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 March 31, 2019

OR

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

Commission File Number 001-35892

GW PHARMACEUTICALS PLC

(Exact name of Registrant as specified in its charter)

England and Wales **(State or other jurisdiction of incorporation or organization)**	**Not Applicable** **(I.R.S. Employer Identification No.)**
Sovereign House, Vision Park **Chivers Way, Histon** **Cambridge, CB24 9BZ** **United Kingdom** **(Address of principal executive offices)**	**+44 1223 266800** **(Registrant's telephone number, including area code)**

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 ☑

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**

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

None

As of April 30, 2019, 368,625,620 shares were outstanding including 353,893,356 shares held as American Depositary Shares, each representing twelve Ordinary Shares, par value of £0.001 per share and 14,732,264 Ordinary Shares.

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PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 521,669	$ 591,497
Accounts receivable, net	19,251	4,192
Inventory	48,559	33,030
Prepaid expenses and other current assets	19,389	17,903
Total current assets	608,868	646,622
Property, plant, and equipment, net	102,029	90,832
Operating lease assets	20,077	—
Goodwill	6,959	6,959
Deferred tax assets	8,584	8,720
Other assets	3,040	2,935
Total assets	$ 749,557	$ 756,068
Liabilities and stockholders' equity		
Accounts payable	$ 10,794	$ 9,796
Accrued liabilities	59,782	52,477
Current tax liabilities	1,730	2,384
Other current liabilities	5,651	1,559
Total current liabilities	77,957	66,216
Long-term liabilities:		
Finance lease liabilities	5,801	5,690
Operating lease liabilities	16,374	—
Other liabilities	9,696	10,082
Total long-term liabilities	31,871	15,772
Total liabilities	109,828	81,988
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Ordinary shares par value £0.001; 368,613,440 shares outstanding as of March 31, 2019; 366,616,688 shares outstanding as of December 31, 2018	567	564
Additional paid-in capital	1,593,056	1,581,144
Accumulated deficit	(879,004)	(828,940)
Accumulated other comprehensive loss	(74,890)	(78,688)
Total stockholders' equity	639,729	674,080
Total liabilities and stockholders' equity	$ 749,557	$ 756,068

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues		
Product net sales	$ 38,974	$ 2,812
Other revenue	273	229
Total revenues	39,247	3,041
Operating expenses		
Cost of product sales	5,131	1,625
Research and development	30,375	43,485
Selling, general and administrative	55,078	26,173
Total operating expenses	90,584	71,283
Loss from operations	(51,337)	(68,242)
Interest income	2,087	759
Interest expense	(265)	(325)
Foreign exchange loss	(1,114)	(640)
Loss before income taxes	(50,629)	(68,448)
Income tax (benefit) expense	(565)	1,013
Net loss	$ (50,064)	$ (69,461)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.20)
Weighted average common shares outstanding, basic and diluted	369,823	340,252

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	2018
Net loss	$ (50,064)	$ (69,461)
Other comprehensive gain:		
Foreign currency translation adjustments	3,798	4,108
Comprehensive loss	$ (46,266)	$ (65,353)

See accompanying notes to these condensed consolidated financial statements.

GW PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)
(unaudited)

	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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2017	337,964	$ 527	$ 1,220,206	$ (523,683)	$ (73,952)	$ 623,098
Issuance of common stock from exercise of stock options	549	1	—	—	—	1
Net loss	—	—	—	(69,461)	—	(69,461)
Share-based compensation	—	—	6,858	—	—	6,858
Other comprehensive income	—	—	—	—	4,108	4,108
Balances at March 31, 2018	338,513	$ 528	$ 1,227,064	$ (593,144)	$ (69,844)	$ 564,604

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (50,064)	$ (69,461)
Adjustments to reconcile net loss to net cash used in operating activities:		
Foreign exchange loss	797	873
Share-based compensation	11,142	6,859
Depreciation and amortization	2,417	2,307
Deferred income taxes	—	2,128
Changes in operating assets and liabilities:		
Accounts receivable, net	(14,998)	(320)
Inventory	(14,295)	672
Prepaid expenses and other current assets	(874)	(492)
Other assets	659	(3)
Accounts payable	1,998	652
Current tax liabilities	(654)	(2,684)
Accrued liabilities	6,328	(7,005)
Other current liabilities	191	1,103
Long-term liabilities	(1,029)	(30)
Net cash used in operating activities	(58,382)	(65,401)
Cash flows from investing activities		
Additions to property, plant and equipment	(12,087)	(6,056)
Additions to capitalized software	(199)	(338)
Net cash used in investing activities	(12,286)	(6,394)
Cash flows from financing activities		
Proceeds from exercise of stock options	773	1
Payments on finance leases	(179)	(72)
Payments on landlord financing obligation	(138)	(137)
Net cash provided by (used in) financing activities	456	(208)
Effect of exchange rate changes on cash	384	11
Net decrease in cash and cash equivalents	(69,828)	(71,992)
Cash and cash equivalents at beginning of period	591,497	559,227
Cash and cash equivalents at end of period	$ 521,669	$ 487,235
Supplemental disclosure of cash flow information:		
Income taxes paid	88	1,672
Interest paid	265	325
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	714	1,823

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") are primarily involved in the development of cannabinoid prescription medicines using botanical extracts derived from the cannabis plant. The Company is developing a portfolio of cannabinoid medicines, of which the lead product is *Epidiolex*®, an oral medicine for the treatment of refractory childhood epilepsies.

The Company is a public limited company, which has had 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 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.

In September 2018, the Company changed its fiscal year end to December 31 from September 30 and filed a transition annual report on Form 10-KT ("Annual Report on Form 10-KT") with the SEC for the three-month transition period ended December 31, 2018 on February 28, 2019.

Note 2: Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual financial statements. These accounting principles were applied on a basis consistent with those of the consolidated financial statements contained in the Company's Annual Report on Form 10-KT for the three-month transition period ended December 31, 2018. In the Company's opinion, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of our financial statements for interim periods.

The condensed consolidated balance sheet as of December 31, 2018 was derived from audited annual financial statements but does not include all annual disclosures required by U.S. GAAP. These interim financial statements should be read in conjunction with the audited financial statements for the transition period ended December 31, 2018 included in our Annual Report on Form 10-KT. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the full year or any other future periods.

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Fair Value of Financial Instruments

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

Accounts Receivable

Accounts receivable are recorded net of customer allowances for prompt payment discounts, chargebacks, and doubtful accounts. Allowances for prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. As of March 31, 2019 and December 31, 2018, the Company determined that an allowance for doubtful accounts was not required and 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.

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

Revenue Recognition

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

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

Epidiolex Product Net Sales

Epidiolex was approved by the FDA in June 2018. Subsequent to the approval by the FDA, the United States Drug Enforcement Agency ("DEA") took action to change the classification of Epidiolex from a Schedule I controlled substance to a Schedule V controlled substance, thereby allowing Epidiolex to be prescribed and distributed in the United States. On November 1, 2018, the Company launched sales of Epidiolex to specialty pharmacies ("SPs") and specialty distributors ("SDs"). The Company recognizes revenue from product sales upon receipt of product at the SPs and SDs, the date at which the control is transferred, net of the following allowances which are reflected each of these as either 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 with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. 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.

The total amount deducted from gross sales for the allowances described above was $7.5 million for the three months ended March 31, 2019.

Sativex® Product Net Sales

Sales of Sativex, which is currently being commercialized for spasticity due to multiple sclerosis ("MS") outside the United States, are made pursuant to license agreements with commercial partners. The Company has entered into license agreements for the commercialization of Sativex in Europe, Canada, Israel, Mexico, and South America. Under these license agreements, the Company sells fully labeled Sativex vials to its commercial partners for a contractually agreed price, which is generally based on percentages of the commercial partners' in-market net selling price charged to end customers. Product net sales revenue related to Sativex shipments to commercial license partners is recognized when shipped, the date at which the control is transferred. The Company commercializes Sativex in Australia and New Zealand through a consignment relationship with a local distributor. Product net sales revenue related to Sativex sales in Australia and New Zealand are recognized when the product is sold through to the end customer.

Other Revenue

The Company's other revenue primarily consists of research and development fee revenue for research and development services provided under a collaboration agreement with Otsuka Pharmaceutical Co. Ltd ("Otsuka") that was terminated in December 2017 and variable consideration milestone payments related to the Sativex license agreements.

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

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

Research and Development Expenses

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

Research and development expense is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government. Reimbursable research and development tax and expenditure credits were $0.8 million and $1.1 million for the three months ended March 31, 2019 and 2018, respectively.

Concentration Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, investment securities, and accounts receivable. The Company's cash and cash equivalents balances are primarily in depository accounts 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.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period. For the purpose of this calculation, vested nominal strike-price options are considered common shares outstanding. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury stock method. The Company incurred net losses for all periods presented and therefore excluded all potentially dilutive securities in the calculation of diluted net loss per share. For the three months ended March 31, 2019 and 2018, options totaling approximately 12.4 million and 13.4 million ordinary shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

New Accounting Pronouncements

On January 1, 2019, the Company adopted a new accounting standard issued by the Financial Accounting Standards Board ("FASB") on accounting for leases using the modified retrospective method. This new accounting

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

As a result of adoption of the new standard, the Company recorded operating lease assets and liabilities of approximately $20.5 million and $21.1 million, respectively as of January 1, 2019. The operating lease liability was determined based on the present value of the remaining minimum rental payments and the operating lease asset was determined based on the value of the lease liability, adjusted for existing deferred rent balances, which were previously included in other current liabilities and other liabilities. Accounting for the Company's finance leases remains substantially unchanged. As a result of the adoption of the new leasing accounting standard, the Company's build-to-suit asset has been reclassified to buildings and the build-to-suit financing obligation has been reclassified to finance lease obligation in the condensed consolidated balance sheets. The adoption of the new standard did not materially impact the Company's consolidated results of operations or cash flows.

In addition, the adoption of this new accounting standard resulted in increased qualitative and quantitative disclosures regarding the amount, timing, and uncertainty of cash flows arising from leases. For further details, see Note 8 *Leases*.

Note 3: Fair Value Measurements

At March 31, 2019 and December 31, 2018, the Company's cash equivalents consisted of money market funds, which are classified as Level 1 within the fair value hierarchy defined by authoritative guidance.

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

Note 4: Composition of Certain Balance Sheet Captions:

Inventory consisted of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Raw materials	$ 1,255	$ 676
Work in process	41,179	28,709
Finished goods	6,125	3,645
	$ 48,559	$ 33,030

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

	March 31, 2019	December 31, 2018
	(in thousands)	
Buildings	$ 4,710	$ 4,573
Machinery and equipment	33,717	32,598
Leasehold improvements	37,142	36,004
Office and IT equipment	2,689	2,481
Construction-in-process	55,847	44,546
	134,105	120,202
Accumulated depreciation	(32,076)	(29,370)
	$ 102,029	$ 90,832

Depreciation of property and equipment was $2.1 million and $2.2 million for the three months ended March 31, 2019 and 2018, respectively. The Company did not retire any property, plant, or equipment in the three months ended March 31, 2019 and 2018.

