ (233,351)
Net (loss) income per share:				
Basic	$ (0.04)	$ (0.23)	$ 0.04	$ (0.68)
Diluted	$ (0.04)	$ (0.23)	$ 0.04	$ (0.68)
Weighted average shares outstanding:				
Basic	372,246	341,302	371,286	340,675
Diluted	372,246	341,302	376,985	340,675

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,	
	2019	2018	2019	2018
Net (loss) income	$ (13,757)	$ (79,879)	$ 15,927	$ (233,351)
Foreign currency translation adjustments	(7,783)	561	(8,863)	(1,242)
Comprehensive (loss) income	$ (21,540)	$ (79,318)	$ 7,064	$ (234,593)

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	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
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 loss	—	—	—	(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

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balances at December 31, 2017	337,964	$ 527	$ 1,220,206	$ (523,683)	$ (73,952)	$ 623,098
Issuance of common stock from exercise of stock options	549	1	—	—	—	1
Net loss	—	—	—	(69,461)	—	(69,461)
Share-based compensation	—	—	6,858	—	—	6,858
Other comprehensive income	—	—	—	—	4,108	4,108
Balances at March 31, 2018	338,513	$ 528	$ 1,227,064	$ (593,144)	$ (69,844)	$ 564,604
Issuance of common stock from exercise of stock options	634	1	—	—	—	1
Net loss	—	—	—	(84,011)	—	(84,011)
Share-based compensation	—	—	9,568	—	—	9,568
Other comprehensive loss	—	—	—	—	(5,911)	(5,911)
Balances at June 30, 2018	339,147	$ 529	$ 1,236,632	$ (677,155)	$ (75,755)	$ 484,251
Issuance of common stock from exercise of stock options	1,100	1	616	—	—	617
Net loss	—	—	—	(79,879)	—	(79,879)
Share-based compensation	—	—	9,609	—	—	9,609
Other comprehensive income	—	—	—	—	561	561
Balances at September 30, 2018	340,247	$ 530	$ 1,246,857	$ (757,034)	$ (75,194)	$ 415,159

See accompanying notes to these condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities		
Net income (loss)	$ 15,927	$ (233,351)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Foreign exchange (gain) loss	(418)	5,097
Share-based compensation	35,633	26,035
Depreciation and amortization	7,096	7,127
Deferred income taxes	—	835
Gain from sale of priority review voucher	(104,117)	—
Other	39	233
Changes in operating assets and liabilities:		
Accounts receivable, net	(37,691)	(581)
Inventory	(37,561)	(14,024)
Prepaid expenses and other current assets	(14,869)	15,005
Other assets	2,968	(398)
Accounts payable	(1,161)	4,040
Current tax liabilities	(601)	(4,844)
Accrued liabilities	29,176	13,503
Other liabilities	(1,943)	1,013
Net cash used in operating activities	(107,522)	(180,310)
Cash flows from investing activities		
Proceeds from sale of priority review voucher	104,117	—
Additions to property, plant and equipment	(29,915)	(23,614)
Additions to capitalized software	(1,183)	(1,049)
Proceeds from disposal of property, plant and equipment	-	517
Net cash provided by (used in) investing activities	73,019	(24,146)
Cash flows from financing activities		
Proceeds from exercise of stock options	2,878	619
Payments on finance leases	(317)	(211)
Payments on landlord financing obligation	(404)	(397)
Net cash provided by financing activities	2,157	11
Effect of exchange rate changes on cash	(4,469)	131
Net decrease in cash and cash equivalents	(36,815)	(204,314)
Cash and cash equivalents at beginning of period	591,497	559,227
Cash and cash equivalents at end of period	$ 554,682	$ 354,913
Supplemental disclosure of cash flow information:		
Income taxes paid	7,052	4,341
Interest paid	(805)	(935)
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	1,534	322

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. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Transition Report on Form 10-KT for the three-month transition period ended December 31, 2018. 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, 2018 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 three-month transition period ended December 31, 2018 included in the Company's Transition Report on Form 10-KT. The results of operations for the three and nine months ended September 30, 2019 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.

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, 2019, the allowance for doubtful accounts was $0.1 million and at December 31, 2018, the Company determined that an allowance for doubtful accounts was not requiredNo 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.

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 approval of Epidiolex by the United States Food and Drug Administration (FDA), 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 expects to receive 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.

Epidiolex Product Net Sales

Epidiolex was approved by the FDA in June 2018. Subsequent to the approval by the FDA, the United States Drug Enforcement Agency (DEA) took action to change the classification of Epidiolex from a Schedule I controlled substance to a Schedule V controlled substance, thereby allowing Epidiolex to be prescribed and distributed in the United States. On November 1, 2018, the Company launched sales of 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.

