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 June 30, 2020

OR

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

Commission File Number 001-35892

GW PHARMACEUTICALS PLC
(Exact name of Registrant as specified in its charter)

England and Wales **(State or other jurisdiction of incorporation or organization)**	**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 July 31, 2020, 373,717,172 Ordinary Shares were outstanding including 362,979,720 Ordinary Shares held as American Depositary Shares, each representing twelve Ordinary Shares, par value of £0.001 per share and 10,737,452 Ordinary Shares.

Table of Contents

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	$ 477,557	$ 536,933
Accounts receivable, net	80,357	48,883
Inventory	99,620	85,528
Prepaid expenses and other current assets	30,183	28,292
Total current assets	687,717	699,636
Property, plant, and equipment, net	125,106	127,765
Operating lease assets	22,333	24,916
Intangible assets	5,627	—
Goodwill	6,959	6,959
Deferred tax assets	18,123	18,123
Other assets	4,715	4,850
Total assets	$ 870,580	$ 882,249
Liabilities and stockholders' equity		
Accounts payable	$ 16,238	$ 9,990
Accrued liabilities	93,313	99,374
Current tax liabilities	2,004	437
Other current liabilities	6,947	7,760
Total current liabilities	118,502	117,561
Long-term liabilities:		
Finance lease liabilities	5,066	5,573
Operating lease liabilities	19,659	21,650
Other liabilities	10,416	11,431
Total long-term liabilities	35,141	38,654
Total liabilities	153,643	156,215
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock - Ordinary shares par value £0.001; 373,709,720 shares outstanding as of June 30, 2020; 371,068,436 shares outstanding as of December 31, 2019	575	570
Additional paid-in capital	1,655,500	1,632,046
Accumulated deficit	(854,752)	(837,959)
Accumulated other comprehensive loss	(84,386)	(68,623)
Total stockholders' equity	716,937	726,034
Total liabilities and stockholders' equity	$ 870,580	$ 882,249

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues				
Product net sales	$ 121,230	$ 71,489	$ 241,762	$ 110,463
Other revenue	67	549	168	822
Total revenues	121,297	72,038	241,930	111,285
Operating expenses				
Cost of product sales	8,708	6,620	19,477	11,751
Research and development	45,734	32,467	91,608	62,842
Selling, general and administrative	75,894	62,273	147,077	117,351
Total operating expenses	130,336	101,360	258,162	191,944
Loss from operations	(9,039)	(29,322)	(16,232)	(80,659)
Interest income	250	2,310	1,519	4,397
Interest expense	(297)	(268)	(581)	(533)
Other income	-	104,117	-	104,117
Foreign exchange gain	1,386	2,026	1,366	912
(Loss) income before income taxes	(7,700)	78,863	(13,928)	28,234
Income tax expense (benefit)	1,128	(885)	2,865	(1,450)
Net (loss) income	$ (8,828)	$ 79,748	$ (16,793)	$ 29,684
Net loss per share:				
Basic	$ (0.02)	$ 0.21	$ (0.04)	$ 0.08
Diluted	$ (0.02)	$ 0.21	$ (0.04)	$ 0.08
Weighted average shares outstanding:				
Basic	375,525	371,712	374,680	370,776
Diluted	375,525	377,435	374,680	376,674

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net (loss) income	$ (8,828)	$ 79,748	$ (16,793)	$ 29,684
Foreign currency translation adjustments	(1,335)	(4,878)	(15,763)	(1,080)
Comprehensive (loss) income	$ (10,163)	$ 74,870	$ (32,556)	$ 28,604

See accompanying notes to these condensed consolidated financial statements.