Accrued liabilities consisted of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Accrued compensation and benefits	$ 18,223	$ 18,482
Accrued vendor fees	15,108	11,452
Clinical trial accruals	12,309	10,059
Accrued growing fees	1,958	2,717
Accrued sales rebates and discounts	5,181	628
Other	7,003	9,139
	$ 59,782	$ 52,477

Other current liabilities consisted of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Finance lease liabilities	$ 291	$ 400
Operating lease liabilities	4,531	—
Landlord financing	563	539
Other	266	620
	$ 5,651	$ 1,559

Other liabilities consisted of the following:

	March 31, 2019	December 31, 2018
	(in thousands)	
Landlord financing obligation	$ 9,569	$ 9,434
Other	127	648
	$ 9,696	$ 10,082

Note 5: Stockholders' Equity

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

Note 6: 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 March 31,	
	2019	2018
	(in thousands)	
Research and development	$ 2,398	$ 1,287
Sales, general and administrative	8,113	5,158
	$ 10,511	$ 6,445

For the three months ended March 31, 2019 and 2018, $0.6 million and $0.4 million of share-based compensation related to manufacturing operations was capitalized into inventory, respectively.

Note 7: Commitments and Contingencies

As of March 31, 2019, the Company was not a party to any material legal proceedings. The Company is not aware of any other proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

Note 8: Leases

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

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

As of March 31, 2019, the Company has a lease agreement for office space that has not yet commenced with fixed lease payments totaling $3.2 million. The lease is expected to commence in mid-2019.

No operating or finance lease assets were exchanged for lease liabilities in the three months ended March 31, 2019.

The Company's lease costs consist of the following:

	Three Months Ended March 31, 2019
	(in thousands)
Lease cost	
Operating lease cost (1)	$ 1,423
Finance lease cost	
Amortization of leased assets	98
Interest on lease liabilities	84
Total lease cost	$ 1,605

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

For the three months ended March 31, 2019, approximately $0.4 million of operating and finance lease cost related to manufacturing operations was capitalized into inventory.

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

	Three Months Ended March 31, 2019
	(in thousands)
Operating cash used for operating leases	$ 1,100
Operating cash used for finance leases	$ 84
Financing cash used for finance leases	$ 179

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

	As of March 31, 2019
	(in thousands)
Lease assets	
Operating lease assets	$ 20,077
Finance lease assets	5,391
Total lease assets	$ 25,468
Lease liabilities	
Current	
Operating lease liabilities	4,531
Finance lease liabilities	291
Non-current	
Operating lease liabilities	16,374
Finance lease liabilities	5,801
Total lease liabilities	$ 26,997

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

	As of March 31, 2019
Weighted average remaining lease term (years)	
Operating leases	7.6
Finance leases	14.9
Weighted average discount rate	
Operating leases	5.8%
Finance leases	7.6%

The Company's future minimum annual lease payments under operating and finance leases as of March 31, 2019 are as follows:

	Operating Leases	Finance Leases
	(in thousands)	
2019 (remaining 9 months)	$ 3,606	$ 574
2020	4,673	726
2021	3,769	726
2022	2,728	718
2023	2,007	716
Thereafter	9,850	6,869
Total lease payments	$ 26,633	$ 10,329
Less amounts representing interest	5,728	4,237
Total lease obligations	$ 20,905	$ 6,092

Prior to January 1, 2019, the Company accounted for leases under the previous U.S. GAAP lease guidance, Accounting Standards Codification Topic 840, *Leases*. Rent expense for operating leases for the three months ended March 31, 2018 was $1.0 million. The aggregate future minimum rent payments under leases in effect as of December 31, 2018 were $6.4 million in 2019, $6.9 million in 2020, $5.7 million in 2021, $4.2 million in 2022, $2.8 million in 2023, and $11.8 million thereafter

Note 9: Subsequent Events

On March 15, 2019, the Company entered into a definitive agreement to sell its Rare Pediatric Disease Priority Review Voucher ("PRV") for $105.0 million. The Company was awarded the PRV under a FDA program intended to encourage the development of treatments for rare pediatric diseases. The Company received the PRV when Epidiolex was approved by the FDA for the treatment of seizures associated with Lennox-Gastaut Syndrome ("LGS") or Dravet syndrome.

The closing of the sale of the PRV was subject to antitrust review by U.S. federal agencies. Clearance of the transaction was received by the federal agencies subsequent to March 31, 2019 and the transaction closed on April 5, 2019. Because the contingencies preventing the closing of the transaction were not resolved until after March 31, 2019 and the Company maintained control of the PRV as of March 31, 2019, the sale of the PRV will be reflected in the Company's financial statements in the second quarter of 2019.

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

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

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

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from our proprietary cannabinoid product platform in a broad range of disease areas. In our 20 years of operations, we have established a world leading position in the development of plant-derived cannabinoid therapeutics through our proven drug discovery and development processes, our intellectual property portfolio and regulatory and manufacturing expertise. Our lead cannabinoid product is Epidiolex, a pharmaceutical formulation of cannabidiol ("CBD") for which we retain global commercial rights. Epidiolex was approved by the FDA on June 25, 2018, for the treatment of seizures associated with LGS, or Dravet syndrome, in patients two years of age and older. LGS and Dravet syndrome are severe childhood-onset, drug-resistant epilepsy syndromes. Epidiolex became commercially available in the United States on November 1, 2018.

On May 6, 2019, we announced positive top-line results of a randomized, double-blind, placebo-controlled Phase 3 clinical trial of Epidiolex in the treatment of seizures associated with Tuberous Sclerosis Complex ("TSC"), a rare and severe form of childhood-onset epilepsy. In this trial, Epidiolex met its primary endpoint, which was the reduction in seizure frequency of the 25 mg/kg/day dose group vs. placebo (p=0.0009). Results for both the 25 and 50 mg/kg/day dose groups were similar, with seizure reductions of 48.6% and 47.5% from baseline, respectively, vs. 26.5% for placebo (50 mg/kg/day vs. placebo, p=0.0018). All key secondary endpoints were supportive of the effects on the primary endpoint. The safety profile observed was consistent with findings from previous studies, with no new safety risks identified. We expect to file a supplemental new drug application for this indication in the fourth quarter of 2019.

In Europe, we submitted an application to the Committee for Medicinal Products for Human Use ("CHMP") in December 2017. We continue to work through the regulatory process and expect an opinion from the CHMP mid-2019. We have received Orphan Drug Designation from the FDA and the Committee for Orphan Medical Products ("COMP") for Epidiolex for LGS, Dravet syndrome and TSC. We continue to develop Epidiolex for additional indications and will soon commence a pivotal trial in the treatment of Rett syndrome, a rare, non-inherited neurodevelopmental disorder affecting approximately one in 10,000 to 15,000 live female births. This trial will focus on the behavioral abnormalities associated with the disorder.

Previously, we developed the world's first plant-derived cannabinoid prescription drug, Sativex (nabiximols), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States. In the United States, we met with the FDA in December 2018 to discuss the optimal regulatory pathway for U.S. approval of Sativex and are now in the process of planning a pivotal Phase 3 trial, which is expected to commence in the fourth quarter of 2019.

We have a deep pipeline of additional cannabinoid product candidates that includes compounds in Phase 1 and 2 trials for orphan childhood-onset neurological conditions, glioblastoma, and schizophrenia. Our pipeline includes research in autism spectrum disorder and Rett syndrome, using both CBD and cannabidivarin (CBDV). We reported positive Phase 2 data for our CBD:THC product in the treatment of glioblastoma multiforme. We have also reported positive Phase 2 data in schizophrenia. In addition, we have received Orphan Drug Designation and Fast Track Designation from the FDA for intravenous CBD for the treatment of Neonatal Hypoxic Ischemic Encephalopathy ("NHIE"), for which a Phase 1 trial has been completed. NHIE is an acute or sub-acute brain injury due to asphyxia from a sentinel event at birth, such as ruptured placenta, parental shock and even increased heart rate.

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

Recent Accounting Pronouncements

The adoption of new accounting standards, including the new standard related to accounting for leases, is discussed in Note 2 to our interim unaudited condensed consolidated financial statements. For further details regarding our leases, refer to Note 8 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 March 31, 2019 and 2018:

	Three Months Ended March 31,		
	2019	2018	Increase/Decrease
	(in thousands, except per share amounts)		
Consolidated Statement of Operations Data:			
Revenues:			
Product net sales	$ 38,974	$ 2,812	$ 36,162
Other revenue	273	229	44
Total revenues	39,247	3,041	36,206
Operating expenses:			
Cost of product sales	5,131	1,625	3,506
Research and development	30,375	43,485	(13,110)
Selling, general and administrative	55,078	26,173	28,905
Total operating expenses	90,584	71,283	19,301
Loss from operations	(51,337)	(68,242)	16,905
Interest income	2,087	759	1,328
Interest expense	(265)	(325)	60
Foreign exchange loss	(1,114)	(640)	(474)
Loss before income taxes	(50,629)	(68,448)	17,819
Income tax (benefit) expense	(565)	1,013	(1,578)
Net loss	$ (50,064)	$ (69,461)	$ 19,397

Product net sales

Our product net sales consist of sales of Epidiolex, which we launched in the United States in November of 2018 and also sell through certain early access programs outside of the United States, and sales of Sativex outside of the United States pursuant to license agreements with commercial partners.

Product net sales for the three months ended March 31, 2019 consist of $33.5 million in net sales of Epidiolex in the United States, $1.2 million of Epidiolex sales under early access programs outside of the United States, and $4.3 million in net sales of Sativex.

The $36.2 million increase in product net sales to $39.0 million for the three months ended March 31, 2019 compared to $2.8 million for the three months ended March 31, 2018 was primarily due to the recent launch of Epidiolex in the United States.

Other revenue

Other revenue for the three months ended March 31, 2019 and 2018 consists of remaining development fees related to the Otsuka license agreement that was terminated in December 2017.

Costs of product sales

Cost of product sales increased $3.5 million, or 216%, for the three months ended March 31, 2019 to $5.1 million, or 13% of product net sales, compared to $1.6 million, or 58% of product net sales for the three months ended March 31, 2018. The increase in cost of product sales is primarily due to an increase in product net sales, which is primarily due to the launch of Epidiolex in the United States. The reduction in cost of product sales as a percentage of product net sales is due to the positive impact in the three months ended March 31, 2019 of directly commercializing Epidiolex in the United States compared to the same period in the prior year when products net sales consisted only of Sativex sales outside of the United States through license partners.

Research and development expenses

We believe that our future revenues and cash flows are most likely to be affected by the successful development and approval of our significant late-stage research and development candidates. As of March 31, 2019, we consider the following research and development projects to be our most significant late-stage product candidates:

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

We have submitted a marketing authorization application in December 2017 for both the Dravet syndrome and LGS indications in Europe. This application has been validated by the European Medicines Agency. We continue to work through the regulatory process and expect an opinion from the CHMP mid-2019. We have also received Orphan Designation from the COMP for Epidiolex for Dravet syndrome, LGS and TSC.