On September 23, 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 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, 2019 was $8.6 million and $40.7 million, respectively.

Sativex Product Net Sales

Sales of Sativex, which is currently being commercialized for spasticity due to multiple sclerosis (MS) outside the United States, are made pursuant to license agreements with commercial partners. The Company has entered into license agreements for the commercialization of Sativex in Europe, Canada, Israel, Mexico, and South America. Under these 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, the date at which the control is transferred. The Company commercializes Sativex in Australia and New Zealand through a consignment relationship with a local distributor. Product net sales revenue 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 for services provided under a license agreement with Otsuka Pharmaceutical Co. Ltd (Otsuka) that was terminated in December 2017 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 $0.7 million and $2.2 million for the three and nine months ended September 30, 2019, respectively, compared to $1.7 million and $3.3 million for the same periods in 2018, respectively.

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.

For UK tax purposes, it is anticipated that the $104.1 million gain on the sale of the priority review voucher (PRV) will be fully offset by current year operating tax losses generated in the UK.

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.

New Accounting Pronouncements

On January 1, 2019, the Company adopted a new accounting standard issued by the Financial Accounting Standards Board (FASB) on accounting for leases using the modified retrospective method. This new accounting standard requires a lessee to recognize an asset and liability for most leases on its balance sheet. The Company elected the optional transition method that allowed for a cumulative-effect adjustment as of January 1, 2019 and did not restate previously reported results in the comparative periods. The Company also elected to adopt certain practical expedients allowed by the new standard, which among other things, allowed the Company to carry forward its historical lease classification.

As a result of adoption of the new standard, the Company recorded operating lease assets and liabilities of approximately $20.5 million and $21.1 million, respectively, as of January 1, 2019. The operating lease liability was determined based on the present value of the remaining minimum rental payments and the operating lease asset was determined based on the value of the lease liability, adjusted for existing deferred rent balances, which were previously included in other current liabilities and other liabilities. Accounting for the Company's finance leases remains substantially unchanged. As a result of the adoption of the new leasing accounting standard, the Company's build-to-suit asset has been reclassified to buildings and the build-to-suit financing obligation has been reclassified to finance lease obligation in the condensed consolidated balance sheets. In addition, the adoption of this new accounting standard resulted in increased qualitative and quantitative disclosures regarding the amount, timing, and uncertainty of cash flows arising from leases. For further details, see Note 9 *Leases*. The adoption of the new standard did not materially impact the Company's consolidated results of operations or cash flows.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, 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 within those years, with early adoption permitted only as of annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the timing and impact of the adoption of this guidance on the Company's consolidated financial statements.

Note 3: Fair Value Measurements

At September 30, 2019 and December 31, 2018, 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.

Investment 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 investment securities between the classification levels.

Note 4: Composition of Certain Balance Sheet Captions:

Inventory consisted of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Raw materials	$ 1,788	$ 676
Work in process	60,428	28,709
Finished goods	7,072	3,645
	$ 69,288	$ 33,030

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

	September 30, 2019	December 31, 2018
	(in thousands)	
Buildings	$ 4,429	$ 4,573
Machinery and equipment	33,591	32,598
Leasehold improvements	35,908	36,004
Office and IT equipment	2,798	2,481
Construction-in-process	67,478	44,546
	144,204	120,202
Accumulated depreciation	(34,043)	(29,370)
	$ 110,161	$ 90,832

Depreciation of property, plant, and equipment was $2.0 million and $2.1 million for the three months ended September 30, 2019 and 2018, respectively. Depreciation of property, plant, and equipment was $6.2 million and $6.5 million for the nine months ended September 30, 2019 and 2018, respectively. The Company did not have any significant property, plant, or equipment write-offs in the three or nine months ended September 30, 2019 and 2018.

Accrued liabilities consisted of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Accrued compensation and benefits	$ 20,538	$ 18,482
Accrued vendor fees	21,971	11,452
Clinical trial accruals	10,701	10,059
Accrued growing fees	2,969	2,717
Accrued sales rebates and discounts	17,082	628
Other	8,443	9,139
	$ 81,704	$ 52,477

Other current liabilities consisted of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Finance lease liabilities	$ 282	$ 400
Operating lease liabilities	5,398	—
Landlord financing	548	539
Other	399	620
	$ 6,627	$ 1,559

Other liabilities consisted of the following:

	September 30, 2019	December 31, 2018
	(in thousands)	
Landlord financing obligation	$ 8,721	$ 9,434
Other	1,906	648
	$ 10,627	$ 10,082