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

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

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

See accompanying notes to these condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (16,793)	$ 29,684
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange (gain) loss	(488)	882
Share-based compensation	24,677	23,330
Depreciation and amortization	5,514	4,808
Gain from sale of priority review voucher	—	(104,117)
Other	27	21
Changes in operating assets and liabilities:		
Accounts receivable, net	(31,794)	(27,924)
Inventory	(19,669)	(27,070)
Prepaid expenses and other current assets	(4,312)	(6,819)
Other assets	1,884	1,542
Accounts payable	6,625	3,488
Current tax liabilities	2,732	619
Accrued liabilities	(599)	13,887
Other liabilities	(2,145)	(2,192)
Net cash used in operating activities	(34,341)	(89,861)
Cash flows from investing activities		
Proceeds from sale of priority review voucher	—	104,117
Additions to property, plant and equipment	(11,362)	(22,515)
Additions to capitalized software	(1,455)	(1,017)
Additions to intangible assets	(6,404)	—
Net cash (used) provided by in investing activities	(19,221)	80,585
Cash flows from financing activities		
Proceeds from exercise of stock options	5	2,878
Payments in connection with common stock withheld for employee tax obligation	(1,223)	—
Payments on finance leases	(146)	(250)
Payments on landlord financing obligation	(283)	(273)
Net cash (used in) provided by financing activities	(1,647)	2,355
Effect of exchange rate changes on cash	(4,167)	(893)
Net decrease in cash and cash equivalents	(59,376)	(7,814)
Cash and cash equivalents at beginning of period	536,933	591,497
Cash and cash equivalents at end of period	$ 477,557	$ 583,683
Supplemental disclosure of cash flow information:		
Income taxes paid	251	3,907
Interest paid	581	533
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	1,727	856
Right-of-use asset obtained in exchange for operating liabilities	275	—

See accompanying notes to these condensed consolidated financial statements.

Note 1: Business Overview

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

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

Note 2: Summary of Significant Accounting Policies

Basis of Presentation

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

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

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

Use of Estimates

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

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

Fair Value of Financial Instruments

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

Accounts Receivable

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

Inventory

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

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

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

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity 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

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

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

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

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

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

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

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

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

The total amount deducted from gross sales for the allowances described above for the three and six months ended June 30, 2020 was $31.2 million and $62.3 million, respectively. The total amount deducted from gross sales for the allowances described above for the three and six months ended June 30, 2019 was $14.5 million and $22.0 million, respectively.

Sativex Product Net Sales

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

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

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

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

Other Revenue

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

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

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

Research and Development Expenses

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

Research and development expense is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government. Reimbursable research and development tax and expenditure credits were $1.1 million and $1.9 million for the three and six months ended June 30, 2020, respectively, compared to $0.7 million and $1.5 million for the same periods in 2019.

Concentration Risk

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

Share-based Compensation

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

Income Taxes

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

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

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

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

Recently Issued Accounting Standards

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

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

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

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

Note 3: Sativex License Agreements

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

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

Note 4: Fair Value Measurements

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

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

Note 5: Composition of Certain Balance Sheet Captions:

Inventory consisted of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Raw materials	$ 2,576	$ 1,976
Work in process	86,981	78,547
Finished goods	10,063	5,005
	$ 99,620	$ 85,528

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

	June 30, 2020	December 31, 2019
	(in thousands)	
Buildings	$ 4,423	$ 4,725
Machinery and equipment	35,516	36,323
Leasehold improvements	43,726	42,744
Office and IT equipment	5,288	3,837
Construction-in-process	76,270	78,485
	165,223	166,114
Accumulated depreciation	(40,117)	(38,349)
	$ 125,106	$ 127,765

Depreciation of property, plant, and equipment was $2.2 million and $2.1 million for the three months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020 and 2019, depreciation of property, plant, and equipment was $4.3 million and $4.2 million, respectively. The Company did not have any significant property, plant, or equipment write-offs in the three and six months ended June 30, 2020 and 2019.

Accrued liabilities consisted of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Accrued compensation and benefits	$ 21,092	$ 25,469
Accrued vendor fees	22,252	29,731
Clinical trial accruals	6,464	10,382
Accrued growing fees	2,422	3,818
Accrued sales rebates and discounts	34,289	22,995
Other	6,794	6,979
	$ 93,313	$ 99,374

Other current liabilities consisted of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Finance lease liabilities	$ 295	$ 305
Operating lease liabilities	5,579	5,902
Landlord financing	579	595
Other	494	958
	$ 6,947	$ 7,760

Other liabilities consisted of the following:

	June 30, 2020	December 31, 2019
	(in thousands)	
Landlord financing obligation	$ 8,270	$ 9,152
Other	2,146	2,279
	$ 10,416	$ 11,431