We have completed our Phase 3 trial in TSC and have reported positive top-line results. We expect to file an sNDA for this indication in Q4 2019.

In December 2017, we terminated our license agreement with Otsuka and we have reacquired full ownership of the development and commercialization rights to Sativex in the United States. We met with the FDA in December 2018 to discuss the optimal regulatory pathway for U.S. approval of Sativex and are now in the process of planning a pivotal Phase 3 trial, which is expected to commence in the fourth quarter of 2019.

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 consumables used in the conduct of our in-house research programs, payments for research work conducted by sub-contractors and sponsorship of work by our network of academic collaborative research scientists, costs associated with safety studies and costs associated with the development of Epidiolex, Sativex, and our other pipeline product candidates. Research and development expense is presented net of reimbursements from reimbursable tax and expenditure credits from the U.K. government.

We track external third-party costs for clinical trials by product candidate, but do not seek to allocate all research and development costs by individual project. The components of research and development expense for the three months ended March 31, 2019 and 2018 are as follows:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
External clinical trial expense		
Epidiolex	$ 8,482	$ 8,174
Other programs	1,355	30
Total external clinical trial expense	9,837	8,204
Research and development tax and expense credits	(757)	(1,085)
Other internal research and development	21,295	36,366
Total research and development expense	$ 30,375	$ 43,485

Research and development expenses decreased $13.1 million, or 30%, to $30.4 million for the three months ended March 31, 2019 compared to $43.5 million the three months ended March 31, 2018. The decrease in research and development expenses was primarily due to the prior period impact of inventory production costs for Epidiolex that were charged to research and development expenses prior to FDA approval in June 2018.

Sales, general and administrative expenses

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

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

SG&A expenses increased $28.9 million, or 110%, to $55.1 million in three months ended March 31, 2019 compared to $26.2 million in 2018. The increase in SG&A expenses in 2019 was primarily due to an increase in employee-related expenses driven by the build-out of our commercial functions in the United States and Europe, costs related to the November 2018 launch of Epidiolex in the United States, an increase in all of our corporate support functions, and, to a smaller degree, an increase in insurance expenses and an increase audit and legal fees related to our transition to domestic registrant status with the SEC.

Interest Income

Interest income increased $1.3 million for the three months ended March 31, 2019 to $2.1 million compared to interest income of $0.8 million for the three months ended March 31, 2018. The increase in interest income in 2019 is primarily due to higher average cash and cash equivalent balances in 2019 compared to 2018 and increases in interest rates during the period.

Interest Expense

Interest expense remained consistent for the three-month periods ended March 31, 2019 and 2018. Interest expense is primarily related to our finance lease liabilities.

Foreign currency exchange loss

Foreign currency exchange gains and losses are driven primarily by cash balances and accounts payable denominated in a currency other than the transacting entity's functional currency. Our primary exposure to foreign currency exchange gains and losses relates to British Pound denominated cash balances held by GW Pharmaceuticals plc. The functional currency of GW Pharmaceuticals plc is the U.S. dollar.

Foreign currency exchange loss for the three months ended March 31, 2019 was $1.1 million compared to a foreign currency exchange loss of $0.6 million for the three months ended March 31, 2018. The increase in the foreign exchange loss in 2019 was due primarily to the weakening of the U.S. dollar against the British Pound.

Income tax expense (benefit)

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

Income tax benefit for the three months ended March 31, 2019 was $0.6 million compared to an income tax expense of $1.0 million for the three months ended March 31, 2018. Income taxes arise in the United States due to our U.S. subsidiary generating taxable profits. We incur losses in the United Kingdom. The decrease in income tax expense for 2019 was primarily due to the impact of stock option deductions and a lower U.S. tax rate.

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 March 31, 2019 of $521.7 million will be sufficient to fund our operations, including currently anticipated research and development activities and planned capital expenditures, for the foreseeable future, including for at least the next 12 months.

Cash Flows

The following table summarizes the results of our cash flows for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	$ (58,382)	$ (65,401)
Net cash used in investing activities	(12,286)	(6,394)
Net cash provided by (used in) financing activities	456	(208)
Cash and cash equivalents at end of period	$ 521,669	$ 487,235

Operating activities

As of March 31, 2019, we had cash and cash equivalents totaling $521.7 million compared to $487.2 million as of March 31, 2018. Net cash used in operating activities decreased by $7.0 million to $58.4 million for the three months ended March 31, 2019 compared to $65.4 million for the three months ended March 31, 2018. The decrease in cash used in operating activities is primarily attributable to a smaller net loss adjusted for non-cash items in the three months ended March 31, 2019 compared to the three months ended March 31, 2018, partially offset by an increase in cash used to fund changes in operating assets and liabilities.

Investing activities

Net cash used in investing activities increased by $5.9 million to $12.3 million for the three months ended March 31, 2019 compared to $6.4 million for the three months ended March 31, 2018. The increase in cash used in investing activities is primarily due to the continued expansion of our manufacturing facilities.

Financing activities

Financing activities provided an increase in net cash of $0.7 million to $0.5 million for the three months ended March 31, 2019 compared to cash used in financing activities of $0.2 million during the three months ended March 31, 2018. The increase in cash provided by financing activities is primarily due to proceeds received from the exercise of stock options.

Equity Financings

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

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Risk

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

Currency Risk

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

Item 4. Controls and Procedures

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

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

Changes in Internal Control Over Financial Reporting

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

PART II — OTHER INFORMATION

Item 1. ***Legal Proceedings***

As of March 31, 2019, the Company was not a party to any material legal proceedings. The Company is not aware of any other proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

Item 1A. ***Risk Factors***

As of and for the period ended March 31, 2019, 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-KT for the transition period ended December 31, 2018, except for the risk factors below, which have been updated:

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

The United Kingdom is currently negotiating the terms of its exit from the European Union ("Brexit"), the negotiation period of which has now been extended to October 31, 2019, unless further extension is agreed to by the parties. If no agreement can be reached and the United Kingdom leaves the European Union with no agreement ("hard Brexit"), there will be a period of considerable uncertainty particularly in relation to United Kingdom financial and banking markets as well as on the regulatory process in Europe. As a result of this uncertainty, financial markets could experience volatility which could adversely affect the market price of our ADSs. We may also face new regulatory costs and challenges that could have a material adverse effect on our operations, including the potential for a delay in our European launch of Epidiolex. In this regard, the EMA has already issued a notice reminding marketing authorization holders of centrally authorized medicinal products for human and veterinary use of certain legal requirements that need to be considered as part of Brexit, such as the requirement for the marketing authorization holder of a product centrally approved by the European Commission to be established in the European Union, and the requirement for some activities relating to centrally approved products, such as batch release and pharmacovigilance, to be performed in the European Union. As a result of the foregoing developments, and in the absence of any clear indication that any agreed form of a Withdrawal Agreement will contain a contrary requirement, we have taken steps to establish a network of subsidiary undertakings in the major European markets and have established pharmacovigilance and batch release operations in the European Union. Depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business worldwide more difficult. In addition, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue it could cause volatility in our financial results.

We may be classified as a passive foreign investment company, or PFIC, in any taxable year and U.S. holders of our ADSs could be subject to adverse U.S. federal income tax consequences.

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

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

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

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

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

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

- Under our Articles of Association, the quorum for a general meeting of shareholders is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer, and together holding at least one third in number in the total number of shares entitled to vote at the meeting. Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. For a corporation organized under Delaware law, the minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

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

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

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

Item 6. Exhibits.

Exhibit Number	Description
10.1**	PRV Transfer Agreement, dated March 15, 2019, by and between GW Research Ltd. and Biohaven Pharmaceutical Holding Ltd.
10.2*	Offer letter by and between Greenwich Biosciences, Inc. and Darren Cline (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on April 12, 2019)
10.3*	Severance Agreement, dated April 12, 2019, by and between Greenwich Biosciences, Inc. and Julian Gangolli (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on April 12, 2019)
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***	XBRL Instance Document
101.SCH***	XBRL Taxonomy Extension Schema Document
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

* Previously filed.
** Filed herewith.
*** Furnished 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: May 7, 2019

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

Date: May 7, 2019

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

EXHIBIT 10.1

PRV TRANSFER AGREEMENT

BY AND BETWEEN

BIOHAVEN PHARMACEUTICAL HOLDING LTD

AND

GW RESEARCH, LTD.

March 15, 2019

PRV TRANSFER AGREEMENT

This PRV Transfer Agreement (this "***Agreement***") is made and entered into as of March 15, 2019 (the "***Effective Date***"), by and between Biohaven Pharmaceutical Holding Ltd, including its Affiliates (collectively "***Buyer***") and GW Research, Ltd., including its Affiliates (collectively, "***Seller***"). Buyer and Seller may hereinafter be referred to individually as a "***Party***" and collectively as the "***Parties***".

Recitals

WHEREAS, Seller is the holder of all right, title and interest in and to the Priority Review Voucher (as defined below).

WHEREAS, Seller and Buyer each (a) desire that Buyer purchase from Seller, and Seller sell, transfer and assign to Buyer, the Transferred Rights (as defined below), all on the terms set forth herein (such transaction, the "***PRV Transfer***") and (b), in furtherance thereof, have duly authorized, approved and executed this Agreement and the other transactions contemplated by this Agreement in accordance with all applicable Legal Requirements (as defined below).

WHEREAS, Seller and Buyer desire to make certain representations, warranties, covenants and other agreements in connection with the PRV Transfer as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and their mutual undertakings hereinafter set forth, and intending to be legally bound, the Parties hereto agree as follows:

ARTICLE I
DEFINITIONS

1.1 Certain Definitions. As used in this Agreement, the following capitalized terms shall have the meanings indicated below:

(a) "***Affiliate***" means any Person which, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, for so long as such control exists, whether such Person is or becomes an Affiliate on or after the Effective Date. A Person shall be deemed to "control" another Person if it: (i) with respect to such other Person that is a corporation, owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction) of such other Person, or, with respect to such other Person that is not a corporation, has other comparable ownership interest; or (ii) has the power, whether pursuant to Contract, ownership of securities or otherwise, to direct the management and policies of such other Person.

(b) "***Alternative Transaction***" means, other than the transactions contemplated by this Agreement, any sale, assignment, transfer or encumbrance, whether by option, agreement, understanding or other arrangement, of any right, title, or interest in and to the Transferred Rights.

(c) "***Business Day***" means a day (i) other than Saturday or Sunday and (ii) on which commercial banks are open for business in New York, New York.