Note 5: 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 months ended September 30, 2019 and 2018 and the nine months ended September 30, 2018 and therefore did not include potentially dilutive common stock equivalents in the computation of diluted net loss per share. For the three months ended September 30, 2019 and for the three and nine months ended September 30, 2018, options totaling approximately 14.7 million, 13.0 million, and 13.0 million ordinary shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands, except per share amounts)			
Net (loss) income for basic and diluted EPS	$ (13,757)	$ (79,879)	$ 15,927	$ (233,351)
Weighted-average shares for basic EPS	372,246	341,302	371,286	340,675
Effect of dilutive securities	—	—	5,699	—
Weighted-average shares for diluted EPS	372,246	341,302	376,985	340,675
Net (loss) income per share:				
Basic EPS	$ (0.04)	$ (0.23)	$ 0.04	$ (0.68)
Diluted EPS	$ (0.04)	$ (0.23)	$ 0.04	$ (0.68)

Note 6: Stockholders' Equity

In October 2018, the Company completed a public offering of2,185,000 ADSs listed on the Nasdaq Global Market, representing26,220,000 ordinary shares of the Company, at a price of $158.00 per ADS. The net proceeds from this transaction after underwriting discounts and commissions were approximately $324.6 million.

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,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
Research and development	$ 2,384	$ 2,218	$ 7,225	$ 5,638
Sales, general and administrative	9,101	6,851	26,289	18,899
	$ 11,485	$ 9,069	$ 33,514	$ 24,537

For the three months ended September 30, 2019 and 2018, $0.8 million and $0.5 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively. For the nine months ended September 30, 2019 and 2018, $2.1 million and $1.5 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively.

Note 8: Commitments and Contingencies

As of September 30, 2019, the Company was not a party to any material legal proceedings. 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.

Note 9: Leases

The Company leases buildings, land, equipment, and automobiles. Additionally, the Company has growing and cultivation contracts that contain embedded facility leases. The Company determines if an arrangement is a lease or contains a lease at contract inception. For contracts that are or contain leases, the Company records right-of-use (ROU) lease assets and lease liabilities at lease commencement based on the present value of lease payments over the lease term. The lease term includes renewal option periods when those options are reasonably certain to be exercised. The present value of lease payments is calculated using the Company's incremental collateralized borrowing rate unless an implicit rate is readily determinable. ROU lease assets include any upfront payments and exclude lease incentives. The Company accounts for lease and non-lease components as a single lease component for all of its leases except embedded leases, for which the lease and non-lease components are accounted for separately.

Leases are classified at lease commencement as either operating leases or finance leases. Operating lease assets are included in non-current assets and operating lease liabilities are included in other current liabilities and operating lease liabilities in our condensed consolidated balance sheets. Operating lease cost is recognized on a straight-line basis over the lease term. Finance lease assets are included in property, plant and equipment, net, and finance lease liabilities are included in other current liabilities and finance lease liabilities in our condensed consolidated balance sheets. Finance lease cost is recognized as depreciation expense of fixed assets and interest expense on finance lease liabilities. Leases with an initial term of 12 months or less are not recorded in the consolidated balance sheets and expense for these leases is recognized on a straight-line basis over the lease term.

The Company's lease costs consist of the following:

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
	(in thousands)	(in thousands)
Lease cost		
Operating lease cost (1)	$ 1,829	$ 5,079
Finance lease cost		
Amortization of leased assets	92	286
Interest on lease liabilities	104	296
Total lease cost	$ 2,025	$ 5,661

(1) Includes short-term lease expense and variable cost, which are immaterial.

For the three and nine months ended September 30, 2019, approximately $0.5 million and $1.7 million of operating and finance lease cost related to manufacturing operations was capitalized into inventory, respectively.

The following table summarizes cash flow information related to the Company's lease obligations:

	Nine Months Ended September 30, 2019
	(in thousands)
Operating cash used for operating leases	$ 4,062
Operating cash used for finance leases	$ 296
Financing cash used for finance leases	$ 317

In the three and nine months ended September 30, 2019, $3.1 million of operating lease assets were exchanged for lease liabilities.