Note 6: Earnings Per Share

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

The Company incurred net losses for the three and six months ended June 30, 2020 and therefore did not include potentially dilutive common stock equivalents in the computation of diluted net loss per share. For the three and six months ended June 30, 2020, options totaling approximately 15.8 million ordinary shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands, except per share amounts)			
Net (loss) income for basic and diluted EPS	$ (8,828)	$ 79,748	$ (16,793)	$ 29,684
Weighted-average shares for basic EPS	375,525	371,712	374,680	370,776
Effect of dilutive securities	—	5,723	—	5,898
Weighted-average shares for diluted EPS	375,525	377,435	374,680	376,674
Net (loss) income per share:				
Basic EPS	$ (0.02)	$ 0.21	$ (0.04)	$ 0.08
Diluted EPS	$ (0.02)	$ 0.21	$ (0.04)	$ 0.08

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
Research and development	$ 2,625	$ 2,443	$ 4,924	$ 4,841
Sales, general and administrative	9,909	9,074	18,169	17,187
	$ 12,534	$ 11,517	$ 23,093	$ 22,028

For the three months ended June 30, 2020 and 2019, $0.8 million and $0.7 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively. For the six months ended June 30, 2020 and 2019, $1.6 million and $1.3 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively.

Note 8: Commitments and Contingencies

As of June 30, 2020, 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 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

Overview

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

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

On April 6, 2020, we announced that we received notification from the United States Drug Enforcement Administration confirming that Epidiolex is no longer subject to the Controlled Substances Act, effective immediately.

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

We continue to develop Epidiolex for additional indications. In March 2020, we applied for approval of Epidyolex for the treatment of TSC in Europe, which is currently under review by the European Medicines Agency. This filing follows our announcement of positive results from a Phase 3 trial in the use of Epidiolex to treat seizures associated with TSC. Although we had begun to recruit patients for a pivotal trial of Epidiolex in the treatment of Rett syndrome, a rare, non-inherited neurodevelopmental disorder affecting approximately one in 10,000 to 15,000 live female births, the recruitment is currently on hold due to public health concerns related to the COVID-19 pandemic. We are ready to reopen recruitment once conditions allow. This trial will focus on the behavioral abnormalities associated with the disorder.

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

In addition to nabiximols, our pipeline includes cannabinoid product candidates for schizophrenia, autism spectrum disorder, and Neonatal Hypoxic Ischemic Encephalopathy.

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

Impact of COVID-19 on our Business

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

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

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

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

While we are continuing the clinical trials we have underway in sites across the globe, we have currently stopped enrolling new patients for existing trials, and we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our planned clinical trials and other research and development activities during the remainder of 2020.

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

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

Critical Accounting Estimates

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

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

Recent Accounting Pronouncements

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

Results of Operations

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

	Three Months Ended June 30,		
	2020	2019	Increase/Decrease
	(in thousands)		
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	$ 121,230	$ 71,489	$ 49,741
Other revenue	67	549	(482)
Total revenues	121,297	72,038	49,259
Operating expenses:			
Cost of product sales	8,708	6,620	2,088
Research and development	45,734	32,467	13,267
Selling, general and administrative	75,894	62,273	13,621
Total operating expenses	130,336	101,360	28,976
Loss from operations	(9,039)	(29,322)	20,283
Interest income	250	2,310	(2,060)
Interest expense	(297)	(268)	(29)
Other income	—	104,117	(104,117)
Foreign exchange gain	1,386	2,026	(640)
(Loss) income before income taxes	(7,700)	78,863	(86,563)
Income tax expense (benefit)	1,128	(885)	2,013
Net (loss) income	$ (8,828)	$ 79,748	$ (88,576)

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

	Six Months Ended June 30,		
	2020	2019	Increase/Decrease
	(in thousands, except per share amounts)		
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	$ 241,762	$ 110,463	$ 131,299
Other revenue	168	822	(654)
Total revenues	241,930	111,285	130,645
Operating expenses:			
Cost of product sales	19,477	11,751	7,726
Research and development	91,608	62,842	28,766
Selling, general and administrative	147,077	117,351	29,726
Total operating expenses	258,162	191,944	66,218
Loss from operations	(16,232)	(80,659)	64,427
Interest income	1,519	4,397	(2,878)
Interest expense	(581)	(533)	(48)
Other income	—	104,117	(104,117)
Foreign exchange gain	1,366	912	454
(Loss) income before income taxes	(13,928)	28,234	(42,162)
Income tax expense (benefit)	2,865	(1,450)	4,315
Net (loss) income	$ (16,793)	$ 29,684	$ (46,477)

Product net sales

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

Product net sales for the three months ended June 30, 2020 consists of $117.7 million in net sales of Epidiolex and $3.5 million in net sales of Sativex. Product net sales for the three months ended June 30, 2019 consists of $69.2 million in net sales of Epidiolex and $2.3 million in net sales of Sativex. The $49.7 million increase in product net sales for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily due to the growth of U.S. Epidiolex revenue and the launch of Epidiolex in certain European markets.