(d) "***Confidential Information***" means (i) any and all confidential and proprietary information, including, data, results, conclusions, know-how, experience, financial information, plans and forecasts, that may be delivered, made available, disclosed or communicated by a Party or its Affiliates or their respective Representatives to the other Party or its Affiliates or their respective Representatives,

related to the subject matter hereof or otherwise in connection with this Agreement and (ii) the terms, conditions and existence of this Agreement, including the negotiations between the Parties. "*Confidential Information*" will not include information that (A) at the time of disclosure, is generally available to the public, (B) after disclosure hereunder, becomes generally available to the public, except as a result of a breach of this Agreement by the recipient of such information, (C) becomes available to the recipient of such information from a Third Party that is not legally or contractually prohibited by the disclosing Party from disclosing such Confidential Information; or (D) was developed by or for the recipient of such information without the use of or reference to any of the Confidential Information of the disclosing Party or its Affiliates, as evidenced by the recipient's contemporaneous written records. Notwithstanding anything herein to the contrary, all Confidential Information included within the Transferred Rights shall constitute Confidential Information of the Buyer from and after the Closing Date.

(e) "***Contract***" means any written or oral legally binding contract, agreement, instrument, commitment or undertaking (including leases, licenses, mortgages, notes, guarantees, sublicenses, subcontracts and purchase orders).

(f) "***Damages***" means all losses, Liabilities, damages, settlements, claims, causes of action, Orders, awards, suits, taxes, fines, penalties, costs or expenses (including reasonable attorneys' and experts' fees and expenses).

(g) "***Encumbrance***" means any lien, pledge, charge, mortgage, easement, encroachment, imperfection of title, title exception, title defect, right of possession, right of negotiation or refusal, lease, security interest, encumbrance, adverse claim, interference or restriction on use or transfer.

(h) *"**Excluded Liabilities**"* has the meaning set forth in Section 2.1(b).

(i) *"**FDA**"* means the United States Food and Drug Administration.

(j) "***FDA Notification Package***" means, collectively, executed versions of the joint FDA notification cover letter, Seller transfer acknowledgement letter and Buyer transfer acknowledgment letter in the forms set forth in **Exhibits C-1, C-2**, and **C-3**, respectively, and, with respect to such joint FDA notification cover letter as set forth in **EXHIBIT C-1**, any other documentation referred to therein as being attached thereto, in each case, with respect to the purchase and sale of the Priority Review Voucher pursuant to this Agreement to be submitted to the FDA jointly by Buyer and Seller pursuant to Section 3.2(c).

(k) *"**FDC Act**"* means the United States Federal Food, Drug, and Cosmetic Act, 21 USC 301, *et seq*. as amended, and including any rules, regulations and requirements promulgated thereunder.

(l) "***Governmental Entity***" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority.

(m) "***HSR Act***" means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and including any rules, regulations and requirements promulgated thereunder.

(n) "***Knowledge***" means, with respect to Seller, the actual knowledge of Justin Gover, Chief Executive Officer of GW Pharmaceuticals, plc, Scott Giacobello, Chief Financial Officer of GW Pharmaceuticals, plc, Adam George, Director of GW Research, Ltd. and Dr. Volker Knappertz, Chief Medical Officer of GW Pharmaceuticals, plc, each after performing a reasonable inquiry.

(o) "***Legal Requirements***" means any federal, state, foreign, local, municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Entity and any Orders applicable to a Party or to any of its assets, properties or businesses. Legal Requirements shall include, with respect to Seller, any responsibilities, requirements, obligations, parameters and conditions relating to the Priority Review Voucher set forth in (i) the NDA Approval Letter, (ii) any other correspondence received by Seller or its Affiliates from the FDA regarding the Priority Review Voucher, (iii) Section 529 of the FDC Act (21 USC 360ff), or (iv) the November 17, 2014 FDA draft guidance document, "Rare Pediatric Disease Priority Review Vouchers, Guidance for Industry."

(p) "***Liabilities***" means all debts, liabilities and obligations, whether presently in existence or arising hereafter, accrued or fixed, absolute or contingent, matured or unmatured, determined or determinable, asserted or unasserted, known or unknown, including those arising under any law, action or Order and those arising under any Contract.

(q) "***NDA Approval Letter***" means the New Drug Application ("***NDA***") approval letter dated June 25, 2018 from the Department of Health and Human Services to Seller, Reference ID: 4282447, regarding NDA 210365 for Epidiolex® (cannabidiol) 100 mg/mL oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age and older, and granting the Priority Review Voucher. A copy of the NDA Approval Letter is attached hereto as **Exhibit A**.

(r) "***Notice of Intent to Use***" means notification to the FDA not later than ninety (90) days prior to the submission of a human drug application as defined in section 735(1) of the FDC Act (21 U.S.C. 379g(1)) of the intent to use a Priority Review Voucher for the human drug application, as described in section 529(b)(4) of the FDC Act (21 U.S.C. § 360ff(b)(4)).

(s) "***Order***" means any order, decree, edict, injunction, writ, award or judgment of any Governmental Entity.

(t) "***Person***" means any natural person, company, corporation, limited liability company, general partnership, limited partnership, trust, proprietorship, joint venture, business organization or Governmental Entity.

(u) "***Priority Review***" means review and action by the FDA on a human drug application not later than six months after receipt by the FDA of such application, as defined in Section 529(a)(1) of the FDC Act.

(v) "***Priority Review Fee***" has the meaning set forth in Section 12.3.

(w) *"**Priority Review Voucher**"* means the priority review voucher issued by the United States Department of Health and Human Services to Seller, as the sponsor of a rare pediatric disease product application, and assigned tracking number PRV NDA 210365, that entitles the holder of such voucher to Priority Review of a single human drug application submitted under section 505(b)(1) of the FDC Act or Section 3511(a) of the United States Public Health Service Act, as further defined in section 529(a)(2) of the FDC Act (21 USC 360ff(a)(2)), as evidenced by the NDA Approval Letter.

(x) "***Proceeding***" means any claim, action, arbitration, audit, hearing, investigation, litigation, proceeding or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Entity or arbitrator.

(y) *"**Purchase Price**"* has the meaning set forth in Section 2.2.

(z) "***Regulatory Change***" means any (i) new Legal Requirement, amendment, or supplement to any then-existing Legal Requirement, or (ii) new, amended, or supplemented term or condition imposed on the Priority Review Voucher that is not set forth in the NDA Approval Letter, that in either case of (i) or (ii) has been enacted, adopted, approved or imposed between the Effective Date and the Closing Date and adversely impacts the manner in which Buyer may use, receive, hold, transfer or otherwise exploit the Priority Review Voucher.

(aa) "***Representative***" means, with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

(bb) "***Third Party***" means any Person other than a Party and such Party's Affiliates.

(cc) *"**Transferred Rights**"* means (i) the Priority Review Voucher, and (ii) any and all rights, benefits and entitlements afforded to the holder of the Priority Review Voucher.

Other capitalized terms defined elsewhere in this Agreement and not defined in this Section 1.1 shall have the meanings assigned to such terms in this Agreement.

ARTICLE II
PURCHASE AND SALE

2.1 Purchase and Sale; No Assumed Liabilities.

(a) Upon the terms and subject to the conditions of this Agreement, at and as of the Closing, Buyer shall purchase from Seller, and Seller shall sell, transfer, convey, assign and deliver to Buyer, at the Closing, all of the Transferred Rights, in each case free and clear of all Encumbrances.

(b) Buyer shall not assume or be liable for any Liabilities of Seller or its Affiliates (fixed, contingent or otherwise, and whether or not accrued) in connection with the PRV Transfer (such Liabilities, "***Excluded Liabilities***").

2.2 Purchase Price. The total consideration to be paid by Buyer at the Closing for all of the Transferred Rights shall be ONE HUNDRED FIVE MILLION U.S. DOLLARS (U.S. $105,000,000.00) (the "***Purchase Price***").

2.3 Method of Payment. All payments to Seller shall be made in cash by wire transfer of immediately available funds to a bank account specified by Seller in writing to Buyer at least three (3) Business Days prior to the applicable payment date.

ARTICLE III
CLOSING

3.1 Closing. The consummation of the PRV Transfer contemplated by this Agreement (the "***Closing***") shall be conducted telephonically and/or via email or other similar means of correspondence on the third (3rd) Business Day after all of the conditions set forth in ARTICLE VII have been satisfied or waived (other than those conditions to be satisfied only by the delivery of certificates or other documents at the Closing, but subject to satisfaction or waiver of such condition) or such other date as may be mutually agreed upon by Buyer and Seller. The date on which the Closing actually takes place is referred to in this Agreement as the "***Closing Date***".

3.2 Transactions to be Effected at Closing.

(a) At the Closing, Seller shall deliver, or cause to be delivered, to Buyer:

(i) the item referred to in Section 7.2(c), appropriately executed;

(ii) a duly executed Bill of Sale, substantially in the form attached hereto as **EXHIBIT B** (the "***Bill of Sale***"); and

(iii) a copy of the joint FDA notification cover letter and the Seller transfer acknowledgement letter for inclusion in the FDA Notification Package, which FDA cover letter and Seller transfer acknowledgement letter shall be in the form of **EXHIBIT C-1** and **EXHIBIT C-2**, respectively, or such other form as the FDA may require as of the Closing Date.

(b) At the Closing, Buyer shall deliver, or cause to be delivered, to Seller:

(i) the item referred to in Section 7.3(c), appropriately executed;

(ii) a duly executed Bill of Sale;

(iii) payment of the Purchase Price, by wire transfer of immediately available funds to an account or accounts designated in writing by Seller to Buyer, such designation to occur at least three (3) Business Days prior to the Closing Date; and

(iv) a copy of the joint FDA notification cover letter and the Buyer transfer acknowledgement letter for inclusion in the FDA Notification Package, which FDA cover letter and Buyer transfer acknowledgement letter shall be in the form attached hereto as **EXHIBIT C-1** and **Exhibit C-3**, respectively, or such other form as the FDA may require as of the Closing Date.

(c) On the Closing Date, Buyer and Seller shall submit the fully executed FDA Notification Package to the FDA.

3.3 Title Passage; Notification.

(a) Title Passage. Upon the Closing, all of the right, title and interest of Seller in and to the Transferred Rights shall pass to Buyer.

(b) Filings; Notifications. Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Transferred Rights.

ARTICLE IV
PRE-CLOSING NOTIFICATION OF INTENT TO USE THE PRIORITY REVIEW VOUCHER

4.1 Pre-Closing Notification. Buyer may, on or after the Effective Date and prior to Closing, submit a Notice of Intent to Use the Priority Review Voucher substantially in the form attached hereto as **EXHIBIT F** to the FDA of its intent to use the Priority Review Voucher to obtain Priority Review of a human drug application of Buyer's choice in accordance with the applicable provisions of the FDC Act and the Priority Review Voucher (a "***Pre-Closing PRV Notice***").

(a) Upon the Effective Date, Seller shall deliver, or cause to be delivered, to Buyer a letter, substantially in the form set forth on **Exhibit D** hereto and duly executed by Seller, addressed to the FDA confirming the Parties' agreement, subject to approval under the HSR Act, to transfer the Priority Review Voucher to Buyer and confirming that Seller has authorized Buyer to submit a Pre-Closing PRV Notice.

(b) Buyer may submit a copy of the letter referred to in Section 4.1(a) to the FDA together with, or in support of, any Pre-Closing PRV Notice.