The following table summarizes the Company's lease assets and liabilities:

	As of September 30, 2019
	(in thousands)
Lease assets	
Operating lease assets	$ 20,438
Finance lease assets	4,870
Total lease assets	$ 25,308
Lease liabilities	
Current	
Operating lease liabilities	5,398
Finance lease liabilities	282
Non-current	
Operating lease liabilities	17,007
Finance lease liabilities	5,297
Total lease liabilities	$ 27,984

The following table summarizes other supplemental information related to the Company's lease obligations:

	As of September 30, 2019
Weighted average remaining lease term (years)	
Operating leases	7.3
Finance leases	14.5
Weighted average discount rate	
Operating leases	5.9%
Finance leases	7.6%

The Company's future minimum annual lease payments under operating and finance leases as of September 30, 2019 are as follows:

	Operating Leases	Finance Leases
	(in thousands)	
2019 (remaining 3 months)	$ 1,164	$ 180
2020	5,245	683
2021	4,640	683
2022	3,649	676
2023	3,009	673
2024	2,812	673
Thereafter	9,035	5,786
Total lease payments	$ 29,554	$ 9,354
Less amounts representing interest	7,149	3,775
Total lease obligations	$ 22,405	$ 5,579

Prior to January 1, 2019, the Company accounted for leases under the previous U.S. GAAP lease guidance, Accounting Standards Codification Topic 840, *Leases*. Rent expense for operating leases for the three months and nine months ended September 30, 2018 was $1.1 and $3.2 million, respectively. The aggregate future minimum rent payments under leases in effect as of December 31, 2018 were $6.4 million in 2019, $6.9 million in 2020, $5.7 million in 2021, $4.2 million in 2022, $2.8 million in 2023, and $11.8 million thereafter.

Note 10: Sale of Priority Review Voucher

In April 2019, the Company sold the rare pediatric disease PRV it received from the FDA in connection with the United States approval of Epidiolex to Biohaven Pharmaceutical Holding Ltd. for consideration of $105.0 million. The net proceeds of $104.1 million from the sale of the PRV was recognized as a gain on the sale of an intangible asset within other income on the consolidated statements of operations, as the PRV did not have a carrying value on the Company's consolidated balance sheet at the time of sale.

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

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this quarterly report on Form 10-Q (this Quarterly Report), and the audited financial statements and notes thereto as of and for the three-month transition period ended December 31, 2018 included with our Transition Report on Form 10-KT (our Transition Report), filed with the Securities and Exchange Commission, or SEC.

This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Quarterly Report and our Transition Report. Actual results may differ materially from those contained in any forward-looking statements.

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 development of plant-derived cannabinoid therapeutics through our proven drug discovery and development processes, our intellectual property portfolio, and regulatory and manufacturing expertise.

Our lead cannabinoid product is Epidiolex, a pharmaceutical formulation of cannabidiol (CBD) for which we retain global commercial rights. Epidiolex is approved in the United States for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome, in patients two years of age and older. LGS and Dravet syndrome are severe childhood-onset, drug-resistant epilepsy syndromes. We launched Epidiolex in the United States on November 1, 2018. On September 23, 2019, we 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 LGS or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older.

We continue to develop Epidiolex for additional indications. Earlier this year, we announced positive top-line Phase 3 results in the use of Epidiolex to treat seizures associated with Tuberous Sclerosis Complex (TSC), a rare and severe form of childhood-onset epilepsy affecting approximately 50,000 individuals in the United States and one to two million worldwide. In this trial, Epidiolex met its primary endpoint, which was the reduction in seizure frequency of the 25 mg/kg/day dose group vs. placebo (p=0.0009). Results for both the 25 and 50 mg/kg/day dose groups were similar, with seizure reductions of 48.6% and 47.5% from baseline, respectively, vs. 26.5% for placebo (50 mg/kg/day vs. placebo, p=0.0018). All key secondary endpoints were supportive of the effects on the primary endpoint. The safety profile observed was consistent with findings from previous studies, with no new safety risks identified. We expect to file a supplemental new drug application with FDA for this indication in early 2020 and, soon after, expect to seek supplemental approval in Europe. 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 Dravet syndrome and LGS).

We have begun recruiting patients for a pivotal trial in the treatment of Rett syndrome, a rare, non-inherited neurodevelopmental disorder affecting approximately one in 10,000 to 15,000 live female births. This trial will focus on the behavioral abnormalities associated with the disorder.

Previously, we developed the world's first plant-derived cannabinoid prescription drug, Sativex (nabiximols), which was first approved for the treatment of spasticity due to multiple sclerosis in 2010 in the United Kingdom and was subsequently approved in numerous additional countries outside the United States. We are now advancing preparations to seek approval for Sativex in the United States. We met with the Food and Drug Administration in December 2018 to discuss the optimal regulatory pathway for U.S. approval of Sativex and are now in the process of planning an additional clinical program, which is expected to commence in early 2020. We expect to commercialize Sativex in the U.S. using our in-house commercial organization.