Product net sales for the six months ended June 30, 2020 consists of $233.8 million in net sales of Epidiolex and $7.9 million in net sales of Sativex. Product net sales for the six months ended June 30, 2019 consists of $103.9 million in net sales of Epidiolex and $6.6 million in net sales of Sativex. The $131.3 million increase in product net sales for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily due to the growth of U.S. Epidiolex revenue and the launch of Epidiolex in certain European markets.

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

Other revenue

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

Cost of product sales

Cost of sales increased $2.1 million, or 32%, in the three months ended June 30, 2020 to $8.7 million, or 7% of product net sales, compared to $6.6 million, or 9% of product net sales in the three months ended June 30, 2019. The increase in cost of sales in dollars is primarily due to an increase in product net sales. The reduction in cost of sales as a percentage of product net sales is due to the positive impact of a higher mix of Epidiolex sales as a percentage of total product net sales in the quarter ended June 30, 2020 compared to the same period in the prior year and reduction in unit costs due to manufacturing efficiencies.

Cost of sales increased $7.7 million, or 66%, in the six months ended June 30, 2020 to $19.5 million, or 8% of product net sales, compared to $11.8 million, or 11% of product net sales in the six months ended June 30, 2019. The increase in cost of sales in dollars is primarily due to an increase in product net sales. The reduction in cost of sales as a percentage of product net sales is due to the same factors described above with respect to the three month periods ended June 30, 2020 and 2019.

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 June 30, 2020, we consider the following research and development projects to be our most significant late-stage product candidates:

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

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

On September 23, 2019, we announced that the European Commission 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.

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

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

In December 2017, we terminated our license agreement with Otsuka and we have reacquired full ownership of the development and commercialization rights to nabiximols in the United States. We expect to commence five Phase 3 trials of nabiximols for the treatment of spasticity due to multiple sclerosis, two of which are expected to commence in the second half of 2020 and three of which are expected to commence in the first half of 2021.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)		(in thousands)	
External clinical trial expense				
Epidiolex	$ 4,018	$ 5,654	$ 9,931	$ 14,136
Nabiximols	—	530	1,413	602
Other programs	2,443	2,748	6,068	4,031
Total external clinical trial expense	6,461	8,932	17,412	18,769
Research and development tax and expense credits	(1,075)	(753)	(1,891)	(1,510)
Other internal research and development	40,348	24,288	76,087	45,583
Total research and development expense	$ 45,734	$ 32,467	$ 91,608	$ 62,842

Research and development expenses increased $13.2 million, or 41%, to $45.7 million for the three months ended June 30, 2020 compared to $32.5 million for the same period in 2019, primarily due to an increase in internal costs for early stage development programs, partially offset by a reduction expenses related to the Epidiolex open-label extension trial in the United States due to the transition of patients to commercial product in early 2019 and a reduction in other external clinical trial expenses related delays caused by the COVID-19 pandemic.

Research and development expenses increased $28.8 million, or 46%, to $91.6 million for the six months ended June 30, 2020 compared to $62.8 million for the same period in 2019, primarily due to an increase in internal costs for early stage development programs, an increase in external clinical trial expenses for nabiximols, as well as increased spending for the schizophrenia and Rett syndrome programs. These increases were partially offset by a reduction in expenses related to the Epidiolex open-label extension trial in the United States due to the transition of patients to commercial product in early 2019 and a reduction in other external clinical trial expenses related delays caused by the COVID-19 pandemic.

The COVID-19 pandemic impacted the timeline of some of our clinical trials and other research and development activities during the second quarter of 2020 and may cause further clinical trial delays in the remainder of 2020. Accordingly, the COVID-19 pandemic may result in lower research and development expenses in 2020 than was previously anticipated.

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 Epidyolex in Europe.