(c) Buyer shall notify Seller within three (3) Business Days of (i) any Pre-Closing PRV Notice given to the FDA and (ii) the date falling at least ninety (90) days after the date of such Pre-Closing PRV Notice that is specified by Buyer in a notice to the FDA as being the date on which Buyer intends to submit its new drug application to which that Pre-Closing PRV Notice relates (the "***Target PRV Use Date***"). For the avoidance of doubt, subject to the requirements of the FDC Act and the Approval Letter, the Target PRV Use Date shall be determined by Buyer in Buyer's sole discretion.

(d) The Parties shall, or shall cause their respective Affiliates to, keep the other Party reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from, the FDA in connection with any Pre-Closing PRV Notice. The Parties acknowledge and agree that (i) neither Party makes any representation or warranty that the FDA will accept the submission by Buyer prior to the Closing of such Pre-Closing PRV Notice or otherwise agree that such submission by Buyer prior to the Closing will allow the Buyer to submit a human drug application as defined in section 735(1) of the FDC Act (21 U.S.C. 379g(1)) for Priority Review within 90 days of submission by Buyer prior to the Closing of such Pre-Closing PRV Notice and (ii) it is not a condition to either Party's obligation to consummate the Closing that the FDA has so accepted such submission by Buyer or otherwise so agreed that such submission by Buyer will so allow Buyer to so submit such human drug application.

4.2 Withdrawal of Pre-Closing Notification. Without prejudice to Buyer's discretion to withdraw a Notice of Intent to Use the Priority Review Voucher at any time by notice to the FDA, the Parties acknowledge and agree that Buyer may withdraw any Pre-Closing PRV Notice if Closing has not occurred by the date that is forty-five (45) days from the Effective Date.

ARTICLE V
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer, as of the Effective Date and as of the Closing Date (except, in each case, to the extent such representations and warranties speak expressly as of a different date, and then, as of such date), as follows:

5.1 Organization, Standing and Power. Seller is a limited company duly organized and validly existing under the laws of England and Wales. Seller has the company power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect any of the Transferred Rights or Seller's ability to consummate the transactions contemplated by this Agreement. Seller is not in violation of its organizational or governing documents, in each case as amended to date.

5.2 Due Authority. Seller has the requisite company power and authority to enter into and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the PRV Transfer, have been duly and validly approved and authorized by all necessary company action on the part of Seller, and this Agreement has been duly executed and delivered by Seller. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Seller enforceable against Seller in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

5.3 Noncontravention. The execution and delivery by Seller of this Agreement does not, and the consummation of the transactions contemplated hereby, including the transfer of title to, ownership in, and possession of the Transferred Rights, will not, (a) result in the creation of any Encumbrance on any of the Transferred Rights or (b) conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (i) any provision of the organizational or governing documents of Seller, in each case as amended to date, (ii) any Contract to which Seller or any Affiliate of Seller is a party or by which it or its assets are bound which involves or affects in any way any of the Transferred Rights or (iii) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Seller or any Affiliate of Seller or any of the Transferred Rights (except, in the case of clauses (ii) and (iii) above, as would not, individually or in the aggregate, have a material adverse effect on the ability of Seller to consummate the sale of the Transferred Rights at Closing and perform its other obligations under this Agreement).

5.4 No Consents. Except for the submission to the FDA of the FDA Notification Package referenced in Section 3.2(c) and the filing of a premerger notification and report form under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Seller to enter into, and to perform its obligations under, this Agreement.

5.5 Title to Transferred Rights. Seller is the sole and exclusive owner of the Transferred Rights and owns and at the Closing will transfer to Buyer good and transferable title to the Transferred Rights free and clear of any Encumbrances. Seller has the full right to sell, transfer, convey, assign and deliver the Transferred Rights to Buyer at the Closing, free and clear of any Encumbrances. Seller has performed all actions necessary to perfect its ownership of, and its ability to transfer, the Transferred Rights.

5.6 Contracts. Except for this Agreement, there is no Contract to which Seller or any Affiliate of Seller is a party that involves or affects the ownership of, licensing of, title to, or use of any of the Transferred Rights.

5.7 Compliance With Legal Requirements. Seller and its Affiliates are, and at all times have been, in compliance in all material respects with each Legal Requirement that is or was applicable to (a) Seller's and its Affiliates' conduct, acts, or omissions with respect to any of the Transferred Rights or (b) any of the Transferred Rights. Seller and its Affiliates have not received any notice or other communication (whether oral or written) from any Person regarding any actual, alleged, possible or potential violation of, or failure to comply with, any such Legal Requirement.

5.8 Legal Proceedings. There is no pending, or to Seller's Knowledge, threatened Proceeding that involves or affects (or may involve or affect) the ownership of, licensing of, title to, or use of any of the Transferred Rights. None of the Transferred Rights are subject to any Order of any Governmental Entity or arbitrator.

5.9 Governmental Authorizations. Seller is not required to hold any license, registration, or permit issued by any Governmental Entity to own, use or transfer the Transferred Rights, other than such licenses, registrations or permits that have already been obtained.

5.10 Solvency. Seller is not entering into this Agreement with the actual intent to hinder, delay, or defraud any creditor of Seller. The remaining assets of Seller after the Closing will not be unreasonably small in relation to the business in which Seller will engage after the Closing. Upon and immediately following the Closing Date, after giving effect to all of the transactions contemplated by and in this Agreement (including the payment of the Purchase Price), Seller will not be insolvent and will have sufficient capital to continue in business and pay its debts as they become due.

5.11 Revocation; Use of Transferred Rights. The Priority Review Voucher has not been redeemed, transferred, terminated, cancelled or revoked, and neither Seller nor any of its Affiliates or any of their respective Representatives has taken or omitted to take any action, and to Seller's Knowledge there are no facts or circumstances, that would reasonably be expected to (with or without notice or lapse of time or both) result in the termination, cancellation or revocation of the Priority Review Voucher. Seller is not aware or in the possession of any information that would preclude or interfere with Buyer's ability to use the Transferred Rights to obtain Priority Review or any other benefit associated with the Transferred Rights following the Closing. There is no term or condition imposed by the FDA on the Priority Review Voucher that is not set forth in the NDA Approval Letter or Section 529 of the FDC Act. Seller has provided to Buyer true and complete copies of the NDA Approval Letter and all other communications between Seller or any of its Affiliates and the FDA regarding the Priority Review Voucher.

5.12 Marketed Product. Seller has initiated marketing in the United States of the rare pediatric disease product for which the Priority Review Voucher was awarded within the 365-day period beginning on the date of the FDA approval of such rare pediatric disease product and has marketed such product in the United States since such initiation.

5.13 Intent to Use. Neither Seller nor any of its Affiliates has filed or submitted to the FDA a Notice of Intent to Use the Priority Review Voucher to obtain a Priority Review.

5.14 No Broker. Seller has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Seller who would be entitled to any fee or commission payable by Buyer in connection with the transactions contemplated by this Agreement.

ARTICLE VI
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller as follows:

6.1 Organization, Standing and Power. Buyer is a company duly organized and validly existing business company limited under the laws of the British Virgin Islands. Buyer has the corporate power and authority to own, operate and lease its properties and to carry on its business as presently conducted and is duly qualified or licensed to do business and is in good standing in each jurisdiction where the character of its properties owned or leased or the nature of its activities make such qualification or licensing necessary, except where the failure to be so qualified or licensed would not, individually or in the aggregate, reasonably be expected to adversely affect Buyer's ability to consummate the transactions contemplated by this Agreement. Buyer is not in violation of its memorandum and articles of association, in each case as amended to date.

6.2 Authority. Buyer has the requisite corporate power and authority to enter into and perform its obligations under this Agreement. The execution, delivery and performance of this Agreement, and the consummation of the PRV Transfer, have been duly and validly approved and authorized by all necessary corporate action on the part of Buyer, and this Agreement has been duly executed and delivered by Buyer. This Agreement, upon execution by the Parties, will constitute a valid and binding obligation of Buyer enforceable against Buyer in accordance with its terms, subject only to the effect, if any, of (a) applicable bankruptcy and other similar laws affecting the rights of creditors generally and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

6.3 Noncontravention. The execution and delivery by Buyer of this Agreement does not, and the consummation of the transactions contemplated hereby will not, conflict with, or result in any violation of or default under (with or without notice or lapse of time, or both), or give rise to a right of termination, cancellation or acceleration of any obligation or loss of any benefit under, or require any consent, approval or waiver from any Person pursuant to, (a) any provision of the memorandum and articles of association of Buyer, in each case as amended to date, (b) any Contract to which Buyer or any Affiliate of Buyer is a party or by which it or its assets are bound or under which Buyer or any Affiliate of Buyer has material rights or benefits or (c) except as may be required to comply with the HSR Act, any Legal Requirements applicable to Buyer, except, in the case of clauses (b) and (c), as would not reasonably, individually or in the aggregate, be expected to adversely affect the ability of Buyer to consummate the transactions contemplated by this Agreement.

6.4 No Consents. Except for the submission to the FDA of the FDA Notification Package referenced in Section 3.2(c) and the filing of a premerger notification and report form under the HSR Act, no filing, authorization, consent, approval, permit, order, registration or declaration, governmental or otherwise, is necessary to enable or authorize Buyer to enter into, and to perform its obligations under, this Agreement.

6.5 No Broker. Buyer has not engaged, retained or entered into an agreement with any investment banker, broker, finder or other intermediary who has been authorized to act on behalf of Buyer who would be entitled to any fee or commission payable by Seller in connection with the transactions contemplated by this Agreement.

6.6 Financing. Buyer has sufficient funds to consummate the transactions contemplated by this Agreement.

ARTICLE VII
CONDITIONS TO CLOSING

7.1 Conditions Precedent of Buyer and Seller. Each Party's obligations to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) HSR Act. The applicable waiting period under the HSR Act relating to the transactions contemplated by this Agreement shall have expired or been terminated.

(b) No Injunctions or Restraints. No temporary restraining order, preliminary or permanent injunction or other material legal restraint or prohibition issued or promulgated by a Governmental Entity preventing the consummation of the transactions contemplated by this Agreement shall be in effect, and there shall not be any applicable Legal Requirement that makes consummation of the transactions contemplated by this Agreement illegal.

(c) No Governmental Litigation. There shall not be any Proceeding commenced or pending by a Governmental Entity seeking to prohibit, limit, delay, or otherwise restrain the consummation of this Agreement and/or the transactions contemplated hereby.

7.2 Buyer's Conditions Precedent. The obligations of Buyer to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Seller in ARTICLE V (other than the representations and warranties made by Seller in Sections 5.1, 5.2, 5.5, 5.8, 5.9, 5.11, 5.12 and 5.13) shall be true and correct in all material respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), *provided* that any such failure of such representations and warranties to be true and correct shall be disregarded if it would not, individually or in the aggregate, reasonably be expected to adversely impact the manner in which Buyer may use, receive, hold, transfer or otherwise exploit the Transferred Rights. Each of the representations and warranties made by Seller in Sections 5.1, 5.2, 5.5, 5.8, 5.9, 5.11, 5.12 and 5.13 shall be true and correct in all respects at and as of the Closing Date (or, in each case, if made as of a specified period or date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Seller is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Seller shall have delivered to Buyer a certificate, dated the Closing Date and duly executed by Seller, certifying that the conditions set forth in Sections 7.2(a) and 7.2(b) have been satisfied.