We have a deep pipeline of additional cannabinoid product candidates that includes compounds in Phase 1, Phase 2, and Phase 3 trials for orphan childhood-onset neurological conditions, schizophrenia and glioblastoma. Our pipeline includes research in autism spectrum disorder and Rett syndrome, using both CBD and cannabidivarin (CBDV). In addition, we have received Orphan Drug Designation and Fast Track Designation from the FDA for intravenous (IV) CBD for the treatment of Neonatal Hypoxic Ischemic Encephalopathy (NHIE). NHIE is a brain injury caused by lack of oxygen or blood flow during or near birth. The prevalence of NHIE is estimated to range from 0.1 to 1.0% of newborns. A Phase 1 trial of IV CBD formulation in healthy volunteers has been completed and we expect to commence a safety study in patients in the fourth quarter of 2019.

Critical Accounting Estimates

Our 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 Transition Report on Form 10-KT for the transition period ended December 31, 2018. There have been no material changes to the critical accounting estimates previously disclosed in our Transition Report on Form 10-KT for the transition period ended December 31, 2018.

Recent Accounting Pronouncements

The adoption of new accounting standards, including the new standard related to accounting for leases, is discussed in Note 2 to our interim unaudited condensed consolidated financial statements. For further details regarding our leases, refer to Note 9 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, 2019 and 2018:

	Three Months Ended September 30,		
	2019	2018	Increase/Decrease
	(in thousands)		
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	$ 90,849	$ 2,343	$ 88,506
Other revenue	$ 122	77	45
Total revenues	90,971	2,420	88,551
Operating expenses:			
Cost of product sales	8,150	1,399	6,751
Research and development	36,301	28,943	7,358
Selling, general and administrative	64,178	52,685	11,493
Total operating expenses	108,629	83,027	25,602
Loss from operations	(17,658)	(80,607)	62,949
Interest income	2,249	1,283	966
Interest expense	(272)	(297)	25
Other income	—	—	—
Foreign exchange gain (loss)	1,889	(823)	2,712
(Loss) income before income taxes	(13,792)	(80,444)	66,652
Income tax (benefit)	(35)	(565)	530
Net (loss) income	$ (13,757)	$ (79,879)	$ 66,122

The following table summarizes the results of our operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		
	2019	2018	Increase/Decrease
	(in thousands, except per share amounts)		
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	$ 201,312	$ 8,249	$ 193,063
Other revenue	944	496	448
Total revenues	202,256	8,745	193,511
Operating expenses:			
Cost of product sales	19,901	4,815	15,086
Research and development	99,143	117,541	(18,398)
Selling, general and administrative	181,529	116,644	64,885
Total operating expenses	300,573	239,000	61,573
Loss from operations	(98,317)	(230,255)	131,938
Interest income	6,646	3,041	3,605
Interest expense	(805)	(935)	130
Other income	104,117	—	104,117
Foreign exchange gain (loss)	2,801	(5,123)	7,924
Income (loss) before income taxes	14,442	(233,272)	247,714
Income tax (benefit) expense	(1,485)	79	(1,564)
Net income (loss)	$ 15,927	$ (233,351)	$ 249,278

Product net sales

Our product net sales consist of sales of Epidiolex, which we launched in the United States in November 2018 and also sell through certain early access programs outside of the United States, and sales of Sativex outside of the United States pursuant to license agreements with commercial partners. On September 23, 2019, we announced that the European Commission approved the marketing authorization for Epidyolex and we expect to launch Epidyolex in certain European countries beginning in the fourth quarter of 2019.

Product net sales for the three months ended September 30, 2019 consist of $86.1 million in net sales of Epidiolex in the United States, $1.9 million of Epidyolex sales outside of the United States, and $2.8 million in net sales of Sativex.

Product net sales for the nine months ended September 30, 2019 consist of $188.0 million in net sales of Epidiolex in the United States, $3.9 million of Epidyolex sales outside of the United States, and $9.4 million in net sales of Sativex.

The increase in product net sales to $90.8 million and $201.3 million for the three and nine months ended September 30, 2019, respectively, compared to $2.3 million and $8.2 million for the three and nine months ended September 30, 2018, respectively, was primarily due to the recent launch of Epidiolex in the United States.

Other revenue

Other revenue for the three and nine months ended September 30, 2019 and 2018 consists of remaining development fees related to the Otsuka license agreement that was terminated in December 2017.

Costs of product sales

Cost of product sales increased $6.8 million, or 483%, for the three months ended September 30, 2019 to $8.2 million, or 9% of product net sales, compared to $1.4 million, or 60% of product net sales, for the three months ended September 30, 2018. The increase in cost of product sales is primarily due to an increase in product net sales of Epidiolex in the United States. The reduction in cost of product sales as a percentage of product net sales is due to the positive impact in the three months ended September 30, 2019 of directly commercializing Epidiolex in the United States compared to the same period in the prior year when product net sales consisted only of Sativex sales outside of the United States through license partners.