SG&A expenses increased $13.6 million, or 22%, to $75.9 million for the three months ended June 30, 2020 compared to $62.3 million for the same period in 2019. The increase in SG&A expenses in 2020 was primarily due to an increase in employee-related expenses driven by the build-out of our commercial functions in Europe, an increase in all of our corporate support functions, including information technology infrastructure, and, to a smaller degree, an increase in insurance expenses and legal fees. These increases were partially offset by a decrease in travel related expenses due to the impact of COVID-19.

SG&A expenses increased $29.7 million, or 25%, to $147.1 million for the six months ended June 30, 2020 compared to $117.4 million for the same period in 2019. The increase in SG&A expenses in the six months ended June 30, 2020 was primarily due to the same factors discussed above with respect to the increase in SG&A expenses for the second quarter of 2020.

Interest income

Interest income decreased $2.0 million for the three months ended June 30, 2020 to $0.3 million compared to interest income of $2.3 million for the same period in 2019. Due to uncertainties in the financial markets related to COVID-19, we transitioned a large portion of our cash equivalent balances to lower interest earning U.S. government securities money market funds from relatively higher interest rate bearing commercial money market funds in early 2020.

Interest income decreased $2.9 million for the six months ended June 30, 2020 to $1.5 million compared to interest income of $4.4 million for the same period in 2019. The decrease in interest income in is primarily due to the same factor described above with regard to the decrease in interest income for the three months ended June 30, 2020.

Interest expense

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

Foreign currency exchange gain

Foreign currency exchange gain was $1.4 million for both the three and six month periods ended June 30, 2020 compared to foreign currency exchange gains of $2.0 million and $0.9 for the three and six months ended June 30, 2019, respectively. Foreign currency exchange gains and losses are driven primarily by cash balances, accounts payable and intercompany balances denominated in a currency other than the transacting entity’s functional currency. Our primary foreign currency exposure is the exchange rate between the British pound and the U.S. dollar.

Income tax expense (benefit)

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

Income taxes arise in the United States due to our U.S. subsidiary generating taxable profits. We incur losses in the United Kingdom. Income tax expense for the three months ended June 30, 2020 was $1.1 million compared to an income tax benefit of $0.9 million for the three months ended June 30, 2019. For the six months ended June 30, 2020, income tax expense was $2.9 million compared to an income tax benefit of $1.5 million for the six months ended June 30, 2019. The increase in income tax expense for 2020 was primarily due to the impact of stock option deductions and higher pre-tax income.

Liquidity and Capital Resources

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

- the timing of achievement of future 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 June 30, 2020 of $477.6 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 six months ended June 30, 2020 and 2019:

	Six Months Ended June 30,	
	2020	2019
Net cash used in operating activities	$ (34,341)	$ (89,861)
Net cash used in investing activities	(19,221)	80,585
Net cash (used in) provided by financing activities	(1,647)	2,355
Cash and cash equivalents at end of period	$ 477,557	$ 583,683

Operating activities

As of June 30, 2020, we had cash and cash equivalents totaling $477.6 million compared to $583.7 million as of June 30, 2019. Net cash used in operating activities decreased by $55.6 million to $34.3 million for the six months ended June 30, 2020 compared to $89.9 million for the six months ended June 30, 2019. The decrease in cash used in operating activities is primarily attributable to a $131.3 million increase in net product sales, partially offset by a $7.7 million increase in cost of product sales, a $29.7 million increase in SG&A expenses, $28.8 million increase in research and development spend, and a $2.8 million increase in cash used to fund changes in net operating assets and liabilities.

Investing activities

Net cash used in investing activities was $19.2 million for the six months ended June 30, 2020 compared to net cash provided by investing activities of $80.6 million for the six months ended June 30, 2019. The cash used in investing activities as of June 30, 2020 included $11.4 million in capital expenditures, primarily due to the continued expansion of our manufacturing facilities, and $6.4 million used to require the rights to commercialize Sativex in the U.K. from Bayer. In the six months ended June 30, 2019, the increase in cash provided by investing activities was primarily attributed to the cash received on the sale of the priority review voucher of $104.1 million.

Financing activities

Net cash used in financing activities increased by $4.0 million to $1.6 million for the six months ended June 30, 2020 compared to financing activities providing cash of $2.4 million during the six months ended June 30, 2019. The increase in cash used in financing activities is primarily attributable to payments made in connection with common stock withheld for employee tax obligations and a decrease in proceeds received from the exercise of stock options.