(d) No Regulatory Change. There shall not have occurred and remain in effect any Regulatory Change.

7.3 Seller's Conditions Precedent. The obligations of Seller to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver, at or prior to the Closing Date, of each of the following conditions precedent:

(a) Accuracy of Representations. Each of the representations and warranties made by Buyer in this Agreement shall be true and correct in all material respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date), except to the extent that such representations and warranties are qualified by the term "material", or words of similar import, in which case such representations and warranties (as so written, including the terms "material", or words of similar import) shall be true and correct in all respects at and as of the Closing Date (or, if made as of a specified period or date, as of such period or date).

(b) Performance of Covenants. All of the covenants and obligations that Buyer is required to comply with or to perform hereunder at or prior to the Closing Date shall have been complied with and performed in all material respects.

(c) Closing Certificate. Buyer shall have delivered to Seller a certificate, dated the Closing Date and duly executed by Buyer, certifying that the conditions set forth in Sections 7.3(a) and 7.3(b) have been satisfied.

ARTICLE VIII
PRE-CLOSING COVENANTS AND AGREEMENTS

8.1 Antitrust Notification.

(a) Seller and Buyer shall file, or shall cause their ultimate parent entities as defined in the HSR Act and its implementing rules thereto to file, as soon as practicable (but not later than seven (7) Business Days) after the Effective Date, any notifications required under the HSR Act, and shall respond as promptly as practicable to all inquiries or requests received from the Federal Trade Commission, the Antitrust Division of the Department of Justice or any other Governmental Entity for additional information or documentation. In connection therewith, the Parties shall, or shall cause their respective Affiliates to, (i) furnish to the other Party such necessary information and reasonable assistance as the other Party may reasonably request in connection with its preparation of any filing or submission that is necessary under the HSR Act, and (ii) keep the other Party reasonably apprised of the status of any communications with, and any inquiries or requests for additional information from the applicable Governmental Entity.

(b) Subject to applicable confidentiality restrictions or restrictions required by applicable Legal Requirements, each Party will notify the other promptly upon the receipt of (i) any comments or questions from any Governmental Entity in connection with any filings made pursuant to Section 8.1 or the transactions contemplated by this Agreement and (ii) any request by any Governmental Entity for information or documents relating to an investigation of the transactions contemplated by this Agreement. Without limiting the generality of the foregoing, each Party shall provide to the other (or the other's respective advisors) upon request copies of all correspondence between such Party and any Governmental Entity relating to the transactions contemplated by this Agreement. In addition, to the extent reasonably practicable, all discussions, telephone calls, and meetings with a Governmental Entity regarding the transactions contemplated by this Agreement shall include representatives of both Parties. Subject to applicable Legal Requirements, the Parties will consult and cooperate with each other in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, and proposals made or submitted to any Governmental Entity regarding the transactions contemplated by this Agreement by or on behalf of any Party.

(c) Notwithstanding the foregoing, nothing in this Agreement shall require, or be construed to require, the Parties or any of their respective Affiliates to offer or agree to (A) (i) sell, hold, hold separate, divest, license, discontinue or limit, before or after the Closing Date, any assets, businesses, equity holdings, intellectual property, or other interests or (ii) any conditions relating to, or changes or restrictions in, the operations of any such assets, businesses, equity holdings, intellectual property or interests (including but not limited to any requirements to enter into new contracts or modify or terminate existing contracts) or (B) any material modification or waiver of the terms and conditions of this Agreement.

8.2 No Solicitation. During the period from the Effective Date and continuing until the earlier of the termination of this Agreement or the Closing Date, Seller shall not, nor shall it authorize, instruct, or permit any of its Affiliates or any of their respective Representatives to, (i) solicit, initiate, or encourage the submission of, any proposal or indication of interest relating to an Alternative Transaction or any inquiry, proposal or offer that is reasonably likely to lead to an Alternative Transaction, (ii) participate in any discussions or negotiations regarding, or furnish to any person any information with respect to, or take any other action to facilitate any inquires or the making of any proposal that constitutes, or may reasonably be expected to lead to, any Alternative Transaction, (iii) accept any proposal or offer from any Person in respect of an Alternative Transaction, or (iv) resolve to propose or agree to do any of the foregoing. Upon the execution of this Agreement, Seller and its Affiliates shall immediately cease and cause to be terminated any existing discussions with any Person that are in respect of an Alternative Transaction.

ARTICLE IX
INDEMNIFICATION

9.1 Indemnification.

(a) Indemnification by Seller. From and after the Closing, Seller will indemnify, defend and hold Buyer and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Damages to the extent arising out of or resulting from (i) any breach of Seller's representations, warranties, covenants or obligations under this Agreement or any certificate delivered by Seller hereunder, (ii) Seller's grossly negligent and/or wrongful acts, omissions or misrepresentations, regardless of the form of action, in connection with this Agreement, and/or (iii) any Excluded Liabilities.

(b) Indemnification by Buyer. From and after the Closing, Buyer will indemnify, defend and hold Seller and its Affiliates, and their respective directors, officers, employees and agents harmless for, from and against any and all Damages to the extent arising out of or resulting from (i) any breach of Buyer's representations, warranties, covenants or obligations under this Agreement or any certificate delivered by Buyer hereunder, (ii) Buyer's grossly negligent and/or wrongful acts, omissions or misrepresentations, regardless of the form of action, in connection with this Agreement, and/or (iii) Buyer's, its Affiliates', or any subsequent transferee's use of the Transferred Rights after Closing.

9.2 Indemnification Procedures for Third Party Claims.

(a) A Person entitled to indemnification pursuant to Section 9.1 will hereinafter be referred to as an *"**Indemnitee**."* A Party obligated to indemnify an Indemnitee hereunder will hereinafter be referred to as an *"**Indemnitor**."* Indemnitee shall inform Indemnitor of any indemnifiable Damages arising out of a claim by a Third Party in respect of which an Indemnitee may seek indemnification pursuant to Section 8.1 (a "***Third Party Claim***") as soon as reasonably practicable after the Third Party Claim arises, it being understood and agreed that the failure to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that such Indemnitor is actually and materially prejudiced as a result of such failure to give notice.

(b) If the Indemnitor has acknowledged in writing to the Indemnitee within thirty (30) days of receipt of the Third Party Claim the Indemnitor's responsibility for defending such Third Party Claim, the Indemnitor shall have the right to defend, at its sole cost and expense, such Third Party Claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnitor to a final conclusion or settled at the discretion of the Indemnitor; provided, however, that the Indemnitor may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnitee of a release from all liability in respect of such Third Party Claim; and (ii) the Indemnitee consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnitee, (B) any payment by the Indemnitee that is not indemnified hereunder or (C) the imposition of any equitable relief against the Indemnitee. If the Indemnitor does not elect to assume control of the defense of a Third Party Claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, upon at least ten (10) Business Days' prior written notice to the Indemnitor of its intent to do so, to undertake the defense of such Third Party Claim for the account of the Indemnitor (with counsel reasonably selected by the Indemnitee and approved by the Indemnitor, such approval not to be unreasonably withheld or delayed), provided, that the Indemnitee shall keep the Indemnitor apprised of all material developments with respect to such Third Party Claim and promptly provide the Indemnitor with copies of all correspondence and documents exchanged by the Indemnitee and the opposing party(ies) to such litigation. The Indemnitee may not compromise or settle such litigation without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed.

(c) The Indemnitee may participate in, but not control, any defense or settlement of any Third Party Claim controlled by the Indemnitor pursuant to this Section 9.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnitor shall bear such costs and expenses if counsel for the Indemnitor shall have reasonably determined that such counsel may not properly represent both the Indemnitor and the Indemnitee.

9.3 Direct Claims. A claim for indemnification for any matter not involving a Third Party Claim may be asserted by written notice to the Party from whom indemnification is sought. Such notice shall include the facts constituting the basis for such claim for indemnification, the Sections of this Agreement upon which such claim for indemnification is then based, and an estimate, if possible, of the amount of Damages suffered or reasonably expected to be suffered by the Indemnitee.

9.4 Buyer Knowledge. The right to indemnification pursuant to this Article IX shall not be affected by any investigation conducted or any knowledge acquired by Buyer, its Affiliates or Representatives at any time, whether before or after the execution and delivery of this Agreement or the Closing, with respect to the accuracy or inaccuracy of, or compliance with, any representation, warranty, covenant, or obligation.

ARTICLE X
TERMINATION

10.1 Termination Prior to Closing. Notwithstanding any contrary provisions of this Agreement, the respective obligations of the Parties hereto to consummate the transactions contemplated by this Agreement may be terminated and abandoned at any time before the Closing only as follows:

(a) Upon the mutual written consent of Buyer and Seller; or

(b) By either Party, by written notice to the other Party if the Closing has not occurred on or before one hundred twenty (120) days from the Effective Date for any reason; provided, however, that the right to terminate this Agreement under this Section 10.1(b) shall not be available to any Party whose material breach of any provision set forth in this Agreement has resulted in the failure of the Closing to occur on or before such date.

10.2 Effect of Termination. In the event of the termination of this Agreement as provided in Section 10.1, written notice thereof shall forthwith be given to the other Party hereto specifying the provision hereof pursuant to which such termination is made, and this Agreement shall forthwith become null and void (except for the provisions of this Section 10.2, Section 11.4, ARTICLE I and ARTICLE XII, which shall survive any such termination) and there shall be no liability on the part of Buyer or Seller except for Damages resulting from any breach prior to termination of this Agreement by Buyer or Seller. If this Agreement is terminated, Buyer will promptly withdraw any Pre-Closing PRV Notice submitted to the FDA prior to the Closing.

ARTICLE XI
ADDITIONAL COVENANTS

11.1 Further Assurances.

(a) The Parties shall cooperate reasonably with each other in connection with any steps required to be taken as part of their respective obligations under this Agreement, including any notifications or filings required to be made to the FDA in connection with the transfer of the Transferred Rights, and shall (i) furnish upon request to each other such further information, (ii) execute and deliver to each other such other documents, and (iii) do such other acts and things, all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement and the transactions contemplated by this Agreement, including the use by Buyer, its Affiliates and/or their respective successors and assigns of the Priority Review Voucher in accordance with its terms and applicable Legal Requirements.

(b) Without limiting the foregoing, Buyer and Seller agree to cooperate and assist each other with respect to all filings or notifications to any Governmental Entity related to the transfer and assignment of the Transferred Rights.