Cost of product sales increased $15.1 million, or 313%, for the nine months ended September 30, 2019 to $19.9 million, or 10% of product net sales, compared to $4.8 million, or 58% of product net sales, for the nine months ended September 30, 2018. The increase in cost of product sales is primarily due to an increase in product net sales of Epidiolex in the United States. The reduction in cost of product sales as a percentage of product net sales is due to the positive impact in the three months ended September 30, 2019 of directly commercializing Epidiolex in the United States compared to the same period in the prior year when product net sales consisted only of Sativex sales outside of the United States through license partners.

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, 2019, we consider the following research and development projects to be our most significant late-stage product candidates:

- Epidiolex for the treatment of TSC (United States and Europe)
- Sativex for spasticity associated with MS (United States)

On September 23, 2019, we announced that the European Commission (EC) approved the marketing authorization for Epidyolex in Europe.We have received Orphan Designation from the European Commission for Orphan Medicinal Products for Epidyolex for Dravet syndrome and LGS.

We have completed our Phase 3 trial in TSC and have reported positive top-line results. We expect to file a supplemental new drug application with the FDA for this indication in early 2020 and, soon after, expect to seek supplemental approval in Europe.

In December 2017, we terminated our license agreement with Otsuka and we have reacquired full ownership of the development and commercialization rights to Sativex in the United States. We met with the FDA in December 2018 to discuss the optimal regulatory pathway for U.S. approval of Sativex and are now in the process of planning an additional clinical program, which is expected to commence in early 2020.

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 external third-party costs for clinical trials by product candidate, but do not seek to allocate all research and development costs by individual project. The components of research and development expense for the three and nine month periods ended September 30, 2019 and 2018 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)		(in thousands)	
External clinical trial expense				
Epidiolex	$ 5,745	$ 9,081	$ 19,881	$ 25,022
Other programs	3,904	750	8,537	1,848
Total external clinical trial expense	9,649	9,831	28,418	26,870
Research and development tax and expense credits	(681)	(1,723)	(2,191)	(3,322)
Other internal research and development	27,333	20,835	72,916	93,993
Total research and development expense	$ 36,301	$ 28,943	$ 99,143	$ 117,541

Research and development expenses increased $7.4 million, or 25%, to $36.3 million for the three months ended September 30, 2019 compared to $28.9 million in 2018, primarily due to an increase in internal costs for both early and late stage development programs. For the nine months ended September 30, 2019, research and development expenses decreased $18.4 million, or 16%, to $99.1 million compared to $117.5 million for the nine months ended September 30, 2018, primarily due to the prior period impact of inventory production costs for Epidiolex that were charged to research and development expenses prior to FDA approval in June 2018.

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 in preparation for commercialization of Epidiolex in Europe.

SG&A expenses increased $11.5 million, or 22%, to $64.2 million for the three months ended September 30, 2019 compared to $52.7 million in 2018. For the nine months ended September 30, 2019, SG&A expenses increased $64.9 million, or 56%, to $181.5 million compared to $116.6 million in 2018. The increase in SG&A expenses in 2019 was primarily due to an increase in employee-related expenses driven by the build-out of our commercial functions in the United States and Europe, costs related to the launch of Epidiolex in the United States, an increase

in all of our corporate support functions, and, to a smaller degree, an increase in insurance expenses and anincrease audit and legal fees.

Interest income

Interest income increased $1.0 million for the three months ended September 30, 2019 to $2.2 million compared to interest income of $1.2 million for the three months ended September 30, 2018. For the nine months ended September 30, 2019, interest income increased by $3.6 million to $6.6 million compared to interest income of $3.0 million for the nine months ended September 30, 2018. The increase in interest income in 2019 is primarily due to higher average cash and cash equivalent balances in 2019 compared to 2018.

Interest expense

Interest expense remained consistent for the three and nine months ended September 30, 2019 and 2018. Interest expense is primarily related to our finance lease liabilities.

Other income

Other income for the nine months ended September 30, 2019 consisted of $104.1 million in net proceeds from the sale of the priority review voucher that we received from the FDA in connection with the approval of Epidiolex in the United States.

Foreign currency exchange gain (loss)

Foreign currency exchange gains and losses are driven primarily by cash balances and accounts payable denominated in a currency other than the transacting entity's functional currency.

Foreign currency exchange gain for the three months ended September 30, 2019 was $1.9 million compared to a foreign currency exchange loss of $0.8 million for the three months ended September 30, 2018. For the nine months ended September 30, 2019, foreign currency exchange gain was $2.8 million compared to foreign currency exchange loss of $5.1 million for the nine months ended September 30, 2018. The gain for three and nine months ended September 30, 2019 compared to the loss for the three and nine months ended September 30, 2018 was primarily due to changes in our cash balances and the strengthening of the U.S. dollar against the British Pound.