Contractual Obligations

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

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Interest Rate Risk

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

Currency Risk

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

Item 4. Controls and Procedures

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

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

Changes in Internal Control Over Financial Reporting

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

PART II — OTHER INFORMATION

Item 1. ***Legal Proceedings***

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

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

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

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

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

In July 2020, the FDA expanded the approval of Epidiolex, adding a new indication of seizures associated with TSC and expanding all indications to patients one year of age and older. Epidiolex is now approved to treat seizures associated with LGS, Dravet syndrome, or TSC in patients one year of age and older. In September 2019, we received EC approval of the marketing authorization for Epidyolex. We have received Orphan Drug Designation from the FDA for Epidiolex for seizures associated with LGS, Dravet syndrome and TSC. We also received Orphan Designation from the EMA's COMP for Epidyolex for Dravet syndrome, LGS and TSC, and the COMP reconfirmed the designation for LGS and Dravet syndrome upon the EC's approval. In Europe, Epidyolex has only been approved for use as adjunctive therapy of seizures associated with LGS or Dravet syndrome, in conjunction with clobazam, for patients two years of age and older. We are focusing a significant portion of our activities and resources on Epidiolex, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize Epidiolex in the U.S. and Europe.

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, mandatory safety labeling changes or product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us, or suspension or revocation of product approvals;

- imposition of risk evaluation and mitigation strategies, or REMS;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

- successfully complete pre-clinical and other nonclinical studies and clinical trials, including assessment of abuse potential;
- demonstrate to the FDA, EMA and similar foreign regulatory authorities that the efficacy of Epidiolex, nabiximols or any other product candidates in clinical trials can be attributed to the investigative product and not exclusively to its interaction with concomitant medications. It is possible that FDA may convene an advisory committee of external experts to consider any of our other drug candidates, and the course and outcome of meetings with these advisory committees can be hard to predict;
- receive regulatory approvals from the FDA, EMA and similar foreign regulatory authorities;
- produce, through a validated process, in manufacturing facilities inspected and approved by regulatory authorities, including the FDA and EMA, sufficiently large quantities of the product candidate, and the related Botanical Drug Substances, or BDSs, to permit successful commercialization;
- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates, or otherwise establish collaborations with third parties for the commercialization of our product candidates;
- obtain reimbursement from payers such as government health care programs and insurance companies and other third-party payers, as well as achieve commercially attractive levels of pricing;
- secure acceptance of our product candidates from physicians, health care payers, patients and the medical community;
- create positive publicity surrounding our product candidates;

- manage our spending as costs and expenses increase due to clinical trials and commercialization; and
- obtain and enforce sufficient intellectual property for our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

Our operations have consumed substantial amounts of cash since inception. As of June 30, 2020, we reported a net operating cash outflow of $34.3 million and a net cash outflow from investing activities of $19.2 million.

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

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

- the timing of FDA approval, if any, and approvals in international markets of our product candidates, if at all;
- the timing and amount of revenue from sales of our products, or revenue from grants or other sources;
- the rate of progress and cost of our clinical trials and other product development programs;
- costs of establishing or outsourcing sales, marketing and distribution capabilities;

- costs and timing of completion of expanded in-house manufacturing facilities as well as any outsourced growing and commercial manufacturing supply arrangements for our product candidates;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs of operating as a U.S. public company;
- the effect of competing technological and market developments;
- personnel, facilities and equipment requirements;
- general economic, industry and market conditions other events or factors, many of which are beyond our control, such as the recent COVID-19 outbreak; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

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

Operating results may vary significantly in future periods.

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

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

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

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

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

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

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

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

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

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

Item 6. Exhibits

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

Exhibit Number	Description
3.1*	Substituted Articles of Association of GW Pharmaceuticals plc (incorporated by reference to Exhibit 3.1 to our Annual Report on Form 10-K filed with the SEC on November 29, 2018).
10.1*	GW Pharmaceuticals plc 2020 Long-Term Incentive Plan (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form S-8 (File No. 333-238737)), filed with the SEC on May 27, 2020
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: August 7, 2020

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

Date: August 7, 2020

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: August 7, 2020

/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: August 7, 2020

/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 June 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 7, 2020

/s/ Justin Gover

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

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

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

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 June 30, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 7, 2020

/s/ Scott Giacobello

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

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

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