11.2 Compliance with Legal Requirements. Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the rare pediatric disease product for which the Priority Review Voucher was awarded to, at all times comply with all Legal Requirements applicable to the Transferred Rights, including any and all Legal Requirements applicable to the use or transfer of the Priority Review Voucher. Seller shall promptly forward to Buyer any communications or notices it or its Affiliates receive from any Governmental Entity to the extent relating to the Transferred Rights (and not otherwise with respect to the product approved in the NDA Approval Letter). Without limiting the generality of the foregoing, to the extent required, now or in the future, under applicable Legal Requirements or otherwise by the FDA for the use or transfer of the Priority Review Voucher, or to avoid revocation of the Priority Review Voucher, Seller shall, and shall cause its Affiliates and each of their respective successors in interest to the rare pediatric disease product for which the Priority Review Voucher was awarded, to submit a post-approval production report to the United States Secretary of Health and Human Services not later than five (5) years after the approval of such rare pediatric disease product in accordance with section 529(e)(2) of the FDC Act.

11.3 Marketing. Seller will market in the United States the rare pediatric disease product for which the Priority Review Voucher was awarded for the 365-day period beginning on the date of the FDA approval of such rare pediatric disease product to the extent required, now or in the future, under applicable Legal Requirements or otherwise by any applicable Governmental Entity for the use or transfer of the Priority Review Voucher.

11.4 Nondisclosure.

(a) With respect to Confidential Information received from a Party, the other Party will (i) not use such Confidential Information for any reason other than to carry out the intent and purpose of this Agreement, and (ii) not disclose such Confidential Information to any Person, except in each case as otherwise expressly permitted by this Agreement or with the prior written consent of the disclosing Party.

(b) A Party may disclose Confidential Information to its Affiliates and their respective Representatives on a need-to-know basis.

(c) A Party will (i) enforce the terms of this Section 11.4 as to its Representatives, (ii) take such action to the extent necessary to cause its Representatives to comply with the terms and conditions of this Section 11.4, and (iii) be responsible and liable for any breach of this Section 11.4 by it or its Representatives.

(d) If a Party becomes compelled by a court or is requested by a Governmental Entity to make any disclosure that is prohibited or otherwise constrained by this Section 11.4, such Party shall provide the disclosing Party with prompt notice of such compulsion or request so that it may seek an appropriate protective order or other appropriate remedy or waive compliance with the provisions of this Section 11.4. In the absence of a protective order or other remedy, the Party subject to the requirement to disclose may disclose that portion (and only that portion) of the Confidential Information that, based upon advice of its counsel, it is legally compelled to disclose or that has been requested by such Governmental Entity; provided, however, that such Party shall use reasonable efforts to obtain reliable assurance that confidential treatment will be accorded by any Person to whom any Confidential Information is so disclosed.

11.5 Disclosures Concerning this Agreement. Buyer and Seller agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except (i) the Buyer and Seller shall each be entitled to issue a press release with respect to the execution of this Agreement, in a form attached as **Exhibit E-1** and **Exhibit G** hereto, respectively, and (iii) as required by a Governmental Entity or applicable Legal Requirement (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall provide the other Party with advance notice of such required disclosure, and provide the other Party a reasonable opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party). Each Party acknowledges that the other Party, or the other Party's parent entity, as a publicly traded company, is legally obligated to make timely disclosures of material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission (the "***SEC***"). Without limiting the foregoing, any Party so obligated shall request confidential treatment of this Agreement pursuant to applicable rules under the Securities Exchange Act of 1934, as amended, and the Freedom of Information Act and the rules promulgated thereunder to permit the filing of a redacted exhibit, provided that there is no assurance that such request will be granted by the SEC and the SEC may require filing of the Agreement in full. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement.

ARTICLE XII
GENERAL PROVISIONS

12.1 Survival. Except as expressly set forth herein, the representations and warranties contained in this Agreement, and liability for the breach thereof, shall survive the Closing Date and shall remain in full force and effect for a period of two (2) years following the Closing Date; provided, however, that the representations and warranties contained in Sections 5.1, 5.2, 5.5, 5.11, 5.12 and 5.13 hereof, shall, in each case, survive the Closing Date and remain in full force and effect until the expiration of the applicable statute of limitations.

12.2 Transfer Taxes and Fees. Notwithstanding any other provision in this Agreement to the contrary, each respective Party shall bear and pay any and all sales taxes, value added taxes, use taxes, transfer taxes, documentary charges, recording fees or similar taxes, charges, or fees (including any penalties, interest and additions thereto) that may become payable by it or its Affiliates in connection with the PRV Transfer.

12.3 Priority Review Fee. The priority review user fee described in section 529(c) of the FDC Act (21 U.S.C. § 360ff(c)) (the "***Priority Review Fee***") and all other user fees under the FDC Act applicable to the human drug application for which the Priority Review Voucher is redeemed, following the Closing shall be borne exclusively by the Buyer, its Affiliates or any transferee of the Priority Review Voucher. In any event, Seller shall have no liability or obligation for any such fees. In furtherance and not in limitation of the foregoing, Buyer shall timely pay all amounts due with respect to the Priority Review Fee in connection any submission of a Pre-Closing PRV Notice as contemplated by Section 4.1 or other Notice of Intent to Use the Priority Review Voucher by Buyer.

12.4 Notices. Any notice or other communication required or permitted to be delivered to any Party shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; or (b) upon such Party's receipt after being sent by registered mail, by courier or express delivery service, in any case to the address set forth beneath the name of such Party below (or to such other address as such Party shall have specified in a written notice given to the other Party in accordance with this Section 12.3):

(i) if to Buyer, to:

Biohaven Pharmaceutical Holding Ltd
215 Church Street
New Haven, CT 06510
Attn: Chief Executive Officer
Email:

with a copy (which shall not constitute notice) to:

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5656
Attn: Darren DeStefano
Email:
Fax:

(ii) if to Seller, to:

GW Pharmaceuticals, plc
Sovereign House
Vision Park
Histon
Cambridge CB24 9BZ
United Kingdom
Attn Adam George, Managing Director UK
Email:

and to:

Greenwich Biosciences, Inc.
5750 Fleet Street, Suite 200
Carlsbad, CA 92008
Attn Douglas Snyder, Chief Legal Officer
Email:

with a copy (which shall not constitute notice) to:

Covington & Burling LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
Attn: Stephen A. Infante
Email:

12.5 Construction.

(a) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not be applied in the construction or interpretation of this Agreement.

(b) As used in this Agreement, the words "include" and "including," and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words "without limitation."

(c) Except as otherwise indicated, all references in this Agreement to "Articles" and "Sections" are intended to refer to Articles and Sections of this Agreement.

12.6 Counterparts. This Agreement may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties hereto and delivered to the other Party hereto, it being understood that all Parties hereto need not sign the same counterpart. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic transmission or facsimile shall be sufficient to bind the Parties hereto to the terms and conditions of this Agreement.

12.7 Entire Agreement. This Agreement, including all exhibits and schedules attached hereto, sets forth the entire understanding of the Parties relating to the subject matter hereof and supersedes all prior agreements and understandings among or between the Parties relating to the subject matter hereof.

12.8 Assignment. No Party will have the right to assign this Agreement, in whole or in part, by operation of law or otherwise, without the other Party's express prior written consent. Any attempt to assign this Agreement without such consent, will be null and void. Notwithstanding the foregoing, any Party may assign this Agreement, in whole or in part, without the consent of the other Party: (a) to a Third Party that succeeds to all or substantially all of its assets or business related to this Agreement (whether by sale, merger, operation of law or otherwise); or (b) to an Affiliate of such Party. Notwithstanding the foregoing, Buyer may assign this Agreement, in whole or in part, without Seller's consent, to any purchaser, transferee, or assignee of any of the Transferred Rights. For the avoidance of doubt, no assignment made pursuant to this Section 12.7 shall relieve the assigning Party of any of its obligations under this Agreement. Subject to the foregoing, this Agreement will bind and inure to the benefit of each Party's successors and permitted assigns.

12.9 Severability. If any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and shall be interpreted so as reasonably to effect the intent of the Parties hereto. The Parties hereto shall use commercially reasonable efforts to replace such void or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

12.10 Remedies Cumulative. Except as otherwise provided herein, any and all remedies herein expressly conferred upon a Party hereto shall be deemed cumulative with and not exclusive of any other remedy conferred hereby or by law or equity upon such Party, and the exercise by a Party hereto of any one remedy shall not preclude the exercise of any other remedy and nothing in this Agreement shall be deemed a waiver by any Party of any right to specific performance or injunctive relief.

12.11 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, regardless of the laws that might otherwise govern under applicable principles of conflicts of law. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York (or if such court does not have subject matter jurisdiction, State Court of the State of New York located in New York County) solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.

12.12 Amendment; Extension; Waiver. Subject to the provisions of applicable law, the Parties hereto may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties hereto. At any time, any Party hereto may, to the extent legally allowed, (a) extend the time for the performance of any of the obligations or other acts of the other Party hereto, (b) waive any inaccuracies in the representations and warranties made to such Party contained herein or (c) waive compliance with any of the agreements or conditions for the benefit of such Party contained herein. Any agreement on the part of a Party hereto to any such extension or waiver shall be valid only if set forth in an instrument in writing signed on behalf of such Party. Without limiting the generality or effect of the preceding sentence, no delay in exercising any right under this Agreement shall constitute a waiver of such right, and no waiver of any breach or default shall be deemed a waiver of any other breach or default of the same or any other provision in this Agreement.

12.13 Representation By Counsel; Interpretation. Seller and Buyer each acknowledge that it has been represented by its own legal counsel in connection with this Agreement and the transactions contemplated by this Agreement. Accordingly, any rule of law, or any legal decision that would require interpretation of any claimed ambiguities in this Agreement against the Party that drafted it, has no application and is expressly waived.

12.14 Expenses. Whether or not the purchase and sale of the Transferred Rights and the other transactions contemplated by this Agreement are consummated, and except as otherwise set forth in this Agreement, each of the Parties shall bear its own fees and expenses incurred in connection with this Agreement and the transactions contemplated hereby.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this PRV Transfer Agreement to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

BIOHAVEN PHARMACEUTICAL HOLDING LTD

By: /s/ Vlad Coric
Name: Vlad Coric
Title: Chief Executive Officer

GW RESEARCH, LTD.

By: /s/ Adam George
Name: Adam George
Title: Director

[Signature Page to PRV Transfer Agreement]

Exhibit A

Priority Review Voucher Letter

See attached.

Exhibit B

Form of Bill of Sale

This Bill of Sale (this "***Bill of Sale***") is entered into as of [DATE], 2019, by and between Biohaven Pharmaceutical Holding Ltd ("***Buyer***") and [GW Research, Ltd.] ("***Seller***").

Upon the terms and subject to the conditions of the PRV Transfer Agreement, dated as of March 15, 2019 (the "***PRV Transfer Agreement***"), by and between Buyer and Seller, Seller has agreed to sell, and Buyer has agreed to purchase, all right, title and interest in, to and under the Transferred Rights, including the Priority Review Voucher, in each case free and clear of all Encumbrances.

For good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Buyer and Seller, intending to be legally bound, hereby agree as follows:

1. Defined Terms; Interpretation. Except as otherwise set forth herein, capitalized terms used in this Bill of Sale shall have the meanings assigned to them in the PRV Transfer Agreement. This Bill of Sale shall be interpreted in accordance with the rules of construction set forth in Section 12.4 of the PRV Transfer Agreement.