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 tax benefit for the three months ended September 30, 2019 was less than $0.1 million compared to an income tax benefit of $0.6 million for the three months ended September 30, 2018. For the nine months ended September 30, 2019, income tax benefit was $1.5 million compared to an income tax expense of less than $0.1 million for the nine months ended September 30, 2018. Income taxes arise in the United States due to our U.S. subsidiary generating taxable profits. We incur losses in the United Kingdom. The decrease in income tax expense for 2019 was primarily due to excess tax benefits related to the exercise of stock options.

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 Epidiolex 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, 2019 of $554.7 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, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (107,522)	$ (180,310)
Net cash provided by (used in) investing activities	73,019	(24,146)
Net cash provided by financing activities	2,157	11
Cash and cash equivalents at end of period	$ 554,682	$ 354,913

Operating activities

As of September 30, 2019, we had cash and cash equivalents totaling $554.7 million compared to $354.9 million as of September 30, 2018. Net cash used in operating activities decreased by $72.8 million to $107.5 million for the nine months ended September 30, 2019 compared to $180.3 million for the nine months ended September 30, 2018. The decrease in cash used in operating activities is primarily attributable to a smaller net loss adjusted for non-cash items in the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018, partially offset by an increase in cash used to fund changes in operating assets and liabilities.

Investing activities

Net cash provided by investing activities increased by $97.1 million to $73.0 million for the nine months ended September 30, 2019 compared to net cash used by investing activities of $24.1 million for the nine months ended September 30, 2018. The increase in cash provided by investing activities is primarily due to the cash received on the sale of the priority review voucher of $104.1 million offset by cash used in the continued expansion of our manufacturing facilities.

Financing activities

Financing activities provided an increase in net cash of $2.2 million to $2.2 million for the nine months ended September 30, 2019 compared to financing activities providing cash of less than $0.1 million during the nine months ended September 30, 2018. The increase in cash provided by financing activities is primarily due to proceeds received from the exercise of stock options.

Equity Financings

In October 2018, we completed a public offering of 2,185,000 ADSs listed on the Nasdaq Global Market, representing 26,220,000 ordinary shares of the Company, at a price of $158.00 per ADS. The ADSs were sold pursuant to a shelf registration statement filed with the SEC.The net proceeds from this transaction after underwriting discounts and commissions were approximately $324.6 million.

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 currently operate in the United Kingdom 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

During the fiscal quarter ended March 31, 2019, we implemented certain internal controls over financial reporting in connection with our adoption of ASC Topic 842, *Leases*. There were no other changes in our internal controls in the nine months ended September 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II — OTHER INFORMATION

Item 1. ***Legal Proceedings***

As of September 30, 2019, the Company was not a party to any material legal proceedings. 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 1A. ***Risk Factors***

As of and for the period ended September 30, 2019, there have been no material changes from the risk factors previously disclosed by us in Part I, Item 1A "Risk Factors" of our Transition Report on Form 10-KT for the transition period ended December 31, 2018, except for the risk factors below, which have been updated:

The United Kingdom's vote in favor of withdrawing 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 is currently negotiating the terms of its exit from the European Union (Brexit), the negotiation period of which has now been extended up to January 31, 2020, unless further extension is agreed to by the parties. If no agreement can be reached and the United Kingdom leaves the European Union with no agreement (hard Brexit), there will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as on 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, including the potential for a delay in our European launch of Epidyolex. 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 Withdrawal 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.

In 2018, we received FDA approval for Epidiolex for the treatment of seizures associated with LGS or Dravet syndrome in patients two years of age and older. In September 2019, we received European Commission (EC) approval of the marketing authorization for Epidyolex. That approval subjects 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.

In 2018, we received FDA regulatory approval for Epidiolex for the treatment of seizures associated with LGS and Dravet syndrome in patients two years of age and older. In September 2019, we received the 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 Epidyolex for Dravet syndrome, LGS and TSC, and the COMP reconfirmed the designation for Dravet syndrome and LGS upon the EC's approval. The FDA approval 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 approval 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 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 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 may be classified as a passive foreign investment company, or PFIC, in any taxable year and U.S. holders of our ADSs could be subject to adverse U.S. federal income tax consequences.

The rules governing PFICs can have adverse effects for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. The determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. Based on our estimated gross income, the average value of our assets, including goodwill and the nature of our active business, we do not believe that we were classified as a PFIC for U.S. federal income tax purposes for the U.S. taxable year ending December 31, 2018. There can be no assurance, however, that we will not be considered to be a PFIC for this taxable year or any particular year in the future because PFIC status is factual in nature, depends upon factors not wholly within our control, generally cannot be determined until the close of the taxable year in question and is determined annually.