2. Transfer of Transferred Rights. Pursuant to the terms and subject to the conditions of the PRV Transfer Agreement, Seller hereby sells, assigns, transfers, and conveys to Buyer and its successors and its assigns, and Buyer hereby does purchase from Seller, all of Seller's right, title and interest in, to and under the Transferred Rights (including the Priority Review Voucher), in each case free and clear of all Encumbrances. The right, title and interest in and to the Transferred Rights that are sold, transferred, conveyed, assigned and delivered by Seller to Buyer hereunder collectively constitute the entire right, title and interest in and to the Transferred Rights and upon the Closing, Buyer shall have all right, title and interest in and to the Transferred Rights, free and clear of all Encumbrances.

3. Effective Time. This Bill of Sale shall be effective as of the Closing.

4. Conflicts. In the event of any conflict between the terms of the Bill of Sale and the PRV Transfer Agreement, the PRV Transfer Agreement shall control.

5. Binding Effect. This Bill of Sale shall be binding upon, inure to the benefit of, and be enforceable by, the Parties hereto and their respective legal representatives, successors and permitted assigns.

6. Amendment. Subject to the provisions of applicable law, the Parties hereto may amend this Agreement at any time pursuant to an instrument in writing signed on behalf of each of the Parties hereto.

7. Governing Law. This Bill of Sale and any disputes arising under or related hereto shall be governed by the rules set forth in Section 12.10 of the PRV Transfer Agreement.

8. Counterparts. This Bill of Sale may be executed in two or more counterparts, all of which shall be considered one and the same instrument, and shall become effective when one or more counterparts have been signed by each of the Parties hereto and delivered to the other Party hereto, it being understood that all Parties hereto need not sign the same counterpart. The exchange of a fully executed Bill of Sale (in counterparts or otherwise) by electronic transmission or facsimile shall be sufficient to bind the Parties hereto to the terms and conditions of this Bill of Sale.

[*Signature Page Follows*]

IN WITNESS WHEREOF, each of Buyer and Seller has caused this Bill of Sale to be executed and delivered by their respective officers thereunto duly authorized, all as of the date first written above.

BIOHAVEN PHARMACEUTICAL HOLDING LTD

By: _____
Name:
Title:

GW RESEARCH, LTD.

By: _____
Name:
Title:

[Signature Page to Bill of Sale]

Exhibit C-1

Form of Joint FDA Notification Cover Letter

[Date]

[FDA Contact]
[FDA Address]

Re: NDA 210365
Epidiolex® (cannabidiol) 100 mg/mL oral solution
Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 210365

Dear [FDA Contact]:

Reference is made to the above-referenced NDA and the June 25, 2018 letter approving the NDA issued by the Department of Health and Human Services to GW Research, Ltd., ("***GW***") (the "***Approval Letter***"). The Approval Letter also grants GW the above-referenced rare pediatric disease priority review voucher (the "***Voucher***"). A copy of the Approval Letter is enclosed as Exhibit A for your convenience. GW is the original recipient of the Voucher and has not transferred the Voucher to any other person.

In accordance with section 529(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 USC 360ff(b)(2)(B), please be advised that as of [Date], GW has transferred the Voucher to Biohaven Pharmaceutical Holding Ltd ("***Biohaven***"). Specifically, GW has sold, transferred, assigned, conveyed, and delivered the Voucher to Biohaven, and Biohaven has legally accepted complete ownership of the Voucher from GW. This transfer is free and clear of all liens and provides Biohaven with all of GW's right, title, and interest in, to, and under the Voucher. GW and Biohaven have exchanged letters acknowledging the transfer, copies of which are enclosed as Exhibits B and C.

[*Signature Page Follows*]

Sincerely,

GW RESEARCH, LTD.

By: _____
Name:
Title:

BIOHAVEN PHARMACEUTICAL HOLDING LTD

By: _____
Name:
Title:

[Signature Page to Joint FDA Notification Cover Letter]

Exhibit C-2

Form of Seller Transfer Acknowledgement Letter

[Seller Letterhead]

[Date]

[Buyer]
[Buyer Notices Address]

Re: NDA 210365
Epidiolex® (cannabidiol) 100 mg/mL oral solution
Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 210365

Dear [ ]:

Reference is made to the above-referenced NDA and the June 25, 2018 letter approving the NDA issued by the Department of Health and Human Services to GW Research, Ltd., ("***GW***") (the "***Approval Letter***"). The Approval Letter also grants GW the above-referenced rare pediatric disease priority review voucher (the "***Voucher***"). A copy of the Approval Letter is enclosed as Exhibit A for your convenience. GW is the original recipient of the Voucher and has not transferred the Voucher to any other person.

Further reference is made to that certain PRV Transfer Agreement, dated March 15, 2019, (the "***Agreement***"), by and between GW and Biohaven Pharmaceutical Holding Ltd ("***Biohaven***"). Pursuant to the Agreement, GW has sold, transferred, assigned, conveyed and delivered the Voucher to Biohaven, and Biohaven has legally accepted, complete ownership of the Voucher from GW, effective as of [ ], 2019. This transfer is free and clear of all liens and provides Biohaven with all of GW's right, title, and interest in, to, and under the Voucher.

This letter acknowledges that GW has transferred, assigned, conveyed, and delivered the Voucher to Biohaven.

This letter will be presented to FDA as evidence that GW acknowledges the sale and transfer of the Voucher from GW to Biohaven.

Sincerely,

[GW Contact]

Exhibit C-3

Form of Buyer Transfer Acknowledgement Letter

[Buyer Letterhead]

[Date]

[GW Research, Ltd.
Sovereign House
Vision Park
Histon
Cambridge CB24 9BZ
United Kingdom
Attn: [●]

Re: NDA 210365
Epidiolex® (cannabidiol) 100 mg/mL oral solution
Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 210365

Dear [ ]:

Reference is made to the above-referenced NDA and the June 25, 2018 letter approving the NDA issued by the Department of Health and Human Services to GW Research, Ltd., ("***GW***") (the "***Approval Letter***"). The Approval Letter also grants GW the above-referenced rare pediatric disease priority review voucher (the "***Voucher***"). A copy of the Approval Letter is enclosed as Exhibit A for your convenience. GW is the original recipient of the Voucher and has not transferred the Voucher to any other person.

Further reference is made to that certain PRV Transfer Agreement, dated March 15, 2019, (the "***Agreement***"), by and between GW and Biohaven Pharmaceutical Holding Ltd ("***Biohaven***"). Pursuant to the Agreement, GW has sold, transferred, assigned, conveyed and delivered the Voucher to Biohaven, and Biohaven has legally accepted, complete ownership of the Voucher from GW, effective as of [ ], 2019. This transfer is free and clear of all liens and provides Biohaven with all of GW's right, title, and interest in, to, and under the Voucher.

This letter acknowledges Biohaven's acquisition and acceptance of the Voucher from GW.

This letter will be presented to FDA as evidence that Biohaven acknowledges the sale and transfer of the Voucher from GW to Biohaven.

Sincerely,

[Biohaven Contact]

Exhibit D

Seller's Pre-Closing FDA Letter

[Seller's Letterhead]

[Date]

William Dunn, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-126

Re: Reference ID : 4282447 for NDA 210365
Epidiolex® (cannabidiol) 100 mg/mL oral solution
Contemplated Transfer of Rare Pediatric Disease Priority Review Voucher PRV NDA 210365

Dear Dr. Dunn:

Reference is made to the above-referenced NDA and the June 25, 2018 letter approving the NDA issued by the Department of Health and Human Services to GW Research, Ltd., ("***GW***") (the "***Approval Letter***"). The Approval Letter also grants GW the above-referenced rare pediatric disease priority review voucher (the "***Voucher***"). A copy of the Approval Letter is enclosed as Exhibit A for your convenience. GW is the original recipient of the Voucher and has not transferred the Voucher to any other person.

Please be advised that as of March 15, 2019, GW and Biohaven Pharmaceutical Holding Company Ltd ("***Biohaven***") have entered into an agreement pursuant to which Biohaven will, subject to the expiration or termination of any applicable waiting periods under the HSR Act, acquire complete ownership of the Voucher from GW.

Pending transfer of the Voucher, GW has agreed that Biohaven may, in accordance with Section 529(b)(4)(B) of the Food, Drug and Cosmetic Act and the applicable terms of the Approval Letter, notify the Food and Drug Administration (" ***FDA***") of Biohaven's intent to use the Voucher in connection with the submission of a new drug application (the "***Biohaven NDA***").

Please do not hesitate to contact me should you have any questions or comments.

Sincerely,

[GW Contact]

Exhibit E

Buyer's Press Release

See attached.

Exhibit F

Pre-Closing PRV Notice

[Buyer's Letterhead]

[Date], 2019

[FDA Contact]
[FDA Address]

Re: Reference ID : 4282447 for NDA 210365
Epidiolex® (cannabidiol) 100 mg/mL oral solution
Notification of Intent to Submit an Application with a Rare Pediatric Disease Priority Review Voucher (PRV NDA 210365)

Dear [FDA Contact]:

Reference is made to the above-referenced NDA and the June 25, 2018 letter approving the NDA issued by the Department of Health and Human Services to GW Research, Ltd., ("***GW***") (the "***Approval Letter***"). As of March 15, 2019, GW and Biohaven Pharmaceutical Holding Company Ltd ("***Biohaven***") have entered into an agreement pursuant to which Biohaven will, subject to the expiration or termination of any applicable waiting periods under the HSR Act, acquire complete ownership of the Voucher from GW, and a copy of the confirmation from GW to the FDA is attached as Exhibit A hereto.

Pending transfer of the Voucher, GW has agreed that Biohaven may, in accordance with Section 529(b)(4)(B) of the Food, Drug and Cosmetic Act and the applicable terms of the Approval Letter, notify the Food and Drug Administration (" ***FDA***") of Biohaven's intent to use the Voucher in connection with the submission of a new drug application (the "***Biohaven NDA***").

This letter serves as notice of intent to use the priority review voucher (as described in section 529(b)(4) of the FDC Act (21 U.S.C. § 360ff(b)(4))) granted in the Approval Letter for the submission of a human drug application (as defined in section 735(1) of the FDC Act (21 U.S.C. 379g(1))) with respect to [NDA].

Please do not hesitate to contact me should you have any questions or comments.

Sincerely,

[Biohaven Contact]

Exhibit G

Seller's Press Release

See attached.

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: May 7, 2019

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

Exhibit 31.2

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

I, Scott Giacobello, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of GW Pharmaceuticals plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the registrant's audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/s/ Scott Giacobello

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

Exhibit 32.1

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

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

1. The Quarterly Report on Form 10-Q for the three-month period ended March 31, 2019 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: May 7, 2019

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

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

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

Exhibit 32.2

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

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

1. The Quarterly Report on Form 10-Q for the three-month period ended March 31, 2019 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: May 7, 2019

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

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

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