If we are a PFIC, U.S. holders of our ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. A U.S. holder of our ADSs may be able to mitigate some of the adverse U.S. federal income tax consequences described above with respect to owning the ADSs if we are classified as a PFIC, provided that such U.S. investor is eligible to make, and validly makes, a "mark-to-market" election. In certain circumstances a U.S. holder can make a "qualified electing fund" election to mitigate some of the adverse tax consequences described with respect to an ownership interest in a PFIC by including in income its share of the PFIC's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable a U.S. holder to make a qualified electing fund election.

Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares, and therefore certain of the rights of shareholders, are governed by English law, including the provisions of the Companies Act 2006, and by our substituted articles of association (Articles of Association). These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. Certain differences between the provisions of the Companies Act 2006 applicable to us and the Delaware General Corporation Law (DGCL), relating to shareholders' rights and protections include, but are not limited to, the following.

- Under English law and our Articles of Association, each shareholder present at a general meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings. However, the voting rights of our shares are also governed by the provisions of a deposit agreement with our depositary bank.
- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to be offered on a proportionate basis any ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares proposed to be allotted for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- In the U.K., takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, where a bidder seeking to acquire us by means of a takeover offer has made an offer for our outstanding ordinary shares or ADSs and has acquired or unconditionally contracted to acquire not less than 90% of the ordinary shares or ADSs under the offer, under English law, the bidder can complete a "squeeze out" to obtain 100% of the shares to which the offer relates. Accordingly, acceptances of 90% of our outstanding ordinary shares or ADSs will likely be a condition in any takeover offer to acquire us, not 50% as is more common for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders present and voting at the shareholders' meeting convened to consider the scheme and representing 75% of the ordinary shares voting for approval.
- Under English law, certain matters require the approval by special resolution. To be passed, a special resolution requires (on a show of hands) not less than 75% of the votes cast by those entitled to vote or (on a poll) not less than 75% of the total voting rights of the members who (being entitled to do so) vote in person or by proxy on the resolution. The matters requiring approval by special resolution include amendments to the Articles of Association. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.
- Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.
- Under our Articles of Association, the quorum for a general meeting of shareholders is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer, and together holding at least one third in number in the total number of shares entitled to vote at the meeting. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. For a corporation organized under Delaware law, the minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

The U.K. City Code on Takeovers and Mergers (the Takeover Code), which is issued and administered by the U.K. Panel on Takeovers and Mergers (the Takeover Panel), provides a framework within which takeovers of companies subject to it are conducted, including, in particular, certain rules in respect of mandatory offers. In March 2018, the Takeover Panel confirmed that, based on our current circumstances, we are not subject to the Takeover Code. As a result, our shareholders are not entitled to the benefit of certain takeover offer protections provided under the Takeover Code. We believe that this position is unlikely to change at any time in the near future but, in accordance with good practice, we will review the situation on a regular basis and consult with the Takeover Panel if there is any change in our circumstances on this subject.

The legalization and use of medical and recreational marijuana in the United States and elsewhere may impact our business.

There is a substantial amount of change occurring in the United States regarding the use of medical and recreational marijuana products. While federal laws prohibit the sale and distribution of most marijuana products not approved or authorized by the FDA, at least 30 jurisdictions and the District of Columbia have enacted state laws to enable possession and use of marijuana for medical purposes, and at least ten jurisdictions for recreational purposes. Under the U.S. Farm Bill, enacted in late 2018, certain extracts and other material derived from certain marijuana plants are now descheduled. Although the marketing of such products as a food, dietary supplement, or for medical purposes remains subject to FDA requirements and is not permitted, the FDA is currently evaluating regulatory pathways to permit CBD in conventional foods and dietary supplements and held a public meeting on the subject in May 2019. In addition, proposed legislation in Congress could result in broader legalization of marijuana products. Although our business is quite distinct from that of unapproved marijuana and dietary supplement companies, future legislation or FDA action authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved marijuana products could affect our business.

Item 6. Exhibits.

Exhibit Number	Description
3.1*	Amended and Restated Memorandum & 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).
31.1**	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.
31.2**	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.
32.1**	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.
32.2**	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.
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 5, 2019

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

Date: November 5, 2019

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

Exhibit 31.1

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 5, 2019

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

Exhibit 31.2

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 5, 2019

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

Exhibit 32.1

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, 2019 (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 5, 2019

/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.

Exhibit 32.2

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, 2019 (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 5, 2019

/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.